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Rosiglitazone

BRL-049653

**A multicentre, open label extension study to assess the long term safety,
tolerability and efficacy of rosiglitazone when administered to patients with
type 2 diabetes mellitus**

009

Assembled Report Title Page

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Report Title: A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of rosiglitazone when administered to patients with type 2 diabetes mellitus

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I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

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9/10/02

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Report Synopsis

Study Title

A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of rosiglitazone when administered to patients with type 2 diabetes mellitus.

Investigators and Centres

The study was conducted in 92 centres in France, UK, Germany, Italy, Sweden, Belgium, Spain, Netherlands and Ireland.

Publication

No publications at the time this report were written.

Study Dates

The first patient received the first dose of open label study medication on 14 February 1997 and the last patient received the last dose of open label medication on 02 January 2001.

Objective(s)

The primary objective was to evaluate the long term safety and tolerability of rosiglitazone administered as 4mg bd monotherapy, or as 2mg bd in combination with other oral hypoglycaemic agents, in the treatment of patients with type 2 diabetes mellitus. The secondary objective was to evaluate the long term efficacy of rosiglitazone in terms of glycaemia. Pharmacodynamic parameters have also been summarised. The maximum duration of therapy permitted was 48 months. However, having met its objectives, the study was terminated by the sponsor at a time when only a small proportion of patients had been treated for more than 36 months.

Study Design

A phase IIIa multicentre, open label extension study of rosiglitazone (4mg bd monotherapy, 2mg bd combination therapy) administered to patients with type 2 diabetes mellitus. Patients on monotherapy in the previous study (studies 020, 025) received rosiglitazone 4mg bd monotherapy in this extension study. Patients on combination therapy with a sulphonylurea in the previous study (study 015) received rosiglitazone 2mg bd in addition to their sulphonylurea (glibenclamide, gliclazide, glipizide).

In light of the regulatory approval of Avandia within Europe, and the extensive data that have already been obtained demonstrating that treatment with rosiglitazone 2mg bd (in combination with a sulphonylurea) or 4mg bd in long term treatment is safe and well tolerated in this study, the study was terminated early.

Study Population

Patients with type 2 diabetes mellitus who had completed a rosiglitazone monotherapy study (49653/020, 49653/025) or a rosiglitazone and sulphonylurea combination therapy study (49653/015) were eligible provided treatment in the preceding study was adequately tolerated.

Treatment and Administration

Rosiglitazone was supplied as white, bi-convex film coated (7mm) tablets containing 2mg rosiglitazone. The batch numbers were [REDACTED] and [REDACTED]. Rosiglitazone tablets were to be taken before breakfast (am) and before the evening meal (pm), 1 tablet was taken by the combination group and 2 tablets were taken by the monotherapy group.

Evaluation Criteria

Efficacy Parameters

The protocol specified primary efficacy variable for the study was change from baseline (double-blind (DB) and open label (OL)) in HbA1c at Month 48. The protocol specified secondary efficacy parameters were change from baseline (DB and OL) in fasting plasma glucose (FPG), fasting insulin (specific) and urinary albumin at Month 48.

However, presentation of primary and secondary variables were changed retrospectively; this final clinical report does not present change from baseline but summary statistics at each visit instead. The interim report for this open label extension study, dated 29-Sep-1998, presents change from baseline in both primary and secondary efficacy parameters for the first 12 months of the study. Assessment of change from baseline is more applicable during the initial months of the study due to patients having previously been treated with different doses of rosiglitazone as monotherapy or as combination therapy, or other hypoglycaemic agents or placebo. Assessment of maintenance of effect is more applicable for analysis of treatment effect over longer durations.

Safety Parameters

Safety and tolerability of rosiglitazone was assessed by physical examination, adverse experiences (AEs), laboratory safety data, ECG parameters, body weight and vital signs.

Pharmacodynamics

For all pharmacodynamic parameters (total cholesterol (TC), HDL-cholesterol (HDL), LDL-cholesterol (LDL), triglycerides and free fatty acids), summary statistics at each visit are presented. The protocol specified that summary statistics for percent change from baseline and change from baseline will be calculated for TC, HDL, LDL, triglycerides and free fatty acids and change from baseline calculated for TC:HDL and LDL:HDL ratios. However, this final clinical report does not present percent change from baseline or change from baseline for any pharmacodynamic parameters for the reasons outlined in 'Efficacy parameters'. Summary statistics alone are presented by visit for the above mentioned parameters and in addition TC:HDL and LDL:HDL ratios.

Statistical Methods

Due to the study consisting of a non-randomised, pre-selected population of patients all receiving rosiglitazone, hypothesis testing was not performed. Patients were grouped according to whether they received rosiglitazone 4mg bd as monotherapy or 2mg bd in combination with another oral hypoglycaemic agent. Data were summarised from patients who took at least one dose of study medication in the study. Descriptive statistics for both treatment groups were used to summarise the efficacy variables. Evaluation of safety data included all patients who received study medication. Clinical interpretation was based upon review of summary displays of adverse events, patient withdrawals and laboratory values. Body weight, vital signs and ECGs are summarised.

Patient Disposition and Key Demographic Data

A total of 659 patients entered the open label extension study and received at least one dose of study medication. The mean duration of treatment with rosiglitazone was 772.5 days in the rosiglitazone 2mg bd combination therapy group and 710.1 days in the rosiglitazone 4mg bd monotherapy group. Due to the early termination of the study by SmithKline Beecham, no patients are recorded as ongoing, and as no patients attended the scheduled Month 48 visit, no patients are recorded as completing. Patients withdrawing due to study termination have been classified as 'other'. Of those patients not classified as withdrawing for 'other' reason, the main reason for patient withdrawal in both treatment groups was lack of efficacy: 62 patients (27.1%) in the combination therapy group and 82 patients (19.1%) in the monotherapy group.

Summary of Reasons for Withdrawal		
Withdrawal Reason, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Adverse Experience*	29 (12.7)	47 (10.9)
Lack of Efficacy	62 (27.1)	82 (19.1)
Protocol Deviation	7 (3.1)	6 (1.4)
Lost to Follow-up	3 (1.3)	9 (2.1)
Other	128 (55.9)	286 (66.5)
Total Withdrawn	229 (100.0)	430 (100.0)

* Includes all adverse experiences leading to withdrawal (pre-, on- and post-therapy) and death as an outcome.

For patients who entered this study, the mean age was 61.9 years (range 34-79) and 60.2 years (range 37-81) in the rosiglitazone 2mg bd combination therapy and rosiglitazone 4mg bd monotherapy groups respectively. The majority of patients in both groups were white (97%) and male (66%). Patients had been diagnosed with diabetes for an average of 9.3 years and 5.8 years while 100% and 56.7% of patients were receiving oral antidiabetic agents (prior to the preceding study) in the combination therapy and monotherapy groups respectively. At open label baseline, mean HbA1c was 8.4% and 7.4% and mean FPG was 170.6mg/dL and 152.8mg/dL in the rosiglitazone 2mg bd combination and 4mg bd monotherapy groups respectively.

Efficacy Results

Data Sets

Data were summarised with the patients who took at least one dose of study medication after entering the study. No assumptions were made for missing values (i.e., last value was not carried forward). Two baselines were defined: double-blind (DB) baseline and open label (OL) baseline, where the DB baseline was the baseline before the double-blind medication was issued in the

previous studies (studies 015, 020 and 025) and the OL baseline was the first day of open label medication but prior to the ingestion of medication.

Primary Efficacy Variables

Overall, patients receiving rosiglitazone 2mg bd in addition to a sulphonylurea in this extension study maintained their HbA1c close to OL baseline values (mean 8.4%) for at least 36 months' duration. This compares with a mean HbA1c of 9.1% at DB baseline. In the rosiglitazone 4mg bd monotherapy group, mean HbA1c was also similar to OL baseline (mean 7.4%) over 36 months of open label medication compared to a DB baseline of 8.0%.

In the combination therapy group, in those patients receiving rosiglitazone for the first time, mean HbA1c further decreased over the first 3 months (OL baseline: 8.8%, Month 3: 8.1%) which was maintained for at least a further 33 months. Patients who previously received rosiglitazone in combination maintained their OL baseline mean HbA1c over at least 36 months of treatment.

In the monotherapy group, those patients who were switched from glibenclamide in the preceding study to rosiglitazone 4mg bd monotherapy had an increase in mean HbA1c over the first 3 months (OL Baseline: 7.2%, Month 3: 8.0%) which subsequently decreased over the following 30 months to 7.3% at Month 33. In those patients continuing with rosiglitazone mean values for HbA1c were maintained close to the OL baseline over a treatment period of at least 33 months.

Secondary Efficacy Variables

Fasting Plasma Glucose: Overall, patients receiving rosiglitazone 2mg bd in combination showed a decrease in their mean FPG from OL baseline (mean 170.6 mg/dL) over the first 3 months of treatment (Month 3: 161.2mg/dL); mean FPG values ranged between 160.0 and 167.8mg/dL for the following 33 months. This compares with a mean FPG of 197.1mg/dL at the start of the preceding study. Mean FPG decreased during the first 6 months of treatment in patients receiving rosiglitazone 4mg bd monotherapy (OL baseline: 152.8mg/dL, Month 6: 141.5mg/dL) which was maintained over a treatment period of at least 30 months, and compares to a double-blind baseline value of 184.6mg/dL.

Fasting Plasma Insulin: In the rosiglitazone 2mg bd combination therapy group, mean plasma insulin generally decreased over 36 months of treatment (OL baseline: 52.1pmol/L, Month 36: 47.9pmol/L). This compares to a double-blind baseline value of 57.2pmol/L. In the rosiglitazone 4mg bd monotherapy group, mean plasma insulin decreased at Month 6 (OL baseline: 65.4pmol/L, Month 6: 50.4pmol/L) after which mean insulin values were mostly maintained over the following 30 months. The mean baseline value at the start of the preceding studies was 67.2pmol/L.

Urinary albumin: In the combination therapy group, following 6 months of open label treatment, mean urinary albumin had increased from 34.78mg/L at OL baseline to 55.64mg/L at Month 6 and was maintained at this level for the following 30 months. In the monotherapy group, mean urinary albumin was similar to OL baseline (30.30mg/L) following 36 months of treatment.

Safety Results

Adverse Experiences

Overall, treatment with rosiglitazone was well tolerated. During the study AEs were reported by a total of 552 patients; 189 patients (82.5%) in the rosiglitazone 2mg bd combination group and 363 patients (84.4%) in the rosiglitazone 4mg bd monotherapy group. The most common AE in the combination therapy group was hyperglycaemia followed by injury, and in the monotherapy

group, bronchitis followed by injury (see table below). 22 patients experienced hepatic-related AEs; 14 (6.1%) in the combination therapy group and 8 (1.9%) in the monotherapy group. Only 2 (0.3%) events were severe and only 3 patients withdrew due to hepatic-related events: increased GGT, increased ALT and fatty liver. The majority of AEs reported were mild/moderate in intensity and had a relationship to study medication of not related/unlikely.

On-therapy Adverse Experiences by Preferred Term (Incidence $\geq 5\%$)

AE by Preferred Term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Patients with ≥ 1 On-therapy AE*	189 (82.5)	363 (84.4)
Bronchitis	9 (3.9)	69 (16.0)
Injury	36 (15.7)	60 (14.0)
Back pain	18 (7.9)	51 (11.9)
Hypercholesterolaemia	19 (8.3)	43 (10.0)
Arthritis	15 (6.6)	42 (9.8)
Urinary tract infection	24 (10.5)	40 (9.3)
Infection viral	28 (12.2)	38 (8.8)
Neuralgia	8 (3.5)	32 (7.4)
Arthralgia	20 (8.7)	30 (7.0)
Pharyngitis	15 (6.6)	29 (6.7)
Upper respiratory tract infection	29 (12.7)	29 (6.7)
Oedema legs	6 (2.6)	25 (5.8)
Respiratory disorder	19 (8.3)	25 (5.8)
Arthrosis	4 (1.7)	23 (5.3)
Hyperlipaemia	11 (4.8)	23 (5.3)
Abdominal pain	13 (5.7)	23 (5.3)
Diabetes mellitus aggravated	23 (10.0)	22 (5.1)
Pain	13 (5.7)	19 (4.4)
Hyperglycaemia	46 (20.1)	16 (3.7)
Coughing	19 (8.3)	15 (3.5)
Hypoglycaemia	14 (6.1)	6 (1.4)

* On-therapy AEs defined as those AEs which were emergent during the open label study

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Serious Adverse Experiences

There were 10 deaths during open label treatment or within 30 days of end of therapy, 7 in the rosiglitazone 4mg bd monotherapy group and 3 in the combination therapy group. All deaths were considered as unlikely/not related to study medication.

135 patients had serious nonfatal on-therapy AEs during open label treatment; 49 (21.4%) patients in the combination therapy group and 86 (20.0%) patients in the monotherapy group. Five serious on-therapy AEs in four patients were considered by the investigator to have a probable/suspected relationship to study medication: hyperglycaemia, arthralgia, pulmonary oedema/cardiac failure and gynecomastia.

Withdrawals Due to Adverse Experiences

A total of 66 patients were withdrawn from the study due to on-therapy AEs; 26 (11.4%) in the rosiglitazone 2mg bd combination therapy group and 40 (9.3%) in the rosiglitazone 4mg bd monotherapy group. The most frequent AE leading to withdrawal was hyperglycaemia in the combination therapy group (4 patients (1.7%)) and in the monotherapy group myocardial infarction (6 patients (1.4%)). All other events led to the withdrawal of less than 1.0% of patients in either treatment group.

Laboratory Tests

Both treatment groups showed small, clinically insignificant, reductions in mean haemoglobin and haematocrit over the first 3 months of therapy with no further decrease for the duration of the study. Decreased haemoglobin and haematocrit values of potential clinical concern were recorded in 3 patients (1.3%) and 5 patients (2.2%) respectively in the combination therapy group and 15 patients (3.7%) and 17 patients (4.2%) respectively in the monotherapy group. No mean changes from baseline in parameters related to liver function were considered to be clinically significant. Only 2 reports of elevated AST and 2 reports of ALT above predetermined levels of potential clinical concern were recorded with elevated GGT ($>3\times$ upper limit reference range) reported in 9 patients (4.0%) in the combination group and 12 patients (3.0%) in the monotherapy group. Increased GGT was recorded as an AE in 6 patients (2.6%) in the combination therapy group and 5 patients (1.2%) in the monotherapy group.

Vital Signs, ECGs and Weight

There were no clinically relevant changes in SBP, DBP or heart rate and no clinically significant changes in ECG parameters were noted in either of the treatment groups. No clinically significant findings were observed in the occurrence of new on-therapy abnormal ECG parameters. An increase in weight with treatment duration was observed in both patient groups; in the rosiglitazone 2mg bd combination group, mean weight at Month 36 was 83.2 kg compared to 78.8 kg at OL baseline and in the rosiglitazone 4mg bd monotherapy group, mean weight at Month 36 was 86.9 kg compared to 83.3 kg at OL baseline.

Pharmacodynamic Results

Following an initial small rise in mean TC over the first 6 months of treatment in both the combination therapy (+2.5mg/dL) and monotherapy (+8.5mg/dL) groups, mean TC decreased over the following 30 months of therapy to below OL baseline in both groups. Mean LDL decreased to below the OL baseline at Month 36 in both groups (2mg bd in combination: -9.2mg/dL, 4mg bd monotherapy: -9.5mg/dL) whereas mean HDL increased over the 36 month treatment period in both groups (2mg bd in combination: +5.7mg/dL, 4mg bd monotherapy: +5.1mg/dL). Following the amendment of the protocol to permit the initiation of and changes in doses of anti-dyslipidaemic agents (including statins and fibrates), it is possible that improvements in the lipid profile during the last year of treatment, were due in part to this additional pharmacological intervention.

In general, mean TC/HDL ratio decreased for the duration of the 36 months' treatment in both treatment groups, with a decrease from an OL baseline ratio of 5.10 to 4.40 at Month 36 in the combination therapy group and from 4.76 to 4.26 respectively in the monotherapy group. Similar decreases in mean LDL/HDL ratio were observed from an OL baseline ratio of 3.18 to 2.66 at Month 36 in the combination therapy group and from 2.98 to 2.63 respectively in the monotherapy group.

Mean free fatty acids were lower than OL baseline in both treatment groups at Month 36.

Conclusion(s)

Long term treatment with rosiglitazone 2mg bd used in combination with a sulphonylurea or with rosiglitazone 4mg bd as monotherapy is effective in maintaining HbA1c and FPG at clinically significant levels. Initial increases in HbA1c and fasting plasma glucose in patients who changed therapy from glibenclamide to rosiglitazone 4mg bd were shown to be transient. Decreases in total

cholesterol:HDL-cholesterol and LDL-cholesterol:HDL-cholesterol ratios and free fatty acids were observed for the three year duration of this extension study.

The majority of adverse events were mild or moderate in intensity and were not considered related to study medication. Treatment with rosiglitazone was associated with an increase in body weight. There was no indication of any hepatic safety issues following long term therapy.

This analysis demonstrated that long term treatment with rosiglitazone 2mg bd (in combination with a sulphonylurea) or 4mg bd is safe, well tolerated and an effective therapy for patients with type 2 diabetes mellitus.

Table of Contents

	Page
Report Synopsis	3
List of Tables	13
List of Figures	15
List of Appendices	16
List of Abbreviations & Definitions	17
1 Introduction	20
2 Objectives	22
2.1 Primary Objective	22
2.2 Secondary Objectives	22
3 Methodology	22
3.1 Study Design	22
3.1.1 Protocol Amendments	24
3.2 Investigators	25
3.3 Ethics	25
3.4 Eligibility Criteria	25
3.4.1 Inclusion Criteria	25
3.4.2 Exclusion Criteria	26
3.5 Study Medication and Administration	27
3.5.1 Study Medication	27
3.5.2 Dosage and Administration	28
3.6 Compliance with Study Medication	28
3.7 Prior and Concomitant Medication	29
3.8 Study Procedures	29
3.8.1 Schedule of Assessments	29
3.8.2 Enrolment	32
3.8.3 Treatment Phase	32
3.8.4 Unscheduled visits	35
3.8.5 Reasons for Concluding Study	35
3.9 Efficacy Assessments	36
3.9.1 Primary Efficacy Parameter	37
3.9.2 Secondary Efficacy Parameters	37
3.10 Safety Assessments	38
3.10.1 Adverse Experiences	38
3.10.2 Serious Adverse Experiences	39
3.10.3 Physical Examination and Vital Signs	39
3.10.4 Clinical Laboratory Tests	40
3.10.5 Electrocardiograms	42
3.11 Pharmacokinetic Assessments	42
3.12 Pharmacodynamic Assessments	42

3.13 Pharmacoeconomic Assessments	42
3.14 Data Quality Assurance	42
3.15 Statistical Evaluation	43
3.15.1 Target Sample Size	43
3.15.2 Method of Randomisation	43
3.15.3 Planned Efficacy Evaluations	43
3.15.4 Methods of Analysis	44
3.15.5 Populations/Data Sets to be Evaluated	44
3.15.6 Safety Evaluations	44
3.15.7 Other Evaluations	46
4 Study Population	46
4.1 Study Dates	46
4.2 Patient Disposition	46
4.2.1 Number and Distribution of Patients	46
4.2.2 Number of Patients Present at Each Phase	47
4.2.3 Withdrawal Reasons	47
4.3 Protocol Violations	48
4.4 Demographic and Baseline Characteristics	49
4.4.1 Demographic Characteristics	49
4.4.2 Baseline Characteristics	50
4.5 Presenting Conditions and Medical History	51
4.6 Adverse Experiences Ongoing at Open Label Baseline	52
4.7 Concomitant Medications	53
4.8 Treatment Compliance	55
5 Efficacy Results	57
5.1 Efficacy Evaluation	57
5.1.1 Data Sets Summarised	57
5.2 Primary Efficacy Parameter	57
5.3 Secondary Efficacy Parameters	61
5.3.1 Glycaemic Parameters	61
5.3.2 Urinary Albumin	69
6 Safety Results	72
6.1 Extent of Exposure	72
6.2 Adverse Experiences	73
6.2.1 Cardiac-related AEs	77
6.2.2 Hepatic-related AEs	83
6.2.3 Oedema-related AEs	84
6.2.4 Anaemia-related AEs	84
6.2.5 Lipid related AEs	85
6.2.6 Adverse Experiences by Intensity	85
6.2.7 Adverse Experiences by Causality	86
6.3 Deaths	87
6.4 Serious Nonfatal Adverse Experiences	90

6.4.1 Serious Nonfatal Adverse Experiences Ongoing at Open Label Baseline	90
6.4.2 On-therapy Serious Nonfatal Adverse Experiences	90
6.4.3 Post-therapy Serious Nonfatal Adverse Experiences	99
6.5 Withdrawals Due to Adverse Experiences	99
6.6 Vital Signs	104
6.7 Weight	108
6.8 Electrocardiographic Data	110
6.9 Laboratory Tests	115
7 Pharmacokinetic Evaluation	128
8 Pharmacodynamic Evaluation	128
9 Pharmacoeconomic Evaluation	137
10 Discussion	137
11 Conclusions	144
12 References	145
13 Source Tables: Study Population	150
14 Source Tables: Efficacy Results	423
15 Source Tables: Safety Results	589
Appendices	2172

List of Tables

	Page
Table 1 Outline of Study Procedures	30
Table 2 Patient Numbers by Previous Treatment Groups	47
Table 3 Summary of Reasons for Withdrawal	48
Table 4 Summary of Demographic Characteristics	49
Table 5 Summary of Baseline Characteristics	51
Table 6 Presenting Conditions (at Double-blind Baseline) Reported by $\geq 5.0\%$ of Patients in Either Treatment Group	52
Table 7 Baseline Signs and Symptoms Reported as Ongoing at Open Label Baseline by $\geq 2.0\%$ of Patients in Either Treatment Group	53
Table 8 Concomitant Medication by ATC Classification Level 2 Received by $\geq 25.0\%$ of Patients in Either Treatment Group	54
Table 9 Concomitant Medication Received by $\geq 5.0\%$ of Patients in Either Treatment Group	55
Table 10 Compliance with Rosiglitazone Study Medication	56
Table 11 Mean HbA1c by Visit	61
Table 12 Mean Fasting Plasma Glucose by Visit	65
Table 13 Mean Fasting Plasma Insulin by Visit	68
Table 14 Mean Urinary Albumin by Visit	72
Table 15 Duration of Exposure to Study Medication	73
Table 16 Most Common Adverse Experiences by Body System ($\geq 10\%$ in Either Treatment Group)	74
Table 17 On-therapy Adverse Experiences Reported by $\geq 5.0\%$ of Patients in Either Treatment Group by Preferred Term	76
Table 18 On-Therapy Cardiac-related Adverse Experiences by Body System and Preferred Term	78
Table 19 Severe On-therapy Adverse Experiences Reported by $\geq 1\%$ of Patients in Either Treatment Group	86
Table 20 On-therapy Adverse Experiences Considered to be Suspected/Probably Related to Study Medication Occurring in $\geq 1\%$ of Patients in Either Treatment Group	87
Table 21 Summary of Deaths Occurring On-Therapy	88
Table 22 Summary of Serious Nonfatal On-therapy Adverse Experiences Occurring in More Than One Patient in Either Treatment Group	92
Table 23 Patients with Serious Nonfatal On-therapy and/or Post-therapy Adverse Experiences	93
Table 24 Summary of On-therapy Adverse Experiences Leading to Withdrawal in More Than One Patient in Either Treatment Group	100
Table 25 Patients Withdrawn from the Study Due to On-Therapy Adverse Experiences	101
Table 26 Summary Statistics for Vital Signs by Visit	105
Table 27 Number (%) of Patients with On-therapy Changes in Vital Signs of Potential Clinical Concern from Open Label Baseline	108
Table 28 Summary Statistics for Weight by Visit	109

Table 29 Patients with On-therapy ECG Values of Potential Clinical Concern Based on the Open Label Baseline	111
Table 30 Summary of Abnormal ECG New Onset Observations On-therapy not Present at Open Label Baseline Occurring in More Than One patient in Either Treatment Group.	112
Table 31 Predetermined Laboratory Values of Potential Clinical Concern. . .	116
Table 32 Patients with On-therapy Laboratory Values of Potential Clinical Concern (F3 Flag)	118
Table 33 Mean Haemoglobin and Haematocrit by Visit	121
Table 34 Mean Values in Selected Blood Chemistry Parameters Related to Liver Function by Visit	124
Table 35 Mean Values for Selected Blood Chemistry Parameters Related to Renal Function by Visit	127
Table 36 Mean Lipid Parameters by Visit.	135

List of Figures

	Page
Figure 1 HbA1c (mean± SE) by Visit	58
Figure 2 HbA1c (mean± SE) by Visit and by Previous Treatment (Combination Therapy)	59
Figure 3 HbA1c (mean± SE) by Visit and by Previous Treatment (Monotherapy)	60
Figure 4 Fasting Plasma Glucose (mean± SE) by Visit	62
Figure 5 Fasting Plasma Glucose (mean± SE) by Visit and Previous Treatment (Combination Therapy)	63
Figure 6 Fasting Plasma Glucose (mean± SE) by Visit and Previous Treatment (Monotherapy)	64
Figure 7 Fasting Plasma Insulin (mean± SE) by Visit	66
Figure 8 Fasting Plasma Insulin (mean± SE) by Visit and Previous Treatment (Combination Therapy)	67
Figure 9 Fasting Plasma Insulin (mean± SE) by Visit and Previous Treatment (Monotherapy)	68
Figure 10 Urinary Albumin (mean± SE) by Visit	69
Figure 11 Urinary Albumin (mean± SE) by Visit and Previous Treatment (Combination Therapy)	70
Figure 12 Urinary Albumin (mean± SE) by Visit and Previous Treatment (Monotherapy)	71
Figure 13 Body Weight (mean± SE) Over Time	110
Figure 14 Haemoglobin (mean± SE) by Visit	122
Figure 15 Haematocrit (mean± SE) by Visit	123
Figure 16 Total Cholesterol (mean± SE) by Visit	129
Figure 17 LDL (mean± SE) by Visit	131
Figure 18 HDL (mean± SE) by Visit	132
Figure 19 Triglycerides (mean± SE) by Visit	133
Figure 20 Free Fatty Acids (mean± SE) by Visit	134

List of Appendices

	Page
Appendix A Protocols (including Amendments), Blank Case Report Form (CRF), Investigator CVs, Certificates of Analysis	2173
Appendix B Patient Data Listings of Demographic and Baseline Characteristics.	2724
Appendix C Patient Data Listings of Efficacy	2725
Appendix D Patient Data Listings of Adverse Experiences	2726
Appendix E Patient Data Listings of Vital Signs and Electrocardiograms . . .	2727
Appendix F Patient Data Listings of Laboratory Tests	2728
Appendix G Annotated CRFs for Patients with Serious Nonfatal Adverse Experiences and Adverse Experiences Leading to Withdrawal or Death .	2729

List of Abbreviations & Definitions

Abbreviation	Unabridged Term(s)
AE	Adverse Experience/Event
ALT	Alanine Aminotransaminase (SGPT)
AST	Aspartate Aminotransaminase (SGOT)
ATC	Anatomical Therapeutic Chemical
bd	Twice daily
BMI	Body Mass Index (weight [kg]/square of height [m ²])
BP	Blood Pressure
bpm	Beats Per Minute
BUN	Blood Urea Nitrogen
CFR	Code of Federal Regulations
CPMP	Committee for Proprietary Medicinal Products
CRF	Case Report Form
DB	Double-blind
DBP	Diastolic Blood Pressure
dL	Decilitre
DM	Diabetes Mellitus
ECG	Electrocardiogram
ERC	Ethics Review Committee
EU	European Union
F1	Normal range flagging. Denotes all laboratory values above or below the normal range.
F2	Baseline shift flagging. Denotes laboratory values which have increased or decreased from baseline by more than a sponsor-defined level.
F3	Clinical concern flagging. Denotes a laboratory value considered by the sponsor to be a potential clinical concern.
FDA	Food and Drug Administration
FPG	Fasting Plasma Glucose
GCP	Good Clinical Practice
GGT	Gamma Glutamyl Transpeptidase
Hb	Haemoglobin
HbA1c	Glycosylated haemoglobin
HCT	Haematocrit
HDL	High Density Lipoprotein
HDPE	High Density Polyethylene
HR	Heart rate
ICD9	International Classification of Diseases
IRB	Institutional Review Board
IV	Intravenous

LDH	Lactate Dehydrogenase
LDL	Low Density Lipoprotein
LLRR	Lower Limit Reference Range
MCHC	Mean Corpuscular Haemoglobin Concentration
mg	Milligrammes
mL	Millilitres
mmHg	Millimetres of Mercury
NEFA	Non-esterified fatty acids (also termed free fatty acids)
NIDDM	Non-Insulin Dependent Diabetes Mellitus (Type 2 Diabetes)
NOS	Not Otherwise Specified
OL	Open label
PID	Patient Identification
pmol	Picomole
PPAR γ	Peroxisomal Proliferator Activated Nuclear Receptor gamma
QTc	QT Interval Corrected for Heart Rate
RBC	Red Blood Cell
RR	Reference Range
RSG	Rosiglitazone
SAE	Serious Adverse Experience/Event
SB	SmithKline Beecham
SBCL	SmithKline Beecham Clinical Laboratories
SBP	Systolic Blood Pressure
SD	Standard Deviation
SE	Standard Error
SGOT	Serum Glutamic Oxaloacetic Transaminase (see AST)
SGPT	Serum Glutamic Pyruvic Transaminase (see ALT)
SI	International system of units
SOPs	Standard Operating Procedures
SQRT	Square Root
SU	Sulphonylurea
TC	Total Cholesterol
ULRR	Upper Limit Reference Range
US/USA	United States of America
VLDL	Very Low Density Lipoprotein
WBC	White Blood Cell
WHO	World Health Organisation
yrs	Years
WRC-GCP	Worldwide Regulatory Compliance - Good Clinical Practice

Definitions

Double-blind baseline	The baseline before the double-blind medication was issued in the previous study.
Open label baseline	The first day of open label medication but prior to the ingestion of medication
Adverse experience	Any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs,

Serious adverse experience	symptoms and/or laboratory changes occurring in any phase of the clinical study whether associated with the study drug, active comparator or placebo and whether or not considered drug related. This included an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the significant worsening of the disease under investigation that was not recorded elsewhere in the CRF under specific efficacy assessments. Any event which was fatal, life threatening, disabling/ incapacitating or resulted in hospitalisation, prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regarded as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug was to be documented as a serious event. WHOART a hierarchical system of defining and categorising an adverse experience under a "preferred/ common term" in one of 12 body systems.

1 Introduction

Diabetes mellitus is a syndrome which results from disturbances in carbohydrate, fat and protein metabolism. It is characterised by chronic hyperglycaemia as the primary manifestation. Type 2 diabetes mellitus (non-insulin dependent diabetes mellitus [NIDDM]) is the most common form of the disease, accounting for more than 85% of the total number of cases[1]. It is a major healthcare issue due to the impact it has on patients and the costs associated with the management of its complications, especially cardiovascular, renal and neurologic disease [7].

Type 2 diabetes is a chronic, progressive disease associated with a high morbidity and mortality. It is characterised by impaired insulin secretion and insulin resistance in the liver, adipose tissue and skeletal muscle [5]. Together, these abnormalities contribute to abnormal glucose metabolism and loss of glucose homeostasis. Improved glycaemic control is associated with reductions in long-term microvascular complications [6].

The medical management of patients with type 2 diabetes mellitus consists of diet and exercise and weight reduction together with oral or insulin therapy as appropriate. Available oral therapies enhance insulin secretion (e.g., sulphonylureas) [8], reduce hepatic glucose output (e.g., metformin) [9] or delay absorption of carbohydrates (e.g., α -glucosidase inhibitors) [10]. Metformin also increases peripheral glucose uptake [9]. Recently, a new class of compounds, the thiazolidinediones, have become available for the treatment of type 2 diabetes mellitus. These novel agents, which include rosiglitazone, act directly to reduce insulin resistance by sensitising the liver, muscle and adipose tissue to the actions of circulating insulin [2]. They exert their effect by binding to the nuclear peroxisome proliferator activated receptor-gamma (PPAR-gamma), thus modifying transcriptional regulation of factors involved in the regulation of insulin action. Rosiglitazone is therefore a potentially important treatment advance.

The safety, tolerability and efficacy of rosiglitazone has been evaluated in approximately 5400 patients with type 2 diabetes mellitus in 19 clinical studies. Rosiglitazone given once or twice daily as monotherapy or in combination with other oral anti-diabetic therapeutic agents was well tolerated at daily doses of up to 12mg for up to 52 weeks. Rosiglitazone was significantly more effective than placebo in improving glycaemic control when used as a single agent [3][11][12][13][4] or when added to sulphonylurea therapy [17].

Study 015 was a 26 week, double-blind, placebo-controlled, comparative study to evaluate the efficacy, safety and tolerability of rosiglitazone in combination with sulphonylurea therapy in patients with type 2 diabetes mellitus. Study 015 showed that rosiglitazone 1 and 2mg twice daily taken in addition to sulphonylurea therapy for 6 months is a safe, well tolerated and effective therapy for patients with type 2 diabetes mellitus [17][29].

Study 020 was a 52 week, double-blind, placebo-controlled, comparative study to evaluate the efficacy, safety and tolerability of rosiglitazone vs. glibenclamide in patients with type 2 diabetes mellitus. Study 020 showed that after 52 weeks treatment, rosiglitazone 4mg bd was as effective as glibenclamide uptitrated for the first 12 weeks of the study, as measured by reduction in HbA1c from baseline [14][15][16][18][32].

Study 025 was a 16 week, double-blind, parallel group study to determine the effects of rosiglitazone on insulin sensitivity, endothelial function and vascular reactivity in comparison with metformin and placebo when administered to patients with type 2 diabetes mellitus.

Results from an interim analysis of study 009 [19] showed that rosiglitazone 2mg bd in combination with a sulphonylurea or rosiglitazone 4mg bd as monotherapy was effective in maintaining HbA1c and FPG in patients who continued to take these treatments for up to 12 months. Additional glycaemic control was observed when patients were increased from rosiglitazone 2mg bd to 4mg bd monotherapy. In patients who changed therapy from glibenclamide to rosiglitazone 4mg bd, initial increases in HbA1c and FPG were seen, although it was proposed that this may have been a transient effect reflecting the time it takes for rosiglitazone to achieve full effect. Treatment with rosiglitazone 2mg bd (in combination with a sulphonylurea) or 4mg bd was shown to be safe and well tolerated.

The objectives of this study were to evaluate the long term safety, tolerability and efficacy of rosiglitazone administered as 4mg bd monotherapy, or as 2mg bd in combination with a sulphonylurea, in the treatment of patients with type 2 diabetes. The protocol was amended on 2 December 1999 to allow for a total of four years of treatment. Since this decision to extend the study was made, there have been a number of new developments in the regulatory approval of rosiglitazone (Avandia) within Europe. In mid-year of 2000 the CPMP recommended granting marketing approval for rosiglitazone, and the acquisition of further long-term data in an uncontrolled setting was deemed inappropriate. Additional controlled studies were planned, and ongoing open-label, uncontrolled, studies, including study 009, were stopped.

The analysis of safety data in study 009 and throughout the clinical programme as a whole, has demonstrated that treatment with rosiglitazone 2mg bd (in combination with a sulphonylurea) or 4mg bd in long term treatment is safe and well tolerated. In light of the regulatory approval of Avandia within Europe, and the extensive data that have already been obtained from this study, the additional information that would have been gained from continuing study 009 until all patients have completed four years of treatment no longer justified the need to continue with this study. For this reason, the decision was made to stop the study early.

The data described in this report are the final data of the open label extension of studies 015, 020 and 025 to assess the safety, tolerability and efficacy of rosiglitazone administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents (sulphonylurea).

2 Objectives

2.1 Primary Objective

To evaluate the long term safety and tolerability of rosiglitazone administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents, for up to 48 months in the treatment of patients with type 2 diabetes mellitus.

2.2 Secondary Objectives

To evaluate the long term efficacy of rosiglitazone in terms of glycaemia. Pharmacodynamic parameters have also been summarised.

3 Methodology

3.1 Study Design¹

This was a phase IIIa multicentre, open label extension study of rosiglitazone (4mg bd monotherapy, 2mg bd combination therapy) administered to patients

¹ [Appendix A](#) contains the protocol and sample case report form.

with type 2 diabetes mellitus. Patients on monotherapy in the previous study (studies 020, 025) received rosiglitazone 4mg bd monotherapy in this extension study. Patients on combination therapy with a sulphonylurea in the previous study (study 015) received rosiglitazone 2mg bd in addition to their sulphonylurea (glibenclamide, gliclazide, glipizide). During the study patients received study medication for up to 48 months.

Patients with type 2 diabetes mellitus who had completed a rosiglitazone monotherapy study (49653/020, 49653/025) or a rosiglitazone and sulphonylurea combination therapy study (49653/015) and who satisfied the eligibility criteria ([Section 3.4](#)) could have entered the study. Patients then received open label rosiglitazone (4mg bd monotherapy or 2mg bd combination therapy) and were scheduled to attend a further 21 visits at Months 1, 2, 3, 4, 6, 8, 9, 10, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42, 45 and 48 for safety and efficacy assessments.

Patients on monotherapy in studies 020 (glibenclamide, rosiglitazone 2mg bd or rosiglitazone 4mg bd) or 025 (metformin, rosiglitazone 4mg bd or placebo) received rosiglitazone 4mg bd as monotherapy in this study and were not permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy with a sulphonylurea in study 015 (sulphonylurea plus placebo, rosiglitazone 1mg bd or rosiglitazone 2mg bd) received rosiglitazone 2mg bd in addition to a sulphonylurea (glibenclamide, glipizide or gliclazide) in this study. The dose of the sulphonylurea could have been altered during this study if necessary, but it could not have been switched for another treatment nor may a further hypoglycaemic agent have been added. Note that although the dose of the sulphonyl urea could have been altered, in most cases this would have been to control hypoglycaemia. Increasing the dose of the sulphonylurea would have had little effect on efficacy because the vast majority of patients had reached a fully effect dose prior to entry into the study. The use of insulin was prohibited during the study.

At the start of the study, it was expected that approximately 1000 patients with type 2 diabetes mellitus, completing previous rosiglitazone studies would be invited to participate. It was estimated that between 400 and 1000 patients would enter the study.

3.1.1 Protocol Amendments²

The final protocol was dated 22 November 1996. The following amendments have been generated.

Amendment 1: 11 December 1997 (all centres)

Amendment 2: 15 October 1998 (all centres)

Amendment 3: 02 December 1999 (all centres)

Amendment 4: 14 January 2000 (all centres except France)

Amendment 5: 14 January 2000 (French centres only)

Amendments 1, 2 and 3 extended the dosing period of study 009 to 24, 36 and 48 months, respectively. The option to extend the dosing period was at the discretion of the investigator and patient and could have only been considered for patients for whom rosiglitazone has been adequately tolerated.

Amendment 4 resulted in additional sections to the protocol relating to the monitoring of liver function tests (LFTs) and treatment guidelines for management of signs or symptoms of congestive heart failure (CHF), oedema, angina and anaemia. The frequency of liver function test monitoring was modified to conform with other study protocols to include LFTs at baseline and at least every 2 months during the first year of treatment and at least every 6 months thereafter. As the effects of rosiglitazone on lipids was well documented during the first 2-3 years of treatment in this and other studies, the use of statins and fibrates was amended to be used as required. Lipid endpoints were updated to pharmacodynamic parameters in order to be consistent with other ongoing protocols. As rosiglitazone has been found to cause mild fluid retention in certain patients, the use of loop diuretics was also permitted to manage such events.

Amendment 5 was applicable for the French centres only and differed from amendment 4 only in the threshold for re-assessing liver function ([Section 3.8.1.1](#)) and the definition of anaemia leading to patient withdrawal from the study.

Amendments 4 and 5 resulted in the addition of 3 visits, Visits 4a, 5a and 6a at Months 4, 8 and 10 respectively, to the protocol for liver function testing.

² The protocol provided in [Appendix A](#) contains the protocol amendments.

All revisions have been taken into account when writing this report.

3.2 Investigators³

The study was conducted in 92 centres: 30 in France, 24 in UK, 14 in Germany, 7 in Italy, 5 in Sweden, 4 in Belgium, 3 in Spain, 3 in Netherlands, and 2 in Ireland. The investigators' names, affiliations and geographical locations are listed in [Section 13, Table 13.0.1](#). The investigators were selected because of their interest in the study, their ability to conduct the study according to Good Clinical Practices (GCP) standards and their ability to enrol patients. To ensure that study procedures were consistent across all investigational sites, SmithKline Beecham (SB) representatives reviewed the protocol, case report form (CRF) and procedures for reporting safety data with the investigators and their staff.

3.3 Ethics

The study was conducted in accordance with Good Clinical Practices⁴ and the Declaration of Helsinki as amended in Somerset West, Republic of South Africa (1996). The protocol and statement of informed consent were approved by an Institutional Review Board (or Ethics Committee) prior to each centre's initiation. Written informed consent⁵ was obtained from each patient before undergoing any study-related procedures. Case report forms (CRFs) were provided for each patient's data to be recorded. A sample CRF is provided in [Appendix A](#).

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

Only patients who fulfilled all the following criteria were eligible for inclusion in the study:

- 1 Patients with type 2 diabetes mellitus (as defined by the criteria of the National Diabetes Data Group ([Appendix F1](#) of protocol) who had

³ [Appendix A](#) contains the curriculum vitae of each principal investigator.

⁴ as stated in EU CPMP for European multi-national studies and 21 CFR for studies filed to the US IND.

⁵ [Appendix A](#) contains the protocol and the sample informed consent is an appendix to the protocol.

successfully completed a rosiglitazone protocol which specified the availability of this open label extension study.

- 2 Patients must not have discontinued study medication in the preceding study for more than 10 days.
- 3 Study medication in the preceding study must have been found to be safe and well tolerated throughout its duration by both the investigator and the patient.
- 4 Female patients must have been post menopausal, i.e., >6 months without menstrual period, surgically sterile, or using hormonal contraceptives or intrauterine contraceptive devices. Female patients taking hormonal contraceptives must also have used an additional barrier form or intrauterine form of birth control.
- 5 Subjects who had given written informed consent to participate.

3.4.2 Exclusion Criteria

Use of an investigational drug within 30 days or 5 half-lives (whichever is longer) preceding the first dose of study medication.

A patient was excluded from the study if any of the following applied:

- 1 Patients who were pregnant or lactating, or who had planned for pregnancy within the time frame of the study.
- 2 Patients who had experienced any significant and/or serious adverse experience during the preceding protocol which, in the opinion of the investigator, could have been attributed to study medication.
- 3 A clinically significant laboratory abnormality had been recorded during the preceding protocol which in the opinion of the investigator, would preclude long term treatment with rosiglitazone.
- 4 The patient had withdrawn from the preceding study for any reason.
- 5 Any clinically significant abnormality identified at the end of study assessments of the preceding study (e.g., physical examination, electrocardiogram, etc. as appropriate) which in the judgement of the investigator would preclude safe completion of this study.

- 6 Symptomatic diabetic neuropathy of sufficient severity to require treatment for control of symptoms (e.g., painful peripheral neuropathy, symptomatic orthostatic hypotension, urinary retention, gastric stasis, pedal ulcers).
- 7 Diabetic retinopathy imminently requiring treatment for preserving or restoring vision.

3.5 Study Medication and Administration

3.5.1 Study Medication

Patients on monotherapy in the previous study continued to receive rosiglitazone 4mg bd and were not permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy in the previous study continued to receive rosiglitazone 2mg bd in addition to a sulphonylurea (glibenclamide, glipizide or gliclazide); the dose of which could have been altered during this study if necessary, but it could not have been switched for another treatment nor may a further hypoglycaemic agent have been added.

Rosiglitazone was supplied as white, bi-convex (7mm) film coated tablets containing 2mg rosiglitazone. Rosiglitazone tablets contained rosiglitazone as the maleate salt (rosiglitazone maleate, BRL 49653C) equivalent to 2mg rosiglitazone base (rosiglitazone, BRL 49653). The batch numbers were [REDACTED] and [REDACTED] (Appendix A contains details of batch numbers and Certificates of Analysis).

For patients for whom the rosiglitazone was added to pre-existing sulphonylurea therapy (i.e., the patients on combination therapy) the non-rosiglitazone agent was continued to be supplied by individual study centres.

Rosiglitazone study medication was packaged in high density polyethylene (HDPE) bottles of 70 tablets. With respect to the rosiglitazone monotherapy and rosiglitazone combination therapy groups, patients were given two bottles or one bottle respectively (sufficient for one months treatment with an overage to allow for some flexibility of the intervals between visits) at Visits 1, 2 and 3, and six or three bottles respectively (sufficient for three months treatment with an overage to allow for some flexibility of the intervals between visits) at Visits 4 to 18. Each bottle of rosiglitazone medication was clearly labelled with the study number, clinical trial supply job number, dosage instructions and expiry date (if required

by local regulations). The patient identification number was to be added at the time of dispensing. The tear-off portion of the label was identified with the study number and medication code.

Study medication was to be stored between 15°C and 30°C in a secured, supervised location and dispensed according to the protocol.

3.5.2 Dosage and Administration

Patients were instructed to take either 1 tablet (rosiglitazone combination therapy group) or 2 tablets (rosiglitazone monotherapy group) in the morning before breakfast and either 1 tablet (rosiglitazone combination therapy group) or 2 tablets (rosiglitazone monotherapy group) in the evening before a meal for the entire study period, except on the mornings of a clinic visit when patients would receive their medication after their clinical assessments. Patients were advised to return all empty medication packs and any remaining medication at the next clinic visit.

Timing of the doses of other hypoglycaemic agents (for patients on combination therapy) were as per the investigator's normal clinical practice. For patients on combination therapy, the investigator could have altered the dose of the non-rosiglitazone hypoglycaemic agent if it was deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment. In order to ensure patient safety, the investigator was instructed to follow his/her normal practice when making such a dose adjustment with respect to when the patient was next reviewed, arranging additional, unscheduled visits if necessary.

3.6 Compliance with Study Medication

The number of rosiglitazone tablets dispensed at each clinic visit was recorded and patients were instructed to return any unused drug at the next visit. Counts of tablets returned were made at the beginning of Visits 2 to 19. Compliance was calculated for rosiglitazone tablets as follows:

$$\frac{\{\text{No. dispensed} - \text{No. returned}\}}{Y \times \{\text{No. days since the last visit}\}} \times 100$$

where Y = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

where Y = 4, for patients on monotherapy (taking 2 x 2 mg tablets bd)

3.7 Prior and Concomitant Medication

The use of insulin was prohibited during the study. Patients on rosiglitazone monotherapy were not permitted to take other hypoglycaemic agents for the duration of the study.

For patients on rosiglitazone combination therapy, the dose of their other hypoglycaemic therapy may have been altered during this study if necessary, but it may not have been switched for another treatment nor may a further hypoglycaemic agent have been added.

Initially, although permitted, the doses of agents used to control dyslipidaemia were held constant, and the initiation of these agents was not permitted on study. Subsequently, during the last 9-12 months of the study, the use of fibrates and statins was allowed without restriction. Dosage levels of all other concomitant medications should, if medically appropriate, have remained unchanged while the patient was enrolled in the study. All concomitant medication taken during the study was to be recorded in the CRF with indication, daily dose and dates of administration. If dosage change of concomitant medication was necessary, information pertaining to the change was also to be documented on the patient's CRF (concomitant medication pages).

Any patient exhibiting signs or symptoms of congestive heart failure was managed with loop diuretics.

3.8 Study Procedures

3.8.1 Schedule of Assessments

The schedule of assessments is shown in [Table 1](#) and is discussed in the following sections, as well as in the protocol (see [Appendix A](#)).

Table 1 Outline of Study Procedures

Visit Month	1	2	3	4	4a#	5	5a #	6	6a#	7	8	9	10	11	12	13	14	15	16	17	18	19
	1	1	2	3	4	6	8	9	10	12	15	18	21	24	27	30	33	36	39	42	45	48
Demography	X																					
Medical history	X																					
Physical examination	X	X	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
AE check	X ¹	X	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
BP & HR	X ²	X	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
ECG	X ²					X				X		X		X		X		X		X		X
Weight	X ²			X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
Compliance		X	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
Labs (blood & urine) - safety	X ²			X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
Labs (safety – LFTs)					X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X ²	X	X	X		X		X		X		X		X		X		X		X		X
Labs (blood) - efficacy - (other) ³	X ²					X				X		X		X		X		X		X		X
Urine albumin	X					X				X	X	X	X	X	X	X	X	X	X	X	X	X
Urine pregnancy test (women of child bearing potential)	X	X	X	X		X																
If the patient withdrew early, then the Conclusion/Early Withdrawal assessment should have been completed. ¹ Adverse events still ongoing at end of the previous study were to be recorded at Visit 1 (in the Adverse Experience section). Concomitant medication still ongoing at end of the previous study was to be recorded at Visit 1 (in the Concomitant Medication section). ² Where duplicated, Visit 1 assessments were to be taken from the final visit of the preceding study. ³ Labs (efficacy - other) = Insulin, lipids. # Visit 4a = Visit 4 + 1 month; Visit 5a = Visit 5 + 2 months; Visit 6a = Visit 6 + 1 month.																						

3.8.1.1 Liver Function Monitoring

At the request of the French Regulatory Agency, the requirements for liver function monitoring in the French centres differed from the other centres participating in the study.

French centres only:

Liver function tests (i.e., ALT, AST, alkaline phosphatase and total bilirubin) were reviewed at **all visits** and the following procedure was followed:

Patients who had an ALT > 1.5 times the upper limit of normal, had an evaluation of viral hepatitis (A, B and C) performed and liver function tests re-assessed within 1 week.

- If ALT remained > 1.5 times the upper limit of normal then liver function tests were re-assessed after a further 2 weeks and monthly thereafter until ALT returned to less than 1.5 times the upper limit of normal.
- If ALT remained > 1.5 but < 3 times the upper limit of normal for 6 months, monitoring of liver function tests was conducted every 3 months.
- If at any time, ALT became > 3 times the upper limit of normal, an evaluation of viral hepatitis (A, B and C) was performed and liver function tests were re-assessed within 1 week. If ALT remained > 3 times the upper limit of normal range, the patient was withdrawn from the study.

If at the final visit (Visit 19), the ALT was > 1.5 times the upper limit of normal, an evaluation of viral hepatitis was performed and liver function tests were re-assessed within 1 week.

All other centres:

Liver function tests (i.e., ALT, AST, alkaline phosphatase and total bilirubin) were reviewed **at all visits**.

If at any visit during the study, the ALT was > 3 times the upper limit of normal range, an evaluation of viral hepatitis (A, B and C) was performed and liver function tests were re-assessed within 1 week. If ALT remained > 3 times the upper limit of normal range, the patient was withdrawn from the study.

If at the final study visit (Visit 19), the ALT > 3 times the upper limit of normal range, an evaluation of viral hepatitis (A, B and C) was performed and liver function tests were re-assessed within one week.

3.8.2 Enrolment

Patients with type 2 diabetes mellitus who had completed a rosiglitazone monotherapy study (49653/020, 49653/025) or a rosiglitazone and sulphonylurea combination therapy study (49653/015) were eligible for enrolment provided treatment in the preceding study was adequately tolerated.

3.8.3 Treatment Phase

3.8.3.1 Visit 1 : start of study

At Visit 1 the investigator was to perform the following:

- Obtain patient's written informed consent.
- Confirm the patient's eligibility and complete the checklist of the inclusion and exclusion criteria.
- Physical examination including standardised measurement of blood pressure, heart rate and a pregnancy test (non-post menopausal women only).
- Measure body weight (without shoes).
- Take fasting blood and urine laboratory specimens.
- Check the patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#) of protocol).
- Standard 12-lead electrocardiogram (ECG).

Where the above assessments duplicated those being performed on the same day as part of the final visit of the previous study, the results were to be transcribed into the CRF for this study without having to re-perform the assessment.

Patients were dispensed 5 weeks of treatment with rosiglitazone and instructed how to take it.

Visit 2 was to be scheduled for 1 month $\pm$ 7 days' time. Patients were instructed to bring all remaining study medication with them to each study visit.

3.8.3.2 Visits 2 to 18 : mid-study visits (Months 1 to 45)

General Instructions – excluding Visits 4a, 5a and 6a

Visits 2, 3 and 4 were scheduled after 1, 2 and 3 months $\pm$ 7 days of treatment, respectively. Visits 5 to 18 were scheduled after 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42 and 45 months $\pm$ 14 days of treatment (see [Table 1](#): Outline of Study Procedures).

At each visit the following were performed :

- check of patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#) of protocol).
- fasting blood laboratory specimens were taken for efficacy assessment of FPG and HbA1c.
- FPG results from the previous visit checked to ensure that they were no greater than 15mmol/L in the first 3 months and no greater than 12mmol/L in the remainder of the study.
- standardised measurement of blood pressure and heart rate.
- compliance check.
- concomitant medication check.
- adverse experience check.
- next visit was scheduled and rosiglitazone was dispensed (5 weeks of medication at Visits 2 and 3; 15 weeks of medication at Visits 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18).

Patients were instructed to bring all remaining study medication with them to **each** study visit.

Visit-specific instructions

Visits 4a, 5a and 6a (Months 4, 8 and 10)

At Visits 4a, 5a and 6a, fasting blood laboratory specimens were taken for safety assessment of LFTs.

Visits 4, 6, 8, 10, 12, 14, 16 and 18 (Months 3, 9, 15, 21, 27, 33, 39 and 45)

At Visits 4, 6, 8, 10, 12, 14, 16 and 18 in addition to the assessments listed under 'General Instructions' above, the investigator was to:

- weigh the patient (without shoes).
- take fasting blood and urine laboratory specimens for safety assessment.

Visits 5, 7, 9, 11, 13, 15 and 17 (Months 6, 12, 18, 24, 30, 36 and 42)

At Visits 5, 7, 9, 11, 13, 15 and 17 in addition to the assessments listed under 'General Instructions' above, the investigator was to:

- weigh the patient (without shoes).
- take fasting blood and urine laboratory specimens for safety assessment, for 'efficacy - other', i.e., insulin and lipids, and for urinary albumin.
- perform a standard 12-lead electrocardiogram (ECG).

3.8.3.3 Visit 19 - final study visit (Month 48)

At the final visit, Visit 19, (Month 48) the following procedures were to be performed:

- physical examination including standardised measurement of blood pressure and heart rate.
- body weight (without shoes).
- fasting blood and urine laboratory specimens for safety assessment, for FPG and HbA1c, for 'efficacy - other', i.e., insulin and lipids, and for urinary albumin.
- diet check, since previous.
- standardised measurement of blood pressure and heart rate.
- standard 12-lead electrocardiogram (ECG).
- concomitant medication check.
- check compliance

- adverse experience check.
- study conclusion record.

Note: Protocol-specified birth control methods were to be continued for a minimum of 30 days after the patient received the last dose of study medication.

3.8.4 Unscheduled visits

For patients on combination therapy, the investigator could alter the dose of the combination hypoglycaemic agent if it was deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment.

In order to ensure patient safety, the investigator was to follow his/her normal practice when making such a dose adjustment with respect to when the patient was next reviewed, arranging additional, unscheduled visits if necessary. All unscheduled visits were to be recorded in the Unscheduled Visit section of the CRF.

3.8.5 Reasons for Concluding Study

All patients were considered to have completed the study upon completion of 48 months' treatment and of the assessments and procedures scheduled at Visit 19. Due to the early termination of the study by SmithKline Beecham (see [Introduction](#)) no patients completed Visit 19 as scheduled.

The investigator could stop study medication and withdraw the patient, or the patient could withdraw himself/herself from participation in the study at any time. The reason for withdrawal of a patient was recorded in the CRF.

Reasons for withdrawal could have included:

- Adverse experience

For all centres other than France, a patient with clinical evidence of anaemia experiencing angina or exacerbation of pre-existing angina were to be withdrawn from the study.

For French centres only, a patient with clinical evidence of anaemia (Hgb < 11g/dL for males, < 10g/dL for females or a fall in Hgb of ≥ 1.5 g/dL for males, ≥ 1.0 g/dL for females) experiencing angina or exacerbation of pre-existing angina were to be withdrawn from the study.

- Lack of efficacy (i.e., insufficient therapeutic effect), as defined below:
 - Patients with a fasting plasma glucose $\geq 15\text{mmol/L}$ on 2 consecutive occasions at any time during the first 3 months of treatment (the second test to be performed within 7 days of recording a value of 15mmol/L).
 - For months 3-48 of treatment, patients with a fasting plasma glucose $\geq 12\text{mmol/L}$ on 2 consecutive occasions (the second test to be performed within 7 days of recording a value of 12mmol/L).
 - Fasting blood glucose had increased to a level that was deemed by the investigator to be a safety risk to the patient.
 - Patients were to be withdrawn if they required insulin.
 - Any other metabolic disorder deemed by the investigator to be a safety risk to the patient.
- A protocol violation, including lack of compliance with visit schedule or treatment prohibited concomitant medications.
- Patient lost to follow-up.
- The patient requested an early discontinuation.
- Termination of the study by SmithKline Beecham.
- Other (reason to be documented in the CRF).

Every effort was made to follow up patients who were withdrawn due to adverse experiences or abnormal laboratory values in order to determine the final outcome of the event.

3.9 Efficacy Assessments

At each study visit, approximately 30ml of blood was to be obtained from an arm vein prior to dosing and the exact time of sample collection and the time of administration of the dose recorded in the CRF.

No more than one hour was to elapse between blood withdrawal and freezing of the separated plasma. Blood samples were to be centrifuged for approximately 15

minutes at approximately 4°C. Plasma samples were to be stored frozen at approximately -70°C to await assay. Urine samples were to be sent to the central laboratory for albumin analysis.

3.9.1 Primary Efficacy Parameter

The planned primary efficacy parameter was the change from baseline in HbA1c at Month 48. There are 2 baselines: open-label baseline and double-blind baseline. Double-blind baseline is defined as the baseline before the double-blind medication was issued in the previous study. Because all assessments should have been performed before open-label medication was issued, open-label baseline is defined as those results obtained on the first day of open-label medication but prior to the ingestion of medication. If test results were not available for the first day of open-label medication, then the values obtained on the nearest preceding date were considered as open-label baseline.

However, this final clinical report does not present data for change from baseline but summary statistics at each visit instead. The interim report for this open label extension study, dated 29-Sep-1998, presents change from baseline for both primary and secondary efficacy parameters for the first 12 months of the study. Assessment of change from baseline is more applicable during the initial months of the study due to patients having previously been treated with different doses of rosiglitazone as monotherapy or as combination therapy, or other hypoglycaemic agents or placebo. Assessment of maintenance of effect is more applicable for analysis of treatment effect over longer durations. Furthermore, due to the early termination of the study by SmithKline Beecham (see [Introduction](#)) no patients completed 48 months of treatment.

3.9.2 Secondary Efficacy Parameters

The planned secondary efficacy parameters were the change from baseline at Month 48 for:

- FPG
- fasting specific insulin levels
- urinary albumin

However, this final clinical report does not present change from baseline for the secondary efficacy parameters for the reasons outlined in [Section 3.9.1](#) and summary statistics by visit are presented instead.

3.10 Safety Assessments

3.10.1 Adverse Experiences

All adverse experiences (AEs) that occurred during the investigation were documented in the CRF. An AE was considered to be any noxious, pathologic or unintended change in anatomical physiologic or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of a clinical trial whether associated with drug or placebo and whether or not thought to be drug related.

AEs were elicited by the investigator asking the patient a non-leading question such as *"Have you felt different in any way since your last visit?"* If the patient responded "Yes", details of the on-therapy AE and its severity including any change in study drug administration, investigator attribution to study drug, any corrective therapy given and outcome status were documented in the CRF.

Attribution or relationship to study drug was judged by the investigator to be not related, unlikely, suspected (reasonable possibility) or probable.

The intensity of AEs was assigned to one of the following categories, based upon the maximum intensity:

Mild	An AE which is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.
Moderate	An AE which is sufficiently discomforting to interfere with normal everyday activities.
Severe	An AE which prevents normal everyday activities.

AEs were presented in the following intervals to estimate the frequency of AEs over time:

Before the start of open label study medication (pre-therapy).

On or after the start date of open label study medication and on or before the last date of open label study medication (on-therapy)

After the last date of open label study medication (post-therapy)

All AEs were coded from the verbatim term according to the WHO Adverse Reaction Terminology (ART) dictionary by body system and preferred term.

In cases where the same patient had multiple occurrences of the same preferred term AE with different relationships or different severities, only a single event, the "worst case" experience (i.e., the most closely related or the highest intensity) was counted. However, when multiple AEs of different preferred terms were demonstrated by the same patient; each event was counted as a separate AE. Any AE which worsened from pre-therapy to on-therapy was counted as a new AE in the on-therapy phase.

In cases where the intensity of an AE was missing, no intensity appears in the Listings in [Appendix D](#) for such an AE, however, for the purposes of tabulation the AE has been considered to be of severe intensity.

3.10.2 Serious Adverse Experiences

A serious adverse experience (SAE) is any event which is fatal, life threatening, disabling, or incapacitating or results in hospitalisation, prolongs a hospital stay, or is associated with congenital abnormality, cancer, or overdose (either accidental or intentional). In addition, any experience which the investigator regarded as serious or which would have suggested any significant hazard, contraindication, side effect, or precaution that might have been associated with the use of the drug was reported as a serious event.

An AE was considered life threatening if the patient was at immediate risk of death as it occurred. An AE was considered to be incapacitating or a temporary or permanent disability if the experience resulted in a substantial and/or permanent disruption of the patient's ability to carry out normal life functions.

Any serious AE which occurred during the clinical trial or within 30 days or five half-lives (whichever was longer) of the patient receiving the last dose of study medication, whether or not the event was judged to be related to the study drug, was to be reported by the investigator to the clinical trial monitor by telephone within 24 hours of the occurrence.

3.10.3 Physical Examination and Vital Signs

Complete physical examinations were required at all study visits (excluding Visits 4a, 5a and 6a). All relevant previous medical history was not recorded again at open label baseline (Visit 1). This information was recorded in the CRF from the previous study. However, any new medical history was to be documented at all visits.

Vital signs (blood pressure, heart rate) were required at all visits (excluding Visits 4a, 5a and 6a) and weight measurements were required at Visits 1 and 4-19 (excluding Visits 4a, 5a and 6a). Any adverse changes in the physical examination were to be recorded in the AE pages of the case report forms (CRFs). Vital signs of potential clinical concern were identified and tabulated (see [Section 6.6](#), [Table 27](#)).

3.10.4 Clinical Laboratory Tests

Values received from the central laboratory (SBCL) are converted to values in SI units and then flagged for values of potential clinical concern. All values, whether converted or not, are then rounded to the number of decimal places shown by the reference range before tabulation into data source tables. Therefore, the rounding occurs before tabulation but after flagging. Thus, a value of creatinine of 159.15umol/L would be flagged against a clinical concern value >159umol/L as high, but it would be displayed in a data source table as 159umol/L and thus would not appear to be high. The following parameters are affected in this manner for this report: total cholesterol, fasting plasma glucose, HDL cholesterol, insulin, LDL cholesterol, mean corpuscular haemoglobin concentration (MCHC), free fatty acids, triglycerides and very low density lipoprotein cholesterol (VLDL cholesterol).

Any clinically significant worsenings were to be recorded in the AE pages of the CRF. In addition, laboratory values of potential clinical concern were identified and tabulated. A table of critical concern values can be found in [Section 6.9](#), [Table 32](#).

The following **fasting** laboratory tests were performed at the times specified in [Section 3.8.1](#):

SafetyBiochemistry

Total Protein	LDH	Uric Acid	Potassium	γ GT
Albumin	Total Bilirubin	Calcium	Chloride	
ALT (SGPT)	Urea Nitrogen	Phosphorus	Bicarbonate	
AST (SGOT)	Creatinine	Sodium	Alkaline Phosphatase	

Haematology

Platelet Count	<i>RBC Indices:</i>	<i>WBC Differential:</i>
RBC Count	MCV	Neutrophils
Haemoglobin	MCH	Lymphocytes
Haematocrit	MCHC	Monocytes
Reticulocyte count	WBC Count	Eosinophils
	Basophils	

Urinalysis

Appearance	Glucose	WBCs / HPF
Specific Gravity	Ketones	Squamous Epithelial Cells
pH	Occult Blood	
Protein	RBCs / HPF	

Hepatitis testing

Hep A antibody total
Hep B antibody total
Hep C antibody

Efficacy

Plasma Glucose
Haemoglobin A1c
Specific insulin levels
Urinary albumin (spot sample)

Pharmacodynamic*Lipid levels:*

Total Cholesterol
HDL Cholesterol
LDL Cholesterol
Triglycerides
Free Fatty Acids

If there were multiple evaluations for a given laboratory, ECG or vital sign parameter within a visit, the second evaluation was used. As a result, any flagged laboratory values from the first evaluation would appear in [Appendix F](#), but would not appear in the data source tables summarising laboratory values of potential clinical concern.

3.10.5 Electrocardiograms

Electrocardiograms were performed at baseline and again after 6, 12, 18, 24, 30, 36, 42 and 48 months of treatment. Values of potential clinical concern for atrial rate, ventricular rate, PR interval, QT and QRS interval were tabulated for each group (see [Section 6.8, Table 30](#)). All clinically significant worsenings were to be recorded in the AE pages of the CRF.

QT_c was calculated as follows:

$$QT_c = QT / \sqrt{(RR \text{ Interval})}$$

where RR interval = 60/Heart Rate

3.11 Pharmacokinetic Assessments

No pharmacokinetic assessments were performed for this study.

3.12 Pharmacodynamic Assessments

The following pharmacodynamic parameters were assayed at Visits 1, 5, 7, 9, 11, 13, 15, 17 and 19: lipids (Total Cholesterol, HDL cholesterol, LDL cholesterol {calculated}, triglycerides, free fatty acids).

3.13 Pharmacoeconomic Assessments

No pharmacoeconomic assessments were performed for this study.

3.14 Data Quality Assurance

This study was conducted according to GCP. To ensure that study procedures across all investigator sites were consistently followed, the protocol, CRF and safety reporting were reviewed with the investigator and his/her personnel

responsible for the conduct of the study by the Company representative(s) at the investigator site.

Adherence to the protocol requirements and verification of data generation accuracy was achieved through monitoring visits to each investigator site. Subsequent data handling and reporting processes were subject to in-process Quality Control and this clinical report has, in addition, been subject to an end-stage Quality Control review. All the above procedures were performed according to methodologies detailed in SmithKline Beecham Standard Operating Procedures (SOPs).

A contract research organisation (CRO), Parexel International Limited, Uxbridge, UK was employed to perform data management and data entry according to an agreed contract. The CRO responsibilities were conducted according to a combination of their own SOPs and SOPs agreed between SmithKline Beecham and Parexel.

No study specific site audits were performed for this study.

3.15 Statistical Evaluation

3.15.1 Target Sample Size

Approximately 1000 patients with type 2 diabetes mellitus, completing previous rosiglitazone studies were to be invited to participate with an estimated 400 to 1000 patients expected to enter.

3.15.2 Method of Randomisation

This was an open label study and treatment allocation was not randomised. This study consists of a non-randomised, pre-selected population of patients all receiving rosiglitazone; hypothesis testing therefore has not been performed. However, patients have been grouped according to whether they were receiving rosiglitazone 2mg bd in combination with sulphonylurea or rosiglitazone 4mg bd as monotherapy. In addition, these groups have been presented according to the treatment they received in the preceding protocols.

3.15.3 Planned Efficacy Evaluations

The protocol specified primary and secondary efficacy variables were to be assessed as changes from baseline at the end of Month 48. However, this final

clinical report does not present change from baseline for the reasons outlined in [Section 3.9.1](#).

3.15.3.1 Primary Efficacy Variable

The primary efficacy parameter was defined in the protocol as change from baseline in HbA1c at Month 48. However, this final clinical report does not present change from baseline in HbA1c for the reasons outlined in [Section 3.9.1](#); summary statistics by visit are presented instead.

3.15.3.2 Secondary Efficacy Variables

The secondary efficacy parameters were defined in the protocol as change from baseline in the following parameters at Month 48:

- fasting plasma glucose
- fasting specific insulin levels
- urinary albumin

However, this final clinical report does not present change from baseline for the above parameters for the reasons outlined in [Section 3.9.1](#); summary statistics by visit are presented instead.

3.15.4 Methods of Analysis

Summary statistics for each treatment group are used to summarise the efficacy variables. Graphs have been constructed for mean values in efficacy variables by visit. Time periods are defined as relative time from the open label baseline.

3.15.5 Populations/Data Sets to be Evaluated

Data has been summarised for the patients who took at least one dose of study medication after entering the study. Missing values have been kept as missing (last value has not been carried forward).

3.15.6 Safety Evaluations

Evaluation of safety data included all patients who received study medication. Clinical interpretation was based upon review of AEs, laboratory values, vital signs and ECGs.

AEs documented in the previous protocol as 'continuing at end of study' have been transcribed onto the CRF for this study. As the onset of these experiences would have been prior to the start of open label medication, these experiences have been considered as pre-therapy for reporting purposes in this study.

Body weight, vital signs (i.e., systolic blood pressure, diastolic blood pressure and heart rate) and ECGs are summarised by study visit.

AEs which occurred on dosing Day 1 were evaluated to determine if they occurred pre-dose or post-dose. Dosing Day 1 AEs related to laboratory values, ECGs or vital signs were slotted as pre-therapy events (i.e., prior to open label baseline), unless otherwise indicated by the investigator.

Laboratory, ECG or vital signs parameters which were assigned to Week 0 (open label baseline visit) were reassigned to Week 4 if they were found to have been collected after the first date of study medication. Any parameter values which were collected more than one day after the last date of study medication dosing were reassigned to a post-therapy visit for data processing. Any parameters which were identified as an early withdrawal visit were checked to see if they should be reassigned to the post-therapy visit (using the definition above) or were during the on-therapy period. If they were collected during the on-therapy period, they were reassigned to a visit based on the number of days the patient had been on-therapy. Following final visit determination as described above, if there were multiple evaluations for a given laboratory, ECG or vital signs parameter within a visit, the second evaluation was used.

Summary patient narratives have been written for the cases listed below and are provided in [Section 15](#) (see [Table 15.0](#) for narrative location):

- patients who died
- patients with serious AEs

NOTE: Serious adverse event narratives for individual patients are generated from a dedicated safety database which collects all the data relevant to that event. There may therefore be some differences between the data in these narratives and the Data Source Tables and Listings. In particular, the age of the patient in the serious adverse event narratives (both fatal and nonfatal) refers to the age of the patient at the time of the event and not on entry to the double-blind, acute study.

- patients who withdrew due to non-serious AEs related to oedema or hepatic events which occurred after enrolment

- patients with on-therapy ALT values $> 3 \times \text{ULN}$, i.e., of potential clinical concern.

3.15.7 Other Evaluations

Other planned evaluations included analysis of the pharmacodynamic parameters. For pharmacodynamic parameters (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids), summary statistics for percent change from baseline and change from baseline were planned to be calculated for total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids; change from baseline was also planned to be calculated for total cholesterol/HDL ratio, LDL/HDL ratio. However, this final clinical report does not present change from baseline for the pharmacodynamic parameters for the reasons outlined in [section 3.9.1](#); summary statistics by visit are presented instead.

4 Study Population

4.1 Study Dates

The first patient received the first dose of open label study medication on 14 February 1997 and the last patient received the last dose of open label medication on 02 January 2001 ([Section 13](#), [Table 13.6.2](#)).

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 659 patients entered the open label extension study at 92 centres in France, Germany, Belgium, Netherlands, UK, Spain, Sweden, Italy and Ireland (see [Appendix B](#), Listing B.L1 for line listing).

Of these 659 patients, 229 received rosiglitazone 2mg bd in combination with a sulphonylurea and 430 received rosiglitazone 4mg bd monotherapy ([Section 13](#), [Table 13.2.1a](#)).



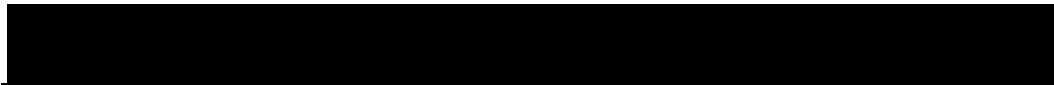
[Table 2](#) shows the numbers of patients entering this study by treatment group in the preceding studies. Patients were previously treated with either placebo, metformin monotherapy, rosiglitazone 2mg or 4mg bd monotherapy, sulphonylurea in combination with placebo, or rosiglitazone 1mg or 2mg in combination with a sulphonylurea.

Table 2 Patient Numbers by Previous Treatment Groups

Preceding Study	Patient Numbers by Previous Treatment Groups, n (%)			
Rosiglitazone 2mg bd Combination Therapy Group				
015	SU	SU+RSG 1mg bd	SU+RSG 2mg bd	TOTAL
	61 (26.6%)	78 (34.1%)	90 (39.3%)	229
Rosiglitazone 4mg bd Monotherapy Group				
020	Glibenclamide	RSG 2mg bd	RSG 4mg bd	TOTAL
	139 (34.8%)	136 (34.1%)	124 (31.1%)	399*
Rosiglitazone 4mg bd Monotherapy Group				
025	Metformin	Placebo	RSG 4mg bd	TOTAL
	11 (36.7%)	9 (30.0%)	10 (33.3%)	30

RSG=rosiglitazone; SU=sulphonylurea

Data Source: [Section 13, Tables 13.1a, 13.1b, 13.1c and 13.2; Appendix B, Listing B.L1](#)



 Patient disposition by centre is presented in [Section 13, Table 13.1a](#). Patient disposition by centre sub-divided by the treatment group in the study prior to this is provided in [Section 13, Table 13.1b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 13, Table 13.1c](#) for the rosiglitazone 4mg bd monotherapy group. Details of the prior study treatment for patients from study 025 who entered 009 (4mg bd monotherapy group) can be obtained from [section 13, Table 13.2](#) cell index.

4.2.2 Number of Patients Present at Each Phase

Due to the early termination of the study by SmithKline Beecham (see [Introduction](#)), no patients are recorded as ongoing and as no patients attended the scheduled Visit 19 no patients are recorded as completing.

4.2.3 Withdrawal Reasons

Patients withdrawing due to study termination have been classified as 'other'. The reasons for withdrawal are summarised by treatment group in [Table 3](#).

Table 3 Summary of Reasons for Withdrawal

Withdrawal Reason, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Adverse Experience*	29 (12.7)	47 (10.9)
Lack of Efficacy	62 (27.1)	82 (19.1)
Protocol Deviation	7 (3.1)	6 (1.4)
Lost to Follow-up	3 (1.3)	9 (2.1)
Other	128 (55.9)	286 (66.5)
Total Withdrawn	229 (100.0)	430 (100.0)

* Includes all adverse experiences leading to withdrawal (pre-, on- and post-therapy) and death as an outcome.

Data Source: [Section 13, Table 13.2.1a](#); [Appendix B, Listing B.L1](#)

Of those patients not classified as withdrawing for 'other' reason, the main reason for patient withdrawal in both treatment groups was lack of efficacy, representing 21.9% of all patients. In the combination therapy group, 62 patients (27.1%) withdrew due to lack of efficacy and 29 (12.7%) withdrew due to an adverse experience compared to 82 patients (19.1%) and 47 (10.9%) respectively in the monotherapy group.

Reasons for withdrawal sub-divided by the treatment group in the study preceding this are provided in [Section 13, Table 13.2.1b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 13, Table 13.2.1c](#) for the rosiglitazone 4mg bd monotherapy group. The incidence of withdrawals by reason for withdrawal was similar between the prior treatment subgroups in the combination therapy arm of the extension study.

With respect to the monotherapy group, more patients were withdrawn due to lack of efficacy from the sub-group of patients who previously received glibenclamide (37 patients (26.6%)) than in the sub-group of patients who previously received rosiglitazone 2mg bd (21 patients (15.4%)) or rosiglitazone 4mg bd (16 patients (12.9%)). A similar percentage of patients withdrew due to an adverse experience in relation to prior treatment groups within both studies 015 and 020.

No specific instructions were given to the investigators to retain patients in the study, which could have contributed to the relatively high withdrawal rates observed.

4.3 Protocol Violations

Protocol violations were not identified for this open label study. One patient who received combination therapy in the preceding study (study 015) and given

rosiglitazone 4mg bd monotherapy in this study was not excluded as a protocol violator. The patient has been included in the analysis of the rosiglitazone 4mg bd monotherapy group, but has been excluded from all analyses by treatment group in the preceding study.

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics at double-blind baseline for all patients are shown in [Table 4](#).

The majority of patients in both groups were white (97%) and there was a greater proportion of males (66%) than females (34%). The mean age was 61.9 years (range 34-79) and 60.2 years (range 37-81) and the mean BMI was 28.2kg/m² (range 20.7-39.2) and 28.9kg/m² (range 20.8-38.3) in the rosiglitazone 2mg bd combination therapy and rosiglitazone 4mg bd monotherapy groups respectively.

Table 4 Summary of Demographic Characteristics

Demographic Characteristics	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Age (years)		
< 65	113 (49.3%)	255 (59.3%)
≥ 65	116 (50.7%)	175 (40.7%)
Mean ± SD	61.9 ± 9.23	60.2 ± 8.60
Median	64.0	61.0
Range	34-79	37-81
Sex		
Male	147 (64.2%)	287 (66.7%)
Female	82 (35.8%)	143 (33.3%)
BMI (kg/m²)		
< 27	94 (41.0%)	140 (32.6%)
≥ 27	135 (59.0%)	290 (67.4%)
Mean ± SD	28.2 ± 3.95	28.9 ± 3.81
Median	27.8	28.4
Range	20.7-39.2	20.8-38.3
Race		
White	223 (97.4%)	416 (96.7%)
Black	2 (0.9%)	2 (0.5%)
Other	4 (1.7%)	12 (2.8%)

Data Source: [Section 13, Tables 13.3.1a and 13.5.1.a; Appendix B, Listing B.L2](#)

A tabulation and listing of demographic information may be found in [Section 13, Tables 13.3.1a and 13.5.1a](#) and [Appendix B, Listing B.L2](#). Tabulations of demographic information sub-divided by the treatment group in the study prior to this are provided in [Section 13, Tables 13.3.1b and 13.5.1b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 13, Tables 13.3.1c and 13.5.1c](#) for the rosiglitazone 4mg bd monotherapy group.

In the rosiglitazone 2mg bd combination therapy group, a smaller proportion of patients in the sub-group of patients who previously received sulphonylurea plus rosiglitazone 2mg bd were male (58.9%) than in the sub-groups who previously received sulphonylurea plus either placebo (68.9%) or rosiglitazone 1mg bd (66.7%).

In the rosiglitazone 4mg bd monotherapy group, a smaller proportion of patients in the sub-group of patients who previously received rosiglitazone 4mg bd were male (57.3%) than in the sub-groups who previously received either glibenclamide (71.9%) or rosiglitazone 2mg bd (68.4%).

There were no other marked differences in demographic information between the prior treatment subgroups in either open label treatment group.

A tabulation of demographic information by gender may be found in [Section 13, Table 13.5.1a](#). Tabulations of demographic information by gender sub-divided by the treatment group in the study prior to this are provided in [Section 13, Table 13.5.1b](#) for the rosiglitazone combination therapy group and in [Section 13, Table 13.5.1c](#) for the rosiglitazone monotherapy group.

4.4.2 Baseline Characteristics

The characteristics of type 2 diabetes present at double-blind and open label baselines by treatment group are provided in [Table 5](#).

The mean duration of diabetes was 9 years in the combination therapy group and 6 years in the monotherapy group, ranging from 0 to 42 years. All patients in the combination therapy group had previously received oral anti hyperglycaemic agents compared to 56.7% in the monotherapy group. Double-blind baseline mean HbA1c and FPG were higher in the combination group (9.1% and 197.1mg/dL respectively) than in the monotherapy group (8.0% and 184.6mg/dL respectively). At open label baseline, mean HbA1c was 8.4% and mean FPG 170.6mg/dL in the combination group compared to 7.4% and 152.8mg/dL respectively in the monotherapy group.

Table 5 Summary of Baseline Characteristics

Baseline Characteristics	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Previous Treatment		
Diet Only	0	186 (43.3%)
Oral Monotherapy	229 (100%)	210 (48.8%)
Oral Combination	0	34 (7.9%)
Double-blind Baseline HbA1c (%)		
Mean $\pm$ SD	9.1 $\pm$ 1.09	8.0 $\pm$ 1.27
Median	8.8	7.90
Range	7.3-13.0	4.8-13.8
Open Label Baseline HbA1c (%)		
Mean $\pm$ SD	8.4 $\pm$ 1.22	7.4 $\pm$ 1.30*
Median	8.3	7.10
Range	5.4-12.7	3.9-11.5
Double-blind Baseline FPG (mg/dL)		
Mean $\pm$ SD	197.1 $\pm$ 37.42	184.6 $\pm$ 47.96
Median	198.0	173.0
Range	93-307	102-407
Open Label Baseline FPG (mg/dL)		
Mean $\pm$ SD	170.6 $\pm$ 41.59	152.8 $\pm$ 40.46
Median	171.0	146.0
Range	66-280	61-292
Number of Years with Diabetes		
Mean $\pm$ SD	9.3 $\pm$ 6.80	5.8 $\pm$ 5.86**
Median	8.0	4.0
Range	1-32	0-42

* N=428; ** N=418

Data Source: [Section 13, Tables 13.3.1a and 13.5.1a](#); [Section 14, Table 14.1Aa](#); [Appendix B](#), Listings B.L2 and B.L4; [Appendix C](#), Listing C.L1

4.5 Presenting Conditions and Medical History

The most commonly recorded presenting conditions (i.e., those occurring in at least 5% of patients in either treatment group) are shown, sorted by descending order of frequency in the rosiglitazone 4mg bd monotherapy group, in [Table 6](#). A total of 188 patients (82.1%) in the rosiglitazone 2mg bd combination therapy group and 358 (83.3%) in the rosiglitazone 4mg bd monotherapy group had presenting medical conditions at double-blind baseline. The most common presenting conditions in both groups were hypertension (42.2% of all patients) and elevated cholesterol and triglyceride levels (17.6% of all patients).

A summary and listing of all presenting conditions at double-blind baseline according to the ICD9 dictionary is provided in [Section 13, Table 13.4.1a](#) and listed by patient and verbatim terms in [Appendix B](#), Listing B.L3.

Table 6 Presenting Conditions (at Double-blind Baseline) Reported by ≥5.0% of Patients in Either Treatment Group

Medical Condition by Preferred Term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N =229)	RSG 4mg bd Monotherapy (N = 430)
Patients with at least one Presenting Condition	188 (82.1)	358 (83.3)
Hypertension	94 (41.0)	184 (42.8)
Cholesterol/triglyceride elevated	45 (19.7)	71 (16.5)
Osteoarthritis	22 (9.6)	34 (7.9)
Hyperlipaemia	26 (11.4)	30 (7.0)
Circulatory system disorder	11 (4.8)	28 (6.5)
Ischaemic heart disease	24 (10.5)	26 (6.0)
Lipid metabolism disorder	6 (2.6)	22 (5.1)
Angina pectoris	21 (9.2)	8 (1.9)
Peripheral nervous system disorder	14 (6.1)	8 (1.9)
Retinopathy	14 (6.1)	1 (0.2)

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 13, Table 13.4.1a](#); [Appendix B, Listing B.L3](#)

Tabulations of presenting medical conditions at double-blind baseline sub-divided by the treatment group in the study prior to this are provided in [Section 13, Table 13.4.1b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 13, Table 13.4.1c](#) for the rosiglitazone 4mg bd monotherapy group.

4.6 Adverse Experiences Ongoing at Open Label Baseline

The most frequent baseline signs and symptoms (i.e., those adverse experiences recorded as ongoing at the open label baseline in ≥ 2.0% of patients) are shown, sorted by descending order of frequency in the rosiglitazone 4mg bd monotherapy group, in [Table 7](#).

Table 7 Baseline Signs and Symptoms Reported as Ongoing at Open Label Baseline by $\geq 2.0\%$ of Patients in Either Treatment Group

Baseline Signs/Symptoms*, n (%) by Preferred Term	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Patients with at least one Baseline Sign/ Symptom	87 (38.0)	194 (45.1)
Hypercholesterolaemia	7 (3.1)	27 (6.3)
Arthritis	1 (0.4)	14 (3.3)
Hypertriglyceridaemia	3 (1.3)	13 (3.0)
Urinary tract infection	4 (1.7)	12 (2.8)
Diabetes mellitus aggravated	0	10 (2.3)
Coughing	5 (2.2)	5 (1.2)
Hyperglycaemia	5 (2.2)	4 (0.9)
Back pain	6 (2.6)	3 (0.7)

* Baseline signs and symptoms are adverse experiences which were ongoing at the open label baseline visit and prior to the first dose of open label study medication

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 15, Table 15.1.1a](#); [Appendix D](#), Listing D.L1

Tabulations of baseline signs and symptoms at open label baseline sub-divided by the treatment group in the study prior to this are provided in [Section 15, Table 15.1.1b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 15, Table 15.1.1c](#) for the rosiglitazone 4mg bd monotherapy group.

4.7 Concomitant Medications

The most frequently recorded concomitant medications by Anatomical Therapeutic Chemical (ATC) classification level 2 (defined as medications ongoing at open label baseline or initiated during the open label study in $\geq 25\%$ of patients) are shown in [Table 8](#).

At least 45% of patients were receiving concomitant hypotensives, 46% analgesics, 35% antibiotics and 35% cholesterol reducers.

**Table 8 Concomitant Medication by ATC Classification Level 2 Received by ≥ 25.0
% of Patients in Either Treatment Group**

Concomitant Medication*, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Patients with Medication	210 (91.7)	401 (93.3)
Hypotensives	103 (45.0)	206 (47.9)
Analgesics	110 (48.0)	199 (46.3)
Antibiotics	81 (35.4)	171 (39.8)
Cholesterol reducers	96 (41.9)	153 (35.6)
Antiinflammatory/ antirheumatic products	61 (26.6)	149 (34.7)
Ophthalmologicals	59 (25.8)	126 (29.3)
Diuretics	54 (23.6)	125 (29.1)
Anticoagulants	71 (31.0)	105 (24.4)
Mouth preparations	62 (27.1)	86 (20.0)

* Generic terms

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 13, Table 13.5.2a](#); [Appendix B, Listing B.L4](#)

The most frequently recorded concomitant medications (defined as medications ongoing at open label baseline or initiated during the open label study in $\geq 5\%$ of patients) are shown in [Table 9](#).

A total of 210 patients (91.7%) in the rosiglitazone 2mg bd combination therapy group and 401 patients (93.3%) in the rosiglitazone 4mg bd monotherapy group received concomitant medication. The most frequently taken concomitant medications in the combination therapy group were acetylsalicylic acid, paracetamol and simvastatin and in the monotherapy group paracetamol, acetylsalicylic acid and polyvalent influenza virus vaccine. A summary and listing of all concomitant medications taken is provided in [Section 13, Table 13.5.2a](#) and [Appendix B, Listing B.L4](#).

Table 9 Concomitant Medication Received by ≥ 5.0 % of Patients in Either Treatment Group

Concomitant Medication*, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Patients with Medication	210 (91.7)	401 (93.3)
Paracetamol	38 (16.6)	84 (19.5)
Acetylsalicylic acid	60 (26.2)	67 (15.6)
Influenza virus vaccine polyvalent	24 (10.5)	60 (14.0)
Simvastatin	34 (14.8)	43 (10.0)
Frusemide	20 (8.7)	43 (10.0)
Diclofenac sodium	21 (9.2)	38 (8.8)
Acetylcysteine	10 (4.4)	38 (8.8)
Dextropropoxyphene hydrochloride/paracetamol	21 (9.2)	36 (8.4)
Ibuprofen	18 (7.9)	34 (7.9)
Fenofibrate	16 (7.0)	32 (7.4)
Amoxicillin trihydrate	10 (4.4)	31 (7.2)
Atenolol	17 (7.4)	30 (7.0)
Ketoprofen	8 (3.5)	28 (6.5)
Omeprazole	17 (7.4)	27 (6.3)
Piroxicam	5 (2.2)	27 (6.3)
Glyceryl trinitrate	20 (8.7)	26 (6.0)
Allopurinol	5 (2.2)	25 (5.8)
Amoxicillin	24 (10.5)	24 (5.6)
Enalapril maleate	18 (7.9)	24 (5.6)
Nifedipine	15 (6.6)	22 (5.1)
Atorvastatin calcium	16 (7.0)	21 (4.9)
Amoxicillin trihydrate/ clavulanic acid	12 (5.2)	20 (4.7)
Isosorbide mononitrate	14 (6.1)	19 (4.4)

* Generic terms

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 13, Table 13.5.2a; Appendix B, Listing B.L4](#)

Tabulations of concomitant medications sub-divided by the treatment group in the study prior to this are provided in [Section 13, Table 13.5.2b](#) for the rosiglitazone 2mg bd combination therapy group and in [Section 13, Table 13.5.2c](#) for the rosiglitazone 4mg bd monotherapy group.

4.8 Treatment Compliance

Compliance was calculated and expressed as overall compliance, that is compliance with rosiglitazone study medication over the whole study period, and is summarised in [Table 10](#).

Compliance with study medication was high in both treatment groups, with 99.1% of patients in the rosiglitazone 2mg bd combination therapy group and 94.4% of patients in the rosiglitazone 4mg bd monotherapy group taking 80-120% of study medication.

Table 10 Compliance with Rosiglitazone Study Medication

Treatment Compliance (RSG only), n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
< 50% Compliant	0	2 (0.5)
50 - <80% Compliant	1 (0.4)	13 (3.0)
80% - <100% Compliant	179 (78.2)	325 (75.6)
100% - 120% Compliant	48 (21.0)	81 (18.8)
>120% Compliant	0	1 (0.2)*
Missing	1 (0.4)	8 (1.9)

Data Source: [Section 13, Table 13.6.3a](#); [Appendix B, Listing B.L5](#)

Percentage compliance sub-divided by previous treatment group for the rosiglitazone 2mg bd combination therapy and rosiglitazone 4mg bd monotherapy groups can be found in [Section 13, Tables 13.6.3b](#) and [13.6.3c](#) respectively.

5 Efficacy Results

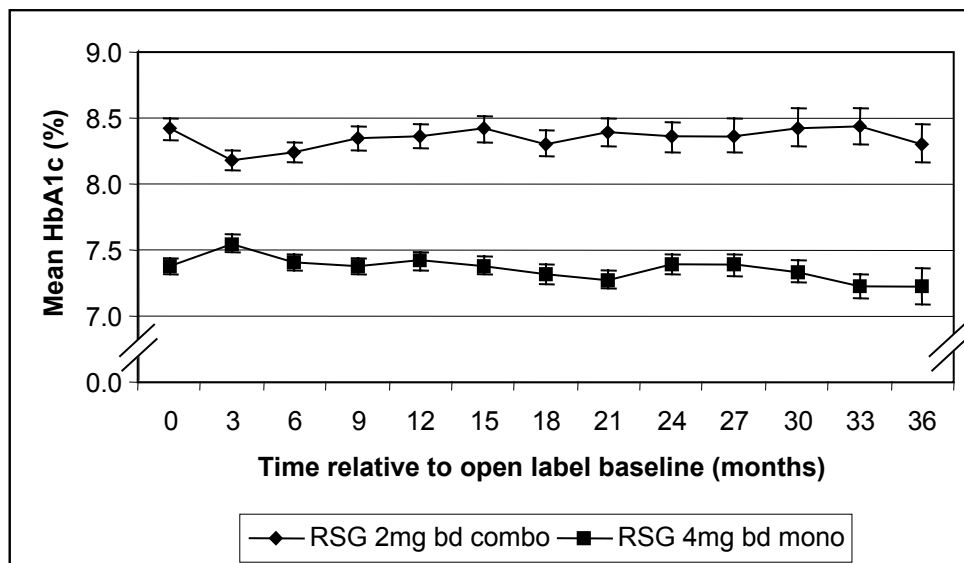
5.1 Efficacy Evaluation

5.1.1 Data Sets Summarised

Data for efficacy variables were analysed for patients who took at least one dose of study medication as defined in [Section 3.15.5](#). A complete tabulation and listing of both primary and secondary efficacy variables by visit, including double-blind and open label baselines, is provided in [Section 14, Table 14.1Aa](#) and in [Appendix C](#), Listing C.L1 and [Appendix F](#), Listing F.L1. A complete tabulation of both primary and secondary efficacy variables by visit, including double-blind and open label baselines, and sub-divided by the treatment group in the preceding study is provided in [Section 14, Table 14.1Ab](#) for the rosiglitazone 2mg bd combination therapy group and [Table 14.1Ac](#) for the rosiglitazone 4mg bd monotherapy group.

5.2 Primary Efficacy Parameter

Overall, patients receiving rosiglitazone 2mg bd in addition to a sulphonylurea in this extension study maintained their HbA1c close to open label baseline values (mean 8.4%) for at least 36 months duration ([Figure 1](#) and [Table 11](#)). This compares with a mean HbA1c of 9.1% at the start of the preceding study. In the monotherapy group, mean HbA1c was also similar to open label baseline (mean 7.4%) over 36 months of open label medication compared to a double-blind baseline of 8.0%.

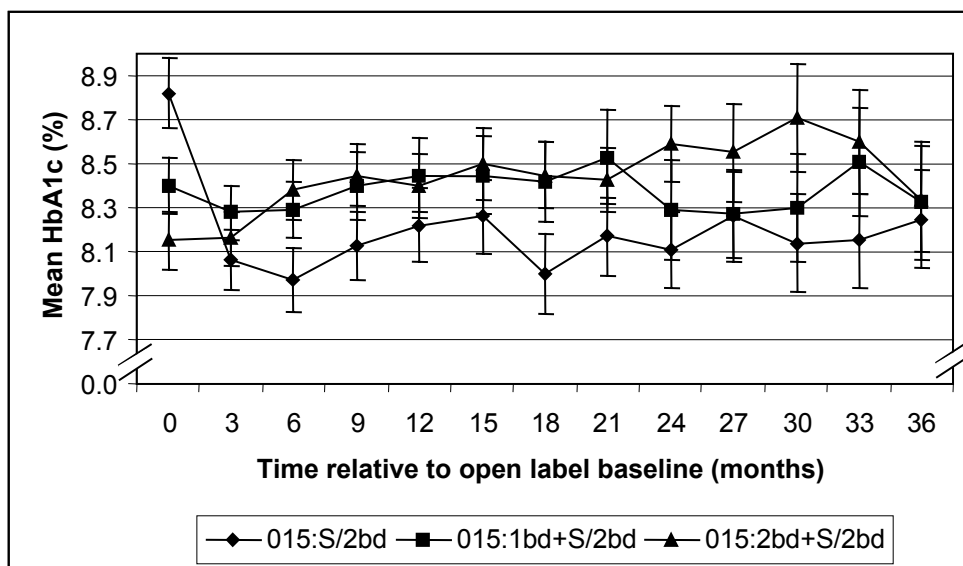
Figure 1 HbA1c (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14](#), [Table 14.1Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

[Figure 2](#) shows mean HbA1c by visit and treatment group in the preceding study (study 015) for the combination therapy group. In patients switching from sulphonylurea plus placebo to combination therapy with rosiglitazone 2mg bd, mean HbA1c decreased from an open label baseline of 8.8% to a mean value of 8.1% at Month 3. This reduction in mean HbA1c was maintained for at least a further 33 months with mean values ranging from 8.0% to 8.3%. Patients who increased their dose of rosiglitazone on starting the extension study (1mg bd to 2mg bd) maintained their open label baseline mean HbA1c (8.4%) over 36 months of treatment with mean HbA1c values ranging between 8.2-8.5%. Patients who continued on 2mg bd had the lowest open label baseline mean HbA1c (8.2%) which was maintained over 36 months of treatment (range 7.9-8.7%) with a mean HbA1c value of 8.3% at Month 36.

Figure 2 HbA1c (mean $\pm$ SE) by Visit and by Previous Treatment (Combination Therapy)

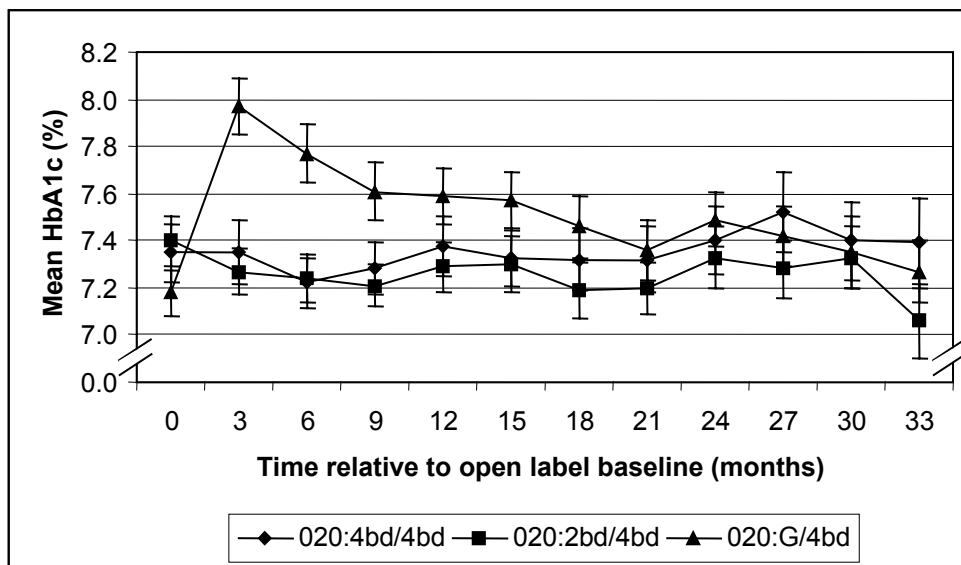


NOTE: Treatment in preceding study/treatment in this study; S=sulphonylurea; 1bd=rosiglitazone 1mg bd; 2bd=rosiglitazone 2mg bd

Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Ab](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

[Figure 3](#) shows mean HbA1c by visit and treatment group in the preceding study (study 020) for the monotherapy group. In patients who were switched from glibenclamide in the preceding study to rosiglitazone 4mg bd monotherapy in the extension study an increase in mean HbA1c was observed over the first 3 months from an open label baseline value of 7.2% to a value of 8.0% at Month 3. Over the following 30 months of open label treatment, mean HbA1c decreased to 7.3% at Month 33. In patients who had an increase in dose of rosiglitazone from 2mg bd to 4mg bd, mean values for HbA1c were found to be maintained close to the open label baseline value of 7.4% over a treatment period of 33 months, ranging from 7.1-7.3%. In patients who were continuing with the same dose of rosiglitazone (4mg bd), mean HbA1c values over 33 months' open label treatment ranged from 7.2 to 7.5% which were similar to the open label baseline value of 7.4%.

Figure 3 HbA1c (mean $\pm$ SE) by Visit and by Previous Treatment (Monotherapy)

NOTE: Treatment is shown as treatment in preceding study/treatment in this study. G=glibenclamide; 2bd=rosiglitazone 2mg bd; 4bd=rosiglitazone 4mg bd

Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Ac](#); [Appendix C, Listing C.L1](#); [Appendix F, F.L1](#)

Table 11 Mean HbA1c by Visit

HbA1c Parameter	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
HbA1c (%)		
Double-blind (DB) Baseline (n)	229	430
mean $\pm$ SD	9.1 $\pm$ 1.09	8.0 $\pm$ 1.27
Open label (OL) Baseline (n)	229	428
mean $\pm$ SD	8.4 $\pm$ 1.22	7.4 $\pm$ 1.30
Month 1 (n)	220	410
mean $\pm$ SD	8.5 $\pm$ 1.23	7.6 $\pm$ 1.35
Month 2 (n)	220	401
mean $\pm$ SD	8.3 $\pm$ 1.19	7.6 $\pm$ 1.33
Month 3 (n)	217	397
mean $\pm$ SD	8.2 $\pm$ 1.09	7.6 $\pm$ 1.34
Month 6 (n)	209	384
mean $\pm$ SD	8.2 $\pm$ 1.14	7.4 $\pm$ 1.23
Month 9 (n)	202	375
mean $\pm$ SD	8.4 $\pm$ 1.23	7.4 $\pm$ 1.15
Month 12 (n)	184	342
mean $\pm$ SD	8.4 $\pm$ 1.27	7.4 $\pm$ 1.23
Month 15 (n)	173	314
mean $\pm$ SD	8.4 $\pm$ 1.30	7.4 $\pm$ 1.22
Month 18 (n)	157	293
mean $\pm$ SD	8.3 $\pm$ 1.24	7.3 $\pm$ 1.21
Month 21 (n)	153	279
mean $\pm$ SD	8.4 $\pm$ 1.28	7.3 $\pm$ 1.14
Month 24 (n)	129	252
mean $\pm$ SD	8.4 $\pm$ 1.28	7.4 $\pm$ 1.19
Month 27 (n)	122	226
mean $\pm$ SD	8.4 $\pm$ 1.36	7.4 $\pm$ 1.20
Month 30 (n)	107	180
mean $\pm$ SD	8.4 $\pm$ 1.47	7.3 $\pm$ 1.07
Month 33 (n)	94	156
mean $\pm$ SD	8.4 $\pm$ 1.32	7.2 $\pm$ 1.16
Month 36 (n)	84	78
mean $\pm$ SD	8.3 $\pm$ 1.26	7.2 $\pm$ 1.17
Month 39 (n)	50	16
mean $\pm$ SD	8.4 $\pm$ 1.33	6.8 $\pm$ 0.95
Month 42 (n)	32	0
mean $\pm$ SD	8.4 $\pm$ 1.26	
Month 45 (n)	20	0
mean $\pm$ SD	7.7 $\pm$ 0.86	
Month 48 (n)	2	0
mean $\pm$ SD	8.4 $\pm$ 2.19	

NOTE: All laboratory values are fasting

Data Source: [Section 14, Table 14.1Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

5.3 Secondary Efficacy Parameters

5.3.1 Glycaemic Parameters

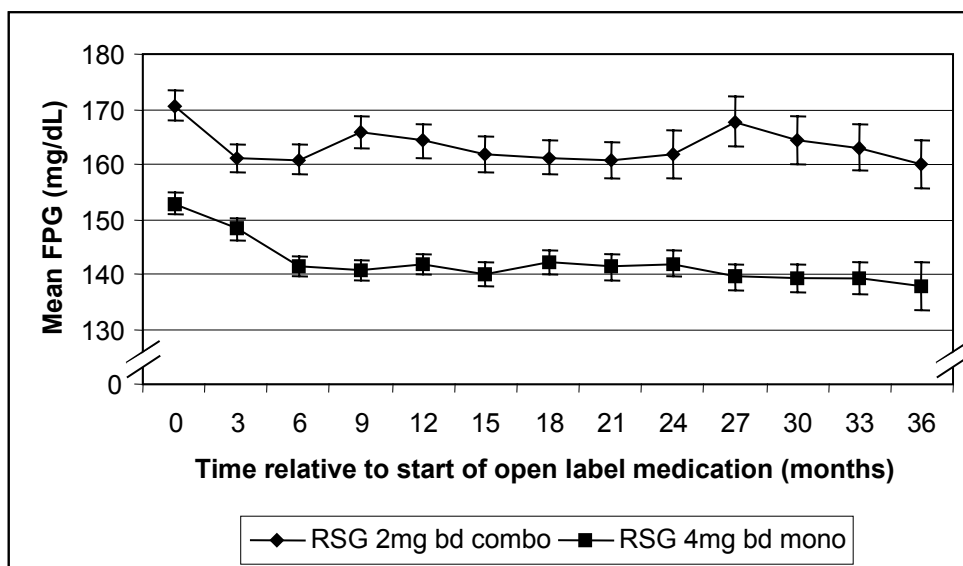
Fasting Plasma Glucose

Overall, patients receiving rosiglitazone 2mg bd in addition to a sulphonylurea showed a decrease in their mean FPG from open label baseline (mean 170.6

mg/dL) over the first 3 months of treatment, with a mean FPG of 161.2mg/dL at Month 3; mean FPG values ranged between 160.0 and 167.8mg/dL for the following 33 months of treatment (Figure 4 and Table 12). This compares with a mean FPG of 197.1mg/dL at the start of the preceding study.

Mean FPG was found to decrease during the first 6 months of treatment in patients receiving rosiglitazone 4mg bd monotherapy, from an open baseline value of 152.8mg/dL to 141.5mg/dL at Month 6. This decrease in mean FPG was maintained over the subsequent 30 months of treatment, with mean FPG values ranging from 137.8 to 142.1mg/dL, and compares to a double-blind baseline value of 184.6mg/dL.

Figure 4 Fasting Plasma Glucose (mean±SE) by Visit



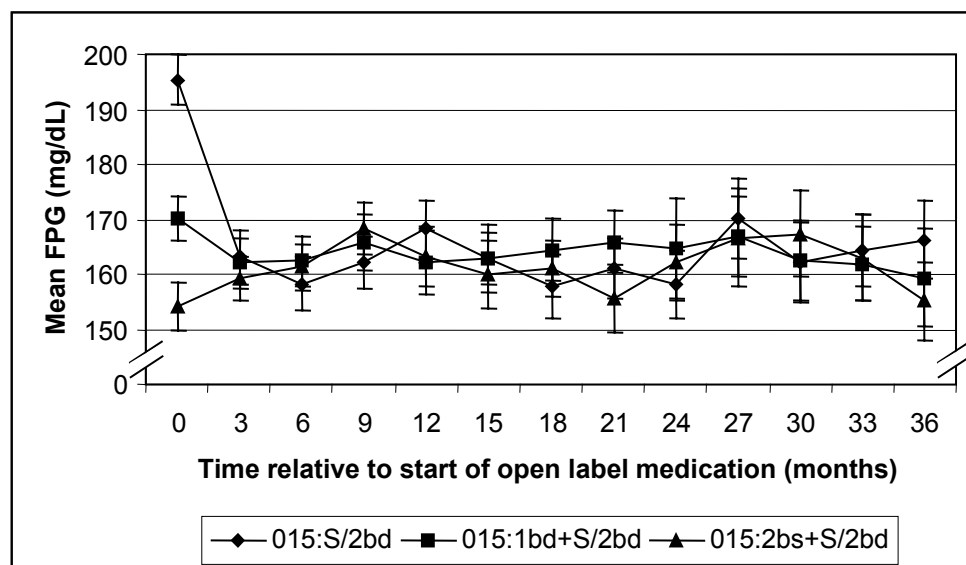
NOTE: Data has not been presented where patient numbers are too low

Data Source: Section 14, Table 14.1Aa; Appendix C, Listing C.L1; Appendix F, F.L1

Figure 5 shows mean FPG by visit and treatment in the preceding study for the combination therapy group (study 015). In patients receiving rosiglitazone for the first time, mean FPG decreased from an open label baseline value of 195.4mg/dL to 163.2mg/dL at Month 3. This reduction was maintained for a further 33 months with a mean FPG value of 166.3mg/dL observed at Month 36. Patients who increased their dose on starting the extension study (1mg bd to 2mg bd) showed a small reduction in FPG from an open label baseline of 170.2mg/dL to 162.1mg/dL at Month 3 which was maintained over the subsequent 33 months, with mean FPG values ranging from 159.4 to 166.9mg/dL. Patients who received

rosiglitazone 2mg bd combination therapy throughout this extension and the preceding study, had the lowest open label mean baseline FPG value of 154.2mg/dL. Following treatment in the extension study, an increase in mean FPG was observed over the first 9 months to 168.4mg/dL at Month 9 with a subsequent decrease over the following 27 months to a mean FPG value of 155.1mg/dL at Month 36.

Figure 5 Fasting Plasma Glucose (mean±SE) by Visit and Previous Treatment (Combination Therapy)



NOTE: Treatment in preceding study/treatment in this study; S=sulphonylurea; 1bd=rosiglitazone 1mg bd; 2bd=rosiglitazone 2mg bd

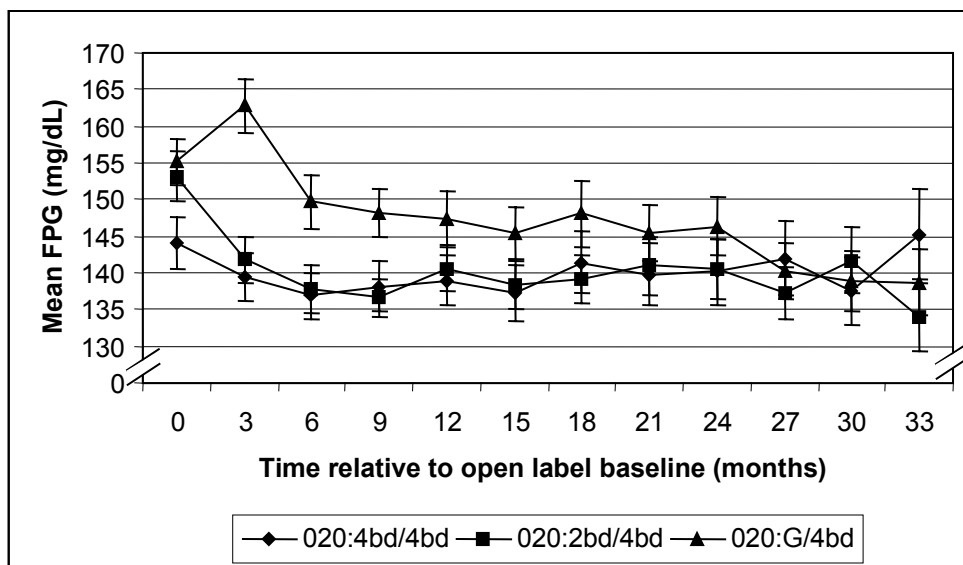
Data has not been presented where patient numbers are too low

Data source: Section 14, Table 14.1Ab; Appendix C, Listing C.L1; Appendix F, F.L1

With respect to the monotherapy group, in those patients who received glibenclamide in the preceding study (020) there was an increase in mean FPG from an open label baseline value of 155.2mg/dL over the first 3 months of treatment to 162.8mg/dL at Month 3 (Figure 6). However, this increase was reduced by Month 6 to 149.7mg/dL with a further gradual decrease over the subsequent 27 months of open label treatment to a mean FPG value of 138.7mg/dL at Month 33. In patients increasing their dose of rosiglitazone monotherapy from 2mg bd to 4mg bd, mean FPG decreased from an open label baseline value of 153.2mg/dL to 141.8mg/dL at Month 3 and 137.8mg/dL at Month 6, after which mean FPG values were generally maintained over the following 27 months of treatment. Patients continuing therapy with rosiglitazone 4mg bd monotherapy had the lowest open label baseline mean FPG value of 144.1mg/dL. A further decrease in mean FPG was observed over the first 3

months of open label treatment with a mean FPG value of 139.5mg/dL at Month 3 which was maintained over the following 27 months of treatment.

Figure 6 Fasting Plasma Glucose (mean $\pm$ SE) by Visit and Previous Treatment (Monotherapy)



NOTE: Treatment is shown as treatment in preceding study/treatment in this study. G=glibenclamide; 2bd=rosiglitazone 2mg bd; 4bd=rosiglitazone 4mg bd
Data has not been presented where patient numbers are too low

Data source: [Section 14, Table 14.1.Ac](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

Table 12 Mean Fasting Plasma Glucose by Visit

FPG Parameter	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
FPG (mg/dL)		
Double-blind (DB) Baseline (n)	229	430
mean $\pm$ SD	197.1 $\pm$ 37.42	184.6 $\pm$ 47.96
Open Label (OL) Baseline (n)	229	430
mean $\pm$ SD	170.6 $\pm$ 41.59	152.8 $\pm$ 40.46
Month 1 (n)	220	411
mean $\pm$ SD	163.8 $\pm$ 40.91	157.1 $\pm$ 47.88
Month 2 (n)	218	402
mean $\pm$ SD	158.9 $\pm$ 39.90	149.6 $\pm$ 38.73
Month 3 (n)	217	397
mean $\pm$ SD	161.2 $\pm$ 37.69	148.3 $\pm$ 39.72
Month 6 (n)	208	381
mean $\pm$ SD	160.9 $\pm$ 37.55	141.5 $\pm$ 36.67
Month 9 (n)	200	374
mean $\pm$ SD	165.8 $\pm$ 39.18	140.8 $\pm$ 34.51
Month 12 (n)	182	343
mean $\pm$ SD	164.2 $\pm$ 43.39	141.9 $\pm$ 35.39
Month 15 (n)	171	320
mean $\pm$ SD	161.8 $\pm$ 43.94	140.0 $\pm$ 36.11
Month 18 (n)	154	295
mean $\pm$ SD	161.2 $\pm$ 39.57	142.1 $\pm$ 39.15
Month 21 (n)	151	279
mean $\pm$ SD	160.7 $\pm$ 41.88	141.3 $\pm$ 37.83
Month 24 (n)	128	250
mean $\pm$ SD	161.8 $\pm$ 48.85	141.9 $\pm$ 37.92
Month 27 (n)	119	229
mean $\pm$ SD	167.8 $\pm$ 50.12	139.5 $\pm$ 35.94
Month 30 (n)	107	180
mean $\pm$ SD	164.5 $\pm$ 44.93	139.2 $\pm$ 34.16
Month 33 (n)	94	157
mean $\pm$ SD	163.0 $\pm$ 40.15	139.1 $\pm$ 36.55
Month 36 (n)	83	77
mean $\pm$ SD	160.0 $\pm$ 40.05	137.8 $\pm$ 38.49
Month 39 (n)	49	16
mean $\pm$ SD	168.4 $\pm$ 44.90	130.4 $\pm$ 24.49
Month 42 (n)	32	0
mean $\pm$ SD	160.8 $\pm$ 48.07	
Month 45 (n)	18	0
mean $\pm$ SD	145.9 $\pm$ 45.42	
Month 48 (n)	2	0
mean $\pm$ SD	167.5 $\pm$ 65.76	

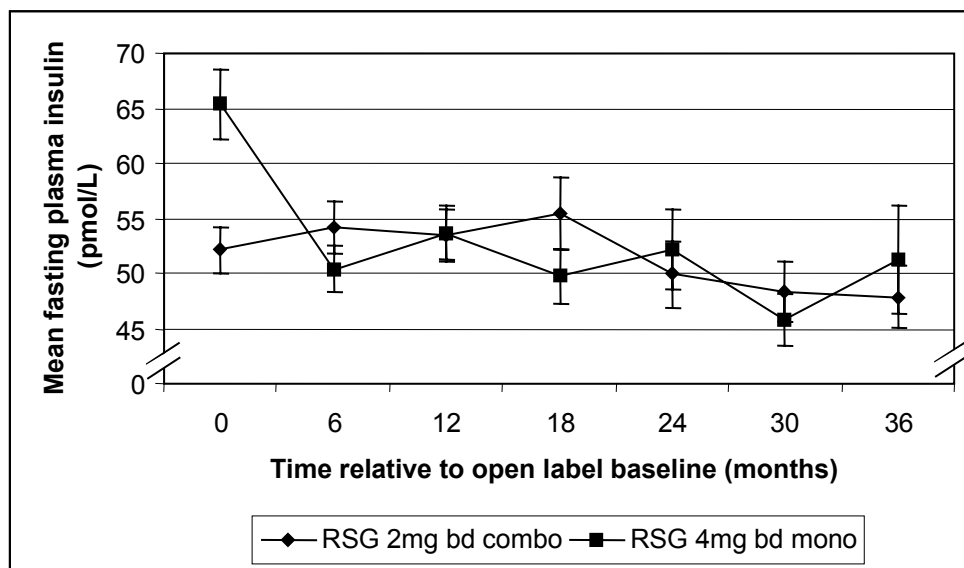
NOTE: All laboratory values are fasting

Data Source: [Section 14, Table 14.1.Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1***Fasting Plasma Insulin***

[Figure 7](#) and [Table 13](#) summarise mean fasting plasma insulin by visit. In the rosiglitazone 2mg bd combination therapy group, mean plasma insulin generally decreased from an open label baseline of 52.1pmol/L over 36 months of treatment to a mean value of 47.9pmol/L at Month 36. This compares to a double-blind baseline value of 57.2pmol/L. In the rosiglitazone 4mg bd monotherapy group, mean plasma insulin markedly decreased from an open label baseline of

65.4pmol/L to 50.4pmol/L at Month 6 after which mean insulin values were mostly maintained over the following 30 months of treatment ranging from 45.8pmol/L at Month 30 to 53.6pmol/L at Month 12. The mean baseline value at the start of the preceding studies was 67.2pmol/L.

Figure 7 Fasting Plasma Insulin (mean $\pm$ SE) by Visit

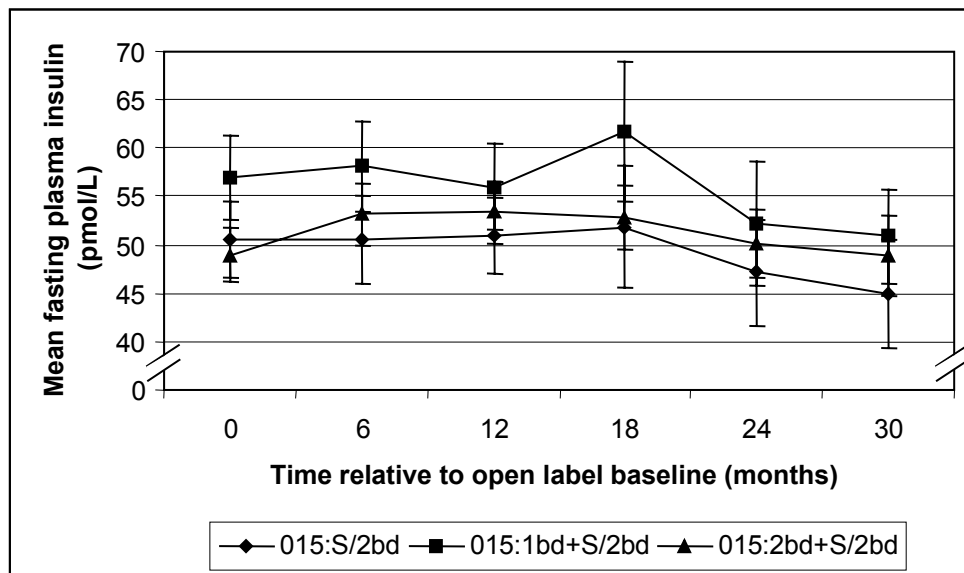


NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14](#), [Table 14.1Aa](#); [Appendix C](#). Listing C.L1; [Appendix F](#), F.L1

When the rosiglitazone 2mg bd combination therapy group was sub-divided by treatment group in the previous study, mean fasting plasma insulin was found to generally decrease from open label baseline over a 36 month treatment period in patients switching from sulphonylurea plus placebo to rosiglitazone 2mg bd combination therapy (OL baseline: 50.50pmol/L, Month 36: 42.63pmol/L) and in patients increasing their dose of combination rosiglitazone therapy from 1mg bd to 2mg bd (OL baseline: 56.99pmol/L, Month 36: 50.77pmol/L). Patients who were maintained on a rosiglitazone dose of 2mg bd had the lowest open label mean baseline fasting plasma insulin value of 48.95pmol/L which was maintained over 36 months of treatment (Month 36: 50.32pmol/L).

Figure 8 Fasting Plasma Insulin (mean $\pm$ SE) by Visit and Previous Treatment (Combination Therapy)

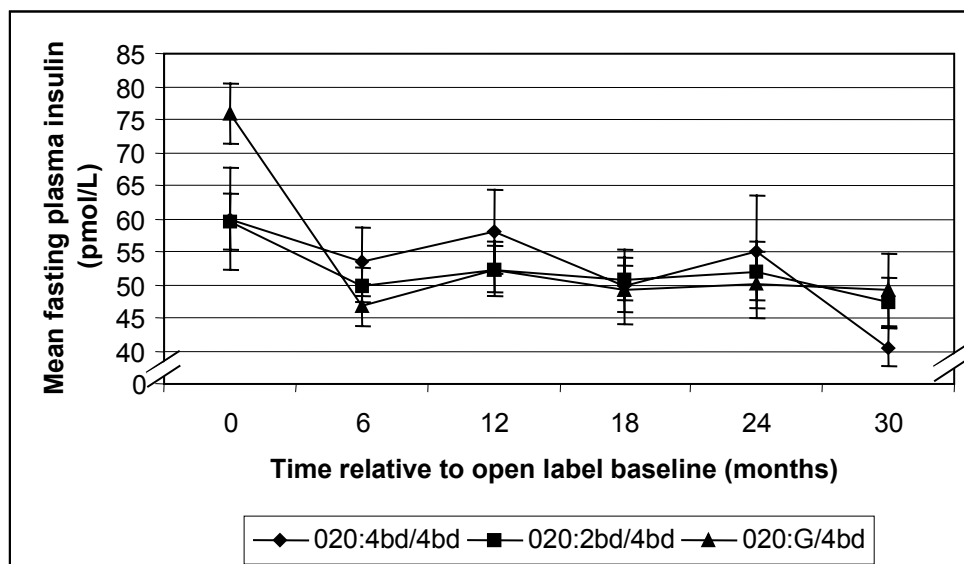


NOTE: Treatment in preceding study/treatment in this study; S=sulphonylurea; 1bd=rosiglitazone 1mg bd; 2bd=rosiglitazone 2mg bd

Data has not been presented where patient numbers are too low

Data source: [Section 14](#), [Table 14.1Ab](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

When the rosiglitazone 4mg bd monotherapy group was sub-divided by treatment group in the previous study, mean fasting plasma insulin was found to generally decrease over a 36 month treatment period in all subgroups. The largest decrease was observed in patients switching from glibenclamide monotherapy to rosiglitazone monotherapy, with a reduction in mean insulin from an open label baseline value of 75.87pmol/L to 49.33pmol/L at Month 30 which compared to a decrease in patients continuing on rosiglitazone 4mg bd monotherapy from an open label baseline of 59.94pmol/L to 40.59pmol/L at Month 30 and in patients increasing their dose of rosiglitazone from 2mg bd to 4mg bd from an open label baseline of 59.62pmol/L to 47.33pmol/L at Month 30.

Figure 9 Fasting Plasma Insulin (mean±SE) by Visit and Previous Treatment (Monotherapy)

NOTE: Treatment is shown as treatment in preceding study/treatment in this study. G=glibenclamide; 2bd=rosiglitazone 2mg bd; 4bd=rosiglitazone 4mg bd

Data has not been presented where patient numbers are too low

Data source: [Section 14, Table 14.1Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

Table 13 Mean Fasting Plasma Insulin by Visit

Plasma Insulin Parameter	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Plasma Insulin (pmol/L)		
Double-blind Baseline (n)	229	366
mean ± SD	57.2 ± 35.50	67.2 ± 49.97
Open Label (OL) Baseline (n)	229	381
mean ± SD	52.1 ± 32.03	65.4 ± 63.11
Month 6 (n)	189	354
mean ± SD	54.1 ± 32.76	50.4 ± 39.44
Month 12 (n)	172	299
mean ± SD	53.5 ± 29.42	53.6 ± 44.88
Month 18 (n)	140	249
mean ± SD	55.5 ± 38.46	49.8 ± 38.44
Month 24 (n)	123	208
mean ± SD	49.9 ± 32.39	52.2 ± 52.06
Month 30 (n)	93	133
mean ± SD	48.4 ± 26.12	45.8 ± 26.87
Month 36 (n)	72	58
mean ± SD	47.9 ± 24.51	51.3 ± 37.37
Month 42 (n)	27	0
mean ± SD	49.6 ± 25.11	
Month 48 (n)	1	0
mean ± SD	23.0	

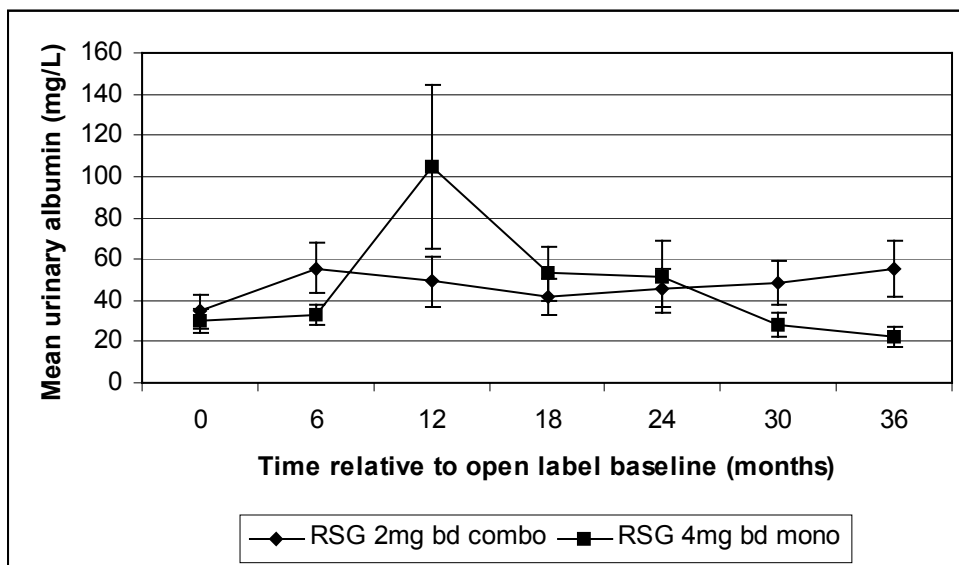
NOTE: All laboratory values are fasting

Data Source: [Section 14, Table 14.1Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

5.3.2 Urinary Albumin

Mean urinary albumin values in the combination therapy group were similar at double-blind (33.5mg/L) and open label baselines (34.8mg/L) (Figure 10 and Table 14). Following 6 months of open label treatment, mean urinary albumin had increased to 55.6mg/L and was maintained at this level for the following 30 months of treatment. In the monotherapy group, mean urinary albumin values were similar at both double-blind (25.9mg/L) and open label baselines (30.3mg/L). An outlying value for one patient at Month 12 precludes any assessment at this timepoint, however, mean values at Months 18 and 24 were increased (52.9mg/L and 51.5mg/L, respectively), but subsequently decreased to baseline levels at Months 30 and 36 (28.5mg/L and 22.2mg/L, respectively).

Figure 10 Urinary Albumin (mean±SE) by Visit



[REDACTED]

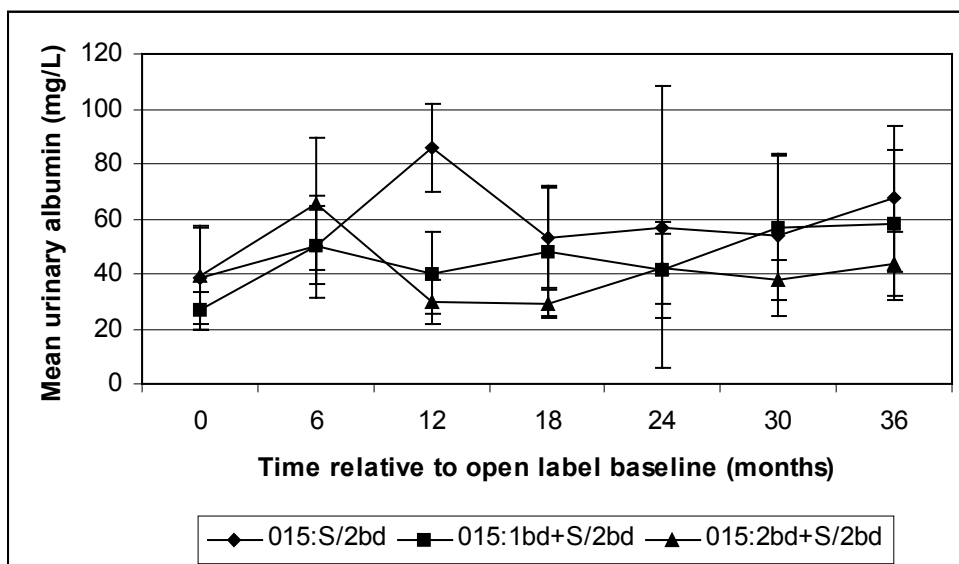
Data has not been presented where patient numbers are too low

Data Source: Section 14, Table 14.1Aa; Appendix C. Listing C.L1; Appendix F, F.L1

On assessment of mean urinary albumin values by prior treatment group in the combination treatment arm (Figure 11), an increase was observed in those patients changing from sulphonylurea plus placebo therapy to combination rosiglitazone 2mg bd treatment from 38.45mg/L at open label baseline to 85.65mg/L at Month 12; mean values decreased and were mostly maintained over the following 24 months. In patients whose dose of rosiglitazone was increased from 1mg bd to 2mg bd, mean urinary albumin values increased from open label baseline

(26.69mg/L) at Month 6 (49.87mg/L) and were generally maintained for the following 33 months. An increase in mean urinary albumin was found in patients who continued treatment with rosiglitazone 2mg bd from open label baseline (39.34mg/L) to Month 6 (65.41mg/L), with mean values decreasing to 30.09mg/L at Month 12 which was generally maintained over the following 24 months.

Figure 11 Urinary Albumin (mean±SE) by Visit and Previous Treatment (Combination Therapy)



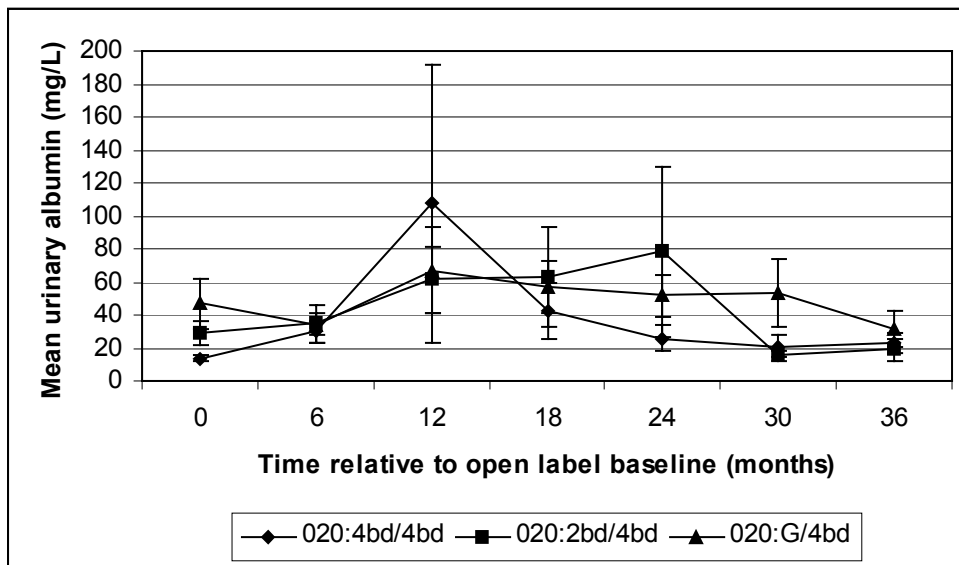
NOTE: Treatment in preceding study/treatment in this study; S=sulphonylurea; 1bd=rosiglitazone 1mg bd; 2bd=rosiglitazone 2mg bd

Data has not been presented where patient numbers are too low

Data Source: [Section 14](#), [Table 14.1Ab](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

Patients receiving glibenclamide in the previous study had the highest mean urinary albumin value at open label baseline (46.77mg/L) with those patients continuing treatment with rosiglitazone 4mg bd having the lowest mean value (13.78mg/L). Although urinary albumin values showed a high degree of variation and fluctuation, and any trend over time was difficult to assess, in general mean urinary albumin levels were similar to open label baseline in each subgroup at Month 36.

Figure 12 Urinary Albumin (mean $\pm$ SE) by Visit and Previous Treatment (Monotherapy)



NOTE: Treatment is shown as treatment in preceding study/treatment in this study. G=glibenclamide; 2bd=rosiglitazone 2mg bd; 4bd=rosiglitazone 4mg bd

Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Ac](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

Table 14 Mean Urinary Albumin by Visit

Urinary albumin Parameter	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Urinary albumin (mg/L)		
Double-blind Baseline (n)	206	359
mean $\pm$ SD	33.5 $\pm$ 100.18	25.9 $\pm$ 88.05
Open Label (OL) Baseline (n)	228	397
mean $\pm$ SD	34.8 $\pm$ 125.11	30.3 $\pm$ 116.75
Month 6 (n)	174	333
mean $\pm$ SD	55.6 $\pm$ 162.67	33.1 $\pm$ 90.37
Month 12 (n)	155	306
mean $\pm$ SD	49.0 $\pm$ 152.61	104.9 $\pm$ 694.15*
Month 18 (n)	132	247
mean $\pm$ SD	41.7 $\pm$ 103.85	52.9 $\pm$ 199.77
Month 24 (n)	108	211
mean $\pm$ SD	45.7 $\pm$ 96.25	51.5 $\pm$ 249.99
Month 30 (n)	90	150
mean $\pm$ SD	48.3 $\pm$ 99.96	28.5 $\pm$ 70.67
Month 36 (n)	72	62
mean $\pm$ SD	55.3 $\pm$ 113.85	22.2 $\pm$ 39.53
Month 42 (n)	27	0
mean $\pm$ SD	70.9 $\pm$ 147.54	
Month 48 (n)	2	0
mean $\pm$ SD	25.0 $\pm$ 4.24	

NOTE: All laboratory values are fasting

Data Source: [Section 14, Table 14.1Aa](#); [Appendix C](#), Listing C.L1; [Appendix F](#), F.L1

6 Safety Results

6.1 Extent of Exposure

[Table 15](#) displays the number of patients exposed to rosiglitazone and the duration of exposure by treatment group in study 009. Exposure time has been calculated from the open label baseline only, and does not include the period on double blind therapy.

Table 15 Duration of Exposure to Study Medication

Study Drug Exposure, n (%) [*]	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Duration (days):		
≤ 28	2 (0.9)	11 (2.6)
29 – 90	9 (3.9)	19 (4.4)
91 – 180	6 (2.6)	14 (3.3)
181 – 270	13 (5.7)	18 (4.2)
271 – 360	19 (8.3)	28 (6.5)
361 – 450	15 (6.6)	32 (7.4)
451 – 540	8 (3.5)	15 (3.5)
541 – 630	14 (6.1)	15 (3.5)
631 – 720	12 (5.2)	27 (6.3)
721 – 810	16 (7.0)	20 (4.7)
811 – 900	9 (3.9)	46 (10.7)
901 – 990	11 (4.8)	87 (20.2)
991 – 1080	31 (13.5)	81 (18.8)
1081 – 1170	20 (8.7)	17 (4.0)
1171 – 1260	23 (10.0)	0
1261 – 1350	19 (8.3)	0
1351 – 1440	2 (0.9)	0
> 1440	0	0
Mean ± SD	772.5 ± 392.19	710.1 ± 337.39
Median	819.0	864.0
Range	2 – 1373	1 – 1134

* days from open label study baseline

Data Source: [Section 13, Table 13.6.1a](#); [Appendix B, Listing B.L5](#)

The median duration of exposure to rosiglitazone in the extension study was 819 days in the rosiglitazone 2mg bd combination therapy group and 864 days in the rosiglitazone 4mg bd monotherapy group.

[Tables 13.6.1b](#) and [13.6.1c](#) ([Section 13](#)) give the patient exposure to treatment in study 009 in relation to the treatment group in the acute phase studies 015 and 020 and for all patients from study 025 respectively.

6.2 Adverse Experiences

All patients who were enrolled and received at least one dose of study medication were included in the safety evaluations.

A total of 552 patients (83.8% of all patients) reported treatment emergent AEs in the extension study; 189 patients (82.5%) in the rosiglitazone 2mg bd combination therapy group, and 363 patients (84.4%) in the rosiglitazone 4mg bd monotherapy group. The most common AEs by body system (≥10% in either

treatment group) are shown in [Table 16](#). In the rosiglitazone 2mg bd combination therapy group the most common AEs by body system occurred in the metabolic and nutritional body system (100 patients, 43.7%) and in the rosiglitazone 4mg bd monotherapy group in the respiratory system (153 patients, 35.6%). Events relating to the cardiovascular general (10.5%), heart rate and rhythm (7.1%) and myocardial, endocardial, pericardial valve (7.1%) systems were relatively less frequent (see [Section 6.2.1](#)). Event rates in patient years were not calculated for this study. They are available elsewhere ([Section 15](#), [Tables 15.9.1](#), [15.9.2](#), and [15.9.3](#)) and demonstrate that the event rates of edema and cardiac AEs in patients treated with long-term monotherapy with rosiglitazone are consistent with event rates in patients treated with rosiglitazone in combination with metformin or rosiglitazone in combination with a sulfonylurea.

Table 16 Most Common Adverse Experiences by Body System (≥10% in Either Treatment Group)

AE* by Body System, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Respiratory system	60 (26.2)	153 (35.6)
Musculoskeletal	63 (27.5)	143 (33.3)
Body as a whole general	70 (30.6)	126 (29.3)
Metabolic and nutritional	100 (43.7)	126 (29.3)
Gastrointestinal system	58 (25.3)	113 (26.3)
Resistance mechanism	70 (30.6)	94 (21.9)
Central and peripheral nervous system	46 (20.1)	77 (17.9)
Urinary system	38 (16.6)	71 (16.5)
Vascular extracardiac	23 (10.0)	55 (12.8)
Skin and appendages	39 (17.0)	53 (12.3)
Vision	22 (9.6)	49 (11.4)
Psychiatric	25 (10.9)	46 (10.7)
Cardiovascular general	26 (11.4)	43 (10.0)

* On-therapy AEs emergent during the open label study

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 15](#), [Table 15.2.4a](#); [Appendix D](#), Listing D.L2

[Tables 15.2.4b](#) and [15.2.4c](#) ([Section 15](#)) present the number and percentage of patients who reported adverse experiences by body system in the rosiglitazone 2mg bd combination therapy group and rosiglitazone 4mg bd monotherapy group according to the treatment received during the acute phase studies 015 and 020 and for all patients from study 025.

The most commonly occurring AEs (i.e., those occurring in at least 5.0% of patients in either group) are shown in [Table 17](#). The most common AE in the

rosiglitazone 2mg bd combination therapy group was hyperglycaemia followed by injury, and in the rosiglitazone 4mg bd monotherapy group, bronchitis followed by injury. Hepatic-related AEs (GGT increased, hepatic enzymes increased, hepatic function abnormal, liver fatty, SGPT increased, hepatomegaly) were reported for 14 patients (6.1%) in the rosiglitazone combination therapy group and eight patients (1.9%) in the rosiglitazone monotherapy group, and are described in more detail below along with cardiac, oedema, anaemia and lipid related AEs.

Bronchitis occurred more frequently in the rosiglitazone 4mg bd monotherapy group (16.0%) compared to the rosiglitazone 2mg bd combination therapy group (3.9%), whereas hyperglycaemia occurred more frequently in the rosiglitazone 2mg bd combination therapy group (20.1%) compared to the rosiglitazone 4mg bd monotherapy group (3.7%) as did upper respiratory tract infection (12.7% vs 6.7% respectively) and aggravated diabetes mellitus (10.0% vs 5.1% respectively). All other AEs occurred with a similar incidence in both treatment groups.

The highest incidence of hyperglycaemia in the combination therapy group occurred in patients continuing therapy with rosiglitazone 2mg bd (21/76 (23.3%)) and those who previously received sulphonylurea plus placebo (13/61 (21.3%)) compared to patients who previously received rosiglitazone 1mg bd (12/62 (15.4%)).

Table 17 On-therapy Adverse Experiences Reported by $\geq 5.0\%$ of Patients in Either Treatment Group by Preferred Term

AE by Preferred Term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Patients with at least one on-therapy AE*	189 (82.5)	363 (84.4)
Bronchitis	9 (3.9)	69 (16.0)
Injury	36 (15.7)	60 (14.0)
Back pain	18 (7.9)	51 (11.9)
Hypercholesterolaemia	19 (8.3)	43 (10.0)
Arthritis	15 (6.6)	42 (9.8)
Urinary tract infection	24 (10.5)	40 (9.3)
Infection viral	28 (12.2)	38 (8.8)
Neuralgia	8 (3.5)	32 (7.4)
Arthralgia	20 (8.7)	30 (7.0)
Pharyngitis	15 (6.6)	29 (6.7)
Upper respiratory tract infection	29 (12.7)	29 (6.7)
Oedema legs	6 (2.6)	25 (5.8)
Respiratory disorder	19 (8.3)	25 (5.8)
Arthrosis	4 (1.7)	23 (5.3)
Hyperlipaemia	11 (4.8)	23 (5.3)
Abdominal pain	13 (5.7)	23 (5.3)
Diabetes mellitus aggravated	23 (10.0)	22 (5.1)
Pain	13 (5.7)	19 (4.4)
Hyperglycaemia	46 (20.1)	16 (3.7)
Coughing	19 (8.3)	15 (3.5)
Hypoglycaemia	14 (6.1)	6 (1.4)

* On-therapy AEs defined as those AEs which were emergent during the open label study

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 15, Table 15.2.4a](#); [Appendix D, Listing D.L2](#)

A by-patient listing of all on-therapy adverse experiences is presented in Listing D.L2, [Appendix D](#) and summary tabulations of the number and percentage of patients who reported adverse experiences are presented by body system and preferred term in [Section 15, Table 15.2.4a](#).

[Tables 15.2.4b](#) and [X15.2.4b](#) in [Section 15](#) present the number and percentage of patients who reported adverse experiences by preferred term in the rosiglitazone 2mg bd combination therapy group by study 015 treatment group. [Tables 15.2.4c](#) and [X15.2.4c](#) in [Section 15](#) present the number and percentage of patients who reported adverse experiences by preferred term in the rosiglitazone 4mg bd monotherapy group by study 020 treatment group and for all patients from study 025. When examined in this way there were no differences in the incidences of total AEs or individual AEs between groups in relation to prior treatment.

A complete patient listing of post-therapy adverse experiences in this study may be found in [Appendix D](#), Listing D.L3.

6.2.1 Cardiac-related AEs

The percentage of patients with on-therapy cardiac-related adverse experiences was similar for the two treatment groups, 2mg bd plus sulphonylurea and 4mg bd monotherapy ([Table 18](#)).

**Table 18 On-Therapy Cardiac-related Adverse Experiences by Body System
and Preferred Term**

Body System AE by Preferred Term, n (%)	Treatment Group		
	2mg bd Combination N = 229	4mg bd Monotherapy N = 430	Total - N = 659
Cardiovascular General	26 (11.4)	43 (10.0)	69 (10.4)
Cardiac failure*	5 (2.2)	8 (1.9)	13 (2.0)
Cardiac failure left*	1 (0.4)	2 (0.5)	3 (0.5)
ECG Abnormal	1 (0.4)	1 (0.2)	2 (0.3)
ECG Abnormal Specific	0	2 (0.5)	2 (0.3)
Heart Disorder	0	1 (0.2)	1 (0.2)
Heart Valve Disorders	1 (0.4)	1 (0.2)	2 (0.3)
Hypertension	9 (3.9)	13 (3.0)	22 (3.3)
Hypertension Aggravated	10 (4.4)	9 (2.1)	19 (2.9)
Hypotension	0	3 (0.7)	3 (0.5)
Hypotension Postural	1 (0.4)	1 (0.2)	2 (0.3)
Syncope	4 (1.7)	5 (1.2)	9 (1.4)
Heart Rate and Rhythm	14 (6.1)	33 (7.7)	47 (7.1)
Arrhythmia Atrial	1 (0.4)	1 (0.2)	2 (0.3)
Arrhythmia Ventricular	0	1 (0.2)	1 (0.2)
Atrioventricular Block	1 (0.4)	4 (0.9)	5 (0.8)
Atrioventricular Block Complete	0	1 (0.2)	
Bradycardia	1 (0.4)	3 (0.7)	4 (0.6)
Bundle Branch Block	1 (0.4)	5 (1.2)	6 (0.9)
Extrasystoles	1 (0.4)	6 (1.4)	7 (1.1)
Fibrillation Atrial	4 (1.7)	10 (2.3)	14 (2.1)
Palpitation	2 (0.9)	3 (0.7)	5 (0.8)
QT Increased	2 (0.9)	0	2 (0.3)
Tachycardia	3 (1.3)	3 (0.7)	6 (0.9)
Tachycardia Supraventricular	0	1 (0.2)	1 (0.2)
Myocardial/endocardial/ pericardial valve	17 (7.4)	30 (7.0)	47 (7.1)
Angina Pectoris	9 (3.9)	15 (3.5)	24 (3.6)
Angina Pectoris Aggravated	1 (0.4)	0	1 (0.2)
Aortic Stenosis	0	1 (0.2)	1 (0.2)
Cardiomyopathy	1 (0.4)	0	1 (0.2)
Coronary Artery Disorder	1 (0.4)	0	1 (0.2)
Myocardial Infarction	4 (1.7)	10 (2.3)	14 (2.1)
Myocardial Ischaemia	2 (0.9)	5 (1.2)	7 (1.1)
Thrombosis Coronary	1 (0.4)	1 (0.2)	2 (0.3)

Data Source: [Section 15, Table 15.2.4.a](#); [Appendix D](#), Listing D.L2

6.2.1.1 Cardiac Failure

In total, 20 patients were reported with at least one event with the preferred term cardiac failure or pulmonary oedema; 7 (5.7%) in the rosiglitazone 2mg bd combination group, 13 (3.0%) in the rosiglitazone 4mg bd monotherapy group. Only one event of cardiac failure/pulmonary oedema (0.2%), in the rosiglitazone 4mg bd monotherapy group, was considered to have a suspected/probable relationship to study medication ([Section 15, Table 15.2.1a](#)) for which the patient was withdrawn ([Section 15, Table 15.5a](#)). Two further patients, in the combination therapy group, were withdrawn due to cardiac failure/pulmonary oedema. In total, 4 (1.7%) events in the monotherapy group and 2 (0.5%) events in the combination therapy group were severe in intensity ([Section 15, Table 15.2.2a](#)).

Six patients (1.2%) in the monotherapy group and 6 (2.6%) in the combination group were classified as having serious nonfatal AEs for which narratives are provided in [Section 15, Table 15.2.3x](#). Brief narratives on these 12 patients are given below.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In addition to the twelve patients with serious adverse events of cardiac failure/pulmonary oedema, there were eight patients with non-serious events in this category. In all eight cases the events were mild/moderate in severity, were deemed either unrelated or unlikely to be related to study drug by the investigator, none required study medication to be withdrawn and three of the eight had resolved by the end of the study.

6.2.2 Hepatic-related AEs

In total, 14 (6.1%) AEs related to hepatic abnormalities (GGT increased, hepatic enzymes increased, hepatic function abnormal, liver fatty, SGPT increased) were reported in the rosiglitazone 2mg bd combination therapy group with 8 (1.9%) events (GGT increased, hepatic function abnormal, hepatomegaly) reported in the rosiglitazone 4mg bd monotherapy group. The most frequently occurring hepatic-related AE in either treatment group was increased GGT; 6 patients (2.6%) in the combination therapy group, 5 patients (1.2%) in the monotherapy group. All other hepatic-related AEs occurred with an incidence less than 1.0% in either treatment group.

[REDACTED]

[REDACTED]

The patient continued in the study and the event was considered unlikely to be related to study drug.

[REDACTED]

No AST laboratory values were recorded as being outside the normal range for the duration of the trial. Full patient narratives are provided for hepatic-related AE withdrawals in [Section 15, Table 15.5x](#).

6.2.3 Oedema-related AEs

The incidence of oedema (oedema, oedema dependent, oedema legs) was 7.4% in the rosiglitazone 4mg bd monotherapy group and 4.8% in the rosiglitazone 2mg bd combination therapy group. Three severe AEs related to oedema (oedema, oedema dependent, oedema legs) were reported in three patients in the monotherapy group with three reported in two patients in the combination therapy group. [REDACTED]

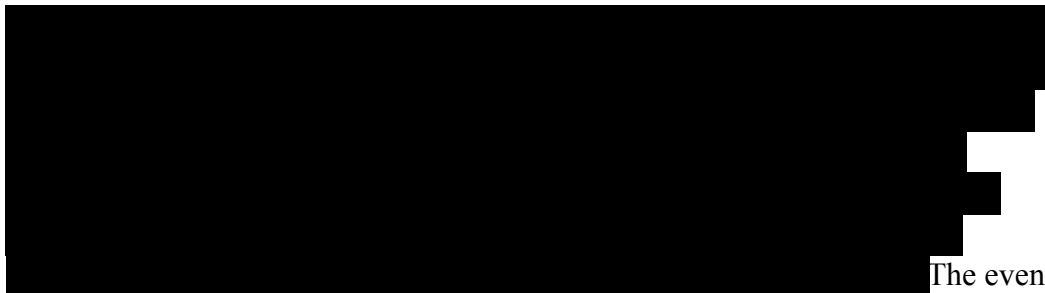
[REDACTED]

The event was considered to have a suspected relationship to study drug (see [Section 15, Table 15.5x](#) for full narrative). The five other severe events were all considered to be unrelated or unlikely to be related to study medication and resolved following corrective therapy.

6.2.4 Anaemia-related AEs

A total of 11 patients (4.8%) in the rosiglitazone 2mg bd combination therapy group and 25 patients (5.8%) in the rosiglitazone 4mg bd monotherapy group had

anaemia-related AEs. Three (1.3%) events of anaemia in the combination group and 1 (0.2%) in the monotherapy group were severe. All three events in the combination group were classified as serious AEs and narratives are located in [Section 15, Table 15.2.3x](#) for these patients. All four severe events were considered to be unlikely/not related to study medication, resolved on-therapy and did not lead to patient withdrawal.



The event was considered to be moderate and unlikely to be related to study drug.

6.2.5 Lipid related AEs

A total of 32 patients (14.0%) in the rosiglitazone 2mg bd combination therapy group and 72 patients (16.7%) in the rosiglitazone 4mg bd monotherapy group had lipid-related AEs, the most frequent being hypercholesterolaemia in both treatment groups (8.3% and 10.0% respectively). Only four lipid-related events were severe: hypercholesterolaemia in 2 patients (0.5%) and hyperlipaemia in 2 patients (0.5%), all in the rosiglitazone 4mg bd monotherapy group. Only one severe lipid-related AE was considered to have a suspected relationship to study drug. No patients were withdrawn due to lipid-related AEs.

Mean values for lipid parameters by visit can be found in [Section 8](#).

6.2.6 Adverse Experiences by Intensity

A total of 153 patients (23.2% of all patients) experienced severe AEs; 52 patients (22.7%) in the rosiglitazone 2mg bd combination therapy group and 101 patients (23.5%) in the rosiglitazone 4mg bd monotherapy group. The numbers of patients with severe events and those occurring in 1% or more patients in either treatment group are shown in [Table 19](#).

Table 19 Severe On-therapy Adverse Experiences Reported by $\geq 1\%$ of Patients in Either Treatment Group

Preferred term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Patients with at least one severe on-therapy AE*	52 (22.7)	101 (23.5)
Injury	5 (2.2)	13 (3.0)
Myocardial infarction	1 (0.4)	8 (1.9)
Arthritis	1 (0.4)	8 (1.9)
Back pain	0	5 (1.2)
Cardiac failure	4 (1.7)	2 (0.5)
Vascular disorder	3 (1.3)	2 (0.5)
Anaemia	3 (1.3)	1 (0.2)

* On-therapy AEs emergent during the open label study

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Includes AEs with missing intensity

Data Source: [Section 15, Table 15.2.2a; Appendix D, Listing D.L2](#)

[Table 15.2.2b \(Section 15\)](#) presents the number and percentage of patients with adverse experiences by intensity in the rosiglitazone 2mg bd combination therapy group by prior treatment group in study 015. [Table 15.2.2c \(Section 15\)](#) presents the number and percentage of patients with adverse experiences by intensity in the rosiglitazone 4mg bd monotherapy group by prior treatment group in study 020 and for all patients in study 025. There were no differences between these subgroups of patients and their respective combined open label groups.

6.2.7 Adverse Experiences by Causality

[Table 20](#) summarises on-therapy adverse experiences considered by the investigator to be suspected/probably related to study medication in 1% or more of patients in either treatment group.

In the rosiglitazone 2mg bd combination therapy group 51 (22.3%) adverse experiences were recorded as suspected/probably related to study medication with 82 (19.1%) in the rosiglitazone 4mg bd monotherapy group. Hyperglycaemia (9.6%) and aggravated diabetes mellitus (6.6%) were the most frequently reported AEs with a causal relationship to study medication in the combination therapy group and aggravated diabetes mellitus (5.1%) was the most frequently reported suspected/probably related AE in the monotherapy group.

Table 20 On-therapy Adverse Experiences Considered to be Suspected/Probably Related to Study Medication Occurring in $\geq 1\%$ of Patients in Either Treatment Group

Preferred Term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Number of patients with at least one suspected/probably related on-therapy AE*	51 (22.3)	82 (19.1)
Diabetes mellitus aggravated	15 (6.6)	22 (5.1)
Hyperglycaemia	22 (9.6)	10 (2.3)
Weight increase	1 (0.4)	10 (2.3)
Hypercholesterolaemia	2 (0.9)	6 (1.4)
Headache	1 (0.4)	5 (1.2)
Hypoglycaemia†	9 (3.9)	5 (1.2)
Hyperlipaemia	5 (2.2)	4 (0.9)

* On-therapy AEs emergent during the open label study

† symptoms suggestive of hypoglycaemia

NOTE: Sorted by descending order in the rosiglitazone 4mg bd monotherapy group

Data Source: [Section 15, Table 15.2.1a; Appendix D, Listing D.L2](#)

A complete tabulation and listing of on-therapy adverse experiences by all investigator determined attributions to study medication may be found in [Section 15, Table 15.2.1a](#), and sub-divided by previous treatment group in [Section 15, Tables 15.2.1b and 15.2.1c](#) for the combination and monotherapy groups respectively, and [Appendix D, Listing D.L2](#). There were no differences between prior treatment subgroups of patients and their respective combined open label groups.

6.3 Deaths

There were 6 deaths (0.9% of all patients) which occurred on-therapy; 1 (0.4%) in the rosiglitazone 2mg bd combination therapy group and 5 (1.2%) in the rosiglitazone 4mg bd monotherapy group. Details of these deaths are provided in [Section 15, Table 15.4](#) and [Appendix D, Listing D.L2](#).

Full patient narratives for both on-therapy and post-therapy serious fatal AEs are available in [Section 15, Table 15.4x](#).

The patients who died on-therapy are summarised in [Table 21](#) and brief details follow.

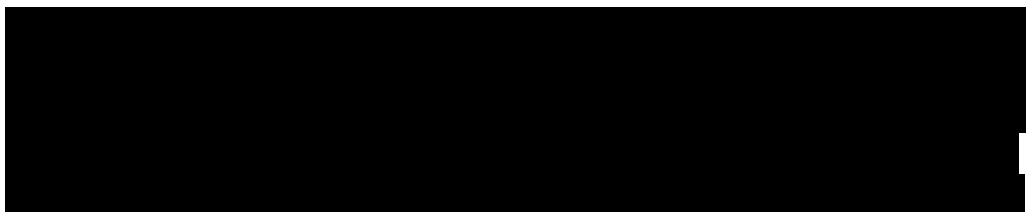
Table 21 Summary of Deaths Occurring On-Therapy



* Day of onset of fatal AE relative to start date of rosiglitazone medication (open label study)

ERRATA: Date of withdrawal incorrectly recorded in database for some PIDs and hence days from last dose incorrectly derived in [Table 15.4](#) Listing D.L4. Day of death relative to start of RSG medication (open label study) is provided in [Table 15.4](#) and not 'Total time on medication (days)' as stated.

Data Source: [Section 15](#), [Table 15.4](#); [Appendix D](#), Listing D.L2

[REDACTED] The investigator reported the suspected myocardial infarction as unrelated to treatment with study medication.

[REDACTED] The investigator reported that the patient's death could be associated with the patient's underlying hypertension.

[REDACTED] The investigator considered the event to be probably unrelated to study medication.

[REDACTED] The investigator considered the bronchopneumopathy and right humerus fracture to be unrelated to study medication.

[REDACTED]

[REDACTED] The investigator reported the death was unlikely to be related to treatment with study medication.

6.4 Serious Nonfatal Adverse Experiences

A serious adverse experience was defined as any event which was fatal, life threatening, disabling or incapacitating or resulted in hospitalisation, prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any experience which the investigator regarded as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may have been associated with the use of the drug was to be documented as a serious event.

6.4.1 Serious Nonfatal Adverse Experiences Ongoing at Open Label Baseline

Serious adverse experiences that were ongoing at the open label baseline are listed in [Appendix D](#), Listing D.L5. One patient (0.4%) in the rosiglitazone 2mg bd combination therapy group and one patient (0.2%) in the rosiglitazone 4mg bd monotherapy group had serious adverse experiences which were ongoing at open label baseline.

[REDACTED]

[REDACTED]

However, as this adverse experience occurred on the first day of open label study medication, the event should have been recorded as on-therapy and is included in [Section 15](#), [Table 15.2.3a](#) and [Appendix D](#), Listing D.L6.

6.4.2 On-therapy Serious Nonfatal Adverse Experiences

[REDACTED]



A summary of serious on-therapy nonfatal adverse experiences occurring in more than one patient is provided in [Table 22](#) and data for all serious on-therapy and/or post-therapy nonfatal adverse experiences are provided in [Table 23](#); detailed patient narratives are presented in [Section 15, Table 15.2.3x](#).

The incidence of individual AEs classified as severe was low, with injury being the most frequently reported severe AE in both treatment groups (2.2% combination therapy group, 3.0% monotherapy group). All other severe AEs occurred with an incidence <2.0%.

**Table 22 Summary of Serious Nonfatal On-therapy Adverse Experiences Occurring
in More Than One Patient in Either Treatment Group**

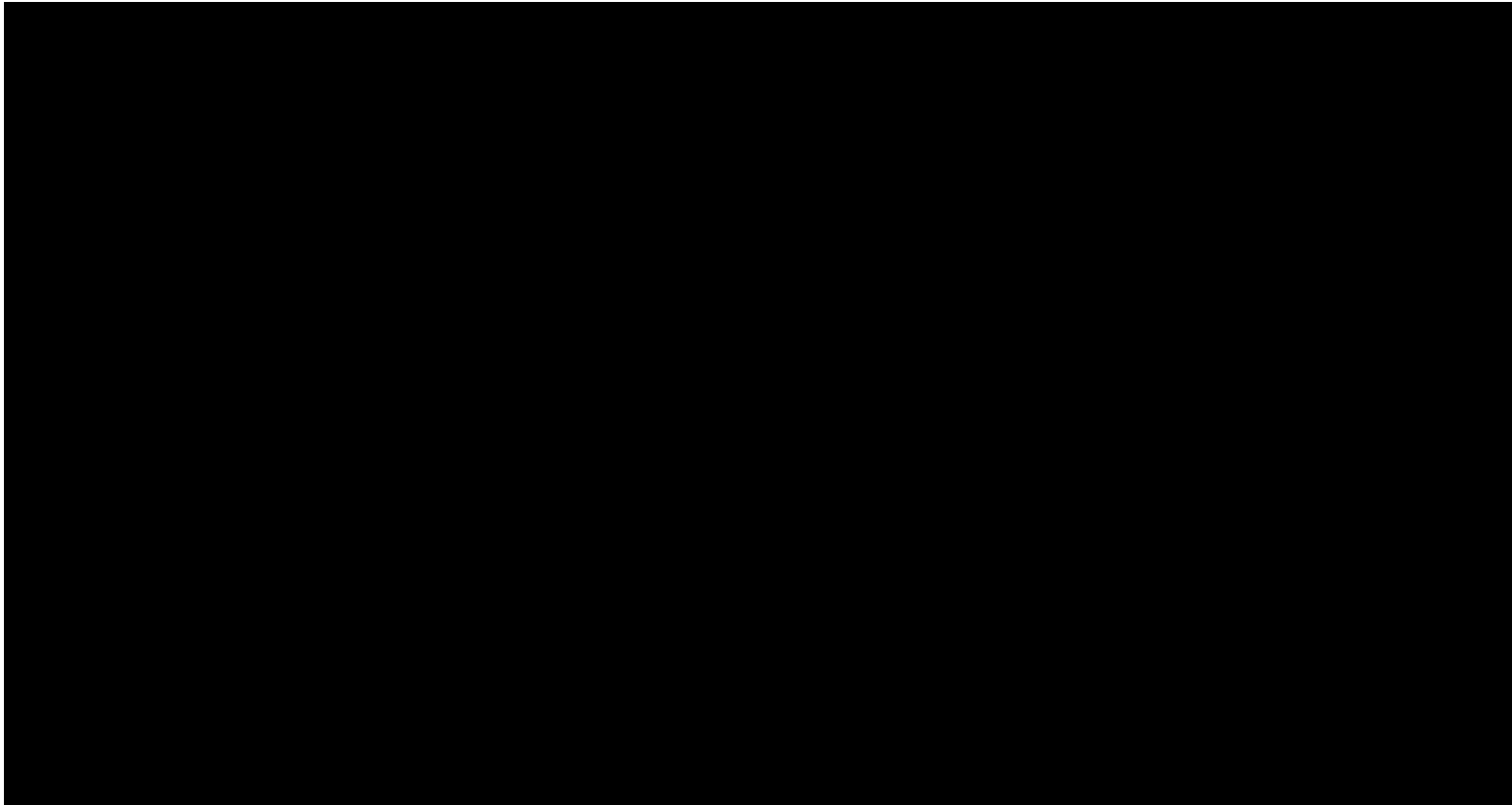
Preferred Term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Patients with at least one serious on-therapy AE*	49 (21.4)	86 (20.0)**
Injury	4 (1.7)	13 (3.0)
Myocardial infarction	4 (1.7)	7 (1.6)
Cardiac failure	4 (1.7)	5 (1.2)
Atrial fibrillation	1 (0.4)	5 (1.2)
Arthritis	1 (0.4)	3 (0.7)**
Cerebrovascular disorder	2 (0.9)	3 (0.7)
Angina pectoris	1 (0.4)	3 (0.7)
Chest pain	1 (0.4)	3 (0.7)
Pneumonia	1 (0.4)	3 (0.7)
Bladder carcinoma	0	3 (0.7)
Cataract	0	3 (0.7)
Pulmonary oedema	2 (0.9)	2 (0.5)
Syncope	2 (0.9)	2 (0.5)
Therapeutic response increased	2 (0.9)	2 (0.5)
Duodenal ulcer	1 (0.4)	2 (0.5)
Infection	1 (0.4)	2 (0.5)
Abdominal pain	0	2 (0.5)
Arteritis	0	2 (0.5)
Atrioventricular block	0	2 (0.5)
Bradycardia	0	2 (0.5)
Carcinoma	0	2 (0.5)
Haematuria	0	2 (0.5)
Hepatic neoplasm malignant	0	2 (0.5)
Neoplasm NOS	0	2 (0.5)
Anaemia	3 (1.3)	1 (0.2)
Dyspnoea	3 (1.3)	0
Gastrointestinal haemorrhage	2 (0.9)	0

* On-therapy AEs defined as those AEs which were emergent during the open label study

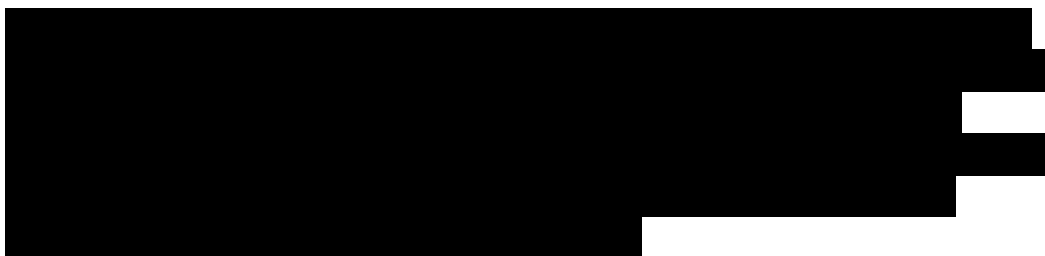
Data Source: [Section 15, Table 15.2.3a](#); [Appendix D, Listing D.L6](#)

[Tables 15.2.3b](#) and [15.2.3c](#) ([Section 15](#)) present the number and percentage of patients with serious on-therapy nonfatal adverse experiences in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 and for all patients in study 025, respectively.

Table 23 Patients with Serious Nonfatal On-therapy and/or Post-therapy Adverse Experiences



Continued



In total, 28 patients were withdrawn due to serious, nonfatal adverse experiences, 15 (3.3%) in the rosiglitazone 4mg bd monotherapy group and 13 (6.6%) in the rosiglitazone 2mg bd combination group (see [Table 25](#)).

6.4.3 Post-therapy Serious Nonfatal Adverse Experiences

A listing of all serious, nonfatal AEs occurring more than 1 day after cessation of study medication are provided [Appendix D](#), Listing D.L7.

A total of 8 patients (1.2% of all patients) experienced serious nonfatal AEs occurring more than 1 day after cessation of study medication; four patients (1.7%) in the rosiglitazone 2mg bd combination therapy group and four (0.9%) patients in the rosiglitazone 4mg bd monotherapy group. The events were pulmonary carcinoma, urinary retention, haemorrhagic duodenal ulcer and deep thrombophlebitis in patients receiving rosiglitazone 2mg bd combination therapy and pulmonary embolism/carcinoma, thrombophlebitis, cholecystitis and back pain in patients receiving rosiglitazone 4mg bd monotherapy.



This serious AE is listed in [Appendix D](#), Listings D.L3 and D.L7.

6.5 Withdrawals Due to Adverse Experiences

Narratives are provided for all withdrawals due to serious AEs. For withdrawals due to non-serious AEs, narratives are provided for AEs related to oedema or hepatic events occurring after open label baseline. The location of the narratives is indicated in [Table 15.0](#) and narratives for patients withdrawn due to adverse experiences are provided in [Section 15, Table 15.5x](#). Annotated CRFs for all withdrawals due to adverse experiences are provided in [Appendix G](#).

In total 29 patients (12.7%) in the rosiglitazone 2mg bd combination therapy group and 47 patients (10.9%) in the 4mg bd rosiglitazone monotherapy group

withdrew due to adverse experiences (see [Section 4.2.3](#)). Two patients (0.9%) in the combination group and 5 patients (1.2%) in the monotherapy group withdrew due to AEs ongoing at open label baseline. Sixty-six patients (10.0% of all patients) had on-therapy adverse experiences which led to their withdrawal from the study; 26 (11.4%) in the rosiglitazone group and 40 (9.3%) in the rosiglitazone 4mg bd monotherapy group. Post-therapy AEs led to the withdrawal of 1 patient (0.4%) in the combination group and 2 patients (0.5%) in the monotherapy group.

Events leading to withdrawal in more than one patient are summarised in [Table 24](#). The most frequent adverse event leading to withdrawal was hyperglycaemia in the rosiglitazone 2mg bd combination therapy group (4 patients (1.7%)) and in the rosiglitazone 4mg bd monotherapy group myocardial infarction (6 patients (1.4%)). All other events led to the withdrawal of less than 1.0% of patients in either treatment group.

Cardiac-related adverse experiences are discussed further in [Section 6.2.1](#).

Table 24 Summary of On-therapy Adverse Experiences Leading to Withdrawal in More Than One Patient in Either Treatment Group

On-therapy AE* leading to withdrawal by preferred term, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
At Least One Event	26 (11.4)	40 (9.3)
Myocardial infarction	2 (0.9)	6 (1.4)
Weight increase	1 (0.4)	4 (0.9)
Diabetes mellitus aggravated	2 (0.9)	3 (0.7)
Nausea	1 (0.4)	3 (0.7)
Hyperglycaemia	4 (1.7)	2 (0.5)
Anaemia	0	2 (0.5)
Cardiac failure	0	2 (0.5)
Hypoglycaemia	0	2 (0.5)

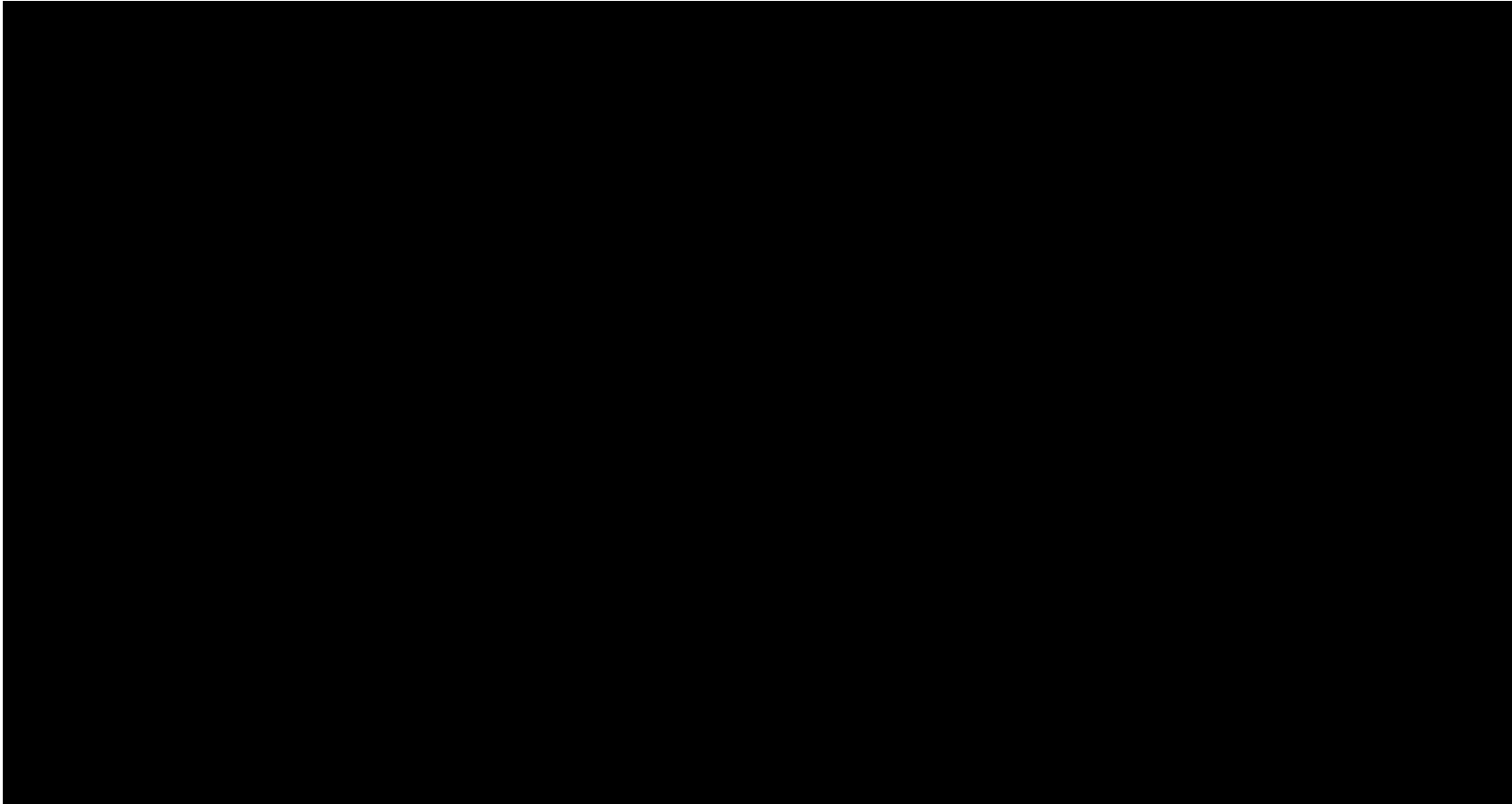
* On-therapy AEs defined as those AEs which were emergent during the open label study.

Data Source: [Section 15, Table 15.5a](#); [Appendix D](#), Listing D.L4

[Tables 15.5b](#) and [15.5c](#) ([Section 15](#)) present the number and percentage of patients withdrawn due to an on-therapy adverse experience in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 and for all patients in study 025, respectively.

Data for all patients who had an adverse experience leading to withdrawal are provided in [Table 25](#).

Table 25 Patients Withdrawn from the Study Due to On-Therapy Adverse Experiences



Continued

In total, 33 adverse experiences leading to the withdrawal of 25 patients were regarded by the investigator as having a probable/suspected relationship to study medication. Those adverse experiences with a causality of probable/suspected leading to the withdrawal of more than one patient comprised diabetes mellitus aggravated (4 (0.6%) patients), hyperglycaemia (2 (0.3%) patients), hypoglycaemia/hypoglycaemic reaction (3 (0.5%) patients), weight increase (5 (7.6%) patients) and nausea (2 (0.3%) patients).

6.6 Vital Signs

Group mean values for systolic and diastolic blood pressure and pulse rate at each visit are shown in [Table 26](#). For both treatment groups, all changes in vital signs from double-blind or open label baseline were small and of no clinical significance.

Table 26 Summary Statistics for Vital Signs by Visit

Vital Signs	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Sitting Systolic BP (mmHg)		
DB Baseline (n)	229	430
mean ± SD	141.5 ± 16.77	139.1 ± 14.92
OL Baseline (n)	229	430
mean ± SD	141.4 ± 16.87	138.8 ± 14.12
Month 1 (n)	225	421
mean ± SD	141.1 ± 16.11	139.0 ± 14.55
Month 2 (n)	224	411
mean ± SD	141.0 ± 16.81	138.6 ± 13.61
Month 3 (n)	219	402
mean ± SD	140.6 ± 15.48	137.6 ± 13.84
Month 6 (n)	212	394
mean ± SD	142.0 ± 17.58	138.1 ± 13.65
Month 9 (n)	204	379
mean ± SD	142.7 ± 16.51	139.4 ± 13.74
Month 12 (n)	188	345
mean ± SD	144.6 ± 16.25	140.5 ± 14.22
Month 15 (n)	174	325
mean ± SD	143.4 ± 17.08	139.1 ± 14.64
Month 18 (n)	157	302
mean ± SD	141.1 ± 17.05	138.1 ± 14.12
Month 21 (n)	153	285
mean ± SD	142.5 ± 18.76	137.7 ± 12.95
Month 24 (n)	133	267
mean ± SD	142.1 ± 16.66	138.4 ± 13.66
Month 27 (n)	124	239
mean ± SD	142.6 ± 17.56	138.8 ± 13.45
Month 30 (n)	115	210
mean ± SD	141.3 ± 16.42	135.8 ± 13.20
Month 33 (n)	98	137
mean ± SD	143.0 ± 18.37	138.2 ± 12.51
Month 36 (n)	84	85
mean ± SD	141.6 ± 15.74	136.8 ± 12.05
Month 39 (n)	52	0
mean ± SD	143.3 ± 19.83	
Month 42 (n)	32	0
mean ± SD	145.7 ± 18.78	
Month 45 (n)	11	0
mean ± SD	140.9 ± 7.35	
Sitting Diastolic BP (mmHg)		
DB Baseline (n)	229	430
mean ± SD	81.9 ± 8.66	81.9 ± 8.42
OL Baseline (n)	229	430
mean ± SD	81.7 ± 8.60	80.9 ± 8.60
Month 1 (n)	225	421
mean ± SD	80.7 ± 8.39	80.7 ± 8.60
Month 2 (n)	224	411
mean ± SD	81.1 ± 8.72	80.4 ± 8.56
Month 3 (n)	219	402
mean ± SD	80.7 ± 8.95	80.1 ± 8.47
Month 6 (n)	212	394
mean ± SD	80.7 ± 8.78	80.1 ± 8.24

Continued

Table 26 (continued): Summary Statistics for Vital Signs by Visit

Vital Signs	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Sitting Diastolic BP (mmHg)		
Month 9 (n)	204	379
mean ± SD	80.4 ± 9.10	80.1 ± 8.23
Month 12 (n)	188	345
mean ± SD	81.6 ± 8.02	80.4 ± 8.31
Month 15 (n)	174	325
mean ± SD	80.5 ± 7.47	80.1 ± 7.60
Month 18 (n)	157	302
mean ± SD	80.7 ± 8.17	79.4 ± 7.63
Month 21 (n)	153	285
mean ± SD	80.0 ± 8.82	79.7 ± 7.83
Month 24 (n)	133	267
mean ± SD	79.0 ± 8.75	79.4 ± 7.96
Month 27 (n)	124	239
mean ± SD	79.7 ± 8.50	79.6 ± 7.97
Month 30 (n)	115	210
mean ± SD	78.4 ± 9.20	78.5 ± 7.30
Month 33 (n)	98	137
mean ± SD	79.7 ± 8.66	80.0 ± 7.41
Month 36 (n)	84	85
mean ± SD	79.6 ± 8.25	79.0 ± 7.50
Month 39 (n)	52	0
mean ± SD	79.4 ± 10.55	
Month 42 (n)	32	0
mean ± SD	81.4 ± 10.46	
Month 45 (n)	11	0
mean ± SD	77.0 ± 6.21	
Sitting Heart Rate (bpm)		
DB Baseline (n)	229	430
mean ± SD	73.0 ± 8.95	71.5 ± 9.42
OL Baseline (n)	229	430
mean ± SD	72.5 ± 9.01	72.4 ± 9.61
Month 1 (n)	225	420
mean ± SD	72.7 ± 9.16	71.9 ± 8.95
Month 2 (n)	224	410
mean ± SD	72.8 ± 8.86	71.5 ± 8.80
Month 3 (n)	217	401
mean ± SD	72.6 ± 9.15	71.4 ± 8.91
Month 6 (n)	210	392
mean ± SD	72.6 ± 9.75	72.4 ± 9.12
Month 9 (n)	200	379
mean ± SD	72.1 ± 9.14	71.5 ± 8.74
Month 12 (n)	188	345
mean ± SD	72.7 ± 10.16	72.0 ± 9.21
Month 15 (n)	172	323
mean ± SD	72.6 ± 8.63	72.2 ± 8.10
Month 18 (n)	157	302
mean ± SD	72.3 ± 10.17	71.2 ± 8.52
Month 21 (n)	153	284
mean ± SD	72.3 ± 8.43	71.4 ± 8.16
Month 24 (n)	132	266
mean ± SD	70.7 ± 8.94	71.8 ± 9.26
Month 27 (n)	123	238
mean ± SD	70.3 ± 8.19	71.5 ± 8.55
Month 30 (n)	114	208
mean ± SD	71.9 ± 8.89	70.8 ± 9.45

Continued

Table 26 (continued): Summary Statistics for Vital Signs by Visit

Vital Signs	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Sitting Heart Rate (bpm)		
Month 33 (n)	98	137
mean $\pm$ SD	71.4 $\pm$ 8.39	72.4 $\pm$ 8.53
Month 36 (n)	83	82
mean $\pm$ SD	71.2 $\pm$ 7.89	71.8 $\pm$ 8.69
Month 39 (n)	52	0
mean $\pm$ SD	75.0 $\pm$ 8.87	
Month 42 (n)	32	0
mean $\pm$ SD	71.7 $\pm$ 9.97	
Month 45 (n)	11	0
mean $\pm$ SD	68.2 $\pm$ 5.90	

Data Source: [Section 15, Table 15.6.3Ba](#); [Appendix E, Listing E.L1A](#)

[Tables 15.6.3Bb](#) and [15.6.3Bc](#) ([Section 15](#)) detail summary statistics for vital signs by visit in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 respectively. There were no differences between these subgroups of patients and their respective combined open label groups.

[Table 27](#) presents the number of patients in each treatment group with vital signs of potential clinical concern based on the open label baseline. The most frequent vital sign parameter of potential clinical concern in the rosiglitazone 2mg bd combination therapy group was an increase in sitting SBP (8 patients (3.5%)) and in the rosiglitazone 4mg bd monotherapy group a decrease in sitting heart rate (12 patients (2.8%)). All other vital sign parameters of potential clinical concern occurred with an incidence $\leq 2.2\%$ in either treatment group. All emergent values of potential clinical concern were reviewed by the medical monitor and were considered small and of no clinical significance.

Table 27 Number (%) of Patients with On-therapy Changes in Vital Signs of Potential Clinical Concern from Open Label Baseline

On-therapy Vital Signs* of Potential Clinical Concern	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Blood Pressure		
Sitting Systolic (mmHg)		
>50 increase from baseline**	8 (3.5%)	0
>50 decrease from baseline**	5 (2.2%)	2 (0.5%)
Sitting Diastolic (mmHg)		
>30 increase from baseline**	4 (1.7%)	5 (1.2%)
>30 decrease from baseline**	5 (2.2%)	4 (0.9%)
Sitting Heart Rate (bpm)		
<50	5 (2.2%)	12 (2.8%)
>120	0	0

* On-therapy defined as during the open label study

** Change from baseline calculated only for those patients who had both a baseline and an on-therapy value

Data Source: [Section 15, Table 15.6.2Ba](#); [Appendix E, Listing E.L1A](#)

[Tables 15.6.2Bb](#) and [15.6.2Bc](#) ([Section 15](#)) detail the vital signs of potential clinical concern based on the open label baseline in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 respectively. There were no differences between these subgroups of patients and their respective combined open label groups.

6.7 Weight

[Table 28](#) summarises mean weight by visit. In both treatment groups there was an increase in weight over time; in the rosiglitazone 2mg bd combination therapy group, mean weight at Month 36 was 83.2 kg compared to 78.8 kg at open label baseline and 77.4 kg at double-blind baseline; in the rosiglitazone 4mg bd monotherapy group, mean weight at Month 36 was 86.9 kg compared to 83.3 kg at open label baseline and 81.4 kg at double-blind baseline.

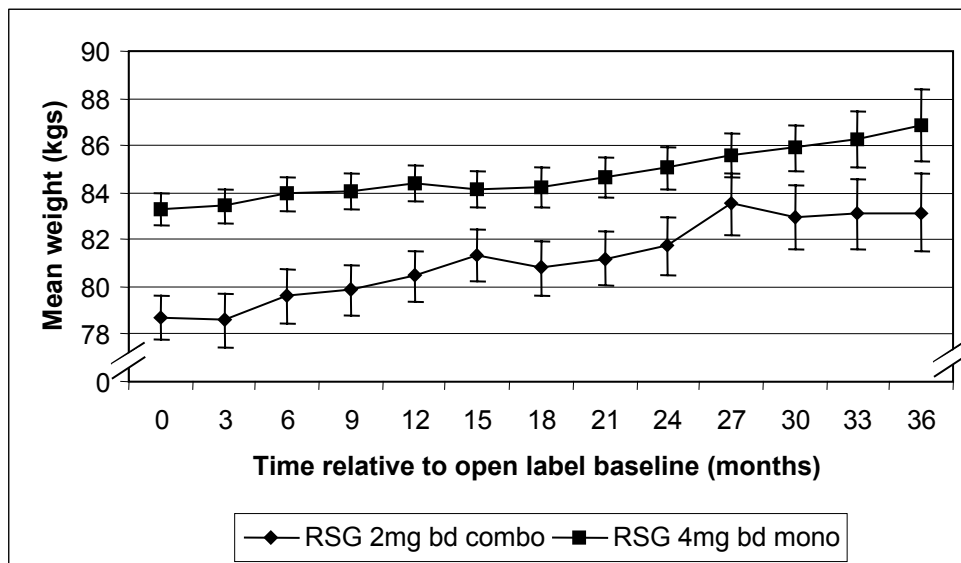
Table 28 Summary Statistics for Weight by Visit

Weight (kg)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
DB Baseline (n)	229	430
mean ± SD	77.4 ± 14.14	81.4 ± 13.33
OL Baseline (n)	229	430
mean ± SD	78.8 ± 14.11	83.3 ± 13.99
Month 3 (n)	148	355
mean ± SD	78.6 ± 14.06	83.4 ± 14.07
Month 6 (n)	158	366
mean ± SD	79.6 ± 14.12	84.0 ± 13.96
Month 9 (n)	168	361
mean ± SD	79.9 ± 13.84	84.1 ± 14.17
Month 12 (n)	172	330
mean ± SD	80.5 ± 13.88	84.4 ± 14.04
Month 15 (n)	172	321
mean ± SD	81.3 ± 14.42	84.1 ± 14.14
Month 18 (n)	158	301
mean ± SD	80.8 ± 14.44	84.2 ± 14.52
Month 21 (n)	153	285
mean ± SD	81.2 ± 14.32	84.7 ± 14.60
Month 24 (n)	133	265
mean ± SD	81.7 ± 14.50	85.1 ± 14.56
Month 27 (n)	123	239
mean ± SD	83.5 ± 14.48	85.6 ± 14.75
Month 30 (n)	115	210
mean ± SD	83.0 ± 14.79	85.9 ± 13.87
Month 33 (n)	98	138
mean ± SD	83.1 ± 14.58	86.3 ± 14.05
Month 36 (n)	84	85
mean ± SD	83.2 ± 15.09	86.9 ± 14.36
Month 39 (n)	52	0
mean ± SD	83.9 ± 15.62	
Month 42 (n)	32	0
mean ± SD	82.6 ± 14.00	
Month 45 (n)	11	0
mean ± SD	79.4 ± 16.85	

Data Source: [Section 15, Table 15.6.3Ba](#); [Appendix E, Listing E.L1A](#)

[Tables 15.6.3Bb](#) and [15.6.3Bc](#) ([Section 15](#)) detail weight by visit in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 and for all patients in study 025, respectively. There were no differences between these subgroups of patients and their respective combined open label groups.

[Figure 13](#) shows mean body weight over time. Data for months with low patient numbers are not included.

Figure 13 Body Weight (mean $\pm$ SE) Over Time

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 15, Table 15.6.3Ba](#); [Appendix E, Listing E.L1A](#)

Tabulations of waist/hip ratio are available in [Section 15, Tables 15.6.3Ba, 15.6.3Bb and 15.6.3Bc](#) ([Appendix E, Listing E.L1A](#)).

6.8 Electrocardiographic Data

[Table 29](#) summarises the number of patients with emergent ECG values of potential clinical concern from open label baseline. The most frequent ECG values of potential clinical concern were increased QRS interval in patients with a baseline QRS ≤ 100 msec (9 patients (3.9%) combination group, 24 patients (5.6%) monotherapy group), high QTc (>500 msec) (11 patients (4.8%) combination group, 23 patients (5.3%) monotherapy group) and low ventricular rate (<50 bpm) (8 patients (3.5%) combination group, 21 patients (4.9%) monotherapy group). All emergent ECG values of potential clinical concern were reviewed by the medical monitor and were considered small and of no real clinical significance.

**Table 29 Patients with On-therapy ECG Values of Potential Clinical Concern
Based on the Open Label Baseline**

Parameter, n (%)	Units	Value of Potential Clinical Concern	Treatment Group	
			RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total No. Patients				
PR interval	msec	>300	1 (0.4%)	2 (0.5%)
		Increase of >25% when baseline PR >200	2 (0.9%)	4 (0.9%)
		Increase of >50% when baseline PR ≤ 200	3 (1.3%)	6 (1.4%)
QRS interval	msec	>200	2 (0.9%)	10 (2.3%)
		Increase of >25% when baseline QRS >100	2 (0.9%)	4 (0.9%)
		Increase of >50% when baseline QRS ≤100	9 (3.9%)	24 (5.6%)
QT _c interval	msec	>500	11 (4.8%)	23 (5.3%)
		Increase of >15% when baseline QT _c >440	2 (0.9%)	1 (0.2%)
		Increase of >30% when baseline QT _c ≤440	4 (1.7%)	7 (1.6%)
Ventricular rate	bpm	<50	8 (3.5%)	21 (4.9%)
		>120	0	1 (0.2%)

NOTE: On-therapy defined as emergent during the open label study
Data Source: [Section 15, Table 15.8.3Ba; Appendix E, Listing E.L1B](#)

[Tables 15.8.3Bb and 15.8.3Bc \(Section 15\)](#) present the number (%) of patients with ECG values of potential clinical concern based on the open label baseline in the rosiglitazone 2mg bd combination therapy group by prior treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by prior treatment group in study 020 and for all patients in study 025, respectively. There were in general no differences between these subgroups of patients and their respective combined open label groups.

[Table 30](#) summarises new abnormal ECG findings on-therapy not present at the open label baseline occurring in more than one patient in either treatment group. The most frequently occurring events in both treatment groups were sinus bradycardia (83 patients (22.9%) monotherapy group; 36 patients (18.8%) combination group) and nonspecific ST-T changes (41 patients (10.0%) monotherapy group; 22 patients (10.0%) combination group).

Table 30 Summary of Abnormal ECG New Onset Observations On-therapy not Present at Open Label Baseline Occurring in More Than One patient in Either Treatment Group

Abnormal On-therapy* Finding, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Sinus bradycardia		
Not present at baseline, n	191	362
New onset, n (%)	36 (18.8)	83 (22.9)
Nonspecific ST-T changes		
Not present at baseline, n	219	410
New onset, n (%)	22 (10.0)	41 (10.0)
First degree AV block		
Not present at baseline, n	216	417
New onset, n (%)	8 (3.7)	22 (5.3)
Left axis deviation		
Not present at baseline, n	209	417
New onset, n (%)	6 (2.9)	17 (4.1)
Right bundle branch block		
Not present at baseline, n	220	419
New onset, n (%)	7 (3.2)	13 (3.1)
Premature ventricular contractions NOS		
Not present at baseline, n	226	427
New onset, n (%)	5 (2.2)	12 (2.8)
Intraventricular conduction delay		
Not present at baseline, n	229	426
New onset, n (%)	2 (0.9)	11 (2.6)
T-wave inversion		
Not present at baseline, n	214	422
New onset, n (%)	12 (5.6)	10 (2.4)
Left anterior hemiblock		
Not present at baseline, n	217	418
New onset, n (%)	6 (2.8)	10 (2.4)
Left atrial hypertrophy, p mitrale		
Not present at baseline, n	224	424
New onset, n (%)	5 (2.2)	10 (2.4)
Sinus arrhythmia		
Not present at baseline, n	229	428
New onset, n (%)	2 (0.9)	9 (2.1)
Atrial fibrillation		
Not present at baseline, n	226	426
New onset, n (%)	2 (0.9)	9 (2.1)

Continued

**Table 30 (continued): Summary of Abnormal ECG New Onset Observations
On-therapy not Present at Open Label Baseline Occurring in More Than
One patient in Either Treatment Group**

Abnormal On-therapy* Finding, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Myocardial ischaemia lateral		
Not present at baseline, n	225	423
New onset, n (%)	8 (3.6)	8 (1.9)
Premature atrial contractions		
Not present at baseline, n	228	426
New onset, n (%)	4 (1.8)	7 (1.6)
Unifocal PVC's		
Not present at baseline, n	228	428
New onset, n (%)	3 (1.3)	7 (1.6)
Myocardial infarction old Inferior		
Not present at baseline, n	226	426
New onset, n (%)	7 (3.1)	6 (1.4)
Q-wave >0.04 sec		
Not present at baseline, n	227	430
New onset, n (%)	4 (1.8)	6 (1.4)
Prolonged QT-interval		
Not present at baseline, n	226	429
New onset, n (%)	4 (1.8)	6 (1.4)
Poor R-wave progression		
Not present at baseline, n	225	430
New onset, n (%)	7 (3.1)	5 (1.2)
Left Ventricular Hypertrophy		
Not present at baseline, n	225	425
New onset, n (%)	5 (2.2)	5 (1.2)
Myocardial ischaemia inferior		
Not present at baseline, n	221	426
New onset, n (%)	3 (1.4)	5 (1.2)
Left bundle branch block		
Not present at baseline, n	226	426
New onset, n (%)	3 (1.3)	5 (1.2)
Sinus tachycardia		
Not present at baseline, n	227	428
New onset, n (%)	2 (0.9)	5 (1.2)
T-wave flat		
Not present at baseline, n	225	422
New onset, n (%)	11 (4.9)	4 (0.9)
Digitalis effect		
Not present at baseline, n	229	429
New onset, n (%)	0	4 (0.9)
Myocardial ischaemia anterior		
Not present at baseline, n	227	430
New onset, n (%)	6 (2.6)	3 (0.7)

Continued

**Table 30 (continued): Summary of Abnormal ECG New Onset Observations
On-therapy not Present at Open Label Baseline Occurring in More Than
One patient in Either Treatment Group**

Abnormal On-therapy* Finding, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
ST segment elevation > 1mm		
Not present at baseline, n	228	429
New onset, n (%)	0	3 (0.7)
Myocardial infarction old anterior		
Not present at baseline, n	224	427
New onset, n (%)	5 (2.2)	2 (0.5)
Ventricular couplets		
Not present at baseline, n	229	430
New onset, n (%)	1 (0.4)	2 (0.5)
Myocardial infarction old septal		
Not present at baseline, n	228	429
New onset, n (%)	2 (0.9)	2 (0.5)
Low ventricular voltage NOS		
Not present at baseline, n	229	430
New onset, n (%)	2 (0.9)	2 (0.5)
Myocardial infarction, acute anterior		
Not present at baseline, n	229	430
New onset, n (%)	1 (0.4)	2 (0.5)
ST segment depression >1mm		
Not present at baseline, n	229	425
New onset, n (%)	1 (0.4)	2 (0.5)
Atrial flutter		
Not present at baseline, n	229	429
New onset, n (%)	1 (0.4)	2 (0.5)
Pacemaker rhythm		
Not present at baseline, n	227	428
New onset, n (%)	0	2 (0.5)
Increased Ventricular Voltage NOS		
Not present at baseline, n	229	430
New onset, n (%)	0	2 (0.5)
Myocardial infarction old (non-specific)		
Not present at baseline, n	229	428
New onset, n (%)	0	2 (0.5)
Myocardial infarction, acute inferior		
Not present at baseline, n	229	430
New onset, n (%)	3 (1.3)	1 (0.2)
Left posterior hemiblock		
Not present at baseline, n	229	430
New onset, n (%)	2 (0.9)	1 (0.2)
Myocardial ischaemia septal		
Not present at baseline, n	228	429
New onset, n (%)	2 (0.9)	1 (0.2)

Continued

Table 30 (continued): Summary of Abnormal ECG New Onset Observations On-therapy not Present at Open Label Baseline Occurring in More Than One patient in Either Treatment Group

Abnormal On-therapy* Finding, n (%)	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Myocardial ischaemia (non-specific)		
Not present at baseline, n	225	429
New onset, n (%)	3 (1.3)	0

* On-therapy defined as during the open label study

Data Source: [Section 15, Table 15.8.5Ba](#); [Appendix E, Listing E.L3](#)

[Tables 15.8.5Bb and 15.8.5Bc \(Section 15\)](#) summarise abnormal ECG observations on-therapy that were not present at the open label baseline, subdivided by previous treatment group for the rosiglitazone 2mg bd combination therapy group and the rosiglitazone 4mg bd monotherapy group respectively. There were no differences between these subgroups of patients and their respective combined open label groups.

[Appendix E, Listing E.L4](#) provides a listing of abnormal ECGs at double-blind baseline, open label baseline and post-therapy.

6.9 Laboratory Tests

Laboratory values considered to be clinically significant by the investigator were recorded as adverse experiences in the CRF (see [Section 6.2](#)).

Laboratory values were compared with both the appropriate normal ranges (F1 flag) and also sponsor defined, predetermined extended ranges (F3 flag) (see [Table 31](#)). Values above or below these extended ranges were considered to be of potential clinical concern. The number of patients with laboratory values of potential clinical concern (as defined by the sponsor) are presented in [Table 32](#).

Table 31 Predetermined Laboratory Values of Potential Clinical Concern

Laboratory Parameter	Reporting Units	Reference Range* (F1 Flag)	Values of Potential Clinical Concern** (F3 Flag)
Haematology			
Haemoglobin	g/dL		>2 below LLRR or >1 above ULRR
male (18-64, ≥65 years)		13.8-17.2, 11.8-16.8	<11.8 or >18.2, <9.8 or >17.8
female (18-64, ≥65 years)		12.0-15.6, 11.1-15.5	<10.0 or >16.6, <9.1 or >16.5
Haematocrit	%		>5 below LLRR or >4 above ULRR
male (18-64, ≥65 years)		41.0-50.0, 36.0-49.0	<36.0 or >54.0, <31.0 or >53.0
female (18-64, ≥65 years)		35.0-46.0, 33.0-46.0	<30.0 or >50.0, <28.0 or >50.0
White Blood Cell Count	10 ⁹ /L	3.8-10.8	>1 below LLRR or >5 above ULRR
Total Neutrophils	%	40-75	<2.8 or >15.8
Lymphocytes	%	16.0-46.0	<0.5x LLRR
Platelet Count	10 ⁹ /L	130-400	<0.5x LLRR
			<80 or >500
Liver Function			
AST (SGOT) (3-64, ≥65 years)	U/L	0-42, 0-55	>3x ULRR
ALT (SGPT)	U/L	0-48	>3x ULRR
Alkaline Phosphatase	U/L	20-125	>3x ULRR
Total Bilirubin	umol/L	0-22	>1.5x ULRR
GGT	U/L		>3x ULRR
male (13-64, ≥65 years)		0-65, 0-75	
female (13-64, ≥65 years)		0-45, 0-75	
Renal Function			
Creatinine (13-64, ≥65 years)	umol/L	60-120, 60-160	>159
BUN (13-64, ≥65 years)	mmol/L	2.5-9.0, 2.5-10.5	>2x ULRR

Continued

Table 31 (continued): Predetermined Laboratory Values of Potential Clinical Concern

Laboratory Parameter	Reporting Units	Reference Range* (F1 Flag)	Values of Potential Clinical Concern** (F3 Flag)
Other Tests			
Glucose (fasting)	mg/dL	59-99	<50 or >400
Albumin	g/L	32-50	>5 below or above RR (<27 or >55)
Uric Acid (male, female)	umol/L	(240-510, 150-450)	>654
Sodium	mmol/L	135-146	>5 below or above RR (<130 or >151)
Potassium	mmol/L	3.5-5.3	>0.5 below LLRR or >1.0 above ULRR
Bicarbonate	mmol/L	20-32	<3.0 or >6.3
Phosphorus	mmol/L	0.8-1.5, 0.7-1.4	<16 or >40
(13-64, ≥65 years)		2.1-2.6	>0.323 below or above RR
Calcium	mmol/L	2.1-2.6	<0.477 or >1.823, <0.377 or >>1.723
LDH	U/L	0-250, 0-270	<1.8 or >3.0
(3-64, ≥65 years)		60-85, 58-81	>2.5x ULRR
Total Protein	g/L	60-85, 58-81	>15 below or above RR
(13-64, ≥65 years)		<198	<45 or >100, <43 or >96
Triglycerides	mg/dL	<198	>800

RR = Reference Range; LLRR = lower limit of the reference range; ULRR = upper limit of the reference range

Data Source: *Appendix F, Listing F.L1; **Sponsor defined

Table 32 Patients with On-therapy Laboratory Values of Potential Clinical Concern (F3 Flag)

On-therapy* laboratory parameter		Treatment Group	
		RSG 2mg bd Combination n/n** (%)	RSG 4mg bd Monotherapy n/n** (%)
Haematology			
Haemoglobin	High	2/224 (0.9)	2/402 (0.5)
	Low	3/224 (1.3)	15/402 (3.7)
Haematocrit	High	3/224 (1.3)	4/402 (1.0)
	Low	5/224 (2.2)	17/402 (4.2)
WBC count	High	0	4/402 (1.0)
	Low	2/224 (0.9)	11/402 (2.7)
Neutrophils (segs)	Low	3/224 (1.3)	7/401 (1.7)
Lymphocytes	Low	3/224 (1.3)	3/401 (0.7)
Platelet count	High	1/224 (0.4)	2/402 (0.5)
	Low	2/224 (0.9)	4/402 (1.0)
Liver function			
Total bilirubin	High	5/224 (2.2)	1/403 (0.2)
AST	High	1/224 (0.4)	1/403 (0.2)
ALT	High	1/224 (0.4)	1/403 (0.2)
GGT	High	9/224 (4.0)	12/403 (3.0)
Alkaline phosphatase	High	0	1/403 (0.2)
Renal function			
Creatinine	High	13/224 (5.8)	19/403 (4.7)
BUN	High	1/224 (0.4)	4/403 (1.0)
Other Tests			
Uric acid	High	0	4/403 (1.0)
Sodium	High	0	4/403 (1.0)
	Low	2/224 (0.9)	3/403 (0.7)
Potassium	High	3/224 (1.3)	5/403 (1.2)
	Low	0	1/403 (0.2)
Bicarbonate	High	1/224 (0.4)	0
	Low	5/224 (2.2)	4/403 (1.0)
Glucose	High	0	1/423 (0.2)
	Low	1/226 (0.4)	1/423 (0.2)
Phosphorus	High	2/224 (0.9)	1/403 (0.2)
Calcium	High	1/224 (0.4)	0
	Low	0	1/403 (0.2)
Triglycerides	High	2/213 (0.9)	3/392 (0.8)

* On-therapy defined as during the open label study

** n/n = Number of patients with value of potential clinical concern/number of patients tested

NOTE: All laboratory values are fasting

Data Source: [Section 15, Table 15.7.4a; Appendix F, Listing F.L1](#)

The most frequently occurring laboratory parameters falling outside the range of potential clinical concern in the rosiglitazone 2mg bd combination therapy group were high creatinine (5.8%) and high GGT (4.0%) and in the rosiglitazone 4mg bd monotherapy group high creatinine (4.7%), low haematocrit (4.2%), low

haemoglobin (3.7%), high GGT (3.0%) and low WBC count (2.7%). All other parameters of potential clinical concern occurred with an incidence $\leq 2.2\%$.

[Tables 15.7.4b](#) and [15.7.4c](#) ([Section 15](#)) detail the on-therapy laboratory parameters of potential clinical concern in the rosiglitazone 2mg bd combination therapy group by treatment group in study 015, and in the rosiglitazone 4mg bd monotherapy group by treatment group in study 020 and for all patients in study 025, respectively. For most parameters the numbers of patients with laboratory values of clinical concern were too small to make any comparisons between the subgroups by previous treatment, but some differences were noted for creatinine. In the 2mg bd combination therapy group, a higher proportion of patients in the group that had previously received sulphonylurea plus rosiglitazone 2mg bd had high creatinine values of potential clinical concern compared with the other 2 groups from study 015 (10.2% Vs 2.6-3.3%). There were no differences observed by prior treatment subgroup in patients in the 4mg bd monotherapy group.

Narratives have been written for patients who had an ALT value $> 3 \times \text{ULN}$ (F3 flag); the location for these narratives is provided in [Section 15](#), [Table 15.0](#).

Assessment of Haemoglobin and Haematocrit Parameters

A summary of mean haemoglobin and haematocrit at each month relative to open label baseline is shown in [Table 33](#) and [Figures 14](#) and [15](#).

With respect to haemoglobin, small reductions were found from open label baseline over the first 3 months of treatment in both the rosiglitazone 2mg bd combination therapy group (Open Label Baseline: 14.24g/dL, Month 3: 13.89g/dL) and in the rosiglitazone 4mg bd monotherapy group (Open Label Baseline: 14.12g/dL, Month 3: 13.55g/dL) which were generally maintained over the following 33 months. After an initial mean decrease in haematocrit from open label baseline at Month 3 in the combination therapy group (Open Label Baseline: 42.44%, Month 3: 41.14%) and in the monotherapy group (Open Label Baseline: 41.11%, Month 3: 40.33%), mean haematocrit increased in both treatment groups over the following 24 months. Mean haematocrit again decreased slightly in both treatment groups from Month 27 to 36.

In total, 3 patients (1.3%) in the rosiglitazone 2mg bd combination therapy group and 15 patients (3.7%) in the rosiglitazone 4mg bd monotherapy group had low haemoglobin values of potential clinical concern and 5 patients (2.2%) and 17 patients (4.2%) respectively had low haematocrit values of potential clinical

concern ([Table 33](#)). Adverse experiences related to anaemia are further discussed in [Section 6.2.4](#).

An examination of mean haemoglobin by visit and prior treatment in studies 015 and 020 (see [Tables 15.7.1b](#) and [15.7.1c](#) in [Section 15](#)) showed that the largest decrease in mean haemoglobin occurred in those patients who had not previously received rosiglitazone compared to those patients who had been previously exposed to rosiglitazone. Similarly in those patients who had received sulphonylurea plus placebo in study 015, mean haematocrit was found to have decreased the most at Month 36 compared to patients who had previously received combination rosiglitazone therapy. In those patients who had received rosiglitazone in study 020, mean haematocrit was similar to baseline at Month 36 compared to a decrease observed in patients who had previously received glibenclamide.

Table 33 Mean Haemoglobin and Haematocrit by Visit

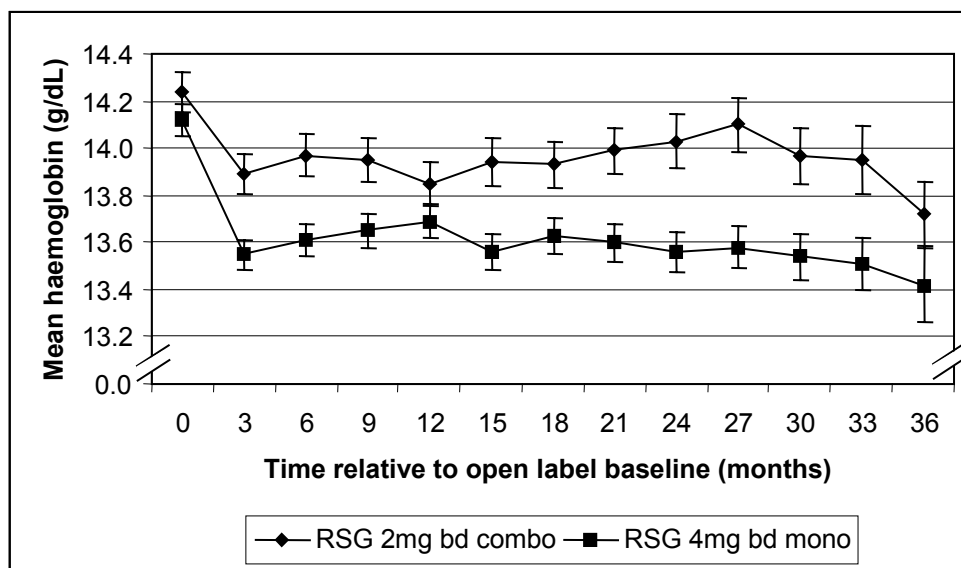
Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
Haemoglobin (g/dL)		
Baseline (n)	229	427
mean ± SD	14.24 ± 1.277	14.12 ± 1.421
Month 3 (n)	212	385
mean ± SD	13.89 ± 1.196	13.55 ± 1.262
Month 6 (n)	203	374
mean ± SD	13.97 ± 1.250	13.61 ± 1.333
Month 9 (n)	199	371
mean ± SD	13.95 ± 1.293	13.65 ± 1.364
Month 12 (n)	181	332
mean ± SD	13.85 ± 1.254	13.69 ± 1.337
Month 15 (n)	164	314
mean ± SD	13.94 ± 1.299	13.56 ± 1.354
Month 18 (n)	155	290
mean ± SD	13.93 ± 1.225	13.63 ± 1.326
Month 21 (n)	152	274
mean ± SD	13.99 ± 1.178	13.60 ± 1.315
Month 24 (n)	128	249
mean ± SD	14.03 ± 1.298	13.56 ± 1.325
Month 27 (n)	118	227
mean ± SD	14.10 ± 1.251	13.58 ± 1.298
Month 30 (n)	104	179
mean ± SD	13.97 ± 1.204	13.54 ± 1.323
Month 33 (n)	91	153
mean ± SD	13.95 ± 1.367	13.51 ± 1.383
Month 36 (n)	83	77
mean ± SD	13.72 ± 1.259	13.42 ± 1.407
Month 39 (n)	49	15
mean ± SD	13.98 ± 1.364	13.47 ± 1.087
Month 42 (n)	32	0
mean ± SD	13.71 ± 1.198	
Month 45 (n)	19	0
mean ± SD	13.93 ± 1.552	
Haematocrit (%)		
Baseline (n)	229	427
mean ± SD	42.44 ± 3.721	41.11 ± 4.005
Month 3 (n)	212	385
mean ± SD	41.14 ± 3.422	40.33 ± 3.604
Month 6 (n)	203	374
mean ± SD	41.62 ± 3.630	40.62 ± 3.859
Month 9 (n)	199	372
mean ± SD	41.29 ± 3.612	40.60 ± 3.904
Month 12 (n)	181	332
mean ± SD	41.36 ± 3.471	40.87 ± 3.905
Month 15 (n)	164	315
mean ± SD	41.70 ± 3.731	40.79 ± 4.001
Month 18 (n)	155	291
mean ± SD	41.53 ± 3.435	41.05 ± 3.908
Month 21 (n)	152	274
mean ± SD	41.83 ± 3.478	41.30 ± 3.939
Month 24 (n)	128	249
mean ± SD	42.14 ± 3.888	41.35 ± 3.992
Month 27 (n)	118	227
mean ± SD	42.66 ± 3.798	41.64 ± 3.928

Continued

Table 33 (continued): Mean Haemoglobin and Haematocrit by Visit

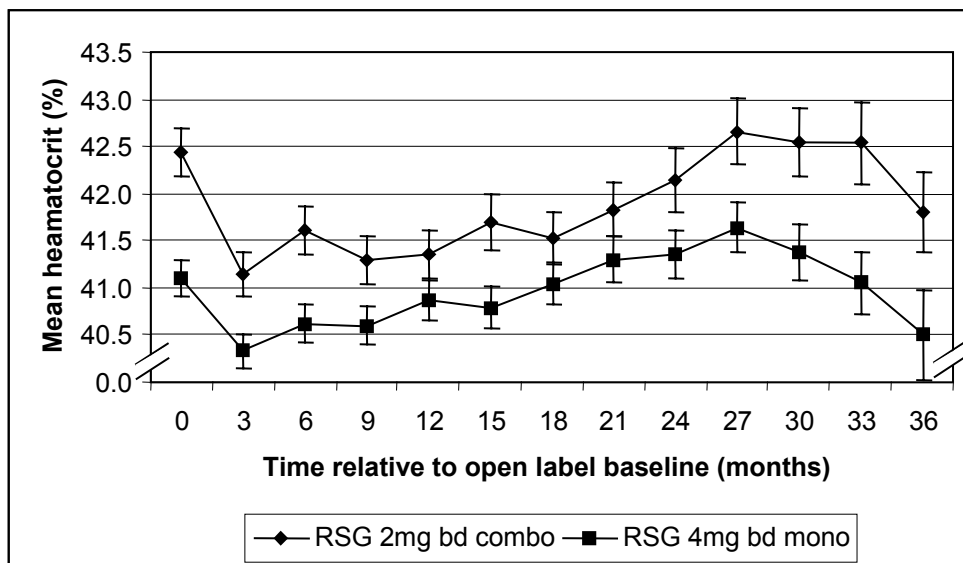
Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
Haematocrit (%)		
Month 30 (n)	104	179
mean $\pm$ SD	42.55 $\pm$ 3.666	41.37 $\pm$ 3.987
Month 33 (n)	91	153
mean $\pm$ SD	42.54 $\pm$ 4.147	41.06 $\pm$ 4.073
Month 36 (n)	83	77
mean $\pm$ SD	41.81 $\pm$ 3.871	40.50 $\pm$ 4.121
Month 39 (n)	49	15
mean $\pm$ SD	42.22 $\pm$ 3.775	40.21 $\pm$ 2.959
Month 42 (n)	32	0
mean $\pm$ SD	41.58 $\pm$ 3.236	
Month 45 (n)	19	0
mean $\pm$ SD	41.95 $\pm$ 4.730	

Data Source: Section 15, Table 15.7.1a; Appendix F, Listing F.L1

Figure 14 Haemoglobin (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: Section 15, Table 15.7.1a; Appendix F, Listing F.L1

Figure 15 Haematocrit (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 15, Table 15.7.1a](#); [Appendix F, Listing F.L1](#)

Assessment of Liver Function Test Parameters

Summary mean values by month relative to open label baseline for AST, ALT and GGT are shown in [Table 34](#). Summary mean values for all blood chemistry parameters assessed related to liver function are provided in [Table 15.7.1a](#), [Section 15](#).

In both rosiglitazone 2mg bd combination therapy and 4mg bd monotherapy treatment groups small, clinically insignificant changes from open label baseline (both increases and decreases) were noted for alkaline phosphatase, AST/ALT, total bilirubin and GGT, but no apparent trends were evident.

**Table 34 Mean Values in Selected Blood Chemistry Parameters Related to Liver
Function by Visit**

Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
AST (U/L)		
Baseline (n)	229	428
mean ± SD	19.8 ± 10.01	20.9 ± 9.68
Month 3 (n)	212	369
mean ± SD	19.9 ± 9.23	20.1 ± 7.83
Month 6 (n)	205	369
mean ± SD	20.0 ± 9.51	20.1 ± 7.86
Month 9 (n)	196	359
mean ± SD	19.6 ± 8.29	19.8 ± 8.09
Month 12 (n)	177	328
mean ± SD	21.4 ± 18.63	21.0 ± 15.10
Month 15 (n)	168	316
mean ± SD	20.3 ± 9.84	20.2 ± 7.95
Month 18 (n)	156	294
mean ± SD	20.6 ± 9.73	20.4 ± 8.18
Month 21 (n)	148	274
mean ± SD	20.4 ± 11.41	20.4 ± 7.43
Month 24 (n)	129	249
mean ± SD	21.1 ± 11.07	19.9 ± 7.45
Month 27 (n)	120	226
mean ± SD	21.4 ± 14.21	20.6 ± 7.31
Month 30 (n)	106	181
mean ± SD	20.6 ± 9.66	20.9 ± 7.57
Month 33 (n)	93	155
mean ± SD	19.5 ± 7.65	20.4 ± 9.14
Month 36 (n)	84	79
mean ± SD	20.9 ± 10.71	20.4 ± 12.02
Month 39 (n)	48	14
mean ± SD	19.9 ± 8.44	19.1 ± 4.70
Month 42 (n)	32	0
mean ± SD	20.0 ± 7.72	
Month 45 (n)	19	0
mean ± SD	20.2 ± 8.82	
ALT (U/L)		
Baseline (n)	229	428
mean ± SD	21.5 ± 12.29	22.5 ± 13.72
Month 3 (n)	212	369
mean ± SD	20.4 ± 9.50	19.3 ± 9.09
Month 6 (n)	205	369
mean ± SD	20.7 ± 10.53	19.2 ± 9.36
Month 9 (n)	196	359
mean ± SD	21.1 ± 11.92	18.6 ± 9.24
Month 12 (n)	177	328
mean ± SD	22.1 ± 18.17	18.9 ± 15.37
Month 15 (n)	168	316
mean ± SD	20.9 ± 12.01	18.5 ± 9.73
Month 18 (n)	156	294
mean ± SD	21.1 ± 11.96	18.5 ± 10.85
Month 21 (n)	148	274
mean ± SD	20.5 ± 11.47	17.9 ± 8.77
Month 24 (n)	129	249
mean ± SD	21.4 ± 13.05	17.9 ± 9.54

Continued

**Table 34 (continued): Mean Values in Selected Blood Chemistry Parameters
Related to Liver Function by Visit**

Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
ALT (U/L)		
Month 27 (n)	120	220
mean ± SD	21.9 ± 12.05	18.2 ± 9.89
Month 30 (n)	105	143
mean ± SD	21.3 ± 11.21	19.3 ± 10.63
Month 33 (n)	87	89
mean ± SD	20.8 ± 10.68	16.6 ± 7.06
Month 36 (n)	79	35
mean ± SD	20.3 ± 9.61	20.3 ± 14.61
Month 39 (n)	45	5
mean ± SD	19.4 ± 9.60	16.6 ± 3.85
Month 42 (n)	23	0
mean ± SD	22.6 ± 13.35	
Month 45 (n)	14	0
mean ± SD	18.9 ± 9.37	
GGT (U/L)		
Baseline (n)	229	428
mean ± SD	32.3 ± 26.28	37.9 ± 43.90
Month 3 (n)	212	370
mean ± SD	32.0 ± 41.46	31.2 ± 28.26
Month 6 (n)	204	368
mean ± SD	29.9 ± 24.92	32.8 ± 42.76
Month 9 (n)	196	359
mean ± SD	31.9 ± 33.90	34.1 ± 40.07
Month 12 (n)	176	326
mean ± SD	34.4 ± 46.43	38.0 ± 51.82
Month 15 (n)	168	316
mean ± SD	35.8 ± 40.49	38.2 ± 46.80
Month 18 (n)	156	293
mean ± SD	36.2 ± 51.76	36.9 ± 37.55
Month 21 (n)	148	274
mean ± SD	42.2 ± 85.41	36.5 ± 36.67
Month 24 (n)	129	249
mean ± SD	38.9 ± 38.61	36.6 ± 35.00
Month 27 (n)	120	226
mean ± SD	38.2 ± 37.36	37.7 ± 47.44
Month 30 (n)	106	180
mean ± SD	42.1 ± 76.81	38.4 ± 43.69
Month 33 (n)	93	155
mean ± SD	33.2 ± 22.46	37.5 ± 37.58
Month 36 (n)	84	79
mean ± SD	43.3 ± 89.03	31.9 ± 29.37
Month 39 (n)	48	14
mean ± SD	40.7 ± 54.89	29.8 ± 25.32
Month 42 (n)	32	0
mean ± SD	32.8 ± 22.15	
Month 45 (n)	19	0
mean ± SD	45.6 ± 77.66	

Data Source: Section 15, Table 15.7.1a; Appendix F, Listing F.L1

Assessment of Renal Function Test Parameters

Summary mean values by month relative to open label baseline for selected blood chemistry parameters related to renal function are shown in [Table 35](#). No clinically relevant trends in either BUN or creatinine were found over time.

Table 35 Mean Values for Selected Blood Chemistry Parameters Related to Renal Function by Visit

Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
BUN (mmol/L)		
Baseline (n)	229	428
mean ± SD	6.55 ± 1.731	6.11 ± 1.909
Month 3 (n)	212	374
mean ± SD	6.52 ± 1.798	6.45 ± 1.942
Month 6 (n)	205	366
mean ± SD	6.59 ± 2.093	6.54 ± 2.088
Month 9 (n)	196	361
mean ± SD	6.70 ± 1.903	6.37 ± 1.756
Month 12 (n)	176	324
mean ± SD	6.90 ± 2.090	6.31 ± 1.832
Month 15 (n)	167	316
mean ± SD	6.80 ± 2.058	6.44 ± 1.915
Month 18 (n)	156	290
mean ± SD	6.97 ± 2.023	6.58 ± 1.977
Month 21 (n)	148	276
mean ± SD	6.86 ± 1.982	6.53 ± 2.013
Month 24 (n)	129	248
mean ± SD	6.86 ± 2.021	6.39 ± 2.019
Month 27 (n)	120	225
mean ± SD	6.73 ± 2.064	6.64 ± 2.367
Month 30 (n)	108	180
mean ± SD	6.86 ± 2.010	6.52 ± 1.965
Month 33 (n)	94	155
mean ± SD	6.79 ± 1.987	6.59 ± 2.059
Month 36 (n)	84	79
mean ± SD	7.02 ± 2.300	7.17 ± 3.850
Month 39 (n)	49	14
mean ± SD	7.12 ± 1.805	5.55 ± 1.446
Month 42 (n)	32	0
mean ± SD	7.15 ± 3.715	
Month 45 (n)	19	0
mean ± SD	6.46 ± 2.089	
Creatinine (umol/L)		
Baseline (n)	229	428
mean ± SD	89.2 ± 19.31	90.4 ± 28.46
Month 3 (n)	212	370
mean ± SD	89.5 ± 19.65	87.4 ± 16.52
Month 6 (n)	204	367
mean ± SD	92.0 ± 26.04	88.8 ± 19.53
Month 9 (n)	196	359
mean ± SD	89.0 ± 18.37	87.9 ± 17.79
Month 12 (n)	176	326
mean ± SD	89.8 ± 20.01	87.7 ± 18.98
Month 15 (n)	168	316
mean ± SD	90.2 ± 21.06	89.8 ± 21.24
Month 18 (n)	156	293
mean ± SD	90.4 ± 21.40	92.8 ± 28.94
Month 21 (n)	148	274
mean ± SD	90.0 ± 21.16	89.3 ± 21.25
Month 24 (n)	128	249
mean ± SD	91.3 ± 21.92	88.2 ± 20.32

Continued

Table 35 (continued): Mean Values for Selected Blood Chemistry Parameters Related to Renal Function by Visit

Laboratory parameter	Treatment Group	
	RSG 2mg bd Combination	RSG 4mg bd Monotherapy
Creatinine (umol/L)		
Month 27 (n)	120	226
mean ± SD	91.8 ± 20.81	89.5 ± 21.01
Month 30 (n)	106	180
mean ± SD	90.2 ± 22.59	87.9 ± 22.44
Month 33 (n)	93	155
mean ± SD	88.3 ± 21.14	89.2 ± 20.95
Month 36 (n)	84	79
mean ± SD	88.1 ± 23.10	93.3 ± 29.95
Month 39 (n)	48	14
mean ± SD	88.8 ± 18.06	82.9 ± 15.90
Month 42 (n)	32	0
mean ± SD	87.8 ± 33.38	
Month 45 (n)	19	0
mean ± SD	86.8 ± 19.16	

Data Source: [Section 15, Table 15.7.1a](#); [Appendix F](#), Listing F.L1

On review of mean values in laboratory parameters at each visit by prior treatment groups in studies 015 and 020, there were no differences between these subgroups of patients and their respective combined open label groups ([Tables 15.7.1b](#) and [15.7.1c](#) ([Section 15](#))).

Assessment of Selected Blood Function Parameters

A review of blood function parameters other than those discussed above (haemoglobin, haematocrit and liver and renal function tests), revealed no changes for either treatment group which were considered to be clinically significant ([Section 15, Table 15.7.1a](#)). An examination of mean values for these parameters by prior treatment in studies 015 and 020 (see [Tables 15.7.1b](#) and [15.7.1c](#) in [Section 15](#)) showed no differences over the entire open label treatment period for these treatment subgroups.

7 Pharmacokinetic Evaluation

No pharmacokinetic evaluation was performed for this study.

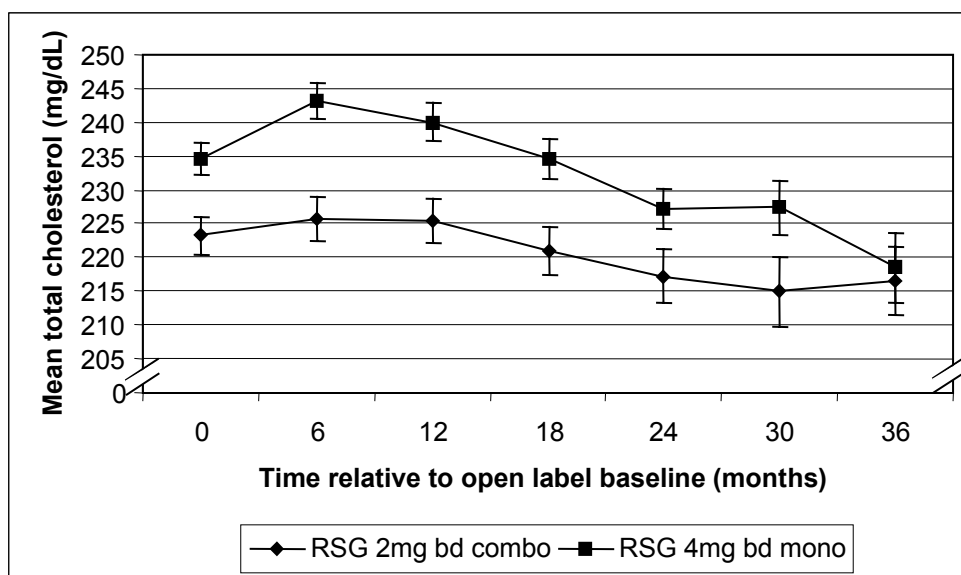
8 Pharmacodynamic Evaluation

A complete tabulation and listing of lipid variables by visit, including double-blind and open label baselines, is provided in [Section 14, Table 14.1Aa](#) and in

[Appendix C](#), Listing C.L1 and [Appendix F](#), Listing F.L1. A complete tabulation of lipid variables by visit, including double-blind and open label baselines, and sub-divided by the treatment group in the preceding study is provided in [Section 14](#), [Tables 14.1Ab](#) and [14.1Ac](#).

[Figure 16](#) and [Table 36](#) show the mean total cholesterol over time relative to open label baseline. Following an initial small rise in mean total cholesterol from open label baseline after 6 months of treatment in both the rosiglitazone 2mg bd combination therapy group (Open Label Baseline: 223.3mg/dL, Month 6: 225.8mg/dL) and rosiglitazone 4mg bd monotherapy group (Open Label Baseline: 234.7mg/dL, Month 6: 243.2mg/dL), mean total cholesterol decreased over the following 30 months of therapy with mean values below the open label baseline in both treatment groups at Month 36 (216.5mg/dL combination therapy group; 218.5mg/dL monotherapy group). It should be noted that the protocol was amended one year before study completion to permit the initiation and/or change in the doses of lipid lowering agents. Therefore, particularly during the last year of the study, lipid lowering agents would have influenced total cholesterol levels.

Figure 16 Total Cholesterol (mean $\pm$ SE) by Visit



NOTE: Data has not been presented where patient numbers are too low

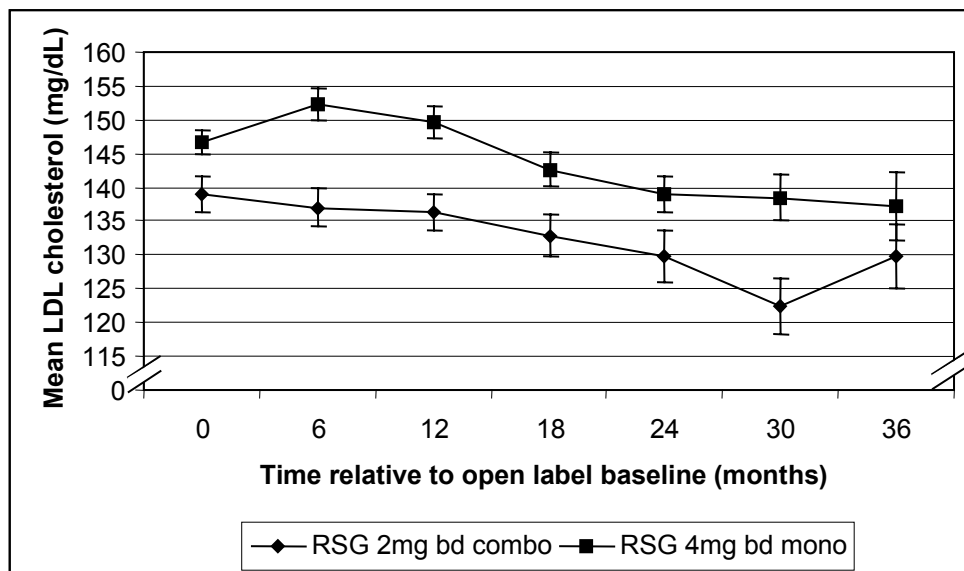
Data Source: [Section 14](#), [Table 14.1Aa](#)(contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1

Following evaluation of mean total cholesterol by visit and previous treatment group in both the combination therapy and monotherapy treatment arms the highest increase over the first 6 months of open label treatment was found in those patients who had not previously received rosiglitazone. In all treatment

subgroups, mean total cholesterol decreased over the subsequent 30 months of open label treatment.

Figure 17 shows mean LDL by time relative to open label baseline. In the combination therapy group, mean LDL decreased for the duration of the 36 months treatment from an open label baseline of 139.0mg/dL to 129.8mg/dL at Month 36. Mean LDL increased from an open label baseline of 146.7mg/dL to 152.2mg/dL at Month 6 in the monotherapy group, however, values decreased over the following 30 months of treatment to below the open label baseline at Month 36 (137.2mg/dL). As with the total cholesterol levels, the amendment of the protocol one year before study end to permit the initiation and/or change in dose for agents used to control dyslipidaemia, would have resulted in dyslipidaemic therapy influencing the LDL levels, particularly during the last year of treatment.

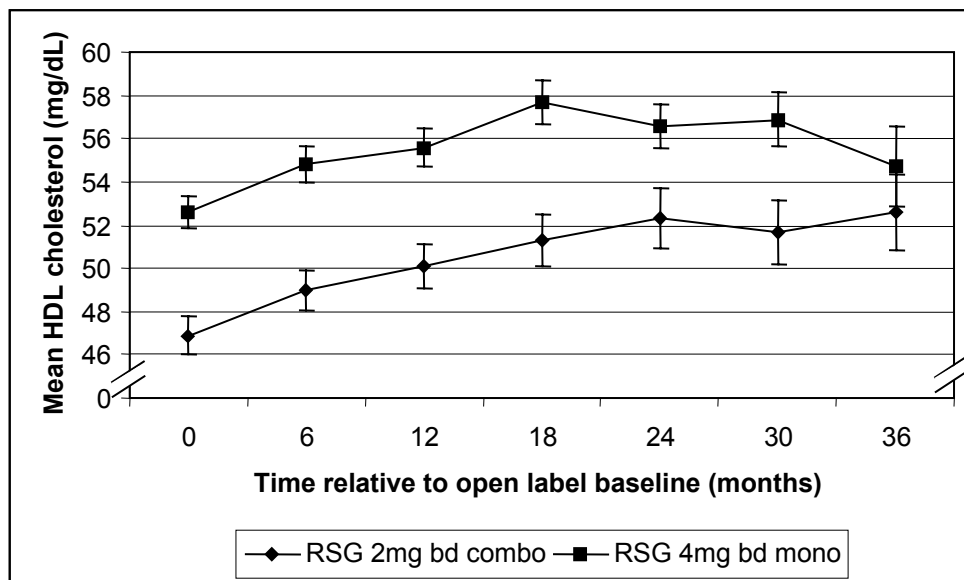
On review of mean LDL by visit and previous treatment group in the combination therapy group, there was no difference apparent between prior treatment subgroups. In the monotherapy group, in those patients who previously received glibenclamide mean LDL increased over the first 6 months and decreased in those patients who had previously received rosiglitazone 4mg bd. In all treatment subgroups, mean LDL decreased over the subsequent 30 months of open label treatment.

Figure 17 LDL (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Aa](#) (contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1; [Appendix F](#), Listing F.L1

[Figure 18](#) shows mean HDL by time relative to open label baseline. In the combination therapy group, mean HDL increased over time with a maximum increase from an open label baseline value of 46.9mg/dL to 52.6mg/dL at Month 36. In the monotherapy group, mean HDL increased above the open label baseline value of 52.6mg/dL to a maximum value of 57.7mg/dL at Month 18 and remained above open label baseline after 36 months of treatment (Month 36: 54.7mg/dL). On review of mean HDL values by treatment group in studies 015 and 020, there was no apparent difference between treatment subgroups. As with the other lipid parameters, the use of agents to control dyslipidaemia may have influenced the HDL levels, particularly during the last year of treatment.

Figure 18 HDL (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Aa](#)(contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1; [Appendix F](#), Listing F.L1.

In general, mean total cholesterol/HDL ratio decreased for the duration of the 36 months' treatment in both treatment groups, with a decrease from an open label baseline ratio of 5.10 to 4.40 at Month 36 in the combination therapy group and from 4.76 to 4.26 respectively in the monotherapy group. Similar decreases in mean LDL/HDL ratio were observed from an open label baseline ratio of 3.18 to 2.66 at Month 36 in the combination therapy group and from 2.98 to 2.63 respectively in the monotherapy group.

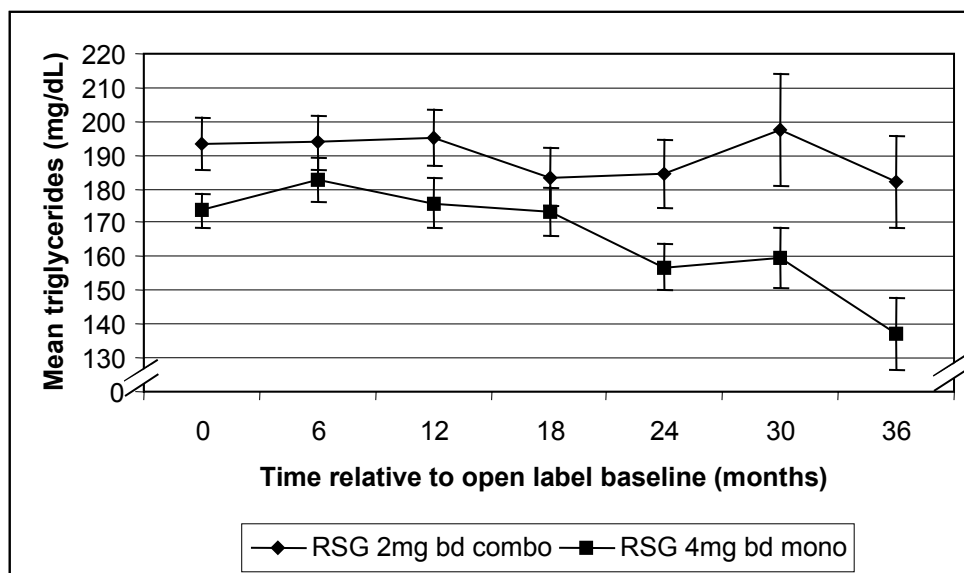
On analysis of mean total cholesterol/HDL and LDL:HDL ratios by prior treatment group, in general decreases in both ratios were found for the sulphonylurea and rosiglitazone 1mg bd and 2mg bd subgroups in study 015 over 36 months of treatment. An increase in both of these ratios over the first 12 months of treatment was found in the sub-group of patients who received glibenclamide in the monotherapy group, with mean values decreasing over the subsequent 24 months. Mean ratios generally decreased over the 36 month treatment period in patients who had previously received rosiglitazone in study 020.

[Figure 19](#) shows mean triglycerides by time relative to open label baseline. In the combination therapy group, mean triglycerides were generally similar to open label baseline (193.4mg/dL) for the duration of the 36 months of treatment with a

mean value of 182.2mg/dL at Month 36. In the monotherapy group, there was a small increase in mean triglycerides from an open label baseline value of 173.6mg/dL to 182.8mg/dL at Month 6 which subsequently decreased over the following 30 months to a mean value of 137.2mg/dL at Month 36.

Although there was large variability in values for triglycerides, there did not appear to be any difference by prior treatment subgroup in mean values over time in the combination therapy group. In the monotherapy group, patients who had previously received glibenclamide had an increase in mean triglyceride over the first 18 months of treatment after which mean values decreased for the following 18 months. Values generally decreased over 36 months' open label treatment in those patients who had previously received rosiglitazone in study 020.

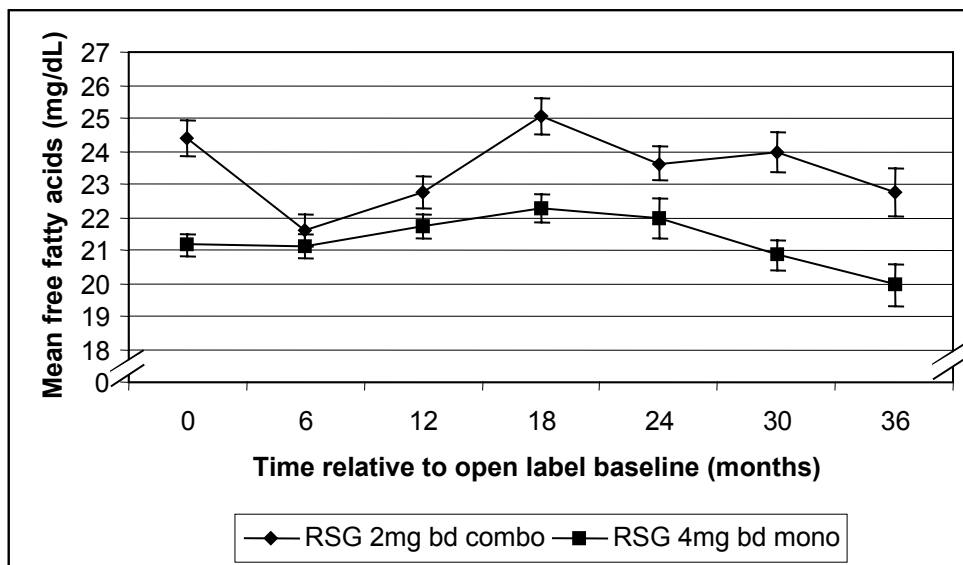
Figure 19 Triglycerides (mean±SE) by Visit



NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Aa](#)(contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1; [Appendix F](#), Listing F.L1

Values for mean free fatty acids (non-esterified fatty acids (NEFA)) were found to vary in both treatment groups over 36 months of treatment with open label rosiglitazone ([Figure 20](#)). Mean values were lower than open label baseline at Month 36 in both the combination therapy group (Open Label Baseline: 24.41mg/dL, Month 36: 22.75mg/dL) and the monotherapy group (Open Label Baseline: 21.16mg/dL, Month 36: 19.96mg/dL). There was no apparent trend observed when mean values were assessed by prior treatment in studies 015 and 020.

Figure 20 Free Fatty Acids (mean $\pm$ SE) by Visit

NOTE: Data has not been presented where patient numbers are too low

Data Source: [Section 14, Table 14.1Aa](#)(contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1; [Appendix F](#), Listing F.L1

Table 36 Mean Lipid Parameters by Visit

Lipid Parameters	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Total Cholesterol (mg/dL)		
Open Label (OL) Baseline (n)	229	426
mean ± SD	223.3 ± 42.02	234.7 ± 49.59
Month 6 (n)	196	358
mean ± SD	225.8 ± 45.27	243.2 ± 51.99
Month 12 (n)	175	320
mean ± SD	225.4 ± 42.12	240.0 ± 49.30
Month 18 (n)	149	274
mean ± SD	220.9 ± 43.67	234.7 ± 49.13
Month 24 (n)	121	222
mean ± SD	217.3 ± 44.30	227.2 ± 43.28
Month 30 (n)	99	156
mean ± SD	215.0 ± 51.84	227.5 ± 49.94
Month 36 (n)	71	61
mean ± SD	216.5 ± 41.87	218.5 ± 41.38
HDL-cholesterol (mg/dL)		
Open Label (OL) Baseline (n)	229	426
mean ± SD	46.9 ± 13.42	52.6 ± 14.88
Month 6 (n)	197	353
mean ± SD	49.0 ± 13.50	54.8 ± 15.54
Month 12 (n)	174	321
mean ± SD	50.1 ± 13.33	55.6 ± 15.60
Month 18 (n)	148	275
mean ± SD	51.3 ± 14.43	57.7 ± 16.61
Month 24 (n)	119	221
mean ± SD	52.3 ± 14.98	56.6 ± 14.81
Month 30 (n)	98	155
mean ± SD	51.7 ± 14.57	56.9 ± 15.23
Month 36 (n)	71	61
mean ± SD	52.6 ± 14.84	54.7 ± 14.41
LDL-cholesterol (mg/dL)		
Open Label (OL) Baseline (n)	226	424
mean ± SD	139.0 ± 35.98	146.7 ± 38.52
Month 6 (n)	182	329
mean ± SD	137.0 ± 37.57	152.2 ± 42.63
Month 12 (n)	164	304
mean ± SD	136.3 ± 34.71	149.7 ± 42.82
Month 18 (n)	142	262
mean ± SD	132.9 ± 37.32	142.6 ± 41.35
Month 24 (n)	110	215
mean ± SD	129.9 ± 39.61	138.9 ± 39.43
Month 30 (n)	91	147
mean ± SD	122.4 ± 38.78	138.5 ± 41.96
Month 36 (n)	69	60
mean ± SD	129.8 ± 38.37	137.2 ± 38.37
Triglycerides (mg/dL)		
Open Label (OL) Baseline (n)	229	426
mean ± SD	193.4 ± 119.09	173.6 ± 108.88
Month 6 (n)	198	360
mean ± SD	193.7 ± 113.41	182.8 ± 123.32
Month 12 (n)	176	321
mean ± SD	195.0 ± 110.54	175.9 ± 132.89

Continued

Table 36 (continued): Mean Lipid Parameters by Visit

Lipid Parameters	Treatment Group	
	RSG 2mg bd Combination (N = 229)	RSG 4mg bd Monotherapy (N = 430)
Triglycerides (mg/dL)		
Month 18 (n)	150	274
mean ± Sd	183.6 ± 101.61	173.2 ± 120.07
Month 24 (n)	122	222
mean ± SD	184.4 ± 111.57	156.9 ± 101.75
Month 30 (n)	99	157
mean ± Sd	197.7 ± 164.47	159.4 ± 111.57
Month 36 (n)	71	61
mean ± SD	182.2 ± 114.72	137.2 ± 83.38
Free Fatty Acids (mg/dL)		
Open Label (OL) Baseline (n)	229	424
mean ± SD	24.41 ± 8.126	21.16 ± 6.762
Month 6 (n)	198	362
mean ± SD	21.63 ± 6.779	21.12 ± 6.570
Month 12 (n)	175	302
mean ± SD	22.78 ± 6.257	21.72 ± 6.666
Month 18 (n)	142	257
mean ± Sd	25.06 ± 6.498	22.27 ± 7.029
Month 24 (n)	120	208
mean ± SD	23.63 ± 5.495	21.95 ± 8.768
Month 30 (n)	97	137
mean ± Sd	23.96 ± 5.781	20.87 ± 5.336
Month 36 (n)	72	57
mean ± SD	22.75 ± 6.315	19.96 ± 4.854
Total cholesterol/HDL ratio		
Open Label (OL) Baseline (n)	229	424
mean ± SD	5.10 ± 1.656	4.76 ± 1.525
Month 6 (n)	195	350
mean ± SD	4.97 ± 1.832	4.86 ± 2.087
Month 12 (n)	173	318
mean ± SD	4.78 ± 1.570	4.70 ± 1.878
Month 18 (n)	148	274
mean ± Sd	4.59 ± 1.426	4.37 ± 1.511
Month 24 (n)	118	220
mean ± SD	4.48 ± 1.469	4.29 ± 1.475
Month 30 (n)	98	153
mean ± Sd	4.53 ± 2.017	4.32 ± 1.737
Month 36 (n)	71	61
mean ± SD	4.40 ± 1.395	4.26 ± 1.408
LDL/HDL ratio		
Open Label (OL) Baseline (n)	226	424
mean ± SD	3.18 ± 1.205	2.98 ± 1.052
Month 6 (n)	182	329
mean ± SD	2.96 ± 1.255	2.93 ± 1.224
Month 12 (n)	164	304
mean ± SD	2.86 ± 1.039	2.90 ± 1.316
Month 18 (n)	142	262
mean ± Sd	2.71 ± 0.954	2.63 ± 1.059
Month 24 (n)	110	215
mean ± SD	2.65 ± 1.065	2.60 ± 0.958
Month 30 (n)	91	147
mean ± Sd	2.49 ± 1.107	2.55 ± 1.026
Month 36 (n)	69	60
mean ± SD	2.66 ± 1.100	2.63 ± 0.963

NOTE: All laboratory values are fasting

Data Source: [Section 14, Table 14.1Aa](#)(contains both efficacy and pharmacodynamic variables); [Appendix C](#), Listing C.L1; [Appendix F](#), Listing F.L1

9 Pharmacoeconomic Evaluation

No pharmacoeconomic evaluation was performed for this study.

10 Discussion

This study was designed to evaluate the safety, tolerability and efficacy of rosiglitazone in type 2 diabetic patients who were being treated either with combination therapy (rosiglitazone 2mg bd plus a sulphonylurea; extension of study 015) or with monotherapy (rosiglitazone 4mg bd; extension of studies 020 and 025).

A total of 659 patients are included in this report; 229 in the rosiglitazone 2mg bd combination therapy group and 430 in the rosiglitazone 4mg bd monotherapy group. The mean duration of treatment with rosiglitazone in this extension study was 772.5 days in the rosiglitazone 2mg bd combination therapy group and 710.1 days in the rosiglitazone 4mg bd monotherapy group.

The mean age of patients in the rosiglitazone 2mg bd combination therapy group was 62 years and in the rosiglitazone 4mg bd monotherapy group 60 years. There was a predominance of males, representing approximately 66% of patients and of caucasians, representing 97% of all patients. Patients entering this open long term extension on combination therapy from study 015 were generally less well controlled in terms of glycaemia than those entering from studies 020 and 025, with higher mean HbA1c and FPG values (9.1% and 197.1mg/dL respectively at entry to study 015) and a mean duration of diabetes of 9 years and all of whom were on oral antihyperglycaemic (OAH) medication prior to enrolment. Those patients entering study 009 from monotherapy studies 020 and 025 had mean double-blind baseline values for HbA1c and FPG of 8.0% and 184.6mg/dL respectively and a mean duration since diagnosis of diabetes of 6 years. Furthermore 43% of patients were treated by diet and exercise alone (no previous OAH therapy). Thus the two groups of patients in this study are representative of mild (monotherapy group) and moderate (combination group) type 2 diabetes mellitus populations.

The percentage of patients withdrawing from the study was relatively high compared to acute studies, which would be expected in a long term extension study, particularly considering the age and health status of the study participants. In the combination therapy group, 62 patients (27.1%) withdrew due to lack of

efficacy and 29 (12.7%) withdrew due to an adverse experience compared to 82 patients (19.1%) and 47 (10.9%) respectively in the monotherapy group.

Efficacy of Rosiglitazone

Patients receiving rosiglitazone 2mg bd combination therapy maintained their HbA1c levels close to extension study baseline levels for at least 36 months of treatment with a further decrease in FPG observed over the first 3 months of open label treatment; plasma insulin was found to generally decrease over 36 months of treatment. In the preceding study, 015 [29], significant decreases in HbA1c and FPG had been achieved following 26 weeks of treatment with rosiglitazone 1mg or 2mg bd in combination with a sulphonylurea (greater reductions with the higher dose). The subset of patients who received 2mg bd plus sulphonylurea (and continued on this regimen in the extension study) maintained their HbA1c levels for a further 36 months. Increasing the rosiglitazone dose from 1mg bd in study 015 to 2mg bd enabled patients to maintain their extension study baseline HbA1c values for a further 36 months and further reduced mean FPG for the first 3 months. Those patients receiving rosiglitazone for the first time showed a reduction in both HbA1c and FPG over the first 3 months of combination therapy. Although patients on combination therapy were permitted to increase their dose of sulphonylurea, there is a significant and growing body of evidence indicating that increasing the dose of a sulphonylurea beyond half the maximum permitted dose produces no additional improvement in glycaemic control [30][31]. Therefore, the maintenance of glycaemic control over 36 months is not due to the effects of increasing the sulphonylurea dose in the combination therapy group.

In the rosiglitazone 4mg bd monotherapy group, mean HbA1c was also maintained close to baseline levels for at least 36 months of treatment, with a reduction in both mean FPG and plasma insulin evident over the first 6 months. Mean HbA1c for those patients who previously received rosiglitazone 2mg bd or 4mg bd in study 020 [32] remained similar to baseline values; further reductions in FPG were initially observed in both population subsets. Patients switching from glibenclamide monotherapy in the preceding study experienced an increase in HbA1c and FPG over the first 3 months of rosiglitazone monotherapy, after which levels decreased to baseline values over the following 30 months. Although switching from glibenclamide to rosiglitazone 4mg bd leads to an acute increase in mean HbA1c and FPG, this has been shown in this study to be transient. During the screening phase of study 020, a large proportion of the patients were withdrawn from sulphonylurea treatment before starting rosiglitazone. Mean HbA1c and FPG both increased initially, but the increase was short-lived and was

followed by reductions to levels significantly below baseline. This may have reflected the time it takes for rosiglitazone to achieve full effect [33][34].

The clinically relevant antihyperglycaemic effects of rosiglitazone as combination therapy with sulphonylurea or as monotherapy have been demonstrated to be sustained over the long term.

In the acute study 015, there were increases in total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides, and decreases in free fatty acids, in the treatment groups which received rosiglitazone plus sulphonylurea. For patients continuing treatment with rosiglitazone from that study, total cholesterol and LDL-cholesterol decreased and triglycerides were unchanged over a period of 36 months' treatment. However, the increases in HDL observed in study 015 were not maximal and further increases in mean HDL were observed for a further three years of treatment with rosiglitazone. Similarly, there were further beneficial reductions in free fatty acids on continuing rosiglitazone plus sulphonylurea in this extension study. As expected, those patients who received treatment with rosiglitazone for the first time in this study had transient increases in total cholesterol consistent with the findings of the acute study.

With respect to double-blind study 020, there were dose-related increases in total cholesterol, LDL-cholesterol and HDL-cholesterol and decreases in free fatty acids in the treatment groups which received rosiglitazone. For patients continuing treatment with rosiglitazone from that study, total cholesterol and LDL-cholesterol decreased, with further increases in HDL apparent, following a further three years of treatment with rosiglitazone monotherapy. Similarly, there were further beneficial reductions in free fatty acids on continuing rosiglitazone in this extension study. Glibenclamide monotherapy did not have an effect on total cholesterol or LDL-cholesterol in the acute study, but on switching to rosiglitazone a transient increase over 6 months in both parameters was observed.

Although the introduction of and changes in the dose of statins and fibrates was permitted, this stipulation was only introduced following a protocol amendment during the final year of recruitment and therefore affected a minority of patients. However, during the last year of treatment in particular, improvements in the lipid profile are likely to be at least partly due to the introduction of anti-dyslipidaemic therapy.

Potentially beneficial effects of long term treatment with rosiglitazone were found with respect to total cholesterol, LDL-cholesterol and HDL-cholesterol as reflected in reductions in both the total cholesterol:HDL-cholesterol and LDL-

cholesterol:HDL-cholesterol ratios in both treatment groups. Analysis of data from the Lipid Research Clinics (LRC) Coronary Primary Prevention Trial, the Framingham Heart Study and the LRC Population Prevalence Study has demonstrated that not only are total cholesterol:HDL-cholesterol and LDL-cholesterol:HDL-cholesterol ratios the best predictors of outcome in epidemiological studies, they are also the best predictors of treatment benefit [37][38][39]. Additionally, a decrease in triglycerides, which was observed following 36 months of treatment with rosiglitazone, have been shown to be not related to the risk of subsequent cardiovascular events [40]. Thus, long term treatment with rosiglitazone, in combination with sulphonylureas or as monotherapy does not appear to pose a risk in terms of lipid-mediated cardiovascular complications.

In the rosiglitazone 2mg bd combination therapy group, there was a trend towards an increase in mean urinary albumin concentration, however, there was a large degree of variability in the data. This is in contrast to the findings in other studies, such as 015 and 020, in which no changes in mean urinary albumin concentration were observed over 26 and 52 weeks respectively. Furthermore, in the rosiglitazone 4mg bd monotherapy group, mean urinary albumin was similar to baseline values after 36 months.

Safety of Rosiglitazone

Long term treatment with rosiglitazone as combination therapy or as monotherapy was found to be safe and well tolerated.

Due to the age and health status of patients enrolled in study 009, combined with a three year assessment period of the study, the incidence of both serious adverse experiences and deaths would be expected to be relatively high. There were ten deaths during the study or within 30 days of study end (ventricular fibrillation, malignant neoplasm, cardiac failure, cerebrovascular disorder, sudden death, intestinal ischaemia, respiratory disorder and myocardial infarction in three patients) none of which were considered to be causally related to study medication. In total, there were 135 patients with serious non-fatal adverse experiences. Five serious on-therapy adverse experiences in four patients were considered by the investigator to have a probable/suspected relationship to study medication: hyperglycaemia, arthralgia, pulmonary oedema/cardiac failure and gynecomastia.

A relatively elderly, diabetic population would be expected to have a higher incidence of underlying cardiovascular-related conditions. Indeed, the most

frequently presenting conditions at double-blind baseline included hypertension, circulatory system disorders, ischaemic heart disease and angina pectoris. In such a patient population predisposed to cardiovascular-related conditions, rosiglitazone was found to have a benign profile with respect to cardiovascular safety parameters with no clinically relevant changes in SBP, DBP or heart rate and no clinically significant changes in ECG parameters in either of the treatment groups. No clinically significant findings were observed in the occurrence of new on-therapy abnormal ECG parameters.

Rosiglitazone, in combination or as monotherapy, was associated with an increase in body weight which is consistent with previously documented associations between weight increase and treatment with sulphonylureas [20] and thiazolidinediones [21]. The increase in weight was generally well tolerated with the majority of cases being mild or moderate resulting in the withdrawal of only five patients. The UKPDS has clearly demonstrated that weight gain is associated with pharmacological glucose-lowering treatments [22], being a feature of long term treatment with all therapies used [23][24].

The mechanisms resulting in weight gain have not been fully elucidated, but are likely to be multifactorial and to include an efficacy-associated reduction in glycosuria and caloric retention. The increase in weight observed in this study was not associated with adverse effects on blood pressure, heart rate or lipid profile which is in accordance with a WHO epidemiological study in type 2 diabetics which demonstrated no significant increase in all-cause mortality with weight gain [41].

Haematological changes (reduction in haemoglobin and haematocrit) have been observed in pre-clinical and clinical studies with thiazolidinediones [35][36]. In both acute phase studies (015 and 020) [29][32] reductions in haemoglobin and haematocrit were observed on rosiglitazone therapy, but in this long term extension study, in patients receiving combination therapy or monotherapy, there was little evidence of further changes in either parameter. The small reductions in haemoglobin and haematocrit observed were in those patients starting rosiglitazone in both groups and were not regarded as clinically significant. Following an initial small reduction in haematocrit, the mean haematocrit for the population at each visit tended to increase, and had returned to baseline levels after approximately 2 years into the study, after which there was a tendency for the mean haematocrit to decrease slightly. It should be noted that the patient population changes from an N of 229 at baseline to 83 (2mg bd combination), and an N of 427 to 77 (4mg bd monotherapy) by month 36, and therefore the mean reflects a different population by the end of the study. From baseline to month 24,

when more than half the patients remain on study, the data suggest a tendency for the haematocrit to return to baseline levels. From month 30 onwards, fewer than half the patients remained on study, and the mean haematocrit level is less representative of the patient population at baseline. Thus, the apparent decrease in haematocrit beyond month 30 may reflect a change in the patient population, rather than a small decrease in haematocrit. Events of anaemia reported as adverse experiences were mainly mild or moderate resulting in only two patients withdrawing from the study. Although three events were classified as serious, all were considered to be unrelated to study drug by the investigator.

No other clinically significant changes in laboratory values were observed in any treatment group. Values regarded as being of potential clinical concern were infrequent and not considered to be of clinical significance. Epidemiological surveys have reported a 2-3 fold increase in the odds of diabetic patients experiencing elevated ALT [42][43]. A recent study conducted with the UK primary Care Database (UK MediPlus) recorded an 8-9 times higher rate for hepatic dysfunction and hepatic failure in diabetics compared to non-diabetics. With an anticipated predisposition to hepatic-related adverse events, the actual event rate of any hepatic-related adverse experience was only 1.9% in the monotherapy group and 6.1% in the combination therapy group. The majority of events were mild or moderate with only three patients withdrawing due to a hepatic-related event. Elevations in ALT, considered to be the most reliable predictors of hepatocellular injury, to above three times the upper limit of normal occurred in only one patient in each treatment group.

The paucity of hepatocellular events following long term treatment with rosiglitazone reaffirms previous findings of the safety of rosiglitazone with respect to liver function [44].

The incidence of new on-therapy AEs was similar in the combination group (82.5%) and the monotherapy group (84.4%). The most common adverse experience in the rosiglitazone 2mg bd combination therapy group was hyperglycaemia (20.1%), which was notably higher than in the monotherapy group (3.7%), and in the rosiglitazone 4mg bd monotherapy group bronchitis (16.0%). Events of hyperglycaemia mainly occurred in those patients who continued to receive rosiglitazone 2mg bd in combination with sulphonylurea in the extension study, with virtually all cases being mild or moderate in intensity.

Hypercholesterolaemia and hyperlipaemia occurred in 9.4% and 5.2% of all patients respectively. Increased fat mobilisation, lipoprotein overproduction and undercatabolism are typical in the type 2 diabetic with consequent dyslipidaemia.

Indeed, elevated cholesterol and triglycerides, hyperlipaemia and lipid metabolism disorder were amongst the most frequent presenting conditions at double-blind baseline. As previously discussed, treatment with rosiglitazone has in fact demonstrated an improvement in the lipid profile of type 2 diabetic patients following long term therapy.

Plasma volume expansion has been observed with rosiglitazone in pre-clinical [25][26] and clinical [27] studies along with other thiazolidinediones [28]. Type 2 diabetics are predisposed to develop oedema due to underlying vascular and neuropathic complications, thus any drug which increases fluid retention would be likely to increase the frequency of oedema in the presence of this disease-related predisposition. Following long term therapy with rosiglitazone in this study, the incidence of oedema was 4.8% in the combination therapy group and 7.4% in the monotherapy group. Oedema-related events were well tolerated, the majority being mild or moderate, resulting in the cessation of treatment in only one patient.

Other adverse experiences occurring more frequently in either treatment group generally reflected conditions commensurate with a relatively elderly, type 2 diabetic population.

Although the incidence of severe adverse experiences was approximately 23%, this was due to a low frequency of a number of individual events and not any specific adverse experience. In total 26 patients (11.4%) in the rosiglitazone 2mg bd combination therapy group and 40 (9.3%) in the rosiglitazone 4mg bd monotherapy group had an on-therapy adverse experiences which led to their withdrawal from the study.

Hypoglycaemia is not expected with rosiglitazone due to its action as an insulin sensitiser rather than as an insulin secretagogue [2] whereas prolonged hypoglycaemia is recognised as being the most common and severe side effect of sulphonylureas [8]. There were only 6 patients (1.4%) with an adverse experience of hypoglycaemia in the monotherapy group compared to 14 patients (6.1%) in the combination therapy group. The majority of events were considered to be mild or moderate resulting in the withdrawal of only two patients.

11 Conclusions

Long term treatment with rosiglitazone 2mg bd used in combination with a sulphonylurea or with rosiglitazone 4mg bd as monotherapy is effective in maintaining HbA1c and FPG in patients who continue to take these treatments. Initial increases in HbA1c and fasting plasma glucose in patients who changed therapy from glibenclamide to rosiglitazone 4mg bd were shown to be transient.

Beneficial decreases in total cholesterol:HDL-cholesterol, LDL-cholesterol:HDL-cholesterol ratios and free fatty acids were observed for the three year duration of this extension study.

The majority of adverse events were mild or moderate in intensity and were not considered related to study medication. Treatment with rosiglitazone was associated with an increase in body weight. The hepatic safety profile was good following long term therapy.

This analysis demonstrated that long term treatment with rosiglitazone 2mg bd (in combination with a sulphonylurea) or 4mg bd is safe, well tolerated and an effective therapy for patients with type 2 diabetes mellitus.

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13 Source Tables: Study Population

	Page
Table 13.0.1 Investigator Affiliation List.	152
Table 13.1a Summary of Patient Disposition by Center, All Patients Who Entered Study 009	158
Table 13.1b Summary of Patient Disposition by Center, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	161
Table 13.1c Summary of Patient Disposition by Center, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	164
Table 13.2 Summary patient disposition by center (protocol 025)	167
Table 13.2.1a Summary of Reasons for Study Conclusion, All Patients Who Entered Study 009	168
Table 13.2.1b Summary of Reasons for Study Conclusion, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	169
Table 13.2.1c Summary of Reasons for Study Conclusion, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	170
Table 13.3.1a Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy, All Patients Who Entered Study 009	171
Table 13.3.1b Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension.	172
Table 13.3.1c Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension.	173
Table 13.4.1a Summary of Presenting Conditions at Double Blind Baseline, All Patients Who Entered Study 009.	174
Table 13.4.1b Summary of Presenting Conditions at Double Blind Baseline, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension.	186
Table 13.4.1c Summary of Presenting Conditions at Double Blind Baseline, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension.	197
Table 13.5.1a Summary of Demography Information by Gender at Double Blind Baseline, All Patients Who Entered Study 009	209
Table 13.5.1b Summary of Demography Information by Gender at Double Blind Baseline, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension.	215
Table 13.5.1c Summary of Demography Information by Gender at Double Blind Baseline, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension.	221
Table 13.5.2a Summary of Concomitant Medications (Continue or Start During Open Label Study), All Patients Who Entered Study 009	227

Table 13.5.2b Summary of Concomitant Medications (Continue or Start During Open Label Study), All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	291
Table 13.5.2c Summary of Concomitant Medications (Continue or Start During Open Label Study), All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	350
Table 13.6.1a Summary of Patient Exposure to Study Treatment During the Open Label Study, All Patients Who Entered Study 009	416
Table 13.6.1b Summary of Patient Exposure to Study Treatment During the Open Label Study, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	417
Table 13.6.1c Summary of Patient Exposure to Study Treatment During the Open Label Study, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	418
Table 13.6.2 First and Last Date of Study Medication During the Open Label Study	419
Table 13.6.3a Summary of Overall Compliance During the Open Label Study, All Patients Who Entered Study 009	420
Table 13.6.3b Summary of Overall Compliance During the Open Label Study, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	421
Table 13.6.3c Summary of Overall Compliance During the Open Label Study, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	422

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BRL-049653

Investigator Affiliation List

009

Table 13.0.1

SB Document Number: BRL-049653/RSD-100VKZ/2

Investigators	Ctr	Investigational Site	City
France			

Investigators	Ctr	Investigational Site	City
Germany			

Investigators	Ctr	Investigational Site	City
Netherlands			
Belgium			
Italy			
Sweden			

Investigators	Ctr	Investigational Site	City

Investigators	Ctr	Investigational Site	City

Data Source Table 13.1a

Summary of Patient Disposition by Center
All Patients Who Entered Study 009

CENTER	Investigator's Last Name	Country	2bd Comb Total			4bd Mono Total		
			E	C	W	E	C	W
		United Kingdom/	0	0	0	30	0	30
		FR	17	0	17	0	0	0
		FR	1	0	1	0	0	0
		FR	7	0	7	1	0	1
		FR	4	0	4	0	0	0
		FR	13	0	13	0	0	0
		FR	5	0	5	0	0	0
		FR	6	0	6	0	0	0
		GE	0	0	0	6	0	6
		GE	0	0	0	1	0	1
		GE	0	0	0	2	0	2
		GE	0	0	0	5	0	5
		GE	0	0	0	1	0	1
		GE	0	0	0	1	0	1
		GE	0	0	0	12	0	12
		GE	0	0	0	2	0	2
		GE	0	0	0	4	0	4
		GE	0	0	0	4	0	4
		GE	0	0	0	2	0	2
		GE	0	0	0	7	0	7
		GE	0	0	0	7	0	7
		GE	0	0	0	4	0	4
		NL	3	0	3	0	0	0
		NL	19	0	19	0	0	0
		BEL	0	0	0	7	0	7
		BEL	0	0	0	5	0	5
		BEL	0	0	0	4	0	4
		BEL	0	0	0	3	0	3
		ITA	3	0	3	0	0	0
		ITA	8	0	8	0	0	0
		ITA	7	0	7	0	0	0
		SWE	0	0	0	13	0	13
		SWE	0	0	0	9	0	9
		SWE	0	0	0	3	0	3
		SWE	0	0	0	5	0	5
		SWE	0	0	0	11	0	11
		SPA	8	0	8	0	0	0
		SPA	18	0	18	0	0	0
		SPA	2	0	2	0	0	0
		FR	0	0	0	2	0	2
		FR	0	0	0	1	0	1
		FR	0	0	0	2	0	2
		FR	0	0	0	3	0	3
		FR	0	0	0	14	0	14
		FR	0	0	0	20	0	20

Data Source Table 13.1a

Summary of Patient Disposition by Center
All Patients Who Entered Study 009

CENTER	Investigator's Last Name	Country	2bd Comb Total			4bd Mono Total		
			E	C	W	E	C	W
		FR	0	0	0	6	0	6
		FR	0	0	0	14	0	14
		FR	0	0	0	21	0	21
		FR	0	0	0	2	0	2
		FR	0	0	0	1	0	1
		FR	0	0	0	13	0	13
		FR	0	0	0	14	0	14
		FR	0	0	0	5	0	5
		FR	0	0	0	8	0	8
		FR	0	0	0	14	0	14
		FR	0	0	0	3	0	3
		FR	0	0	0	3	0	3
		FR	0	0	0	6	0	6
		FR	0	0	0	10	0	10
		FR	0	0	0	4	0	4
		FR	0	0	0	7	0	7
		FR	0	0	0	17	0	17
		NL	0	0	0	12	0	12
		UK	6	0	6	0	0	0
		UK	10	0	10	0	0	0
		UK	4	0	4	0	0	0
		UK	5	0	5	0	0	0
		UK	9	0	9	0	0	0
		UK	7	0	7	0	0	0
		UK	5	0	5	0	0	0
		UK	6	0	6	0	0	0
		UK	8	0	8	0	0	0
		UK	7	0	7	0	0	0
		UK	2	0	2	0	0	0
		UK	10	0	10	0	0	0
		UK	12	0	12	0	0	0
		UK	8	0	8	0	0	0
		UK	7	0	7	0	0	0
		UK	2	0	2	0	0	0
		ITA	0	0	0	10	0	10
		ITA	0	0	0	6	0	6
		ITA	0	0	0	2	0	2
		ITA	0	0	0	8	0	8
		UK	0	0	0	1	0	1
		UK	0	0	0	5	0	5
		UK	0	0	0	6	0	6
		UK	0	0	0	2	0	2
		UK	0	0	0	3	0	3
		UK	0	0	0	4	0	4
		UK	0	0	0	20	0	20
		IRE	0	0	0	5	0	5

BRL 49653C/009

Page 3 of 3

Data Source Table 13.1a

Summary of Patient Disposition by Center
All Patients Who Entered Study 009

CENTER	Investigator's Last Name	Country	2bd Comb Total			4bd Mono Total		
			E	C	W	E	C	W
		IRE	0	0	0	7	0	7
TOTAL			229	0	229	430	0	430

Note: E: Number of Patients who Entered Open Label, C: Number of Patients who Completed the Study
W: Number of Patients who Withdrew Early From the Study

Completed: as determined by the investigator.

Data Source Table 13.1b

Summary of Patient Disposition by Center
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

CENTER	Investigator's Last Name	Country	2bd Comb Total								
			015:S/2bd			015:1bd+S/2b			015:2bd+S/2bd		
			E	C	W	E	C	W	E	C	W
		United Kingdom/	0	0	0	0	0	0	0	0	0
		FR	4	0	4	5	0	5	8	0	8
		FR	1	0	1	0	0	0	0	0	0
		FR	3	0	3	2	0	2	2	0	2
		FR	1	0	1	1	0	1	2	0	2
		FR	2	0	2	4	0	4	7	0	7
		FR	1	0	1	3	0	3	1	0	1
		FR	2	0	2	2	0	2	2	0	2
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		GE	0	0	0	0	0	0	0	0	0
		NL	1	0	1	1	0	1	1	0	1
		NL	5	0	5	8	0	8	6	0	6
		BEL	0	0	0	0	0	0	0	0	0
		BEL	0	0	0	0	0	0	0	0	0
		BEL	0	0	0	0	0	0	0	0	0
		BEL	0	0	0	0	0	0	0	0	0
		ITA	1	0	1	1	0	1	1	0	1
		ITA	2	0	2	2	0	2	4	0	4
		ITA	1	0	1	3	0	3	3	0	3
		SWE	0	0	0	0	0	0	0	0	0
		SWE	0	0	0	0	0	0	0	0	0
		SWE	0	0	0	0	0	0	0	0	0
		SWE	0	0	0	0	0	0	0	0	0
		SWE	0	0	0	0	0	0	0	0	0
		SPA	1	0	1	2	0	2	5	0	5
		SPA	5	0	5	5	0	5	8	0	8
		SPA	1	0	1	0	0	0	1	0	1
		FR	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0

Summary of Patient Disposition by Center
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

[illegible]

Data Source Table 13.1b

Summary of Patient Disposition by Center
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

CENTER	Investigator's Last Name	Country	015:S/2bd			2bd Comb Total 015:1bd+S/2b			015:2bd+S/2bd		
			E	C	W	E	C	W	E	C	W
		UK	0	0	0	0	0	0	0	0	0
		IRE	0	0	0	0	0	0	0	0	0
		IRE	0	0	0	0	0	0	0	0	0
TOTAL			61	0	61	78	0	78	90	0	90

Note: E: Number of Patients who Entered Open Label, C: Number of Patients who Completed the Study
W: Number of Patients who Withdrew Early From the Study

Completed: as determined by the investigator.

Data Source Table 13.1c

Summary of Patient Disposition by Center
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

CENTER	Investigator's Last Name	Country	4bd Mono Total											
			020:4bd/4bd			020:2bd/4bd			020:G/4bd			025:Total		
			E	C	W	E	C	W	E	C	W	E	C	W
		United Kingdom/	0	0	0	0	0	0	0	0	0	30	0	30
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	0	0	0	0	0	0	0	0	0
		GE	2	0	2	3	0	3	1	0	1	0	0	0
		GE	0	0	0	1	0	1	0	0	0	0	0	0
		GE	1	0	1	0	0	0	1	0	1	0	0	0
		GE	2	0	2	2	0	2	1	0	1	0	0	0
		GE	0	0	0	0	0	0	1	0	1	0	0	0
		GE	1	0	1	0	0	0	0	0	0	0	0	0
		GE	4	0	4	5	0	5	3	0	3	0	0	0
		GE	1	0	1	1	0	1	0	0	0	0	0	0
		GE	1	0	1	1	0	1	2	0	2	0	0	0
		GE	1	0	1	1	0	1	2	0	2	0	0	0
		GE	0	0	0	1	0	1	1	0	1	0	0	0
		GE	1	0	1	4	0	4	2	0	2	0	0	0
		GE	2	0	2	3	0	3	2	0	2	0	0	0
		GE	1	0	1	1	0	1	2	0	2	0	0	0
		NL	0	0	0	0	0	0	0	0	0	0	0	0
		NL	0	0	0	0	0	0	0	0	0	0	0	0
		BEL	2	0	2	3	0	3	2	0	2	0	0	0
		BEL	1	0	1	2	0	2	2	0	2	0	0	0
		BEL	1	0	1	1	0	1	2	0	2	0	0	0
		BEL	2	0	2	1	0	1	0	0	0	0	0	0
		ITA	0	0	0	0	0	0	0	0	0	0	0	0
		ITA	0	0	0	0	0	0	0	0	0	0	0	0
		ITA	0	0	0	0	0	0	0	0	0	0	0	0
		SWE	6	0	6	4	0	4	3	0	3	0	0	0
		SWE	4	0	4	2	0	2	3	0	3	0	0	0
		SWE	1	0	1	2	0	2	0	0	0	0	0	0
		SWE	1	0	1	1	0	1	3	0	3	0	0	0
		SWE	3	0	3	4	0	4	4	0	4	0	0	0
		SPA	0	0	0	0	0	0	0	0	0	0	0	0
		SPA	0	0	0	0	0	0	0	0	0	0	0	0
		SPA	0	0	0	0	0	0	0	0	0	0	0	0
		FR	0	0	0	1	0	1	1	0	1	0	0	0

Summary of Patient Disposition by Center
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

CENTER	Investigator's Last Name	Country	4bd Mono Total											
			020:4bd/4bd			020:2bd/4bd			020:G/4bd			025:Total		
			E	C	W	E	C	W	E	C	W	E	C	W
		FR	0	0	0	1	0	1	0	0	0	0	0	0
		FR	1	0	1	1	0	1	0	0	0	0	0	0
		FR	1	0	1	1	0	1	1	0	1	0	0	0
		FR	3	0	3	6	0	6	5	0	5	0	0	0
		FR	6	0	6	7	0	7	7	0	7	0	0	0
		FR	3	0	3	2	0	2	1	0	1	0	0	0
		FR	5	0	5	4	0	4	5	0	5	0	0	0
		FR	5	0	5	9	0	9	7	0	7	0	0	0
		FR	0	0	0	1	0	1	1	0	1	0	0	0
		FR	1	0	1	0	0	0	0	0	0	0	0	0
		FR	4	0	4	4	0	4	5	0	5	0	0	0
		FR	3	0	3	5	0	5	6	0	6	0	0	0
		FR	2	0	2	2	0	2	1	0	1	0	0	0
		FR	1	0	1	3	0	3	4	0	4	0	0	0
		FR	5	0	5	4	0	4	5	0	5	0	0	0
		FR	0	0	0	2	0	2	1	0	1	0	0	0
		FR	1	0	1	2	0	2	0	0	0	0	0	0
		FR	3	0	3	1	0	1	2	0	2	0	0	0
		FR	3	0	3	3	0	3	4	0	4	0	0	0
		FR	1	0	1	2	0	2	1	0	1	0	0	0
		FR	3	0	3	1	0	1	3	0	3	0	0	0
		FR	6	0	6	5	0	5	6	0	6	0	0	0
		NL	4	0	4	2	0	2	6	0	6	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
		UK	0	0	0	0	0	0	0	0	0	0	0	0
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0	0	0	0	0	0	0	0	0	0	0	0		
UK	0													

Data Source Table 13.1c

Summary of Patient Disposition by Center
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

CENTER	Investigator's Last Name	Country	4bd Mono Total											
			020:4bd/4bd			020:2bd/4bd			020:G/4bd			025:Total		
			E	C	W	E	C	W	E	C	W	E	C	W
		ITA	0	0	0	1	0	1	1	0	1	0	0	0
		ITA	3	0	3	2	0	2	3	0	3	0	0	0
		UK	1	0	1	0	0	0	0	0	0	0	0	0
		UK	1	0	1	1	0	1	3	0	3	0	0	0
		UK	2	0	2	2	0	2	2	0	2	0	0	0
		UK	0	0	0	2	0	2	0	0	0	0	0	0
		UK	0	0	0	1	0	1	2	0	2	0	0	0
		UK	2	0	2	1	0	1	1	0	1	0	0	0
		UK	9	0	9	4	0	4	7	0	7	0	0	0
		IRE	2	0	2	2	0	2	1	0	1	0	0	0
		IRE	2	0	2	2	0	2	3	0	3	0	0	0
TOTAL			124	0	124	136	0	136	139	0	139	30	0	30

Note: E: Number of Patients who Entered Open Label, C: Number of Patients who Completed the Study
W: Number of Patients who Withdrew Early From the Study

Completed: as determined by the investigator.

BRL 49653C/025

Data Source Table 13.2

Summary of Patient Disposition by Center

CENTER	Investigator's Last Name	Country	Placebo			Metformin			RSG 4mg bd			Total		
			R	C	E	R	C	E	R	C	E	R	C	E
		United Kingdom	12	9	12	14	11	14	12	10	12	38	30	38
		Italy	16	9	16	14	13	14	14	11	14	44	33	44
		Italy	3	1	3	4	4	4	4	4	4	11	9	11
TOTAL			31	19	31	32	28	32	30	25	30	93	72	93

Note: R: Number of Patients Randomized, C: Number of Patients who Completed the Study, E: Number of Patients who were Efficacy Evaluable.

Completed: as determined by the investigator.

Note:

Therefore, the number of completers can be considered as 75.

BRL 49653C/009

Data Source Table 13.2.1a

Summary of Reasons for Study Conclusion
All Patients Who Entered Study 009

Discontinuation Reason	2bd Comb Total (N= 229)	4bd Mono Total (N= 430)
Adverse experience	29 (12.7%)	47 (10.9%)
Lack of efficacy	62 (27.1%)	82 (19.1%)
Deviation from protocol (including non-compliance)	7 (3.1%)	6 (1.4%)
Lost to follow up	3 (1.3%)	9 (2.1%)
Other	128 (55.9%)	286 (66.5%)
Total withdrawn	229 (100.0%)	430 (100.0%)
Completed study therapy	0 (0.0%)	0 (0.0%)
Ongoing	0 (0.0%)	0 (0.0%)

Completed: as determined by the investigator

Data Source Table 13.2.1b

Summary of Reasons for Study Conclusion
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Discontinuation Reason	2bd Comb Total		
	015:S/2bd (N= 61)	015:1bd+S/2bd (N= 78)	015:2bd+S/2bd (N= 90)
Adverse experience	7 (11.5%)	12 (15.4%)	10 (11.1%)
Lack of efficacy	16 (26.2%)	22 (28.2%)	24 (26.7%)
Deviation from protocol (including non-compliance)	2 (3.3%)	2 (2.6%)	3 (3.3%)
Lost to follow up	0 (0.0%)	2 (2.6%)	1 (1.1%)
Other	36 (59.0%)	40 (51.3%)	52 (57.8%)
Total withdrawn	61 (100.0%)	78 (100.0%)	90 (100.0%)
Completed study therapy	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ongoing	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completed: as determined by the investigator

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 13.2.1c

Summary of Reasons for Study Conclusion
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Discontinuation Reason	4bd Mono Total			
	020:4bd/4bd (N= 124)	020:2bd/4bd (N= 136)	020:G/4bd (N= 139)	025:Total (N= 30)
Adverse experience	13 (10.5%)	11 (8.1%)	17 (12.2%)	6 (20.0%)
Lack of efficacy	16 (12.9%)	21 (15.4%)	37 (26.6%)	8 (26.7%)
Deviation from protocol (including non-compliance)	1 (0.8%)	1 (0.7%)	1 (0.7%)	3 (10.0%)
Lost to follow up	2 (1.6%)	4 (2.9%)	3 (2.2%)	0 (0.0%)
Other	92 (74.2%)	99 (72.8%)	81 (58.3%)	13 (43.3%)
Total withdrawn	124 (100.0%)	136 (100.0%)	139 (100.0%)	30 (100.0%)
Completed study therapy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ongoing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completed: as determined by the investigator

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/1/CPMS-009

Data Source Table 13.3.1a

Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Gender		
Male	147 (64.2%)	287 (66.7%)
Female	82 (35.8%)	143 (33.3%)
Missing	0	0
Race		
White	223 (97.4%)	416 (96.7%)
Black	2 (0.9%)	2 (0.5%)
Other	4 (1.7%)	12 (2.8%)
Missing	0	0
Smoking Status		
Smoker	35 (15.3%)	60 (14.0%)
Non-smoker	194 (84.7%)	358 (83.3%)
Missing	0	12 (2.8%)
Prior Therapy		
Diet	0	186 (43.3%)
Single Agent	229 (100.0%)	210 (48.8%)
Combination	0	34 (7.9%)
Missing	0	0

Data Source Table 13.3.1b

Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Gender			
Male	42 (68.9%)	52 (66.7%)	53 (58.9%)
Female	19 (31.1%)	26 (33.3%)	37 (41.1%)
Missing	0	0	0
Race			
White	60 (98.4%)	74 (94.9%)	89 (98.9%)
Black	1 (1.6%)	1 (1.3%)	0
Other	0	3 (3.8%)	1 (1.1%)
Missing	0	0	0
Smoking Status			
Smoker	9 (14.8%)	13 (16.7%)	13 (14.4%)
Non-smoker	52 (85.2%)	65 (83.3%)	77 (85.6%)
Missing	0	0	0
Prior Therapy			
Diet	0	0	0
Single Agent	61 (100.0%)	78 (100.0%)	90 (100.0%)
Combination	0	0	0
Missing	0	0	0

Data Source Table 13.3.1c

Summary of Demography Information at Double Blind Baseline: Gender, Race, Smoking Status and Prior Therapy
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Gender				
Male	71 (57.3%)	93 (68.4%)	100 (71.9%)	23 (76.7%)
Female	53 (42.7%)	43 (31.6%)	39 (28.1%)	7 (23.3%)
Missing	0	0	0	0
Race				
White	121 (97.6%)	133 (97.8%)	139 (100.0%)	22 (73.3%)
Black	0	0	0	2 (6.7%)
Other	3 (2.4%)	3 (2.2%)	0	6 (20.0%)
Missing	0	0	0	0
Smoking Status				
Smoker	13 (10.5%)	20 (14.7%)	24 (17.3%)	3 (10.0%)
Non-smoker	111 (89.5%)	116 (85.3%)	115 (82.7%)	15 (50.0%)
Missing	0	0	0	12 (40.0%)
Prior Therapy				
Diet	51 (41.1%)	60 (44.1%)	55 (39.6%)	20 (66.7%)
Single Agent	61 (49.2%)	63 (46.3%)	77 (55.4%)	8 (26.7%)
Combination	12 (9.7%)	13 (9.6%)	7 (5.0%)	2 (6.7%)
Missing	0	0	0	0

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
ANOMALIES		
CONGENITAL	1 (0.4%)	2 (0.5%)
CONG ANOM, GU	1 (0.4%)	2 (0.5%)
BLOOD/BLOOD FORMING ORGAN DIS		
BLOOD, OTHER	2 (0.9%)	1 (0.2%)
BLOOD DIS, OTHER	0	1 (0.2%)
ERYTHROCYTOSIS	1 (0.4%)	0
POLYCYTHEMIA	1 (0.4%)	0
DEFICIENCY ANEMIAS, OTHER	0	1 (0.2%)
ANEMIA, PERNICIOUS	0	1 (0.2%)
HEREDITARY HEMOLYTIC ANEMIAS	0	4 (0.9%)
ANEMIA, HEMOLYT, HERED	0	4 (0.9%)
WHITE BLOOD CELL	2 (0.9%)	4 (0.9%)
EOSINOPHILIA	1 (0.4%)	2 (0.5%)
LEUCOCYTOSIS	0	1 (0.2%)
LEUKOPENIA	1 (0.4%)	0
THROMBOCYTHEMIA	0	1 (0.2%)
CIRCULATORY SYST		
ARTERY/ARTERIOLE/CAPILLARY DIS	9 (3.9%)	14 (3.3%)
ARTERIAL DISORD, OTHER	3 (1.3%)	5 (1.2%)
ARTERITIS	1 (0.4%)	3 (0.7%)
ATHEROSCLEROSIS	1 (0.4%)	1 (0.2%)
PERIPH VASCULAR DIS	6 (2.6%)	6 (1.4%)
POLYARTERITIS NODOSA	0	1 (0.2%)
CEREBROVASCULAR DIS	2 (0.9%)	8 (1.9%)
CEREBROVASCULAR DIS	0	5 (1.2%)
PRECEREBRAL ARTERY OCCLUSION	2 (0.9%)	2 (0.5%)
TRANSIENT CEREBRAL ISCHEMIA	0	1 (0.2%)
CHRONIC RHEUMATIC HEART	0	1 (0.2%)
RHEUMATIC HEART DIS	0	1 (0.2%)
HYPERTENSIVE DIS	94 (41.0%)	186 (43.3%)
ESSENTIAL HYPERTENSION	0	2 (0.5%)
HYPERTENSION	94 (41.0%)	184 (42.8%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
HYPERTENSIVE HEART DIS	1 (0.4%)	0
ISCHEMIC HEART	37 (16.2%)	36 (8.4%)
ANGINA PECTORIS	21 (9.2%)	8 (1.9%)
ANGINA PECTORIS, UNSTABLE	0	1 (0.2%)
ATHEROSCLEROSIS, HEART	0	1 (0.2%)
ISCHEMIC HEART DIS	24 (10.5%)	26 (6.0%)
MYOCARDIAL INFARCTION	0	1 (0.2%)
OTHER FORMS OF HEART DIS	17 (7.4%)	28 (6.5%)
AORTIC VALVE DISORD	1 (0.4%)	1 (0.2%)
ARRHYTHMIA	0	2 (0.5%)
AV BLOCK	5 (2.2%)	0
BRADYCARDIA	3 (1.3%)	0
CARDIOMEGALY	6 (2.6%)	5 (1.2%)
CARDIOMYOPATHY, PRIMARY	0	1 (0.2%)
CONDUCTION DISORD	1 (0.4%)	4 (0.9%)
FIBRILLATION	0	1 (0.2%)
FIBRILLATION, ATRIAL	1 (0.4%)	8 (1.9%)
HEART DIS, OTHER	0	1 (0.2%)
HEART FAILURE	2 (0.9%)	5 (1.2%)
MITRAL VALVE DISORD	1 (0.4%)	1 (0.2%)
VEINS/LYMPH/CIRC SYST DIS	16 (7.0%)	36 (8.4%)
CIRCULATORY SYST DISORD	11 (4.8%)	28 (6.5%)
HEMORRHOIDS	1 (0.4%)	3 (0.7%)
LYMPH CHANNEL DIS	1 (0.4%)	0
PHLEBITIS	0	1 (0.2%)
VARICES	3 (1.3%)	6 (1.4%)
DIGESTIVE SYST		
ESOPHAGUS/STOMACH/DUODENUM DIS	14 (6.1%)	25 (5.8%)
DYSPEPSIA	8 (3.5%)	7 (1.6%)
ESOPHAGITIS	3 (1.3%)	6 (1.4%)
ESOPHAGUS DIS	1 (0.4%)	3 (0.7%)
GASTRITIS	1 (0.4%)	6 (1.4%)
/DUODENITIS		

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
STOMACH	1 (0.4%)	2 (0.5%)
/DUODENUM DISORD		
ULCER, DUODENAL	1 (0.4%)	4 (0.9%)
ULCER, PEPTIC, OTHER	1 (0.4%)	2 (0.5%)
HERNIA OF ABDOMINAL CAVITY	3 (1.3%)	11 (2.6%)
HERNIA, ABDOMINAL	3 (1.3%)	11 (2.6%)
NONINFECT ENTERITIS/COLITIS	0	1 (0.2%)
ENTERITIS	0	1 (0.2%)
/COLITIS		
ORAL CAV/SALIV GLAND/JAW DIS	0	2 (0.5%)
DRY MOUTH	0	1 (0.2%)
TEETH DISORD	0	1 (0.2%)
OTHER DIGESTIVE SYST DISORD	7 (3.1%)	13 (3.0%)
CHOLELITHIASIS	0	4 (0.9%)
GALLBLADDER DISORD, OTHER	1 (0.4%)	0
HEPATITIS	1 (0.4%)	0
HEPATOBIL DIS	2 (0.9%)	8 (1.9%)
INTEST MALABSORPTION	1 (0.4%)	0
LIVER DISORD	2 (0.9%)	0
PANCREAS DISORD	0	1 (0.2%)
OTHER INTESTINE/PERITONEUM DIS	11 (4.8%)	9 (2.1%)
CONSTIPATION	3 (1.3%)	3 (0.7%)
DIGESTIVE DISORD, OTHER	6 (2.6%)	2 (0.5%)
DIVERTICULITIS	2 (0.9%)	5 (1.2%)
ENDOCR/METAB/IMMUNITY DISORD		
ENDOCRINE GLANDS, OTHER	2 (0.9%)	9 (2.1%)
DIABETES MELLITUS	1 (0.4%)	5 (1.2%)
ENDOCR DISORD, OTHER	0	1 (0.2%)
GASTRIN SECRET, ABN	1 (0.4%)	0
HYPERALDOSTERONISM	0	1 (0.2%)
HYPERPARATHYROIDISM	0	1 (0.2%)
PITUITARY DISORD	0	1 (0.2%)
METABOLIC/IMMUNITY, OTHER	78 (34.1%)	137 (31.9%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
CHOLEST	45 (19.7%)	71 (16.5%)
/TRIGLYCERIDE, ELEVATED		
GOUT	2 (0.9%)	8 (1.9%)
HYPERLIPEMIA	26 (11.4%)	30 (7.0%)
LIPID METAB DISORD	6 (2.6%)	22 (5.1%)
MINERAL METAB DISORD	0	1 (0.2%)
OBSESITY	5 (2.2%)	10 (2.3%)
SERUM POTASSIUM, DECREASED	0	1 (0.2%)
NUTRITIONAL DEFICIENCIES	0	2 (0.5%)
VITAMIN B DEFIC	0	1 (0.2%)
VITAMIN D DEFIC	0	1 (0.2%)
THYROID GLAND	7 (3.1%)	21 (4.9%)
GOITER	3 (1.3%)	9 (2.1%)
HYPERTHYROIDISM	1 (0.4%)	1 (0.2%)
HYPOTHYROIDISM	2 (0.9%)	11 (2.6%)
THYROIDITIS	1 (0.4%)	0
EXT CAUSES OF INJURY/POISONING		
ADV EFF, THERAP DRUG/BIOLOGIC	1 (0.4%)	5 (1.2%)
ADVERSE EFF	1 (0.4%)	2 (0.5%)
/ANTIBIOTIC		
ADVERSE EFF	0	1 (0.2%)
/BL CONSTITUENT		
ADVERSE EFF	0	1 (0.2%)
/METAB DRUG		
ADVERSE EFF	0	1 (0.2%)
/PSYCHOTROPICS		
FAMILY/PERSONAL HISTORY		
HEALTH SERV(AFTCARE/SP PROCED)	2 (0.9%)	0
UNCLASSIFIABLE	2 (0.9%)	0
HEALTH STATUS COND	0	1 (0.2%)
STATUS, POSTSURGICAL	0	1 (0.2%)
GENITOURINARY SYST DIS		

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
BREAST DISORD	2 (0.9%)	0
BREAST DISORD	2 (0.9%)	0
FEMALE PELVIC ORG, INFLAMM DIS	0	1 (0.2%)
VAGINITIS	0	1 (0.2%)
MALE GENITAL ORGAN DIS	2 (0.9%)	21 (4.9%)
GENITAL MALE DISORD, OTHER	0	1 (0.2%)
PROSTATE DISORD	2 (0.9%)	20 (4.7%)
NEPHRITIS/NEPH SYND/NEPHROSIS	1 (0.4%)	0
RENAL FAILURE	1 (0.4%)	0
OTHER FEM GENITAL TRACT DISORD	5 (2.2%)	24 (5.6%)
GENITAL FEMALE DISORD, OTHER	1 (0.4%)	1 (0.2%)
INCONTINENCE, STRESS	1 (0.4%)	2 (0.5%)
MENOPAUSAL STATES	3 (1.3%)	21 (4.9%)
OTHER URINARY SYST DIS	8 (3.5%)	14 (3.3%)
CYSTITIS	1 (0.4%)	2 (0.5%)
HEMATURIA	1 (0.4%)	1 (0.2%)
KIDNEY DISORD	1 (0.4%)	3 (0.7%)
KIDNEY	2 (0.9%)	2 (0.5%)
/URETER, CALCULUS		
RENAL FUNCTION ABN	1 (0.4%)	0
URETHRAL DISORD	1 (0.4%)	0
URINARY TRACT INFECTION	4 (1.7%)	6 (1.4%)
INFECTIOUS/PARASITIC DIS		
MYCOSES	2 (0.9%)	1 (0.2%)
MYCOSES	2 (0.9%)	1 (0.2%)
RICKETTSIOSSES/ARTHROPOD-BORNE	0	1 (0.2%)
ARTHROPOD-BORNE DIS, OTHER	0	1 (0.2%)
SYPHILIS/VENEREAL	0	1 (0.2%)
VENEREAL DIS	0	1 (0.2%)
VIRAL DIS	1 (0.4%)	2 (0.5%)
VIRAL DIS	1 (0.4%)	2 (0.5%)
/EXANTHEM		
VIRUSES/CHLAMYDIAE	0	4 (0.9%)
HEPATITIS, VIRAL	0	3 (0.7%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
VIRUS	0	1 (0.2%)
/CHLAMYD DIS, OTHER		
INJURY/POISONING		
FRACTURES	1 (0.4%)	2 (0.5%)
FRACTURE, NECK	1 (0.4%)	2 (0.5%)
/TRUNK		
UNSP EFF OF EXTERNAL CAUSES	0	3 (0.7%)
ADVERSE EFF	0	1 (0.2%)
/OTHER		
ALLERGY, NEC	0	1 (0.2%)
INJURY	0	1 (0.2%)
/POIS, OTHER		
UPPER LIMB	1 (0.4%)	0
TRAUMATIC AMPUTATION	1 (0.4%)	0
MENTAL DISORD		
NEUROTIC/PERSONALITY/NONPSY	21 (9.2%)	23 (5.3%)
ALCOHOL ABUSE	1 (0.4%)	0
ANXIETY	5 (2.2%)	9 (2.1%)
DEPRESSION	6 (2.6%)	10 (2.3%)
IMPOTENCE	11 (4.8%)	2 (0.5%)
NEUROSES	0	1 (0.2%)
SEXUAL DYSFUNCTION	0	1 (0.2%)
SCHIZOPHRENIC DISORD	0	5 (1.2%)
PSYCHOSES, AFFECTIVE	0	1 (0.2%)
PSYCHOSES, OTHER	0	1 (0.2%)
SCHIZOPHRENIA	0	3 (0.7%)
MUSCULOSKEL/CONNECT TISSUE DIS		
ARTHROPATHIES/RELATED DISORD	30 (13.1%)	49 (11.4%)
ARTHRITIS, RHEUMATOID	0	3 (0.7%)
ARTHROPATHY	7 (3.1%)	9 (2.1%)
JOINT DISORD, OTHER	0	1 (0.2%)
OSTEOARTHRISIS	22 (9.6%)	34 (7.9%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
PAIN, JOINT	1 (0.4%)	3 (0.7%)
DORSOPATHIES	9 (3.9%)	37 (8.6%)
BACK DISORD, OTHER	1 (0.4%)	1 (0.2%)
BACK PAIN	0	9 (2.1%)
CERVICAL DISORD, OTHER	1 (0.4%)	6 (1.4%)
INTERVERTEB DISC, ABN	1 (0.4%)	5 (1.2%)
NEURALGIA, BACK	0	6 (1.4%)
PAIN, NECK	1 (0.4%)	1 (0.2%)
SPONDYLOPATHY, INFLAM	1 (0.4%)	0
SPONDYLOSIS	6 (2.6%)	14 (3.3%)
OSTEO/CHROND/ACQ MUSC DEFORM	2 (0.9%)	13 (3.0%)
BONE DEFORM, OTHER	1 (0.4%)	0
BONE	0	8 (1.9%)
/CARTIL DISORD, OTHER		
DEFORMITY, ACQUIRED	1 (0.4%)	6 (1.4%)
RHEUMATISM, EXCLUDING THE BACK	7 (3.1%)	16 (3.7%)
CRAMP, LIMB	1 (0.4%)	1 (0.2%)
JOINT DISORD, OTHER	1 (0.4%)	1 (0.2%)
LIMB, DISORD	0	2 (0.5%)
LIMB, WEAKNESS	1 (0.4%)	0
MYALGIA	1 (0.4%)	0
PAIN, LIMB	1 (0.4%)	4 (0.9%)
RHEUMATIC DISORD	2 (0.9%)	5 (1.2%)
RHEUMATISM	0	1 (0.2%)
SOFT TISSUE DISORD	1 (0.4%)	2 (0.5%)
NEOPLASMS		
BENIGN	2 (0.9%)	3 (0.7%)
NEOPLASMS BENIGN	2 (0.9%)	3 (0.7%)
MALIG BONE/TISSUE/SKIN/BREAST	1 (0.4%)	0
NEOPLASM MALIG, BREAST	1 (0.4%)	0
MALIG GENITOURINARY ORGANS	1 (0.4%)	1 (0.2%)
NEOPLASM MALIG, GU	1 (0.4%)	1 (0.2%)
MALIG LYMPHATIC/HEMAT TISSUE	0	1 (0.2%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
NEOPLASM MALIG, LYMPH /HEMAT	0	1 (0.2%)
MALIG NEOPLASM OTHER/UNSP	1 (0.4%)	0
NEOPLASM MALIG, OTHER SITES	1 (0.4%)	0
UNCERTAIN BEHAVIOR	0	2 (0.5%)
NEOPLASMS, UNCERT BEHAV	0	2 (0.5%)
UNSP NATURE	0	1 (0.2%)
NEOPLASM, UNSPEC	0	1 (0.2%)
NERVOUS SYST/SENSE ORGAN DIS		
CENTRAL NERVOUS SYST DISORD	0	6 (1.4%)
EPILEPSY	0	3 (0.7%)
MIGRAINE	0	2 (0.5%)
MULTIPLE SCLEROSIS	0	1 (0.2%)
EAR/MASTOID PROCESS	9 (3.9%)	12 (2.8%)
EAR	3 (1.3%)	1 (0.2%)
/MASTOID DISORD		
HEARING LOSS	5 (2.2%)	6 (1.4%)
TINNITUS	2 (0.9%)	6 (1.4%)
VESTIBULAR DISORD	0	1 (0.2%)
EYE/ADNEXA	34 (14.8%)	29 (6.7%)
BLINDNESS	2 (0.9%)	0
CATARACT	5 (2.2%)	5 (1.2%)
CONJUNCTIVAL DISORD	1 (0.4%)	0
EYE DISORD, OTHER	2 (0.9%)	3 (0.7%)
GLAUCOMA	7 (3.1%)	16 (3.7%)
RETINAL DISORD	3 (1.3%)	2 (0.5%)
RETINOPATHY	14 (6.1%)	1 (0.2%)
RETINOPATHY, DIABETIC	6 (2.6%)	1 (0.2%)
RETINOPATHY, VASCULAR	1 (0.4%)	0
VISUAL DISTURB	0	2 (0.5%)
HEREDITARY/DEGEN DIS (CNS)	4 (1.7%)	6 (1.4%)
AUT NERV SYST DISORD	2 (0.9%)	3 (0.7%)
EXTRAPYRAMID DISORD	1 (0.4%)	1 (0.2%)
PARKINSON'S DIS	1 (0.4%)	1 (0.2%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
SPINAL CORD DIS	0	1 (0.2%)
PERIPHERAL NERVOUS SYST DISORD	14 (6.1%)	8 (1.9%)
PERIPH NERV SYST DISORD	14 (6.1%)	8 (1.9%)
OPERATIONS		
CARDIOVASCULAR SYST	1 (0.4%)	0
OPERATION, OTHER HEART	1 (0.4%)	0
DIGESTIVE SYST	1 (0.4%)	0
OPERATION, APPENDIX	1 (0.4%)	0
ENDOCRINE SYST	1 (0.4%)	1 (0.2%)
OPERATION, ENDOCR	1 (0.4%)	1 (0.2%)
FEMALE GENITAL ORGANS	0	1 (0.2%)
OPERATION, FEM GENITAL	0	1 (0.2%)
INTEGUMENTARY SYST	1 (0.4%)	0
OPERATION, BREAST	1 (0.4%)	0
MUSCULOSKELETAL SYST	1 (0.4%)	2 (0.5%)
OPERATION, BONE /JOINT	1 (0.4%)	2 (0.5%)
PROCEDURES		
DIAGNOSTIC/THERAPEUTIC	2 (0.9%)	0
PROCEDURE, NUCLEAR MEDICINE	1 (0.4%)	0
RADIOLOGY, DIAGNOSTIC	1 (0.4%)	0
RESPIRATORY SYST DIS		
ACUTE RESPIRATORY INFECTIONS	1 (0.4%)	1 (0.2%)
BRONCHITIS, ACUTE	0	1 (0.2%)
NASOPHARYNGITIS, ACUTE	1 (0.4%)	0
CHRONIC OBSTRUCT PULMONARY DIS	7 (3.1%)	27 (6.3%)
ASTHMA	4 (1.7%)	13 (3.0%)
BRONCHITIS, CHRONIC	2 (0.9%)	10 (2.3%)
BRONCHITIS, OTHER	0	2 (0.5%)
EMPHYSEMA	0	3 (0.7%)
LUNG DIS, OBSTRUCTIVE	0	2 (0.5%)
RESP DIS, OTHER	1 (0.4%)	0

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
OTHER RESPIRATORY SYST DIS	2 (0.9%)	8 (1.9%)
LUNG DIS, OTHER	2 (0.9%)	4 (0.9%)
PLEURISY	0	3 (0.7%)
RESP DIS, OTHER	0	1 (0.2%)
UPPER RESPIRATORY TRACT DIS	2 (0.9%)	8 (1.9%)
NASAL POLYPS	1 (0.4%)	2 (0.5%)
RHINITIS, ALLERGIC	0	2 (0.5%)
SINUSITIS, CHRONIC	0	1 (0.2%)
SINUSITIS, OTHER	0	3 (0.7%)
SINUSITIS,NOS	1 (0.4%)	0
SIGNS,SYMPTOMS,ILL-DEFINED CON		
ABNORMAL FINDINGS	7 (3.1%)	39 (9.1%)
ALK PHOS ELEVATED, SERUM	0	1 (0.2%)
CARDIOVAS FUNCTIONS	1 (0.4%)	2 (0.5%)
/ECG, ABN		
PROTEINURIA	1 (0.4%)	4 (0.9%)
RADIOLOGY INTRATHORACIC, ABN	1 (0.4%)	4 (0.9%)
RADIOLOGY LUNG, ABN	0	3 (0.7%)
RBC'S, ABN	1 (0.4%)	0
REFLEX, ABN	0	3 (0.7%)
SED RATE, ELEVATED	0	1 (0.2%)
SERUM URIC ACID, DECREASED	0	1 (0.2%)
SERUM URIC ACID, ELEVATED	3 (1.3%)	19 (4.4%)
TRANSAMINASE	0	6 (1.4%)
/LDH, ELEVATION		
URINARY CASTS	0	2 (0.5%)
/WBC'S		
ILL-DEFINED COND	0	6 (1.4%)
ARREST, RESP	0	1 (0.2%)
CACHEXIA	0	1 (0.2%)
NERVOUSNESS	0	3 (0.7%)
SENILITY	0	1 (0.2%)
SYMPTOMS	24 (10.5%)	54 (12.6%)
APNEA	0	1 (0.2%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
CARDIOVASCULAR SYMPTOMS, OTHER	2 (0.9%)	1 (0.2%)
COUGH	0	2 (0.5%)
DIARRHEA	1 (0.4%)	1 (0.2%)
DISTURBANCE, SLEEP, UNSPEC	0	9 (2.1%)
DISTURBANCE, VOICE	0	1 (0.2%)
DIZZINESS AND GIDDINESS	3 (1.3%)	7 (1.6%)
DYSURIA	1 (0.4%)	0
EDEMA	2 (0.9%)	3 (0.7%)
FLUSHING	0	1 (0.2%)
HEADACHE	2 (0.9%)	2 (0.5%)
HEARTBURN	0	2 (0.5%)
HEPATOMEGALY	0	1 (0.2%)
HYPOESTHESIA	0	1 (0.2%)
INCONTINENCE, FECAL	0	1 (0.2%)
INCONTINENCE, URINARY	2 (0.9%)	0
INSOMNIA	7 (3.1%)	21 (4.9%)
LYMPHADENOPATHY	0	1 (0.2%)
MALAISE AND FATIGUE	1 (0.4%)	1 (0.2%)
MENTAL STATUS, IMPAIRED	0	2 (0.5%)
PAIN UNSP, CHEST	0	1 (0.2%)
PAIN, ABDOMINO-PELVIC	1 (0.4%)	2 (0.5%)
PAIN, GENERAL	1 (0.4%)	0
PALPITATIONS	1 (0.4%)	0
PARESTHESIA	0	1 (0.2%)
POLYURIA	0	1 (0.2%)
RESP CHEST SOUNDS, ABN	0	1 (0.2%)
TACHYCARDIA, UNSPEC	0	1 (0.2%)
TREMOR	0	1 (0.2%)
WEAKNESS	0	1 (0.2%)
SKIN/SUBCUTANEOUS TISSUE DIS		
OTHER INFLAM COND OF TISSUE	7 (3.1%)	19 (4.4%)
INFLAM SKIN	7 (3.1%)	17 (4.0%)
/SUBCUT		
PRURITUS DISORD, UNSPEC	0	2 (0.5%)

Data Source Table 13.4.1a

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Any Conditions	188 (82.1%)	358 (83.3%)
Disease Code Level 1		
Disease Code Level 2		
Preferred Term		
OTHER TISSUE DIS	0	3 (0.7%)
SCARRING	0	2 (0.5%)
SKIN	0	1 (0.2%)
/SUBCUT DISORD, OTHER		
TISSUE INFECTIONS	1 (0.4%)	0
CELLULITIS	1 (0.4%)	0
/ABSCESS		

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
ANOMALIES			
CONGENITAL	1 (1.6%)	0	0
CONG ANOM, GU	1 (1.6%)	0	0
BLOOD/BLOOD FORMING ORGAN DIS			
BLOOD, OTHER	0	0	2 (2.2%)
BLOOD DIS, OTHER	0	0	0
ERYTHROCYTOSIS	0	0	1 (1.1%)
POLYCYTHEMIA	0	0	1 (1.1%)
DEFICIENCY ANEMIAS, OTHER	0	0	0
ANEMIA, PERNICIOUS	0	0	0
HEREDITARY HEMOLYTIC ANEMIAS	0	0	0
ANEMIA, HEMOLYT, HERED	0	0	0
WHITE BLOOD CELL	1 (1.6%)	0	1 (1.1%)
EOSINOPHILIA	0	0	1 (1.1%)
LEUCOCYTOSIS	0	0	0
LEUKOPENIA	1 (1.6%)	0	0
THROMBOCYTHEMIA	0	0	0
CIRCULATORY SYST			
ARTERY/ARTERIOLE/CAPILLARY DIS	0	1 (1.3%)	8 (8.9%)
ARTERIAL DISORD, OTHER	0	0	3 (3.3%)
ARTERITIS	0	0	1 (1.1%)
ATHEROSCLEROSIS	0	0	1 (1.1%)
PERIPH VASCULAR DIS	0	1 (1.3%)	5 (5.6%)
POLYARTERITIS NODOSA	0	0	0
CEREBROVASCULAR DIS	0	2 (2.6%)	0
CEREBROVASCULAR DIS	0	0	0
PRECEREBRAL ARTERY OCCLUSION	0	2 (2.6%)	0
TRANSIENT CEREBRAL ISCHEMIA	0	0	0
CHRONIC RHEUMATIC HEART	0	0	0
RHEUMATIC HEART DIS	0	0	0
HYPERTENSIVE DIS	21 (34.4%)	29 (37.2%)	44 (48.9%)
ESSENTIAL HYPERTENSION	0	0	0
HYPERTENSION	21 (34.4%)	29 (37.2%)	44 (48.9%)
HYPERTENSIVE HEART DIS	0	1 (1.3%)	0
ISCHEMIC HEART	9 (14.8%)	13 (16.7%)	15 (16.7%)
ANGINA PECTORIS	6 (9.8%)	5 (6.4%)	10 (11.1%)

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
ANGINA PECTORIS, UNSTABLE	0	0	0
ATHEROSCLEROSIS, HEART	0	0	0
ISCHEMIC HEART DIS	5 (8.2%)	12 (15.4%)	7 (7.8%)
MYOCARDIAL INFARCTION	0	0	0
OTHER FORMS OF HEART DIS	2 (3.3%)	5 (6.4%)	10 (11.1%)
AORTIC VALVE DISORD	0	0	1 (1.1%)
ARRHYTHMIA	0	0	0
AV BLOCK	1 (1.6%)	2 (2.6%)	2 (2.2%)
BRADYCARDIA	1 (1.6%)	0	2 (2.2%)
CARDIOMEGALY	1 (1.6%)	2 (2.6%)	3 (3.3%)
CARDIOMYOPATHY, PRIMARY	0	0	0
CONDUCTION DISORD	0	1 (1.3%)	0
FIBRILLATION	0	0	0
FIBRILLATION, ATRIAL	0	0	1 (1.1%)
HEART DIS, OTHER	0	0	0
HEART FAILURE	0	1 (1.3%)	1 (1.1%)
MITRAL VALVE DISORD	0	1 (1.3%)	0
VEINS/LYMPH/CIRC SYST DIS	5 (8.2%)	6 (7.7%)	5 (5.6%)
CIRCULATORY SYST DISORD	4 (6.6%)	3 (3.8%)	4 (4.4%)
HEMORRHOIDS	0	0	1 (1.1%)
LYMPH CHANNEL DIS	0	1 (1.3%)	0
PHLEBITIS	0	0	0
VARICES	1 (1.6%)	2 (2.6%)	0
DIGESTIVE SYST			
ESOPHAGUS/STOMACH/DUODENUM DIS	3 (4.9%)	5 (6.4%)	6 (6.7%)
DYSPEPSIA	1 (1.6%)	2 (2.6%)	5 (5.6%)
ESOPHAGITIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
ESOPHAGUS DIS	0	1 (1.3%)	0
GASTRITIS	0	1 (1.3%)	0
/DUODENITIS			
STOMACH	1 (1.6%)	0	0
/DUODENUM DISORD			
ULCER, DUODENAL	0	1 (1.3%)	0
ULCER, PEPTIC, OTHER	0	1 (1.3%)	0
HERNIA OF ABDOMINAL CAVITY	3 (4.9%)	0	0
HERNIA, ABDOMINAL	3 (4.9%)	0	0
NONINFECT ENTERITIS/COLITIS	0	0	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
ENTERITIS	0	0	0
/COLITIS			
ORAL CAV/SALIV GLAND/JAW DIS	0	0	0
DRY MOUTH	0	0	0
TEETH DISORD	0	0	0
OTHER DIGESTIVE SYST DISORD	2 (3.3%)	3 (3.8%)	2 (2.2%)
CHOLELITHIASIS	0	0	0
GALLBLADDER DISORD, OTHER	0	1 (1.3%)	0
HEPATITIS	0	0	1 (1.1%)
HEPATOBIL DIS	1 (1.6%)	0	1 (1.1%)
INTEST MALABSORPTION	0	1 (1.3%)	0
LIVER DISORD	1 (1.6%)	1 (1.3%)	0
PANCREAS DISORD	0	0	0
OTHER INTESTINE/PERITONEUM DIS	1 (1.6%)	7 (9.0%)	3 (3.3%)
CONSTIPATION	0	3 (3.8%)	0
DIGESTIVE DISORD, OTHER	0	3 (3.8%)	3 (3.3%)
DIVERTICULITIS	1 (1.6%)	1 (1.3%)	0
ENDOCR/METAB/IMMUNITY DISORD			
ENDOCRINE GLANDS, OTHER	1 (1.6%)	0	1 (1.1%)
DIABETES MELLITUS	0	0	1 (1.1%)
ENDOCR DISORD, OTHER	0	0	0
GASTRIN SECRET, ABN	1 (1.6%)	0	0
HYPERALDOSTERONISM	0	0	0
HYPERPARATHYROIDISM	0	0	0
PITUITARY DISORD	0	0	0
METABOLIC/IMMUNITY, OTHER	16 (26.2%)	24 (30.8%)	38 (42.2%)
CHOLEST	9 (14.8%)	11 (14.1%)	25 (27.8%)
/TRIGLYCERIDE, ELEVATED			
GOUT	1 (1.6%)	1 (1.3%)	0
HYPERLIPEMIA	5 (8.2%)	10 (12.8%)	11 (12.2%)
LIPID METAB DISORD	1 (1.6%)	2 (2.6%)	3 (3.3%)
MINERAL METAB DISORD	0	0	0
OBESITY	1 (1.6%)	2 (2.6%)	2 (2.2%)
SERUM POTASSIUM, DECREASED	0	0	0
NUTRITIONAL DEFICIENCIES	0	0	0
VITAMIN B DEFIC	0	0	0
VITAMIN D DEFIC	0	0	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
THYROID GLAND	4 (6.6%)	2 (2.6%)	1 (1.1%)
GOITER	1 (1.6%)	2 (2.6%)	0
HYPERTHYROIDISM	1 (1.6%)	0	0
HYPOTHYROIDISM	1 (1.6%)	0	1 (1.1%)
THYROIDITIS	1 (1.6%)	0	0
EXT CAUSES OF INJURY/POISONING			
ADV EFF, THERAP DRUG/BIOLOGIC	0	1 (1.3%)	0
ADVERSE EFF	0	1 (1.3%)	0
/ANTIBIOTIC			
ADVERSE EFF	0	0	0
/BL CONSTITUENT			
ADVERSE EFF	0	0	0
/METAB DRUG			
ADVERSE EFF	0	0	0
/PSYCHOTROPICS			
FAMILY/PERSONAL HISTORY			
HEALTH SERV(AFTCARE/SP PROCED)	0	1 (1.3%)	1 (1.1%)
UNCLASSIFIABLE	0	1 (1.3%)	1 (1.1%)
HEALTH STATUS COND	0	0	0
STATUS, POSTSURGICAL	0	0	0
GENITOURINARY SYST DIS			
BREAST DISORD	0	2 (2.6%)	0
BREAST DISORD	0	2 (2.6%)	0
FEMALE PELVIC ORG, INFLAMM DIS	0	0	0
VAGINITIS	0	0	0
MALE GENITAL ORGAN DIS	1 (1.6%)	1 (1.3%)	0
GENITAL MALE DISORD, OTHER	0	0	0
PROSTATE DISORD	1 (1.6%)	1 (1.3%)	0
NEPHRITIS/NEPH SYND/NEPHROSIS	0	1 (1.3%)	0
RENAL FAILURE	0	1 (1.3%)	0
OTHER FEM GENITAL TRACT DISORD	1 (1.6%)	0	4 (4.4%)
GENITAL FEMALE DISORD, OTHER	0	0	1 (1.1%)
INCONTINENCE, STRESS	0	0	1 (1.1%)
MENOPAUSAL STATES	1 (1.6%)	0	2 (2.2%)
OTHER URINARY SYST DIS	2 (3.3%)	2 (2.6%)	4 (4.4%)

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
CYSTITIS	0	0	1 (1.1%)
HEMATURIA	0	0	1 (1.1%)
KIDNEY DISORD	0	0	1 (1.1%)
KIDNEY	0	1 (1.3%)	1 (1.1%)
/URETER, CALCULUS			
RENAL FUNCTION ABN	0	0	1 (1.1%)
URETHRAL DISORD	0	0	1 (1.1%)
URINARY TRACT INFECTION	2 (3.3%)	1 (1.3%)	1 (1.1%)
INFECTIOUS/PARASITIC DIS			
MYCOSES	0	1 (1.3%)	1 (1.1%)
MYCOSES	0	1 (1.3%)	1 (1.1%)
RICKETTSIOSES/ARTHROPOD-BORNE	0	0	0
ARTHROPOD-BORNE DIS, OTHER	0	0	0
SYPHILIS/VENEREAL	0	0	0
VENEREAL DIS	0	0	0
VIRAL DIS	0	0	1 (1.1%)
VIRAL DIS	0	0	1 (1.1%)
/EXANTHEM			
VIRUSES/CHLAMYDIAE	0	0	0
HEPATITIS, VIRAL	0	0	0
VIRUS	0	0	0
/CHLAMYD DIS, OTHER			
INJURY/POISONING			
FRACTURES	0	0	1 (1.1%)
FRACTURE, NECK	0	0	1 (1.1%)
/TRUNK			
UNSP EFF OF EXTERNAL CAUSES	0	0	0
ADVERSE EFF	0	0	0
/OTHER			
ALLERGY, NEC	0	0	0
INJURY	0	0	0
/POIS, OTHER			
UPPER LIMB	0	0	1 (1.1%)
TRAUMATIC AMPUTATION	0	0	1 (1.1%)
MENTAL DISORD			

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
NEUROTIC/PERSONALITY/NONPSY	8 (13.1%)	3 (3.8%)	10 (11.1%)
ALCOHOL ABUSE	0	0	1 (1.1%)
ANXIETY	1 (1.6%)	0	4 (4.4%)
DEPRESSION	3 (4.9%)	2 (2.6%)	1 (1.1%)
IMPOTENCE	5 (8.2%)	1 (1.3%)	5 (5.6%)
NEUROSES	0	0	0
SEXUAL DYSFUNCTION	0	0	0
SCHIZOPHRENIC DISORD	0	0	0
PSYCHOSES, AFFECTIVE	0	0	0
PSYCHOSES, OTHER	0	0	0
SCHIZOPHRENIA	0	0	0
MUSCULOSKEL/CONNECT TISSUE DIS			
ARTHROPATHIES/RELATED DISORD	6 (9.8%)	15 (19.2%)	9 (10.0%)
ARTHRITIS, RHEUMATOID	0	0	0
ARTHROPATHY	3 (4.9%)	3 (3.8%)	1 (1.1%)
JOINT DISORD, OTHER	0	0	0
OSTEOARTHRITIS	3 (4.9%)	12 (15.4%)	7 (7.8%)
PAIN, JOINT	0	0	1 (1.1%)
DORSOPATHIES	1 (1.6%)	4 (5.1%)	4 (4.4%)
BACK DISORD, OTHER	0	1 (1.3%)	0
BACK PAIN	0	0	0
CERVICAL DISORD, OTHER	0	1 (1.3%)	0
INTERVERTEB DISC, ABN	0	0	1 (1.1%)
NEURALGIA, BACK	0	0	0
PAIN, NECK	0	0	1 (1.1%)
SPONDYLOPATHY, INFLAM	0	0	1 (1.1%)
SPONDYLOSIS	1 (1.6%)	4 (5.1%)	1 (1.1%)
OSTEO/CHOND/ACQ MUSC DEFORM	0	1 (1.3%)	1 (1.1%)
BONE DEFORM, OTHER	0	1 (1.3%)	0
BONE	0	0	0
/CARTIL DISORD, OTHER	0	0	1 (1.1%)
DEFORMITY, ACQUIRED	0	0	1 (1.1%)
RHEUMATISM, EXCLUDING THE BACK	3 (4.9%)	3 (3.8%)	0
CRAMP, LIMB	0	1 (1.3%)	0
JOINT DISORD, OTHER	0	1 (1.3%)	0
LIMB, DISORD	0	0	0
LIMB, WEAKNESS	0	1 (1.3%)	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
MYALGIA	0	1 (1.3%)	0
PAIN, LIMB	1 (1.6%)	0	0
RHEUMATIC DISORD	1 (1.6%)	0	1 (1.1%)
RHEUMATISM	0	0	0
SOFT TISSUE DISORD	1 (1.6%)	0	0
NEOPLASMS			
BENIGN	1 (1.6%)	1 (1.3%)	0
NEOPLASMS BENIGN	1 (1.6%)	1 (1.3%)	0
MALIG BONE/TISSUE/SKIN/BREAST	0	0	1 (1.1%)
NEOPLASM MALIG, BREAST	0	0	1 (1.1%)
MALIG GENITOURINARY ORGANS	0	0	1 (1.1%)
NEOPLASM MALIG, GU	0	0	1 (1.1%)
MALIG LYMPHATIC/HEMAT TISSUE	0	0	0
NEOPLASM MALIG, LYMPH	0	0	0
/HEMAT			
MALIG NEOPLASM OTHER/UNSP	0	0	1 (1.1%)
NEOPLASM MALIG, OTHER SITES	0	0	1 (1.1%)
UNCERTAIN BEHAVIOR	0	0	0
NEOPLASMS, UNCERT BEHAV	0	0	0
UNSP NATURE	0	0	0
NEOPLASM, UNSPEC	0	0	0
NERVOUS SYST/SENSE ORGAN DIS			
CENTRAL NERVOUS SYST DISORD	0	0	0
EPILEPSY	0	0	0
MIGRAINE	0	0	0
MULTIPLE SCLEROSIS	0	0	0
EAR/MASTOID PROCESS	1 (1.6%)	4 (5.1%)	4 (4.4%)
EAR	0	2 (2.6%)	1 (1.1%)
/MASTOID DISORD			
HEARING LOSS	1 (1.6%)	2 (2.6%)	2 (2.2%)
TINNITUS	0	0	2 (2.2%)
VESTIBULAR DISORD	0	0	0
EYE/ADNEXA	13 (21.3%)	12 (15.4%)	9 (10.0%)
BLINDNESS	0	1 (1.3%)	1 (1.1%)
CATARACT	4 (6.6%)	1 (1.3%)	0
CONJUNCTIVAL DISORD	0	1 (1.3%)	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
EYE DISORD, OTHER	1 (1.6%)	0	1 (1.1%)
GLAUCOMA	3 (4.9%)	4 (5.1%)	0
RETINAL DISORD	1 (1.6%)	2 (2.6%)	0
RETINOPATHY	6 (9.8%)	5 (6.4%)	3 (3.3%)
RETINOPATHY, DIABETIC	1 (1.6%)	2 (2.6%)	3 (3.3%)
RETINOPATHY, VASCULAR	0	0	1 (1.1%)
VISUAL DISTURB	0	0	0
HEREDITARY/DEGEN DIS (CNS)	2 (3.3%)	2 (2.6%)	0
AUT NERV SYST DISORD	1 (1.6%)	1 (1.3%)	0
EXTRAPYRAMID DISORD	1 (1.6%)	0	0
PARKINSON'S DIS	0	1 (1.3%)	0
SPINAL CORD DIS	0	0	0
PERIPHERAL NERVOUS SYST DISORD	4 (6.6%)	6 (7.7%)	4 (4.4%)
PERIPH NERV SYST DISORD	4 (6.6%)	6 (7.7%)	4 (4.4%)
OPERATIONS			
CARDIOVASCULAR SYST	0	1 (1.3%)	0
OPERATION, OTHER HEART	0	1 (1.3%)	0
DIGESTIVE SYST	0	0	1 (1.1%)
OPERATION, APPENDIX	0	0	1 (1.1%)
ENDOCRINE SYST	0	1 (1.3%)	0
OPERATION, ENDOCR	0	1 (1.3%)	0
FEMALE GENITAL ORGANS	0	0	0
OPERATION, FEM GENITAL	0	0	0
INTEGUMENTARY SYST	0	0	1 (1.1%)
OPERATION, BREAST	0	0	1 (1.1%)
MUSCULOSKELETAL SYST	0	0	1 (1.1%)
OPERATION, BONE /JOINT	0	0	1 (1.1%)
PROCEDURES			
DIAGNOSTIC/THERAPEUTIC	0	0	2 (2.2%)
PROCEDURE, NUCLEAR MEDICINE	0	0	1 (1.1%)
RADIOLOGY, DIAGNOSTIC	0	0	1 (1.1%)
RESPIRATORY SYST DIS			
ACUTE RESPIRATORY INFECTIONS	0	0	1 (1.1%)
BRONCHITIS, ACUTE	0	0	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
NASOPHARYNGITIS, ACUTE	0	0	1 (1.1%)
CHRONIC OBSTRUCT PULMONARY DIS	0	3 (3.8%)	4 (4.4%)
ASTHMA	0	2 (2.6%)	2 (2.2%)
BRONCHITIS, CHRONIC	0	1 (1.3%)	1 (1.1%)
BRONCHITIS, OTHER	0	0	0
EMPHYSEMA	0	0	0
LUNG DIS, OBSTRUCTIVE	0	0	0
RESP DIS, OTHER	0	0	1 (1.1%)
OTHER RESPIRATORY SYST DIS	1 (1.6%)	0	1 (1.1%)
LUNG DIS, OTHER	1 (1.6%)	0	1 (1.1%)
PLEURISY	0	0	0
RESP DIS, OTHER	0	0	0
UPPER RESPIRATORY TRACT DIS	0	2 (2.6%)	0
NASAL POLYPS	0	1 (1.3%)	0
RHINITIS, ALLERGIC	0	0	0
SINUSITIS, CHRONIC	0	0	0
SINUSITIS, OTHER	0	0	0
SINUSITIS,NOS	0	1 (1.3%)	0
SIGNS,SYMPTOMS,ILL-DEFINED CON			
ABNORMAL FINDINGS	1 (1.6%)	2 (2.6%)	4 (4.4%)
ALK PHOS ELEVATED, SERUM	0	0	0
CARDIOVAS FUNCTIONS	0	1 (1.3%)	0
/ECG, ABN			
PROTEINURIA	0	0	1 (1.1%)
RADIOLOGY INTRATHORACIC, ABN	1 (1.6%)	0	0
RADIOLOGY LUNG, ABN	0	0	0
RBC'S, ABN	0	0	1 (1.1%)
REFLEX, ABN	0	0	0
SED RATE, ELEVATED	0	0	0
SERUM URIC ACID, DECREASED	0	0	0
SERUM URIC ACID, ELEVATED	0	1 (1.3%)	2 (2.2%)
TRANSAMINASE	0	0	0
/LDH, ELEVATION			
URINARY CASTS	0	0	0
/WBC'S			
ILL-DEFINED COND	0	0	0
ARREST, RESP	0	0	0

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
CACHEXIA	0	0	0
NERVOUSNESS	0	0	0
SENILITY	0	0	0
SYMPTOMS	2 (3.3%)	12 (15.4%)	10 (11.1%)
APNEA	0	0	0
CARDIOVASCULAR SYMPTOMS, OTHER	0	2 (2.6%)	0
COUGH	0	0	0
DIARRHEA	0	1 (1.3%)	0
DISTURBANCE, SLEEP, UNSPEC	0	0	0
DISTURBANCE, VOICE	0	0	0
DIZZINESS AND GIDDINESS	1 (1.6%)	1 (1.3%)	1 (1.1%)
DYSURIA	0	1 (1.3%)	0
EDEMA	0	1 (1.3%)	1 (1.1%)
FLUSHING	0	0	0
HEADACHE	0	1 (1.3%)	1 (1.1%)
HEARTBURN	0	0	0
HEPATOMEGALY	0	0	0
HYPOESTHESIA	0	0	0
INCONTINENCE, FECAL	0	0	0
INCONTINENCE, URINARY	0	0	2 (2.2%)
INSOMNIA	1 (1.6%)	3 (3.8%)	3 (3.3%)
LYMPHADENOPATHY	0	0	0
MALaise AND FATIGUE	0	0	1 (1.1%)
MENTAL STATUS, IMPAIRED	0	0	0
PAIN UNSP, CHEST	0	0	0
PAIN, ABDOMINO-PELVIC	0	1 (1.3%)	0
PAIN, GENERAL	0	0	1 (1.1%)
PALPITATIONS	0	1 (1.3%)	0
PARESTHESIA	0	0	0
POLYURIA	0	0	0
RESP CHEST SOUNDS, ABN	0	0	0
TACHYCARDIA, UNSPEC	0	0	0
TREMOR	0	0	0
WEAKNESS	0	0	0
SKIN/SUBCUTANEOUS TISSUE DIS			
OTHER INFLAM COND OF TISSUE	4 (6.6%)	0	3 (3.3%)

Data Source Table 13.4.1b

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Any Conditions	49 (80.3%)	61 (78.2%)	78 (86.7%)
Disease Code Level 1			
Disease Code Level 2			
Preferred Term			
INFLAM SKIN	4 (6.6%)	0	3 (3.3%)
/SUBCUT			
PRURITUS DISORD, UNSPEC	0	0	0
OTHER TISSUE DIS	0	0	0
SCARRING	0	0	0
SKIN	0	0	0
/SUBCUT DISORD, OTHER			
TISSUE INFECTIONS	0	1 (1.3%)	0
CELLULITIS	0	1 (1.3%)	0
/ABSCESS			

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
ANOMALIES				
CONGENITAL	0	2 (1.5%)	0	0
CONG ANOM, GU	0	2 (1.5%)	0	0
BLOOD/BLOOD FORMING ORGAN DIS				
BLOOD, OTHER	0	0	1 (0.7%)	0
BLOOD DIS, OTHER	0	0	1 (0.7%)	0
ERYTHROCYTOSIS	0	0	0	0
POLYCYTHEMIA	0	0	0	0
DEFICIENCY ANEMIAS, OTHER	1 (0.8%)	0	0	0
ANEMIA, PERNICIOUS	1 (0.8%)	0	0	0
HEREDITARY HEMOLYTIC ANEMIAS	0	1 (0.7%)	1 (0.7%)	2 (6.7%)
ANEMIA, HEMOLYT, HERED	0	1 (0.7%)	1 (0.7%)	2 (6.7%)
WHITE BLOOD CELL	1 (0.8%)	3 (2.2%)	0	0
EOSINOPHILIA	0	2 (1.5%)	0	0
LEUCOCYTOSIS	1 (0.8%)	0	0	0
LEUKOPENIA	0	0	0	0
THROMBOCYTHEMIA	0	1 (0.7%)	0	0
CIRCULATORY SYST				
ARTERY/ARTERIOLE/CAPILLARY DIS	3 (2.4%)	5 (3.7%)	5 (3.6%)	1 (3.3%)
ARTERIAL DISORD, OTHER	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
ARTERITIS	1 (0.8%)	0	2 (1.4%)	0
ATHEROSCLEROSIS	1 (0.8%)	0	0	0
PERIPH VASCULAR DIS	1 (0.8%)	3 (2.2%)	1 (0.7%)	1 (3.3%)
POLYARTERITIS NODOSA	0	0	1 (0.7%)	0
CEREBROVASCULAR DIS	2 (1.6%)	5 (3.7%)	1 (0.7%)	0
CEREBROVASCULAR DIS	1 (0.8%)	4 (2.9%)	0	0
PRECEREBRAL ARTERY OCCLUSION	1 (0.8%)	0	1 (0.7%)	0
TRANSIENT CEREBRAL ISCHEMIA	0	1 (0.7%)	0	0
CHRONIC RHEUMATIC HEART	1 (0.8%)	0	0	0
RHEUMATIC HEART DIS	1 (0.8%)	0	0	0
HYPERTENSIVE DIS	54 (43.5%)	66 (48.5%)	58 (41.7%)	8 (26.7%)
ESSENTIAL HYPERTENSION	0	1 (0.7%)	1 (0.7%)	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
HYPERTENSION	54 (43.5%)	65 (47.8%)	57 (41.0%)	8 (26.7%)
HYPERTENSIVE HEART DIS	0	0	0	0
ISCHEMIC HEART	10 (8.1%)	16 (11.8%)	10 (7.2%)	0
ANGINA PECTORIS	1 (0.8%)	5 (3.7%)	2 (1.4%)	0
ANGINA PECTORIS, UNSTABLE	1 (0.8%)	0	0	0
ATHEROSCLEROSIS, HEART	0	1 (0.7%)	0	0
ISCHEMIC HEART DIS	8 (6.5%)	10 (7.4%)	8 (5.8%)	0
MYOCARDIAL INFARCTION	0	0	1 (0.7%)	0
OTHER FORMS OF HEART DIS	10 (8.1%)	11 (8.1%)	7 (5.0%)	0
AORTIC VALVE DISORD	1 (0.8%)	0	0	0
ARRHYTHMIA	1 (0.8%)	1 (0.7%)	0	0
AV BLOCK	0	0	0	0
BRADYCARDIA	0	0	0	0
CARDIOMEGALY	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
CARDIOMYOPATHY, PRIMARY	0	1 (0.7%)	0	0
CONDUCTION DISORD	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
FIBRILLATION	0	1 (0.7%)	0	0
FIBRILLATION, ATRIAL	3 (2.4%)	2 (1.5%)	3 (2.2%)	0
HEART DIS, OTHER	0	1 (0.7%)	0	0
HEART FAILURE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
MITRAL VALVE DISORD	1 (0.8%)	0	0	0
VEINS/LYMPH/CIRC SYST DIS	16 (12.9%)	12 (8.8%)	8 (5.8%)	0
CIRCULATORY SYST DISORD	14 (11.3%)	10 (7.4%)	4 (2.9%)	0
HEMORRHOIDS	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
LYMPH CHANNEL DIS	0	0	0	0
PHLEBITIS	0	0	1 (0.7%)	0
VARICES	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
DIGESTIVE SYST				
ESOPHAGUS/STOMACH/DUODENUM DIS	10 (8.1%)	6 (4.4%)	8 (5.8%)	1 (3.3%)
DYSPEPSIA	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
ESOPHAGITIS	4 (3.2%)	0	2 (1.4%)	0
ESOPHAGUS DIS	1 (0.8%)	1 (0.7%)	1 (0.7%)	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
GASTRITIS	1 (0.8%)	3 (2.2%)	1 (0.7%)	1 (3.3%)
/DUODENITIS				
STOMACH	0	0	2 (1.4%)	0
/DUODENUM DISORD				
ULCER, DUODENAL	2 (1.6%)	0	2 (1.4%)	0
ULCER, PEPTIC, OTHER	1 (0.8%)	0	1 (0.7%)	0
HERNIA OF ABDOMINAL CAVITY	4 (3.2%)	3 (2.2%)	4 (2.9%)	0
HERNIA, ABDOMINAL	4 (3.2%)	3 (2.2%)	4 (2.9%)	0
NONINFECT ENTERITIS/COLITIS	0	1 (0.7%)	0	0
ENTERITIS	0	1 (0.7%)	0	0
/COLITIS				
ORAL CAV/SALIV GLAND/JAW DIS	0	1 (0.7%)	1 (0.7%)	0
DRY MOUTH	0	0	1 (0.7%)	0
TEETH DISORD	0	1 (0.7%)	0	0
OTHER DIGESTIVE SYST DISORD	5 (4.0%)	5 (3.7%)	3 (2.2%)	0
CHOLELITHIASIS	3 (2.4%)	1 (0.7%)	0	0
GALLBLADDER DISORD, OTHER	0	0	0	0
HEPATITIS	0	0	0	0
HEPATOBI DIS	2 (1.6%)	4 (2.9%)	2 (1.4%)	0
INTEST MALABSORPTION	0	0	0	0
LIVER DISORD	0	0	0	0
PANCREAS DISORD	0	0	1 (0.7%)	0
OTHER INTESTINE/PERITONEUM DIS	2 (1.6%)	3 (2.2%)	3 (2.2%)	1 (3.3%)
CONSTIPATION	0	2 (1.5%)	0	1 (3.3%)
DIGESTIVE DISORD, OTHER	1 (0.8%)	1 (0.7%)	0	0
DIVERTICULITIS	1 (0.8%)	0	3 (2.2%)	1 (3.3%)
ENDOCR/METAB/IMMUNITY DISORD				
ENDOCRINE GLANDS, OTHER	2 (1.6%)	3 (2.2%)	4 (2.9%)	0
DIABETES MELLITUS	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
ENDOCR DISORD, OTHER	0	0	1 (0.7%)	0
GASTRIN SECRET, ABN	0	0	0	0
HYPERALDOSTERONISM	0	1 (0.7%)	0	0
HYPERPARATHYROIDISM	0	0	1 (0.7%)	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
PITUITARY DISORD	0	1 (0.7%)	0	0
METABOLIC/IMMUNITY, OTHER	40 (32.3%)	45 (33.1%)	48 (34.5%)	4 (13.3%)
CHOLEST	20 (16.1%)	25 (18.4%)	26 (18.7%)	0
/TRIGLYCERIDE, ELEVATED				
GOUT	2 (1.6%)	2 (1.5%)	4 (2.9%)	0
HYPERLIPEMIA	9 (7.3%)	9 (6.6%)	10 (7.2%)	2 (6.7%)
LIPID METAB DISORD	6 (4.8%)	8 (5.9%)	7 (5.0%)	1 (3.3%)
MINERAL METAB DISORD	0	0	1 (0.7%)	0
OBESITY	4 (3.2%)	3 (2.2%)	2 (1.4%)	1 (3.3%)
SERUM POTASSIUM, DECREASED	0	0	1 (0.7%)	0
NUTRITIONAL DEFICIENCIES	1 (0.8%)	0	0	1 (3.3%)
VITAMIN B DEFIC	0	0	0	1 (3.3%)
VITAMIN D DEFIC	1 (0.8%)	0	0	0
THYROID GLAND	9 (7.3%)	5 (3.7%)	7 (5.0%)	0
GOITER	5 (4.0%)	1 (0.7%)	3 (2.2%)	0
HYPERTHYROIDISM	0	1 (0.7%)	0	0
HYPOTHYROIDISM	4 (3.2%)	3 (2.2%)	4 (2.9%)	0
THYROIDITIS	0	0	0	0
EXT CAUSES OF INJURY/POISONING				
ADV EFF, THERAP DRUG/BIOLOGIC	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
ADVERSE EFF	1 (0.8%)	1 (0.7%)	0	0
/ANTIBIOTIC				
ADVERSE EFF	0	0	1 (0.7%)	0
/BL CONSTITUENT				
ADVERSE EFF	1 (0.8%)	0	0	0
/METAB DRUG				
ADVERSE EFF	1 (0.8%)	0	0	0
/PSYCHOTROPICS				
FAMILY/PERSONAL HISTORY				
HEALTH SERV (AFTCARE/SP PROCED)	0	0	0	0
UNCLASSIFIABLE	0	0	0	0
HEALTH STATUS COND	0	1 (0.7%)	0	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
STATUS, POSTSURGICAL	0	1 (0.7%)	0	0
GENITOURINARY SYST DIS				
BREAST DISORD	0	0	0	0
BREAST DISORD	0	0	0	0
FEMALE PELVIC ORG, INFLAMM DIS	0	1 (0.7%)	0	0
VAGINITIS	0	1 (0.7%)	0	0
MALE GENITAL ORGAN DIS	7 (5.6%)	4 (2.9%)	8 (5.8%)	2 (6.7%)
GENITAL MALE DISORD, OTHER	0	1 (0.7%)	0	0
PROSTATE DISORD	7 (5.6%)	3 (2.2%)	8 (5.8%)	2 (6.7%)
NEPHRITIS/NEPH SYND/NEPHROSIS	0	0	0	0
RENAL FAILURE	0	0	0	0
OTHER FEM GENITAL TRACT DISORD	7 (5.6%)	6 (4.4%)	11 (7.9%)	0
GENITAL FEMALE DISORD, OTHER	1 (0.8%)	0	0	0
INCONTINENCE, STRESS	0	0	2 (1.4%)	0
MENOPAUSAL STATES	6 (4.8%)	6 (4.4%)	9 (6.5%)	0
OTHER URINARY SYST DIS	3 (2.4%)	5 (3.7%)	3 (2.2%)	3 (10.0%)
CYSTITIS	1 (0.8%)	0	1 (0.7%)	0
HEMATURIA	0	0	0	1 (3.3%)
KIDNEY DISORD	1 (0.8%)	0	2 (1.4%)	0
KIDNEY	0	2 (1.5%)	0	0
/URETER, CALCULUS				
RENAL FUNCTION ABN	0	0	0	0
URETHRAL DISORD	0	0	0	0
URINARY TRACT INFECTION	1 (0.8%)	3 (2.2%)	0	2 (6.7%)
INFECTIOUS/PARASITIC DIS				
MYCOSES	0	1 (0.7%)	0	0
MYCOSES	0	1 (0.7%)	0	0
RICKETTSIOSES/ARTHROPOD-BORNE	1 (0.8%)	0	0	0
ARTHROPOD-BORNE DIS, OTHER	1 (0.8%)	0	0	0
SYPHILIS/VENEREAL	1 (0.8%)	0	0	0
VENEREAL DIS	1 (0.8%)	0	0	0
VIRAL DIS	2 (1.6%)	0	0	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
VIRAL DIS	2 (1.6%)	0	0	0
/EXANTHEM				
VIRUSES/CHLAMYDIAE	0	2 (1.5%)	2 (1.4%)	0
HEPATITIS, VIRAL	0	1 (0.7%)	2 (1.4%)	0
VIRUS	0	1 (0.7%)	0	0
/CHLAMYD DIS, OTHER				
INJURY/POISONING				
FRACTURES	0	0	2 (1.4%)	0
FRACTURE, NECK	0	0	2 (1.4%)	0
/TRUNK				
UNSP EFF OF EXTERNAL CAUSES	0	1 (0.7%)	2 (1.4%)	0
ADVERSE EFF	0	0	1 (0.7%)	0
/OTHER				
ALLERGY, NEC	0	1 (0.7%)	0	0
INJURY	0	0	1 (0.7%)	0
/POIS, OTHER				
UPPER LIMB	0	0	0	0
TRAUMATIC AMPUTATION	0	0	0	0
MENTAL DISORD				
NEUROTIC/PERSONALITY/NONPSY	8 (6.5%)	3 (2.2%)	10 (7.2%)	2 (6.7%)
ALCOHOL ABUSE	0	0	0	0
ANXIETY	3 (2.4%)	2 (1.5%)	3 (2.2%)	1 (3.3%)
DEPRESSION	5 (4.0%)	1 (0.7%)	4 (2.9%)	0
IMPOTENCE	0	0	2 (1.4%)	0
NEUROSES	0	0	1 (0.7%)	0
SEXUAL DYSFUNCTION	0	0	0	1 (3.3%)
SCHIZOPHRENIC DISORD	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
PSYCHOSES, AFFECTIVE	0	0	1 (0.7%)	0
PSYCHOSES, OTHER	1 (0.8%)	0	0	0
SCHIZOPHRENIA	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
MUSCULOSKEL/CONNECT TISSUE DIS				

- 202 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
ARTHROPATHIES/RELATED DISORD	15 (12.1%)	19 (14.0%)	15 (10.8%)	0
ARTHROSITIS, RHEUMATOID	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
ARTHRORATHY	3 (2.4%)	2 (1.5%)	4 (2.9%)	0
JOINT DISORD, OTHER	0	1 (0.7%)	0	0
OSTEOARTHRORIS	11 (8.9%)	14 (10.3%)	9 (6.5%)	0
PAIN, JOINT	0	2 (1.5%)	1 (0.7%)	0
DORSOPATHIES	14 (11.3%)	14 (10.3%)	8 (5.8%)	1 (3.3%)
BACK DISORD, OTHER	0	0	1 (0.7%)	0
BACK PAIN	3 (2.4%)	3 (2.2%)	3 (2.2%)	0
CERVICAL DISORD, OTHER	1 (0.8%)	4 (2.9%)	1 (0.7%)	0
INTERVERTEB DISC, ABN	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
NEURALGIA, BACK	2 (1.6%)	4 (2.9%)	0	0
PAIN, NECK	1 (0.8%)	0	0	0
SPONDYLOPATHY, INFLAM	0	0	0	0
SPONDYLOSIS	7 (5.6%)	3 (2.2%)	3 (2.2%)	1 (3.3%)
OSTEO/CHROND/ACQ MUSC DEFORM	6 (4.8%)	3 (2.2%)	4 (2.9%)	0
BONE DEFORM, OTHER	0	0	0	0
BONE	5 (4.0%)	1 (0.7%)	2 (1.4%)	0
/CARTIL DISORD, OTHER				
DEFORMITY, ACQUIRED	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
RHEUMATISM, EXCLUDING THE BACK	2 (1.6%)	4 (2.9%)	7 (5.0%)	3 (10.0%)
CRAMP, LIMB	1 (0.8%)	0	0	0
JOINT DISORD, OTHER	0	0	0	1 (3.3%)
LIMB, DISORD	1 (0.8%)	0	0	1 (3.3%)
LIMB, WEAKNESS	0	0	0	0
MYALGIA	0	0	0	0
PAIN, LIMB	0	0	3 (2.2%)	1 (3.3%)
RHEUMATIC DISORD	0	2 (1.5%)	3 (2.2%)	0
RHEUMATISM	0	1 (0.7%)	0	0
SOFT TISSUE DISORD	0	1 (0.7%)	1 (0.7%)	0
NEOPLASMS				
BENIGN	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
NEOPLASMS BENIGN	1 (0.8%)	0	1 (0.7%)	1 (3.3%)

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
MALIG BONE/TISSUE/SKIN/BREAST	0	0	0	0
NEOPLASM MALIG, BREAST	0	0	0	0
MALIG GENITOURINARY ORGANS	0	0	1 (0.7%)	0
NEOPLASM MALIG, GU	0	0	1 (0.7%)	0
MALIG LYMPHATIC/HEMAT TISSUE	1 (0.8%)	0	0	0
NEOPLASM MALIG, LYMPH	1 (0.8%)	0	0	0
/HEMAT				
MALIG NEOPLASM OTHER/UNSP	0	0	0	0
NEOPLASM MALIG, OTHER SITES	0	0	0	0
UNCERTAIN BEHAVIOR	1 (0.8%)	1 (0.7%)	0	0
NEOPLASMS, UNCERT BEHAV	1 (0.8%)	1 (0.7%)	0	0
UNSP NATURE	0	0	0	1 (3.3%)
NEOPLASM, UNSPEC	0	0	0	1 (3.3%)
NERVOUS SYST/SENSE ORGAN DIS				
CENTRAL NERVOUS SYST DISORD				
EPILEPSY	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
MIGRAINE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
MULTIPLE SCLEROSIS	0	1 (0.7%)	1 (0.7%)	0
EAR/MASTOID PROCESS	0	0	1 (0.7%)	0
EAR	4 (3.2%)	2 (1.5%)	6 (4.3%)	0
/MASTOID DISORD	0	1 (0.7%)	0	0
HEARING LOSS	1 (0.8%)	1 (0.7%)	4 (2.9%)	0
TINNITUS	3 (2.4%)	0	3 (2.2%)	0
VESTIBULAR DISORD	0	0	1 (0.7%)	0
EYE/ADNEXA	7 (5.6%)	8 (5.9%)	11 (7.9%)	3 (10.0%)
BLINDNESS	0	0	0	0
CATARACT	0	1 (0.7%)	2 (1.4%)	2 (6.7%)
CONJUNCTIVAL DISORD	0	0	0	0
EYE DISORD, OTHER	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
GLAUCOMA	5 (4.0%)	4 (2.9%)	7 (5.0%)	0
RETINAL DISORD	0	0	1 (0.7%)	1 (3.3%)
RETINOPATHY	1 (0.8%)	0	0	0
RETINOPATHY, DIABETIC	0	1 (0.7%)	0	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
RETINOPATHY, VASCULAR	0	0	0	0
VISUAL DISTURB	0	2 (1.5%)	0	0
HEREDITARY/DEGEN DIS (CNS)	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
AUT NERV SYST DISORD	2 (1.6%)	1 (0.7%)	0	0
EXTRAPYRAMID DISORD	0	1 (0.7%)	0	0
PARKINSON'S DIS	0	1 (0.7%)	0	0
SPINAL CORD DIS	0	0	1 (0.7%)	0
PERIPHERAL NERVOUS SYST DISORD	0	2 (1.5%)	4 (2.9%)	2 (6.7%)
PERIPH NERV SYST DISORD	0	2 (1.5%)	4 (2.9%)	2 (6.7%)
OPERATIONS				
CARDIOVASCULAR SYST	0	0	0	0
OPERATION, OTHER HEART	0	0	0	0
DIGESTIVE SYST	0	0	0	0
OPERATION, APPENDIX	0	0	0	0
ENDOCRINE SYST	0	0	1 (0.7%)	0
OPERATION, ENDOCR	0	0	1 (0.7%)	0
FEMALE GENITAL ORGANS	0	0	1 (0.7%)	0
OPERATION, FEM GENITAL	0	0	1 (0.7%)	0
INTEGUMENTARY SYST	0	0	0	0
OPERATION, BREAST	0	0	0	0
MUSCULOSKELETAL SYST	1 (0.8%)	0	1 (0.7%)	0
OPERATION, BONE /JOINT	1 (0.8%)	0	1 (0.7%)	0
PROCEDURES				
DIAGNOSTIC/THERAPEUTIC	0	0	0	0
PROCEDURE, NUCLEAR MEDICINE	0	0	0	0
RADIOLOGY, DIAGNOSTIC	0	0	0	0
RESPIRATORY SYST DIS				
ACUTE RESPIRATORY INFECTIONS	0	0	1 (0.7%)	0
BRONCHITIS, ACUTE	0	0	1 (0.7%)	0
NASOPHARYNGITIS, ACUTE	0	0	0	0

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
CHRONIC OBSTRUCT PULMONARY DIS	9 (7.3%)	9 (6.6%)	9 (6.5%)	0
ASTHMA	4 (3.2%)	8 (5.9%)	1 (0.7%)	0
BRONCHITIS, CHRONIC	2 (1.6%)	1 (0.7%)	7 (5.0%)	0
BRONCHITIS, OTHER	1 (0.8%)	1 (0.7%)	0	0
EMPHYSEMA	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
LUNG DIS, OBSTRUCTIVE	2 (1.6%)	0	0	0
RESP DIS, OTHER	0	0	0	0
OTHER RESPIRATORY SYST DIS	4 (3.2%)	0	4 (2.9%)	0
LUNG DIS, OTHER	2 (1.6%)	0	2 (1.4%)	0
PLEURISY	2 (1.6%)	0	1 (0.7%)	0
RESP DIS, OTHER	0	0	1 (0.7%)	0
UPPER RESPIRATORY TRACT DIS	3 (2.4%)	2 (1.5%)	2 (1.4%)	1 (3.3%)
NASAL POLYPS	1 (0.8%)	0	1 (0.7%)	0
RHINITIS, ALLERGIC	0	1 (0.7%)	0	1 (3.3%)
SINUSITIS, CHRONIC	1 (0.8%)	0	0	0
SINUSITIS, OTHER	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
SINUSITIS,NOS	0	0	0	0
SIGNS, SYMPTOMS, ILL-DEFINED CON				
ABNORMAL FINDINGS	9 (7.3%)	15 (11.0%)	13 (9.4%)	2 (6.7%)
ALK PHOS ELEVATED, SERUM	0	0	1 (0.7%)	0
CARDIOVAS FUNCTIONS	1 (0.8%)	0	0	1 (3.3%)
/ECG, ABN				
PROTEINURIA	1 (0.8%)	2 (1.5%)	0	1 (3.3%)
RADIOLOGY INTRATHORACIC, ABN	0	1 (0.7%)	3 (2.2%)	0
RADIOLOGY LUNG, ABN	0	2 (1.5%)	1 (0.7%)	0
RBC'S, ABN	0	0	0	0
REFLEX, ABN	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
SED RATE, ELEVATED	0	1 (0.7%)	0	0
SERUM URIC ACID, DECREASED	0	0	1 (0.7%)	0
SERUM URIC ACID, ELEVATED	4 (3.2%)	8 (5.9%)	7 (5.0%)	0
TRANSAMINASE	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
/LDH, ELEVATION				

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
URINARY CASTS	0	0	2 (1.4%)	0
/WBC'S				
ILL-DEFINED COND	4 (3.2%)	0	2 (1.4%)	0
ARREST, RESP	0	0	1 (0.7%)	0
CACHEXIA	0	0	1 (0.7%)	0
NERVOUSNESS	3 (2.4%)	0	0	0
SENILITY	1 (0.8%)	0	0	0
SYMPTOMS	25 (20.2%)	19 (14.0%)	7 (5.0%)	2 (6.7%)
APNEA	0	1 (0.7%)	0	0
CARDIOVASCULAR SYMPTOMS, OTHER	0	1 (0.7%)	0	0
COUGH	0	1 (0.7%)	1 (0.7%)	0
DIARRHEA	0	0	1 (0.7%)	0
DISTURBANCE, SLEEP, UNSPEC	4 (3.2%)	4 (2.9%)	1 (0.7%)	0
DISTURBANCE, VOICE	0	0	0	1 (3.3%)
DIZZINESS AND GIDDINESS	6 (4.8%)	1 (0.7%)	0	0
DYSURIA	0	0	0	0
EDEMA	2 (1.6%)	1 (0.7%)	0	0
FLUSHING	1 (0.8%)	0	0	0
HEADACHE	0	1 (0.7%)	1 (0.7%)	0
HEARTBURN	0	0	1 (0.7%)	1 (3.3%)
HEPATOMEGALY	0	1 (0.7%)	0	0
HYPOESTHESIA	1 (0.8%)	0	0	0
INCONTINENCE, FECAL	0	0	1 (0.7%)	0
INCONTINENCE, URINARY	0	0	0	0
INSOMNIA	8 (6.5%)	9 (6.6%)	3 (2.2%)	1 (3.3%)
LYMPHADENOPATHY	1 (0.8%)	0	0	0
MALAISE AND FATIGUE	0	1 (0.7%)	0	0
MENTAL STATUS, IMPAIRED	1 (0.8%)	1 (0.7%)	0	0
PAIN UNSP, CHEST	0	1 (0.7%)	0	0
PAIN, ABDOMINO-PELVIC	1 (0.8%)	0	0	0
PAIN, GENERAL	0	0	0	0
PALPITATIONS	0	0	0	0
PARESTHESIA	1 (0.8%)	0	0	0
POLYURIA	1 (0.8%)	0	0	0

Data Source Table 13.4.1c

Summary of Presenting Conditions at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Any Conditions	106 (85.5%)	116 (85.3%)	118 (84.9%)	17 (56.7%)
Disease Code Level 1				
Disease Code Level 2				
Preferred Term				
RESP CHEST SOUNDS, ABN	0	1 (0.7%)	0	0
TACHYCARDIA, UNSPEC	1 (0.8%)	0	0	0
TREMOR	1 (0.8%)	0	0	0
WEAKNESS	0	0	1 (0.7%)	0
SKIN/SUBCUTANEOUS TISSUE DIS				
OTHER INFLAM COND OF TISSUE	4 (3.2%)	7 (5.1%)	8 (5.8%)	0
INFLAM SKIN	3 (2.4%)	6 (4.4%)	8 (5.8%)	0
/SUBCUT				
PRURITUS DISORD, UNSPEC	1 (0.8%)	1 (0.7%)	0	0
OTHER TISSUE DIS	0	1 (0.7%)	1 (0.7%)	1 (3.3%)
SCARRING	0	1 (0.7%)	1 (0.7%)	0
SKIN	0	0	0	1 (3.3%)
/SUBCUT DISORD, OTHER				
TISSUE INFECTIONS	0	0	0	0
CELLULITIS	0	0	0	0
/ABSCESS				

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Entered Study 009
Age (years)

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	147	287
< 65	76 (51.7%)	176 (61.3%)
>= 65	71 (48.3%)	111 (38.7%)
Mean	61.7	60.0
SD	9.42	8.14
Median	63.0	61.0
Minimum	34	37
Maximum	79	77
Female		
Number of patients with values	82	143
< 65	37 (45.1%)	79 (55.2%)
>= 65	45 (54.9%)	64 (44.8%)
Mean	62.4	60.6
SD	8.91	9.47
Median	65.0	62.0
Minimum	38	38
Maximum	78	81
Both Male and Female		
Number of patients with values	229	430
< 65	113 (49.3%)	255 (59.3%)
>= 65	116 (50.7%)	175 (40.7%)
Mean	61.9	60.2
SD	9.23	8.60
Median	64.0	61.0
Minimum	34	37
Maximum	79	81

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Entered Study 009
 Body Mass Index (kg/m²)

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	147	287
< 27	63 (42.9%)	101 (35.2%)
>=27	84 (57.1%)	186 (64.8%)
Mean	27.97	28.56
SD	3.950	3.589
Median	27.72	28.20
Minimum	21.2	21.0
Maximum	39.2	36.7
Female		
Number of patients with values	82	143
< 27	31 (37.8%)	39 (27.3%)
>=27	51 (62.2%)	104 (72.7%)
Mean	28.48	29.53
SD	3.966	4.145
Median	28.06	29.00
Minimum	20.7	20.8
Maximum	36.6	38.3
Both Male and Female		
Number of patients with values	229	430
< 27	94 (41.0%)	140 (32.6%)
>=27	135 (59.0%)	290 (67.4%)
Mean	28.15	28.88
SD	3.954	3.805
Median	27.83	28.40
Minimum	20.7	20.8
Maximum	39.2	38.3

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Entered Study 009
Alcohol Consumption (units/week)

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	147	270
None	59 (40.1%)	98 (34.1%)
1 - 14	57 (38.8%)	137 (47.7%)
> 14 - 21	17 (11.6%)	14 (4.9%)
> 21	14 (9.5%)	21 (7.3%)
Missing	0	17 (5.9%)
Mean	7.6	6.7
SD	10.74	9.23
Median	2.0	3.0
Minimum	0	0
Maximum	61	50
Female		
Number of patients with values	82	138
None	68 (82.9%)	108 (75.5%)
1 - 14	13 (15.9%)	26 (18.2%)
> 14 - 21	1 (1.2%)	3 (2.1%)
> 21	0	1 (0.7%)
Missing	0	5 (3.5%)
Mean	0.8	1.6
SD	2.73	4.64
Median	0.0	0.0
Minimum	0	0
Maximum	15	35
Both Male and Female		
Number of patients with values	229	408
None	127 (55.5%)	206 (47.9%)
1 - 14	70 (30.6%)	163 (37.9%)
> 14 - 21	18 (7.9%)	17 (4.0%)
> 21	14 (6.1%)	22 (5.1%)
Missing	0	22 (5.1%)
Mean	5.2	5.0
SD	9.32	8.33
Median	0.0	0.0
Minimum	0	0
Maximum	61	50

* The clinically acceptable range for alcohol consumption is 0-21 units per week for men and 0-14 units per week for women.

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Entered Study 009
Weight (kg)

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	147	287
Mean	81.93	84.99
SD	13.885	12.770
Median	82.40	84.30
Minimum	53.0	52.8
Maximum	117.0	118.0
Female		
Number of patients with values	82	143
Mean	69.29	74.30
SD	10.567	11.482
Median	68.60	72.50
Minimum	49.5	50.5
Maximum	95.0	112.3
Both Male and Female		
Number of patients with values	229	430
Mean	77.40	81.44
SD	14.143	13.334
Median	76.00	81.00
Minimum	49.5	50.5
Maximum	117.0	118.0

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Entered Study 009
Waist/Hip Ratio

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	137	267
Mean	0.969	0.979
SD	0.0629	0.0607
Median	0.960	0.970
Minimum	0.77	0.81
Maximum	1.24	1.16
Female		
Number of patients with values	73	129
Mean	0.912	0.904
SD	0.0827	0.0752
Median	0.900	0.900
Minimum	0.73	0.75
Maximum	1.23	1.12
Both Male and Female		
Number of patients with values	210	396
Mean	0.949	0.954
SD	0.0753	0.0744
Median	0.950	0.960
Minimum	0.73	0.75
Maximum	1.24	1.16

Data Source Table 13.5.1a

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Entered Study 009
Years Since First Diagnosis of Diabetes

	2bd Comb Total	4bd Mono Total
Male		
Number of patients with values	147	277
Mean	9.3	5.8
SD	6.73	5.87
Median	8.0	4.0
Minimum	1	0
Maximum	30	30
Female		
Number of patients with values	82	141
Mean	9.4	5.7
SD	6.97	5.87
Median	8.0	5.0
Minimum	1	0
Maximum	32	42
Both Male and Female		
Number of patients with values	229	418
Mean	9.3	5.8
SD	6.80	5.86
Median	8.0	4.0
Minimum	1	0
Maximum	32	42

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Age (years)

	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	42	52	53
< 65	21 (50.0%)	27 (51.9%)	28 (52.8%)
>= 65	21 (50.0%)	25 (48.1%)	25 (47.2%)
Mean	61.3	62.3	61.3
SD	9.53	8.92	9.93
Median	64.5	63.5	62.0
Minimum	34	35	38
Maximum	78	76	79
Female			
Number of patients with values	19	26	37
< 65	6 (31.6%)	10 (38.5%)	21 (56.8%)
>= 65	13 (68.4%)	16 (61.5%)	16 (43.2%)
Mean	64.4	61.9	61.7
SD	8.73	9.55	8.62
Median	67.0	65.5	63.0
Minimum	41	38	41
Maximum	78	74	76
Both Male and Female			
Number of patients with values	61	78	90
< 65	27 (44.3%)	37 (47.4%)	49 (54.4%)
>= 65	34 (55.7%)	41 (52.6%)	41 (45.6%)
Mean	62.3	62.2	61.5
SD	9.33	9.08	9.37
Median	65.0	64.0	62.0
Minimum	34	35	38
Maximum	78	76	79

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Body Mass Index (kg/m2)

	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	42	52	53
< 27	17 (40.5%)	20 (38.5%)	26 (49.1%)
>=27	25 (59.5%)	32 (61.5%)	27 (50.9%)
Mean	28.41	28.14	27.45
SD	4.254	3.837	3.824
Median	28.04	27.60	27.47
Minimum	21.7	21.8	21.2
Maximum	39.2	36.0	36.6
Female			
Number of patients with values	19	26	37
< 27	9 (47.4%)	12 (46.2%)	10 (27.0%)
>=27	10 (52.6%)	14 (53.8%)	27 (73.0%)
Mean	27.29	27.92	29.48
SD	4.016	3.990	3.776
Median	27.21	27.62	28.88
Minimum	20.7	22.0	21.9
Maximum	34.9	36.6	35.7
Both Male and Female			
Number of patients with values	61	78	90
< 27	26 (42.6%)	32 (41.0%)	36 (40.0%)
>=27	35 (57.4%)	46 (59.0%)	54 (60.0%)
Mean	28.06	28.07	28.28
SD	4.181	3.864	3.915
Median	27.77	27.60	27.95
Minimum	20.7	21.8	21.2
Maximum	39.2	36.6	36.6

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Alcohol Consumption (units/week)

	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	42	52	53
None	20 (47.6%)	19 (36.5%)	20 (37.7%)
1 - 14	11 (26.2%)	24 (46.2%)	22 (41.5%)
> 14 - 21	6 (14.3%)	6 (11.5%)	5 (9.4%)
> 21	5 (11.9%)	3 (5.8%)	6 (11.3%)
Missing	0	0	0
Mean	8.7	6.8	7.5
SD	11.99	8.20	11.95
Median	4.0	2.0	2.0
Minimum	0	0	0
Maximum	56	28	61
Female			
Number of patients with values	19	26	37
None	14 (73.7%)	22 (84.6%)	32 (86.5%)
1 - 14	5 (26.3%)	4 (15.4%)	4 (10.8%)
> 14 - 21	0	0	1 (2.7%)
> 21	0	0	0
Missing	0	0	0
Mean	1.4	0.7	0.6
SD	3.48	2.34	2.58
Median	0.0	0.0	0.0
Minimum	0	0	0
Maximum	14	10	15
Both Male and Female			
Number of patients with values	61	78	90
None	34 (55.7%)	41 (52.6%)	52 (57.8%)
1 - 14	16 (26.2%)	28 (35.9%)	26 (28.9%)
> 14 - 21	6 (9.8%)	6 (7.7%)	6 (6.7%)
> 21	5 (8.2%)	3 (3.8%)	6 (6.7%)
Missing	0	0	0
Mean	6.4	4.7	4.7
SD	10.65	7.38	9.89
Median	0.0	0.0	0.0
Minimum	0	0	0
Maximum	56	28	61

* The clinically acceptable range for alcohol consumption is 0-21 units per week for men and 0-14 units per week for women.

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Weight (kg)

	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	42	52	53
Mean	83.13	82.73	80.20
SD	13.308	14.762	13.530
Median	82.75	83.00	79.00
Minimum	54.0	54.5	53.0
Maximum	111.5	117.0	112.0
Female			
Number of patients with values	19	26	37
Mean	67.01	67.95	71.40
SD	10.432	9.235	11.358
Median	63.60	67.40	72.00
Minimum	51.0	49.5	52.0
Maximum	87.0	86.0	95.0
Both Male and Female			
Number of patients with values	61	78	90
Mean	78.11	77.80	76.58
SD	14.505	14.872	13.345
Median	77.00	76.40	74.80
Minimum	51.0	49.5	52.0
Maximum	111.5	117.0	112.0

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Waist/Hip Ratio

		2bd Comb Total	
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	39	47	51
Mean	0.981	0.968	0.960
SD	0.0688	0.0576	0.0625
Median	0.970	0.960	0.960
Minimum	0.86	0.84	0.77
Maximum	1.24	1.10	1.12
Female			
Number of patients with values	17	24	32
Mean	0.928	0.912	0.903
SD	0.1057	0.0706	0.0787
Median	0.900	0.910	0.905
Minimum	0.80	0.81	0.73
Maximum	1.23	1.05	1.07
Both Male and Female			
Number of patients with values	56	71	83
Mean	0.965	0.949	0.938
SD	0.0845	0.0673	0.0740
Median	0.960	0.950	0.940
Minimum	0.80	0.81	0.73
Maximum	1.24	1.10	1.12

Data Source Table 13.5.1b

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Years Since First Diagnosis of Diabetes

	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Male			
Number of patients with values	42	52	53
Mean	8.9	7.9	11.0
SD	6.98	5.22	7.55
Median	7.5	7.0	9.0
Minimum	1	1	1
Maximum	30	27	27
Female			
Number of patients with values	19	26	37
Mean	9.5	9.4	9.4
SD	6.83	6.09	7.75
Median	8.0	8.0	8.0
Minimum	1	2	1
Maximum	23	25	32
Both Male and Female			
Number of patients with values	61	78	90
Mean	9.1	8.4	10.3
SD	6.88	5.53	7.63
Median	8.0	7.0	8.5
Minimum	1	1	1
Maximum	30	27	32

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Age (years)

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	71	93	100	23
< 65	44 (62.0%)	59 (63.4%)	59 (59.0%)	14 (60.9%)
>= 65	27 (38.0%)	34 (36.6%)	41 (41.0%)	9 (39.1%)
Mean	59.9	59.5	60.5	60.3
SD	8.57	7.58	8.29	8.70
Median	60.0	61.0	61.0	61.0
Minimum	37	43	42	42
Maximum	76	74	77	75
Female				
Number of patients with values	53	43	39	7
< 65	27 (50.9%)	20 (46.5%)	27 (69.2%)	4 (57.1%)
>= 65	26 (49.1%)	23 (53.5%)	12 (30.8%)	3 (42.9%)
Mean	62.3	61.6	57.7	61.0
SD	9.67	9.18	8.28	12.90
Median	63.0	64.0	58.0	59.0
Minimum	38	39	40	43
Maximum	81	81	74	77
Both Male and Female				
Number of patients with values	124	136	139	30
< 65	71 (57.3%)	79 (58.1%)	86 (61.9%)	18 (60.0%)
>= 65	53 (42.7%)	57 (41.9%)	53 (38.1%)	12 (40.0%)
Mean	60.9	60.2	59.7	60.5
SD	9.09	8.15	8.36	9.59
Median	61.5	62.0	61.0	60.0
Minimum	37	39	40	42
Maximum	81	81	77	77

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Body Mass Index (kg/m²)

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	71	93	100	23
< 27	26 (36.6%)	28 (30.1%)	40 (40.0%)	7 (30.4%)
>=27	45 (63.4%)	65 (69.9%)	60 (60.0%)	16 (69.6%)
Mean	28.54	28.68	28.66	27.77
SD	3.490	3.144	4.077	3.429
Median	28.10	28.50	27.85	27.70
Minimum	21.5	22.0	21.0	22.3
Maximum	35.6	35.9	36.7	34.9
Female				
Number of patients with values	53	43	39	7
< 27	14 (26.4%)	13 (30.2%)	12 (30.8%)	0
>=27	39 (73.6%)	30 (69.8%)	27 (69.2%)	7 (100.0%)
Mean	29.73	29.06	29.23	31.99
SD	4.317	4.442	3.744	2.486
Median	29.00	27.60	28.80	33.00
Minimum	22.5	20.8	23.7	28.9
Maximum	38.3	38.0	38.0	34.7
Both Male and Female				
Number of patients with values	124	136	139	30
< 27	40 (32.3%)	41 (30.1%)	52 (37.4%)	7 (23.3%)
>=27	84 (67.7%)	95 (69.9%)	87 (62.6%)	23 (76.7%)
Mean	29.05	28.80	28.82	28.75
SD	3.894	3.593	3.982	3.673
Median	28.55	28.40	28.20	28.60
Minimum	21.5	20.8	21.0	22.3
Maximum	38.3	38.0	38.0	34.9

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Alcohol Consumption (units/week)

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	71	93	99	7
None	27 (38.0%)	33 (35.5%)	38 (38.0%)	0
1 - 14	38 (53.5%)	44 (47.3%)	49 (49.0%)	6 (26.1%)
> 14 - 21	4 (5.6%)	6 (6.5%)	4 (4.0%)	0
> 21	2 (2.8%)	10 (10.8%)	8 (8.0%)	1 (4.3%)
Missing	0	0	1 (1.0%)	16 (69.6%)
Mean	5.5	7.4	7.1	5.6
SD	6.72	10.47	9.53	9.95
Median	3.0	3.0	4.0	2.0
Minimum	0	0	0	1
Maximum	28	50	42	28
Female				
Number of patients with values	53	43	39	2
None	45 (84.9%)	33 (76.7%)	29 (74.4%)	0
1 - 14	7 (13.2%)	8 (18.6%)	9 (23.1%)	2 (28.6%)
> 14 - 21	1 (1.9%)	1 (2.3%)	1 (2.6%)	0
> 21	0	1 (2.3%)	0	0
Missing	0	0	0	5 (71.4%)
Mean	1.1	2.6	1.3	1.5
SD	3.57	6.66	3.11	0.71
Median	0.0	0.0	0.0	1.5
Minimum	0	0	0	1
Maximum	15	35	16	2
Both Male and Female				
Number of patients with values	124	136	138	9
None	72 (58.1%)	66 (48.5%)	67 (48.2%)	0
1 - 14	45 (36.3%)	52 (38.2%)	58 (41.7%)	8 (26.7%)
> 14 - 21	5 (4.0%)	7 (5.1%)	5 (3.6%)	0
> 21	2 (1.6%)	11 (8.1%)	8 (5.8%)	1 (3.3%)
Missing	0	0	1 (0.7%)	21 (70.0%)
Mean	3.6	5.9	5.5	4.7
SD	5.99	9.67	8.63	8.80
Median	0.0	1.0	1.0	2.0
Minimum	0	0	0	1
Maximum	28	50	42	28

* The clinically acceptable range for alcohol consumption is 0-21 units per week for men and 0-14 units per week for women.

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Weight (kg)

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	71	93	100	23
Mean	85.54	86.02	84.74	80.30
SD	12.694	12.439	13.298	11.652
Median	84.20	85.00	83.05	81.80
Minimum	58.0	52.8	56.5	56.5
Maximum	111.7	116.2	118.0	107.0
Female				
Number of patients with values	53	43	39	7
Mean	74.81	73.30	73.94	78.29
SD	12.345	11.088	11.632	7.204
Median	74.00	71.50	70.00	81.70
Minimum	55.0	50.5	55.0	64.7
Maximum	112.3	102.0	108.4	85.5
Both Male and Female				
Number of patients with values	124	136	139	30
Mean	80.95	82.00	81.71	79.83
SD	13.584	13.377	13.704	10.700
Median	80.45	82.00	80.50	81.75
Minimum	55.0	50.5	55.0	56.5
Maximum	112.3	116.2	118.0	107.0

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Waist/Hip Ratio

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	65	88	93	21
Mean	0.978	0.982	0.983	0.945
SD	0.0622	0.0546	0.0661	0.0470
Median	0.970	0.980	0.990	0.950
Minimum	0.85	0.83	0.81	0.85
Maximum	1.12	1.16	1.15	1.03
Female				
Number of patients with values	48	39	35	7
Mean	0.903	0.928	0.890	0.844
SD	0.0767	0.0806	0.0607	0.0583
Median	0.900	0.910	0.880	0.840
Minimum	0.75	0.79	0.79	0.75
Maximum	1.06	1.12	1.03	0.91
Both Male and Female				
Number of patients with values	113	127	128	28
Mean	0.946	0.965	0.958	0.920
SD	0.0780	0.0680	0.0768	0.0660
Median	0.950	0.960	0.950	0.930
Minimum	0.75	0.79	0.79	0.75
Maximum	1.12	1.16	1.15	1.03

Data Source Table 13.5.1c

Summary of Demography Information by Gender at Double Blind Baseline
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Years Since First Diagnosis of Diabetes

	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Male				
Number of patients with values	71	93	100	13
Mean	5.4	5.9	6.2	3.6
SD	5.99	5.78	6.11	3.20
Median	4.0	4.0	5.0	3.0
Minimum	0	0	0	0
Maximum	30	27	26	11
Female				
Number of patients with values	53	43	39	5
Mean	4.7	6.9	6.1	3.0
SD	4.55	7.44	5.75	2.00
Median	4.0	6.0	5.0	3.0
Minimum	0	0	0	1
Maximum	20	42	22	5
Both Male and Female				
Number of patients with values	124	136	139	18
Mean	5.1	6.2	6.2	3.4
SD	5.42	6.34	5.99	2.87
Median	4.0	4.0	5.0	3.0
Minimum	0	0	0	0
Maximum	30	42	26	11

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ALIMENTARY TRACT/METAB		
ANABOLICS, SYSTEMIC	1 (0.4%)	0
COBAMAMIDE	1 (0.4%)	0
ANTACID/ANTIPLAT/ANTIPEPTIC	47 (20.5%)	83 (19.3%)
ACETYLSALICYLIC ACID	3 (1.3%)	1 (0.2%)
/ALUMINIUM HYDROXIDE		
/MAGNESIUM HYDROXIDE		
ALGIN	4 (1.7%)	9 (2.1%)
/ALGINIC ACID		
/ALUMINIUM HYDROXIDE		
/MAGNESIUM TRISILICATE		
/SODIUM BICARBONATE		
ALMAGATE	1 (0.4%)	0
/CALCIUM SACCHARATE		
ALUMINIUM HYDROXIDE	2 (0.9%)	0
ALUMINIUM HYDROXIDE	2 (0.9%)	4 (0.9%)
/MAGNESIUM HYDROXIDE		
ALUMINIUM HYDROXIDE	0	1 (0.2%)
/MAGNESIUM TRISILICATE		
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE	3 (1.3%)	6 (1.4%)
/LIQUORICE LIQUID EXTRACT		
/SACCHARIN SODIUM		
/SMECTITE		
/VANILLINE		
ALUMINIUM OXIDE	0	1 (0.2%)
/MAGNESIUM OXIDE		
ALVERINE CITRATE	2 (0.9%)	3 (0.7%)
/DIMETICONE, ACTIVATED		
ANTACID NOS	1 (0.4%)	0
CALCIUM CARBONATE	1 (0.4%)	2 (0.5%)
CALCIUM CARBONATE	0	4 (0.9%)
/COLECALCIFEROL		
CALCIUM CARBONATE	0	1 (0.2%)
/MAGNESIUM CARBONATE		
CIMETIDINE	4 (1.7%)	4 (0.9%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DICLOFENAC SODIUM	3 (1.3%)	9 (2.1%)
/MISOPROSTOL		
DIMETICONE	0	1 (0.2%)
/GUAIAZULENE		
FAMOTIDINE	3 (1.3%)	0
LANSOPRAZOLE	4 (1.7%)	11 (2.6%)
MAGNESIUM TRISILICATE	1 (0.4%)	0
MISOPROSTOL	1 (0.4%)	4 (0.9%)
MISOPROSTOL	0	1 (0.2%)
/NAPROXEN		
OMEPRazole	17 (7.4%)	27 (6.3%)
OMEPRazole MAGNESIUM	0	1 (0.2%)
PANTOPRAZOL	0	8 (1.9%)
PANTOPRAZOLE	0	1 (0.2%)
RANITIDINE	5 (2.2%)	6 (1.4%)
RANITIDINE HYDROCHLORIDE	7 (3.1%)	7 (1.6%)
SODIUM BICARBONATE	0	1 (0.2%)
SUCRALFATE	2 (0.9%)	4 (0.9%)
ANTIDIABETIC THERAPY	36 (15.7%)	47 (10.9%)
ACARBOSE	1 (0.4%)	1 (0.2%)
CHLORPROPAMIDE	1 (0.4%)	0
GLIBENCLAMIDE	4 (1.7%)	7 (1.6%)
GLICLAZIDE	6 (2.6%)	13 (3.0%)
GLIMEPIRIDE	0	4 (0.9%)
GLIPIZIDE	4 (1.7%)	0
INSULIN	4 (1.7%)	7 (1.6%)
INSULIN	2 (0.9%)	0
/INSULIN INJECTION, ISOPHANE		
INSULIN HUMAN	2 (0.9%)	0
INSULIN HUMAN INJECTION, ISOPHANE	1 (0.4%)	0
INSULIN INJECTION, BIPHASIC	3 (1.3%)	0
INSULIN INJECTION, ISOPHANE	1 (0.4%)	0
METFORMIN	9 (3.9%)	14 (3.3%)
METFORMIN HYDROCHLORIDE	2 (0.9%)	9 (2.1%)
ANTIDIARRHEA/GI ANTIBIOTICS	17 (7.4%)	24 (5.6%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ACETORPHAN	0	1 (0.2%)
ALBUMIN TANNATE	1 (0.4%)	0
/CODEINE PHOSPHATE		
/DIHYDROSTREPTOMYCIN SULFATE		
/MORPHINE		
/NEOMYCIN SULFATE		
/PAPAVERINE HYDROCHLORIDE		
ANTI-DIARRHEAL, NOS	0	1 (0.2%)
ATROPINE SULFATE	3 (1.3%)	0
/DIPHENOXYLATE HYDROCHLORIDE		
ATTAPULGITE	1 (0.4%)	1 (0.2%)
BACITRACIN	0	1 (0.2%)
/NEOMYCIN SULFATE		
BACTERIA NOS	0	2 (0.5%)
CHARCOAL, ACTIVATED	0	1 (0.2%)
CHARCOAL, ACTIVATED	0	1 (0.2%)
/YEAST DRIED		
CHLOROQUINE	2 (0.9%)	0
LACTOBACILLUS ACIDOPHILUS	0	2 (0.5%)
LOPERAMIDE	0	6 (1.4%)
LOPERAMIDE HYDROCHLORIDE	5 (2.2%)	2 (0.5%)
LOPERAMIDE OXIDE	1 (0.4%)	1 (0.2%)
MONTMORILLONITE BEIDELLITIQUE	1 (0.4%)	3 (0.7%)
NIFUROXAZIDE	2 (0.9%)	5 (1.2%)
NIFURZIDE	0	1 (0.2%)
NYSTATIN	2 (0.9%)	0
POLYVIDONE	0	1 (0.2%)
/STERCULIA		
SACCHAROMYCES BOULARDII	3 (1.3%)	1 (0.2%)
STREPTOMYCIN	1 (0.4%)	0
SULFASALAZINE	0	1 (0.2%)
ANTIEMETICS & ANTINAUSEANTS	6 (2.6%)	14 (3.3%)
DOMPERIDONE	3 (1.3%)	8 (1.9%)
ETHANOLAMINE ACETYLLAUCINATE	1 (0.4%)	5 (1.2%)
HYOSCINE	1 (0.4%)	0

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
METOPIMAZINE	1 (0.4%)	2 (0.5%)
PROMETHAZINE HYDROCHLORIDE	0	1 (0.2%)
ANTIOBESITY PREP	2 (0.9%)	6 (1.4%)
AMFEPRAMONE	0	1 (0.2%)
ORLISTAT	2 (0.9%)	6 (1.4%)
CHOLAG & HEPATIC PROTECTORS	2 (0.9%)	11 (2.6%)
ANETHOLE TRITHIONE	0	2 (0.5%)
CHOLINE DIHYDROGEN CITRATE	1 (0.4%)	0
/SORBITOL		
CYSTEINE HYDROCHLORIDE	0	1 (0.2%)
/METHIONINE		
ERYTHROMYCIN	0	2 (0.5%)
/METHIONINE		
/MULTIVITAMINS, NOS		
/RUTOSIDE		
/SULFAFURAZOLE		
FUMARIA EXTRACT	0	1 (0.2%)
HYMECROMONE	0	1 (0.2%)
SILYMARIN	1 (0.4%)	1 (0.2%)
THIOCTIC ACID	0	3 (0.7%)
THIOCTIC ACID	0	3 (0.7%)
/TROMETHAMINE SALT		
URSODEOXYCHOLIC ACID	0	1 (0.2%)
DIGESTIVES	4 (1.7%)	13 (3.0%)
AMYLASE	1 (0.4%)	1 (0.2%)
BETAINE CITRATE	0	3 (0.7%)
BROMELAINS	0	2 (0.5%)
DIMETICONE	1 (0.4%)	1 (0.2%)
/ENZYMES NOS		
GLUTAMIC ACID HYDROCHLORIDE	0	2 (0.5%)
PANCREATIN	2 (0.9%)	4 (0.9%)
GI ANTISPAS/ANTICHOLIN	22 (9.6%)	42 (9.8%)
ALLOBARBITAL	0	1 (0.2%)
/AMINOPHENAZONE		
/DROFENINE HYDROCHLORIDE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ALVERINE CITRATE	2 (0.9%)	3 (0.7%)
/DIMETICONE, ACTIVATED		
AMOBARBITAL	1 (0.4%)	0
/ATROPINE		
/DIMETICONE		
/HYOSCYAMINE		
ARNICA	0	1 (0.2%)
/HORSE CHESTNUT EXTRACT		
/HYOSCYAMUS DRY EXTRACT		
/SCOPARIUM		
ATROPINE	0	1 (0.2%)
BENZHEXOL HYDROCHLORIDE	0	1 (0.2%)
/DEMELVERINUM HYDROCHLORICUM		
CHARCOAL, ACTIVATED	0	1 (0.2%)
/PAPAVERINE HYDROCHLORIDE		
CHLORDIAZEPOXIDE HYDROCHLORIDE	0	3 (0.7%)
/CLIDINIUM BROMIDE		
CISAPRIDE	1 (0.4%)	4 (0.9%)
CISAPRIDE MONOHYDRATE	0	1 (0.2%)
CLEBOPRIDE	1 (0.4%)	0
/DIMETICONE		
ECHINACEA EXTRACT	0	3 (0.7%)
/SABAL EXTRACT		
/TROSPIUM CHLORIDE		
FENPIVERINIUM BROMIDE	0	3 (0.7%)
/METAMIZOLE SODIUM		
/PITOFENONE HYDROCHLORIDE		
HYOSCINE BUTYLBROMIDE	1 (0.4%)	1 (0.2%)
HYOSCINE BUTYLBROMIDE	0	1 (0.2%)
/PARACETAMOL		
MEBEVERINE	2 (0.9%)	0
MEBEVERINE HYDROCHLORIDE	2 (0.9%)	4 (0.9%)
METOCLOPRAMIDE	2 (0.9%)	7 (1.6%)
METOCLOPRAMIDE DIHYDROCHLORIDE	0	1 (0.2%)
METOCLOPRAMIDE HYDROCHLORIDE	3 (1.3%)	4 (0.9%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
OTILONIUM BROMIDE	1 (0.4%)	0
OXYBUTYNIN	3 (1.3%)	4 (0.9%)
OXYBUTYNIN HYDROCHLORIDE	1 (0.4%)	0
PHLOROGLUCINOL	2 (0.9%)	4 (0.9%)
PHLOROGLUCINOL	0	4 (0.9%)
/TRIMETHYLPHLOROGLUCINOL		
PINAVERIUM BROMIDE	1 (0.4%)	1 (0.2%)
RUSCOGENIN	0	1 (0.2%)
/TRIMEBUTINE		
TIEMONIUM IODIDE	2 (0.9%)	0
TRIMEBUTINE	0	1 (0.2%)
TRIMEBUTINE MALEATE	1 (0.4%)	7 (1.6%)
LAXATIVES	16 (7.0%)	27 (6.3%)
ALOES	0	1 (0.2%)
BEE SWAX WHITE	0	1 (0.2%)
/PARAFFIN		
/WHITE VASELINE		
/ZINC OXIDE		
BISACODYL	3 (1.3%)	4 (0.9%)
DANTRON	2 (0.9%)	1 (0.2%)
/DOCUSATE SODIUM		
DANTRON	1 (0.4%)	0
/POLOXAMER		
ISPAGHULA	3 (1.3%)	2 (0.5%)
ISPAGHULA	0	1 (0.2%)
/SENNOSIDE A+B		
ISPAGHULA HUSKS	0	1 (0.2%)
/PARAFFIN, LIQUID		
LACTITOL MONOHYDRATE	0	2 (0.5%)
LACTULOSE	8 (3.5%)	9 (2.1%)
LACTULOSE	0	1 (0.2%)
/PARAFFIN		
/PARAFFIN, SOFT		
PARAFFIN, LIQUID	1 (0.4%)	1 (0.2%)
PICOSULFURIC ACID	1 (0.4%)	3 (0.7%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
POLOXAMER	0	1 (0.2%)
POTASSIUM TARTRATE	0	1 (0.2%)
/SODIUM BICARBONATE		
SENNA	1 (0.4%)	1 (0.2%)
SENNA FRUIT	1 (0.4%)	1 (0.2%)
SODIUM PICOSULFATE	0	2 (0.5%)
STERCULIA	0	2 (0.5%)
MINERAL SUPPLEMENTS	11 (4.8%)	35 (8.1%)
ALBUMEN	0	1 (0.2%)
/SACCHAROMYCES CEREVISIAE		
CALCIUM	1 (0.4%)	0
CALCIUM	2 (0.9%)	3 (0.7%)
/COLECALCIFEROL		
CALCIUM	1 (0.4%)	1 (0.2%)
/ERGOCALCIFEROL		
CALCIUM CARBONATE	1 (0.4%)	2 (0.5%)
CALCIUM CARBONATE	0	2 (0.5%)
/CITRIC ACID		
CALCIUM CARBONATE	0	4 (0.9%)
/COLECALCIFEROL		
CALCIUM CITRATE	0	1 (0.2%)
/CALCIUM GLUCONATE		
/SODIUM FLUOROPHOSPHATE		
CALCIUM GLUBIONATE	1 (0.4%)	1 (0.2%)
CALCIUM GLUCONATE	0	1 (0.2%)
/CALCIUM PHOSPHATE		
/COLECALCIFEROL		
COPPER	0	1 (0.2%)
DURAPATITE	0	1 (0.2%)
LEVOCARNITINE	0	1 (0.2%)
/MAGNESIUM ASPARTATE		
MAGNESIUM GLUTAMATE	0	1 (0.2%)
MAGNESIUM LACTATE	2 (0.9%)	6 (1.4%)
/PYRIDOXINE		
MAGNESIUM NOS	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
MAGNESIUM NOS	1 (0.4%)	0
/POTASSIUM		
/SODIUM CHLORIDE		
PHOSPHORUS	0	1 (0.2%)
/SODIUM		
POTASSIUM	1 (0.4%)	0
POTASSIUM ASCORBATE	1 (0.4%)	0
POTASSIUM BICARBONATE	0	1 (0.2%)
/POTASSIUM CITRATE		
POTASSIUM CHLORIDE	1 (0.4%)	10 (2.3%)
SODIUM CHLORIDE	1 (0.4%)	1 (0.2%)
SODIUM CHLORIDE COMPOUND INJECTION	0	1 (0.2%)
ZINC	0	1 (0.2%)
ZINC SULFATE	0	1 (0.2%)
MOUTH PREP	62 (27.1%)	86 (20.0%)
ACETYLSALICYLIC ACID	60 (26.2%)	67 (15.6%)
BACITRACIN	0	6 (1.4%)
/LYSOZYME		
/PAPAIN		
BICLOTYMOL	0	1 (0.2%)
/DEQUALINIUM CHLORIDE		
/ENOXOLONE		
/LYSOZYME		
/PAPAIN		
CETYLPRIDINIUM CHLORIDE	0	2 (0.5%)
/CHLOROBUTANOL		
/EUGENOL		
/VERATROLE		
CHLORHEXIDINE DIACETATE	0	2 (0.5%)
/TIXOCORTOL PIVALATE		
CHLORHEXIDINE GLUCONATE	0	1 (0.2%)
CHLORHEXIDINE GLUCONATE	0	1 (0.2%)
/CHLOROBUTANOL		
DOMIPHEN BROMIDE	0	1 (0.2%)
METRONIDAZOLE	6 (2.6%)	5 (1.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
SODIUM CHLORIDE	1 (0.4%)	1 (0.2%)
TRIAMCINOLONE ACETONIDE	1 (0.4%)	3 (0.7%)
VITAMINS	12 (5.2%)	33 (7.7%)
ASCORBIC ACID	1 (0.4%)	3 (0.7%)
ASCORBIC ACID	0	1 (0.2%)
/CYANOCOBALAMIN		
/FOLATE SODIUM		
/HYDROXOCOBALAMIN		
/LIDOCAINE HYDROCHLORIDE		
/NICOTINAMIDE		
/PYRIDOXINE HYDROCHLORIDE		
/THIAMINE HYDROCHLORIDE		
BISBUTIAMINE	1 (0.4%)	3 (0.7%)
CALCIUM	2 (0.9%)	3 (0.7%)
/COLECALCIFEROL		
COD-LIVER OIL	2 (0.9%)	3 (0.7%)
COLECALCIFEROL	0	1 (0.2%)
CYANOCOBALAMIN	0	1 (0.2%)
/PYRIDOXINE HYDROCHLORIDE		
/THIAMINE DISULFIDE		
CYANOCOBALAMIN	1 (0.4%)	2 (0.5%)
/PYRIDOXINE HYDROCHLORIDE		
/THIAMINE HYDROCHLORIDE		
CYSTINE	1 (0.4%)	0
/PYRIDOXINE		
DEXPANTHENOL	0	1 (0.2%)
ERGOCALCIFEROL	0	2 (0.5%)
ERGOCALCIFEROL	0	1 (0.2%)
/HYDROQUINONE		
ERYTHROMYCIN	0	2 (0.5%)
/METHIONINE		
/MULTIVITAMINS, NOS		
/RUTOSIDE		
/SULFAPURAZOLE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
HYDROXOCOBALAMIN	1 (0.4%)	0
/PYRIDOXINE HYDROCHLORIDE		
/THIAMINE HYDROCHLORIDE		
LYCOPENE	0	1 (0.2%)
/RETINOL		
/TOCOPHEROL		
MAGNESIUM LACTATE	2 (0.9%)	6 (1.4%)
/PYRIDOXINE		
PYRIDOXINE	0	2 (0.5%)
PYRIDOXINE HYDROCHLORIDE	0	1 (0.2%)
PYRIDOXINE HYDROCHLORIDE	2 (0.9%)	1 (0.2%)
/THIAMINE HYDROCHLORIDE		
RETINOL	1 (0.4%)	0
RIBOFLAVIN	0	1 (0.2%)
THIAMINE HYDROCHLORIDE	0	1 (0.2%)
TOCOPHEROL	0	1 (0.2%)
TOCOPHERYL ACETATE	0	2 (0.5%)
VITAMIN B	2 (0.9%)	1 (0.2%)
VITAMINS NOS	1 (0.4%)	0
YEAST DRIED	0	1 (0.2%)
ANTIINFECTIVES, SYSTEMIC		
ANTIBIOTICS	81 (35.4%)	171 (39.8%)
ACETYLCYSTEINE	0	1 (0.2%)
/THIAMPHENICOL AMINOACETATE HYDROCHLORIDE		
AMBROXOL HYDROCHLORIDE	0	1 (0.2%)
/DOXYCYCLINE HYDROCHLORIDE		
AMOXICILLIN	24 (10.5%)	24 (5.6%)
AMOXICILLIN TRIHYDRATE	10 (4.4%)	31 (7.2%)
AMOXICILLIN TRIHYDRATE	6 (2.6%)	1 (0.2%)
/CLAVULANATE POTASSIUM		
AMOXICILLIN TRIHYDRATE	12 (5.2%)	20 (4.7%)
/CLAVULANIC ACID		
AMPICILLIN	2 (0.9%)	0

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
AMPICILLIN	1 (0.4%)	0
/FLUCLOXACILLIN		
ANTIBIOTIC NOS	3 (1.3%)	1 (0.2%)
AZITHROMYCIN	2 (0.9%)	11 (2.6%)
BACAMPICILLIN HYDROCHLORIDE	0	4 (0.9%)
BENZYLPENICILLIN	1 (0.4%)	0
BETAMETHASONE	0	1 (0.2%)
/CLOTRIMAZOLE		
/GENTAMICIN		
BETAMETHASONE	0	1 (0.2%)
/NEOMYCIN		
BROMELAINS	0	1 (0.2%)
/TETRACYCLINE HYDROCHLORIDE		
CEFACLOR	1 (0.4%)	6 (1.4%)
CEFADROXIL	0	5 (1.2%)
CEFADROXIL MONOHYDRATE	0	1 (0.2%)
CEFALEXIN	2 (0.9%)	5 (1.2%)
CEFALEXIN MONOHYDRATE	0	2 (0.5%)
CEFALORIDINE	0	1 (0.2%)
CEFATRIZINE	0	5 (1.2%)
CEFAZOLIN SODIUM	0	1 (0.2%)
CEFIXIME	1 (0.4%)	6 (1.4%)
CEFODIZIME	0	1 (0.2%)
CEFONICID DISODIUM	0	1 (0.2%)
CEFOTAXIME	0	1 (0.2%)
CEFOTIAM HEXETIL HYDROCHLORIDE	0	3 (0.7%)
CEFPODOXIME PROXETIL	2 (0.9%)	7 (1.6%)
CEFRADINE	1 (0.4%)	0
CEFTRIAZONE SODIUM	2 (0.9%)	4 (0.9%)
CEFUROXIME	0	1 (0.2%)
CEFUROXIME AXETIL	2 (0.9%)	3 (0.7%)
CEFUROXIME SODIUM	0	1 (0.2%)
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
CHYMOTRYPSIN	1 (0.4%)	0
/TETRACYCLINE HYDROCHLORIDE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CLARITHROMYCIN	5 (2.2%)	18 (4.2%)
CLINDAMYCIN	0	1 (0.2%)
CLINDAMYCIN HYDROCHLORIDE	0	1 (0.2%)
CLOFOCTOL	2 (0.9%)	0
CLOXACILLIN SODIUM	0	2 (0.5%)
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
/PHENYLEPHRINE HYDROCHLORIDE		
/POLYMYXIN B SULFATE		
DICLOXACILLIN SODIUM MONOHYDRATE	0	2 (0.5%)
DOXYCYCLINE	1 (0.4%)	6 (1.4%)
DOXYCYCLINE HYCLATE	1 (0.4%)	3 (0.7%)
DOXYCYCLINE HYDROCHLORIDE	0	5 (1.2%)
ERYTHROMYCIN	11 (4.8%)	6 (1.4%)
ERYTHROMYCIN	0	2 (0.5%)
/METHIONINE		
/MULTIVITAMINS, NOS		
/RUTOSIDE		
/SULFAFURAZOLE		
FLUCLOXACILLIN	8 (3.5%)	2 (0.5%)
FLUCLOXACILLIN SODIUM	0	4 (0.9%)
FOSFOMYCIN	0	5 (1.2%)
FUSIDATE SODIUM	3 (1.3%)	2 (0.5%)
FUSIDIC ACID	2 (0.9%)	4 (0.9%)
GENTAMICIN SULFATE	1 (0.4%)	3 (0.7%)
JOSAMYCIN	0	1 (0.2%)
LOMEFLOXACIN	0	2 (0.5%)
LYMECYCLINE	0	1 (0.2%)
MEPARTRICIN	0	1 (0.2%)
METRONIDAZOLE	1 (0.4%)	5 (1.2%)
/SPIRAMYCIN		
MIDECAMYCIN	1 (0.4%)	0
MINOCYCLINE HYDROCHLORIDE	0	2 (0.5%)
MUPIROCI	1 (0.4%)	0
OXACILLIN	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
OXYTETRACYCLINE	3 (1.3%)	1 (0.2%)
OXYTETRACYCLINE DIHYDRATE	1 (0.4%)	0
PENICILLIN NOS	1 (0.4%)	3 (0.7%)
PHENOXYMETHYLPENICILLIN	2 (0.9%)	1 (0.2%)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	8 (1.9%)
PIPEMIDIC ACID	0	4 (0.9%)
PIVMECILLINAM HYDROCHLORIDE	0	3 (0.7%)
PRISTINAMYCIN	1 (0.4%)	2 (0.5%)
ROXITHROMYCIN	1 (0.4%)	13 (3.0%)
SPIRAMYCIN	0	2 (0.5%)
STREPTOMYCIN	1 (0.4%)	0
SULFAMETHOXAZOLE	2 (0.9%)	11 (2.6%)
/TRIMETHOPRIM		
SULTAMICILLIN	0	1 (0.2%)
TETRACYCLINE	2 (0.9%)	1 (0.2%)
THIAMPHENICOL	0	1 (0.2%)
TRIMETHOPRIM	10 (4.4%)	9 (2.1%)
VANCOMYCIN HYDROCHLORIDE	0	1 (0.2%)
ANTIMYCOTICS	7 (3.1%)	5 (1.2%)
FLUCONAZOLE	4 (1.7%)	1 (0.2%)
ITRACONAZOLE	1 (0.4%)	0
KETOCONAZOLE	2 (0.9%)	2 (0.5%)
MICONAZOLE	0	1 (0.2%)
MICONAZOLE NITRATE	0	1 (0.2%)
ANTIVIRALS	6 (2.6%)	6 (1.4%)
ACICLOVIR	5 (2.2%)	2 (0.5%)
BIOSTIM	0	2 (0.5%)
FAMCICLOVIR	2 (0.9%)	1 (0.2%)
VALACYCLOVIR HYDROCHLORIDE	0	1 (0.2%)
CHEMOTHERAPEUTICS	14 (6.1%)	30 (7.0%)
CIPROFLOXACIN	4 (1.7%)	1 (0.2%)
CIPROFLOXACIN HYDROCHLORIDE	1 (0.4%)	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ERYTHROMYCIN	0	2 (0.5%)
/METHIONINE		
/MULTIVITAMINS, NOS		
/RUTOSIDE		
/SULFAPURAZOLE		
METRONIDAZOLE	6 (2.6%)	5 (1.2%)
METRONIDAZOLE	1 (0.4%)	5 (1.2%)
/SPIRAMYCIN		
OFLOXACIN	2 (0.9%)	11 (2.6%)
SULFAMETHOXAZOLE	2 (0.9%)	11 (2.6%)
/TRIMETHOPRIM		
IMMUNE SERA & IMMUNOGLOB	0	5 (1.2%)
IMMUNOGLOBULIN HUMAN ANTI-TETANUS	0	3 (0.7%)
TETANUS ANTITOXIN	0	2 (0.5%)
TUBERCULOSTATICS	3 (1.3%)	0
ETHAMBUTOL	1 (0.4%)	0
RIFAMPICIN	2 (0.9%)	0
RIFAMYCIN SODIUM	1 (0.4%)	0
VACCINES	29 (12.7%)	67 (15.6%)
BACTERIA NOS	0	2 (0.5%)
DIPHTHERIA AND TETANUS TOXOIDS	0	3 (0.7%)
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS	1 (0.4%)	0
DIPHTHERIA, TETANUS AND POLIOMYELITIS VAC	2 (0.9%)	1 (0.2%)
HEPATITIS A VACCINE	0	1 (0.2%)
HEPATITIS B VACCINE	1 (0.4%)	2 (0.5%)
HEPATITIS VACCINE, NOS	1 (0.4%)	0
INACTIVATED HEPATITIS A VACCINE	1 (0.4%)	0
INFLUENZA VIRUS VACCINE POLYVALENT	24 (10.5%)	60 (14.0%)
MENINGOCOCCAL POLYSACCHARIDE, GROUP A VA	0	1 (0.2%)
PNEUMOCOCCAL VACCINE	3 (1.3%)	5 (1.2%)
POLIOMYELITIS VACCINE	2 (0.9%)	0
POLIOMYELITIS VACCINE INACTIVATED	0	2 (0.5%)
TETANUS TOXOID	1 (0.4%)	6 (1.4%)
TYPHOID VACCINE	2 (0.9%)	0
YELLOW FEVER VACCINE	1 (0.4%)	0

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ANTINEOPLASTIC & IMMUNOSUP		
ANTINEOPLASTIC, HORMONES	3 (1.3%)	12 (2.8%)
BICALUTAMIDE	1 (0.4%)	0
ESTRADIOL	0	4 (0.9%)
ESTRADIOL VALERATE	0	2 (0.5%)
ESTROGENS CONJUGATED	1 (0.4%)	2 (0.5%)
FLUTAMIDE	0	1 (0.2%)
GOSERELIN	1 (0.4%)	1 (0.2%)
GOSERELIN ACETATE	0	1 (0.2%)
LEUPRORELIN	0	1 (0.2%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.2%)
TAMOXIFEN CITRATE	1 (0.4%)	1 (0.2%)
CYTOSTATIC DRUGS	3 (1.3%)	6 (1.4%)
CISPLATIN	0	1 (0.2%)
GEMCITABINE HYDROCHLORIDE	0	1 (0.2%)
LEUPRORELIN	0	1 (0.2%)
SERENO A REPENS	3 (1.3%)	4 (0.9%)
BLOOD/BLOOD FORM ORGANS		
ANTIANAEMIC PREP	9 (3.9%)	26 (6.0%)
AMINOACETIC ACID	0	4 (0.9%)
/FERROUS SULFATE		
CALCIUM PHOSPHATE TRIBASIC	0	1 (0.2%)
/FOLIC ACID		
CYANOCOBALAMIN	0	4 (0.9%)
FERROUS FUMARATE	1 (0.4%)	0
FERROUS GLUCONATE	0	1 (0.2%)
FERROUS SULFATE	6 (2.6%)	17 (4.0%)
FERROUS SULFATE EXSICCATED	1 (0.4%)	0
FOLIC ACID	0	1 (0.2%)
HYDROXOCOBALAMIN	1 (0.4%)	1 (0.2%)
IRON FERRIC	0	1 (0.2%)
ANTICOAGULANTS	71 (31.0%)	105 (24.4%)
ACENOCOUMAROL	3 (1.3%)	2 (0.5%)
ACETYLSALICYLATE LYSINE	2 (0.9%)	13 (3.0%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ACETYLSALICYLIC ACID	60 (26.2%)	67 (15.6%)
ACETYLSALICYLIC ACID /DIPYRIDAMOLE	1 (0.4%)	0
CLOPIDOGREL	0	2 (0.5%)
CLORICROMEN HYDROCHLORIDE	1 (0.4%)	0
DALTEPARIN SODIUM	1 (0.4%)	0
DICOUMAROL	0	1 (0.2%)
DIPYRIDAMOLE	3 (1.3%)	5 (1.2%)
ENOXAPARIN	2 (0.9%)	5 (1.2%)
FLUINDIONE	0	5 (1.2%)
GLYCOL SALICYLATE /HEPARIN SODIUM	0	1 (0.2%)
HEPARIN	2 (0.9%)	4 (0.9%)
HEPARIN SODIUM	0	1 (0.2%)
HEPARIN-FRACTION	0	1 (0.2%)
HEPARIN-FRACTION, CALCIUM SALT	1 (0.4%)	7 (1.6%)
HEPARIN-FRACTION, SODIUM SALT	1 (0.4%)	7 (1.6%)
HIRUDIN	0	2 (0.5%)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	1 (0.2%)
TICLOPIDINE HYDROCHLORIDE	0	8 (1.9%)
WARFARIN	2 (0.9%)	3 (0.7%)
WARFARIN SODIUM	1 (0.4%)	4 (0.9%)
ANTIHAEMORRHAGICS	1 (0.4%)	2 (0.5%)
ETAMSILATE	0	2 (0.5%)
TRANEXAMIC ACID	1 (0.4%)	1 (0.2%)
CHOLESTEROL REDUCERS	96 (41.9%)	153 (35.6%)
ACIPIMOX	2 (0.9%)	0
ATORVASTATIN	9 (3.9%)	11 (2.6%)
ATORVASTATIN CALCIUM	16 (7.0%)	21 (4.9%)
BENFLUOREX HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
BEZAFIBRATE	9 (3.9%)	10 (2.3%)
CARNITINE HYDROCHLORIDE	0	1 (0.2%)
CERIVASTATIN	4 (1.7%)	9 (2.1%)
CHONDROITIN SULFATE	0	1 (0.2%)
CIPROFIBRATE	3 (1.3%)	5 (1.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DUCOSAHEXAENOIC ACID	2 (0.9%)	4 (0.9%)
/EICOSAPENTAENOIC ACID		
ETOFIBRATE	0	3 (0.7%)
EVENING PRIMROSE OIL	1 (0.4%)	2 (0.5%)
FENOFIBRATE	16 (7.0%)	32 (7.4%)
FLUVASTATIN SODIUM	2 (0.9%)	8 (1.9%)
GEMFIBROZIL	5 (2.2%)	4 (0.9%)
L-PROPYONIL CARNITINE HYDROCHLORIDE	0	1 (0.2%)
LOVASTATIN	6 (2.6%)	0
PRAVASTATIN	11 (4.8%)	17 (4.0%)
PRAVASTATIN SODIUM	4 (1.7%)	11 (2.6%)
SIMVASTATIN	34 (14.8%)	43 (10.0%)
HEMORRHEOLOGIC AGENTS	5 (2.2%)	4 (0.9%)
PENTOXIFYLLINE	5 (2.2%)	4 (0.9%)
OTHER HAEMAT AGNTS	0	2 (0.5%)
DEOXYRIBOUNCLEASE	0	2 (0.5%)
/FIBRINOLYSIN		
PLASMA SUBSTIT/PERF SOLUT	2 (0.9%)	11 (2.6%)
ALBUMEN	0	1 (0.2%)
/SACCHAROMYCES CEREVISIAE		
CHLORHEXIDINE GLUCONATE	0	1 (0.2%)
DEXTRAN SULPHATE	0	1 (0.2%)
/PHENYL BUTAZONE		
GLUCOSE	1 (0.4%)	0
GLUCOSE	0	1 (0.2%)
/SODIUM CHLORIDE		
I.V. FLUIDS	0	1 (0.2%)
SODIUM BICARBONATE	0	1 (0.2%)
SODIUM CHLORIDE	1 (0.4%)	1 (0.2%)
SODIUM CHLORIDE COMPOUND INJECTION	0	1 (0.2%)
SOYA OIL	0	1 (0.2%)
UREA	0	2 (0.5%)
CARDIOVASCULAR		
BETA BLOCKING AGENTS	48 (21.0%)	94 (21.9%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ACEBUTOLOL HYDROCHLORIDE	2 (0.9%)	4 (0.9%)
ATENOLOL	17 (7.4%)	30 (7.0%)
ATENOLOL	0	4 (0.9%)
/CHLORTALIDONE		
ATENOLOL	0	2 (0.5%)
/NIFEDIPINE		
BETAXOLOL	2 (0.9%)	3 (0.7%)
BETAXOLOL HYDROCHLORIDE	2 (0.9%)	4 (0.9%)
BISOPROLOL	5 (2.2%)	6 (1.4%)
BISOPROLOL FUMARATE	2 (0.9%)	3 (0.7%)
BISOPROLOL FUMARATE	0	1 (0.2%)
/HYDROCHLOROTHIAZIDE		
CARTEOLOL	0	2 (0.5%)
CARTEOLOL HYDROCHLORIDE	0	2 (0.5%)
CARVEDILOL	0	7 (1.6%)
CELIPROLOL	4 (1.7%)	1 (0.2%)
CLOPAMIDE	0	1 (0.2%)
/PINDOLOL		
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.2%)
/TIMOLOL MALEATE		
FELODIPINE	0	2 (0.5%)
/METOPROLOL		
METOPROLOL	4 (1.7%)	6 (1.4%)
METOPROLOL SUCCINATE	0	7 (1.6%)
METOPROLOL TARTRATE	1 (0.4%)	5 (1.2%)
METOPROLOL TARTRATE	0	1 (0.2%)
/NIFEDIPINE		
NEBIVOLOL	1 (0.4%)	0
NEBIVOLOL HYDROCHLORIDE	0	1 (0.2%)
OXPRENOLOL HYDROCHLORIDE	1 (0.4%)	0
PROPRANOLOL	2 (0.9%)	2 (0.5%)
PROPRANOLOL HYDROCHLORIDE	2 (0.9%)	1 (0.2%)
SOTALOL	2 (0.9%)	3 (0.7%)
SOTALOL HYDROCHLORIDE	0	5 (1.2%)
TERTATOLOL	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
TIMOLOL	1 (0.4%)	1 (0.2%)
TIMOLOL MALEATE	4 (1.7%)	7 (1.6%)
CARDIAC THERAPY	47 (20.5%)	92 (21.4%)
ACETYLDIGOXIN	0	5 (1.2%)
ACETYLSALICYLIC ACID	1 (0.4%)	0
/DIPYRIDAMOLE		
ADENOSINE PHOSPHATE, SODIUM SALT	1 (0.4%)	1 (0.2%)
/DEOXYRIBONUCLEIC ACID		
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	1 (0.2%)
/AMINO ACIDS NOS		
/PYRIDOXINE HYDROCHLORIDE		
ALPROSTADIL	3 (1.3%)	3 (0.7%)
AMIODARONE	0	1 (0.2%)
AMIODARONE HYDROCHLORIDE	2 (0.9%)	4 (0.9%)
ASPARTATE MAGNESIUM	0	2 (0.5%)
/ASPARTATE POTASSIUM		
BISOPROLOL FUMARATE	2 (0.9%)	3 (0.7%)
CALCIUM LACTATE	1 (0.4%)	0
/CIMICIFUGA		
/MAGNESIUM HYPOSULFITE		
/OLEOSACCHARUM OF MARJOLAIN		
CAMPOR	0	1 (0.2%)
/CONVALLARIA TINCTURE		
/CRATAEGUS EXTRACT		
/MENTHOL		
/VALERIAN TINCTURE		
CANDESARTAN CILEXETIL	0	2 (0.5%)
CARVEDILOL	0	7 (1.6%)
DIGITOXIN	0	1 (0.2%)
DIGOXIN	7 (3.1%)	11 (2.6%)
DIPYRIDAMOLE	3 (1.3%)	5 (1.2%)
DOPAMINE HYDROCHLORIDE	0	1 (0.2%)
GLYCERYL TRINITRATE	20 (8.7%)	26 (6.0%)
HEPTAMINOL HYDROCHLORIDE	0	2 (0.5%)
HYDROQUINIDINE HYDROCHLORIDE	0	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ISOSORBIDE DINITRATE	3 (1.3%)	3 (0.7%)
ISOSORBIDE MONONITRATE	14 (6.1%)	19 (4.4%)
LIDOCAINE	0	1 (0.2%)
LIDOCAINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
MAGNESIUM HYDROGEN ASPARTATE	0	1 (0.2%)
/POTASSIUM HYDROGEN ASPARTATE		
MEXILETINE HYDROCHLORIDE	0	1 (0.2%)
MOLSIDOMINE	2 (0.9%)	9 (2.1%)
NICORANDIL	5 (2.2%)	2 (0.5%)
QUININE SULFATE	1 (0.4%)	2 (0.5%)
TRIMETAZIDINE DIHYDROCHLORIDE	3 (1.3%)	11 (2.6%)
DIURETICS	54 (23.6%)	125 (29.1%)
ACETAZOLAMIDE	1 (0.4%)	0
ALTIIZIDE	5 (2.2%)	14 (3.3%)
/SPIRONOLACTONE		
AMILORIDE	1 (0.4%)	0
AMILORIDE HYDROCHLORIDE	0	1 (0.2%)
AMILORIDE HYDROCHLORIDE	3 (1.3%)	3 (0.7%)
/FUROSEMIDE		
AMILORIDE HYDROCHLORIDE	7 (3.1%)	5 (1.2%)
/HYDROCHLOROTHIAZIDE		
AZOSEMIDE	0	1 (0.2%)
BEMETIZIDE	0	4 (0.9%)
/HESPERIDIN COMPLEX		
/THIAMINE MONONITRATE		
/TRIAMTERENE		
BENDROFLUMETHIAZIDE	3 (1.3%)	2 (0.5%)
BENDROFLUMETHIAZIDE	0	1 (0.2%)
/POTASSIUM CHLORIDE		
BENZTHIAZIDE	0	1 (0.2%)
/TRIAMTERENE		
BISOPROLOL FUMARATE	0	1 (0.2%)
/HYDROCHLOROTHIAZIDE		
BUMETANIDE	4 (1.7%)	3 (0.7%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CAPTOPRIL	1 (0.4%)	14 (3.3%)
/HYDROCHLOROTHIAZIDE		
CYCLOTHIAZIDE	0	1 (0.2%)
/TRIAMTERENE		
DORZOLAMIDE HYDROCHLORIDE	3 (1.3%)	4 (0.9%)
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.2%)
/TIMOLOL MALEATE		
ENALAPRIL MALEATE	2 (0.9%)	0
/HYDROCHLOROTHIAZIDE		
ETACRYNIC ACID	0	1 (0.2%)
FOSINOPRIL SODIUM	0	1 (0.2%)
/HYDROCHLOROTHIAZIDE		
FUROSEMIDE	20 (8.7%)	43 (10.0%)
FUROSEMIDE	0	3 (0.7%)
/SPIRONOLACTONE		
FUROSEMIDE	2 (0.9%)	0
/TRIAMTERENE		
HYDROCHLOROTHIAZIDE	1 (0.4%)	1 (0.2%)
HYDROCHLOROTHIAZIDE	0	7 (1.6%)
/LISINOPRIL		
HYDROCHLOROTHIAZIDE	0	3 (0.7%)
/LOSARTAN POTASSIUM		
HYDROCHLOROTHIAZIDE	0	4 (0.9%)
/QUINAPRIL		
HYDROCHLOROTHIAZIDE	1 (0.4%)	2 (0.5%)
/QUINAPRIL HYDROCHLORIDE		
HYDROCHLOROTHIAZIDE	0	1 (0.2%)
/RAMIPRIL		
HYDROCHLOROTHIAZIDE	1 (0.4%)	4 (0.9%)
/TRIAMTERENE		
HYDROCHLOROTHIAZIDE	0	3 (0.7%)
/VALSARTAN		
HYDROFLUMETHIAZIDE	1 (0.4%)	0
/SPIRONOLACTONE		
HYPERICUM EXTRACT	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
INDAPAMIDE	3 (1.3%)	2 (0.5%)
INDAPAMIDE	0	1 (0.2%)
/PERINDOPRIL ERBUMINE		
INDAPAMIDE HEMIHYDRATE	0	1 (0.2%)
ISOSORBIDE	0	1 (0.2%)
METOLAZONE	1 (0.4%)	0
PIRETANIDE	1 (0.4%)	4 (0.9%)
POTASSIUM CANRENOATE	0	1 (0.2%)
SOLIDAGO	0	1 (0.2%)
SPIRONOLACTONE	2 (0.9%)	8 (1.9%)
THEOPHYLLINE	0	9 (2.1%)
TORASEMID	0	1 (0.2%)
HYPOTENSIVES	103 (45.0%)	206 (47.9%)
ALFUZOSIN	0	4 (0.9%)
ALFUZOSIN HYDROCHLORIDE	1 (0.4%)	5 (1.2%)
ALMITRINE DIMESILATE	0	2 (0.5%)
/RAUBASINE		
AMLODIPINE	11 (4.8%)	6 (1.4%)
AMLODIPINE BESYLATE	6 (2.6%)	14 (3.3%)
ATENOLOL	0	2 (0.5%)
/NIFEDIPINE		
BENAZEPRIL	1 (0.4%)	2 (0.5%)
BENAZEPRIL	0	5 (1.2%)
/CHLOROTHIAZIDE		
BENAZEPRIL HYDROCHLORIDE	1 (0.4%)	0
BEPRIDIL HYDROCHLORIDE MONOHYDRATE	0	1 (0.2%)
BETULA LEAF	1 (0.4%)	0
/OLIVE LEAVES EXTRACT		
CANDESARTAN CILEXETIL	0	2 (0.5%)
CAPTOPRIL	4 (1.7%)	20 (4.7%)
CAPTOPRIL	1 (0.4%)	14 (3.3%)
/HYDROCHLOROTHIAZIDE		
CARVEDILOL	0	7 (1.6%)
CICLETANINE HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
CILAZAPRIL	0	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CLONIDINE HYDROCHLORIDE	0	3 (0.7%)
DIHYDROERGOCRISTINE MESILATE	1 (0.4%)	3 (0.7%)
/RAUBASINE		
DILTIAZEM	4 (1.7%)	7 (1.6%)
DILTIAZEM HYDROCHLORIDE	8 (3.5%)	8 (1.9%)
DOXAZOSIN	3 (1.3%)	2 (0.5%)
DOXAZOSIN MESYLATE	0	5 (1.2%)
ENALAPRIL	7 (3.1%)	6 (1.4%)
ENALAPRIL MALEATE	18 (7.9%)	24 (5.6%)
ENALAPRIL MALEATE	2 (0.9%)	0
/HYDROCHLOROTHIAZIDE		
EPROSARTAN	0	1 (0.2%)
FELODIPINE	3 (1.3%)	12 (2.8%)
FELODIPINE	0	2 (0.5%)
/METOPROLOL		
FELODIPINE	0	1 (0.2%)
/RAMIPRIL		
FOSINOPRIL	2 (0.9%)	1 (0.2%)
FOSINOPRIL SODIUM	1 (0.4%)	0
FOSINOPRIL SODIUM	0	1 (0.2%)
/HYDROCHLOROTHIAZIDE		
HYDRALAZINE	1 (0.4%)	0
HYDROCHLOROTHIAZIDE	0	7 (1.6%)
/LISINOPRIL		
HYDROCHLOROTHIAZIDE	0	3 (0.7%)
/LOSARTAN POTASSIUM		
HYDROCHLOROTHIAZIDE	0	4 (0.9%)
/QUINAPRIL		
HYDROCHLOROTHIAZIDE	1 (0.4%)	2 (0.5%)
/QUINAPRIL HYDROCHLORIDE		
HYDROCHLOROTHIAZIDE	0	1 (0.2%)
/RAMIPRIL		
HYDROCHLOROTHIAZIDE	0	3 (0.7%)
/VALSARTAN		
INDAPAMIDE	3 (1.3%)	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
INDAPAMIDE	0	1 (0.2%)
/PERINDOPRIL ERBUMINE		
INDORAMIN	1 (0.4%)	0
IRBESARTAN	3 (1.3%)	3 (0.7%)
ISRODIPINE	0	3 (0.7%)
LACIDIPINE	2 (0.9%)	2 (0.5%)
LISINOPRIL	11 (4.8%)	14 (3.3%)
LOSARTAN	2 (0.9%)	2 (0.5%)
LOSARTAN POTASSIUM	5 (2.2%)	8 (1.9%)
METHYLDOPA	0	1 (0.2%)
METOPROLOL TARTRATE	0	1 (0.2%)
/NIFEDIPINE		
MISTLETOE EXTRACT	0	1 (0.2%)
MOXONIDINE	1 (0.4%)	2 (0.5%)
NICARDIPINE HYDROCHLORIDE	0	5 (1.2%)
NIFEDIPINE	15 (6.6%)	22 (5.1%)
NISOLDIPINE	1 (0.4%)	0
NITRENDIPINE	1 (0.4%)	2 (0.5%)
PERINDOPRIL	5 (2.2%)	8 (1.9%)
PRazosin	0	6 (1.4%)
QUINAPRIL	4 (1.7%)	1 (0.2%)
QUINAPRIL HYDROCHLORIDE	4 (1.7%)	2 (0.5%)
RAMIPRIL	4 (1.7%)	14 (3.3%)
RILMENIDINE PHOSPHATE	3 (1.3%)	4 (0.9%)
SPIRAPRIL HYDROCHLORIDE	0	1 (0.2%)
TERAZOSIN	0	1 (0.2%)
TERAZOSIN HYDROCHLORIDE	0	3 (0.7%)
TRANDOLAPRILAT	4 (1.7%)	1 (0.2%)
TRANDOLAPRILAT	1 (0.4%)	0
/VERAPAMIL		
URAPIDIL	1 (0.4%)	5 (1.2%)
VALSARTAN	1 (0.4%)	4 (0.9%)
VERAPAMIL	1 (0.4%)	1 (0.2%)
VERAPAMIL HYDROCHLORIDE	3 (1.3%)	4 (0.9%)
PERIPHERAL VASODILATORS	20 (8.7%)	39 (9.1%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
BETAHISTINE	1 (0.4%)	0
BETAHISTINE HYDROCHLORIDE	4 (1.7%)	5 (1.2%)
BETAHISTINE MESILATE	0	1 (0.2%)
BUFLOMEDIL HYDROCHLORIDE	1 (0.4%)	7 (1.6%)
BUPHENINE HYDROCHLORIDE	0	1 (0.2%)
/ESCIN		
CAFFEINE	0	1 (0.2%)
/DIHYDROERGOCRYPTINE MESILATE		
DIHYDROERGOCORNINE MESILATE	0	2 (0.5%)
/DIHYDROERGOCRISTINE MESILATE		
/DIHYDROERGOCRYPTINE MESILATE		
DIHYDROERGOCRISTINE MESILATE	1 (0.4%)	0
/PIRACETAM		
DIHYDROERGOCRISTINE MESILATE	1 (0.4%)	3 (0.7%)
/RAUBASINE		
FLUNARIZINE DIHYDROCHLORIDE	2 (0.9%)	2 (0.5%)
GINKGO TREE LEAVES EXTRACT	1 (0.4%)	6 (1.4%)
IFENPRODIL TARTRATE	1 (0.4%)	3 (0.7%)
INOSITOL NICOTINATE	0	1 (0.2%)
MOXISYLYTE HYDROCHLORIDE	0	2 (0.5%)
NAFTIDROFURYL OXALATE	7 (3.1%)	12 (2.8%)
NICERGOLINE	1 (0.4%)	2 (0.5%)
NICOTINYL TARTRATE	1 (0.4%)	0
PENTOXIFYLLINE	5 (2.2%)	4 (0.9%)
PIRIBEDIL	0	1 (0.2%)
VINBURNINE	0	2 (0.5%)
VASOPROTECTIVES	31 (13.5%)	74 (17.2%)
AESCLUS (OLD CODE)	0	1 (0.2%)
/CRATAEGUS EXTRACT		
/METESCULETOL SODIUM		
/PASSIFLORA EXTRACT		
ARNICA	0	1 (0.2%)
/HORSE CHESTNUT EXTRACT		
/HYOSCYAMUS DRY EXTRACT		
/SCOPARIUM		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ASCORBIC ACID	1 (0.4%)	2 (0.5%)
/HERBAL EXTRACTS NOS		
/HESPERIDIN METHYL CHALCONE		
/PANCREAS EXTRACT		
ASCORBIC ACID	4 (1.7%)	3 (0.7%)
/HESPERIDIN METHYL CHALCONE		
/RUSCUS ACULEATUS		
ASCORBIC ACID	0	1 (0.2%)
/RUSCUS ACULEATUS RHIZOME		
BENZQUERCIN	1 (0.4%)	0
BETACAROTENE	1 (0.4%)	3 (0.7%)
/MYRTILLUS		
BETAMETHASONE	1 (0.4%)	10 (2.3%)
BETAMETHASONE	0	1 (0.2%)
/CLOTRIMAZOLE		
/GENTAMICIN		
BISMUTH SUBGALLATE	0	1 (0.2%)
/CARRAGENATE		
/TALC		
/ZINC OXIDE		
BUPHENINE HYDROCHLORIDE	0	1 (0.2%)
/ESCIN		
CALCIUM DOBESILATE	4 (1.7%)	1 (0.2%)
CHROMOCARB DIETHYLAMINE	0	1 (0.2%)
COUMARIN	0	1 (0.2%)
/TROXERUTIN		
DIOSMIN	11 (4.8%)	19 (4.4%)
ERYTHROMYCIN	0	2 (0.5%)
/METHIONINE		
/MULTIVITAMINS, NOS		
/RUTOSIDE		
/SULFAFURAZOLE		
FLAVODATE DISODIUM	0	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
GINKGO TREE LEAVES EXTRACT	3 (1.3%)	6 (1.4%)
/HEPTAMINOL HYDROCHLORIDE		
/TROXERUTIN		
GLYCOL SALICYLATE	0	1 (0.2%)
/HEPARIN SODIUM		
HEPARIN	2 (0.9%)	4 (0.9%)
HEPARIN SODIUM	0	1 (0.2%)
HEPARIN SODIUM, TOPICAL	0	1 (0.2%)
HERBAL EXTRACTS NOS	2 (0.9%)	6 (1.4%)
/VITIS VINIFERA		
HEXAMIDINE ISETHIONATE	1 (0.4%)	0
/TETRACAINE HYDROCHLORIDE		
HIRUDIN	0	2 (0.5%)
HORSE CHESTNUT EXTRACT	0	1 (0.2%)
/THIAMINE HYDROCHLORIDE		
HYDROCORTISONE BUTYRATE	2 (0.9%)	7 (1.6%)
MELILOL	4 (1.7%)	6 (1.4%)
/RUTOSIDE		
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	1 (0.2%)
NAFTAZONE	1 (0.4%)	0
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.4%)	2 (0.5%)
RUTOSIDE	0	3 (0.7%)
TROXERUTIN	3 (1.3%)	6 (1.4%)
CENTRAL NERVOUS SYSTEM		
ANAESTHETICS	6 (2.6%)	11 (2.6%)
ARTICAINE HYDROCHLORIDE	0	1 (0.2%)
/EPINEPHRINE HYDROCHLORIDE		
BUPIVACAINE	0	1 (0.2%)
CETYLPRIDINIUM CHLORIDE	0	2 (0.5%)
/CHLOROBUTANOL		
/EUGENOL		
/VERATROLE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
FENTANYL	0	1 (0.2%)
HEXAMIDINE ISETHIONATE	1 (0.4%)	0
/TETRACAINE HYDROCHLORIDE		
KETAMINE	0	1 (0.2%)
LIDOCAINE	0	1 (0.2%)
LIDOCAINE	3 (1.3%)	0
/METHYLPREDNISOLONE ACETATE		
LIDOCAINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
LOCAL ANESTHESIA	1 (0.4%)	0
MIDAZOLAM MALEATE	0	2 (0.5%)
PRILOCAINE HYDROCHLORIDE	0	1 (0.2%)
PROCAINE	0	2 (0.5%)
PROPOFOL	0	1 (0.2%)
ROPIVACAINE HYDROCHLORIDE	0	1 (0.2%)
ANALGESICS	110 (48.0%)	199 (46.3%)
ACETYLSALICYLATE CALCIUM	2 (0.9%)	1 (0.2%)
ACETYLSALICYLATE LYSINE	2 (0.9%)	13 (3.0%)
ACETYLSALICYLIC ACID	60 (26.2%)	67 (15.6%)
ACETYLSALICYLIC ACID	3 (1.3%)	1 (0.2%)
/ALUMINIUM HYDROXIDE		
/MAGNESIUM HYDROXIDE		
ACETYLSALICYLIC ACID	1 (0.4%)	2 (0.5%)
/ASCORBIC ACID		
ACETYLSALICYLIC ACID	0	2 (0.5%)
/CAFFEINE		
ACETYLSALICYLIC ACID	0	1 (0.2%)
/CAFFEINE		
/PHENACETIN		
ACETYLSALICYLIC ACID	1 (0.4%)	0
/CAFFEINE		
/QUININE SULFATE		
ACETYLSALICYLIC ACID	0	2 (0.5%)
/LITHIUM CITRATE		
/QUININE CITRATE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
AMYLASE	0	4 (0.9%)
/PARACETAMOL		
ASCORBIC ACID	2 (0.9%)	4 (0.9%)
/PARACETAMOL		
BELLADONNA EXTRACT	0	4 (0.9%)
/CAFFEINE		
/OPIUM TINCTURE		
/PARACETAMOL		
BENZALKONIUM CHLORIDE	1 (0.4%)	0
/DICHLORALPHENAZONE		
/DIMETICONE, ACTIVATED		
/HYDROCORTISONE		
/ISOMETHEPTENE		
/NYSTATIN		
/PARACETAMOL		
BENZOCAINE	1 (0.4%)	1 (0.2%)
/SALICYLAMIDE		
BUCLIZINE HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
/CODEINE PHOSPHATE		
/PARACETAMOL		
BUPRENORPHINE	0	1 (0.2%)
BUTALBITAL	1 (0.4%)	0
/CAFFEINE		
/DIHYDROERGOTAMINE MESILATE		
/PROPYPHENAZONE		
BUTALBITAL	0	1 (0.2%)
/CAFFEINE		
/PROPYPHENAZONE		
CAFFEINE	2 (0.9%)	7 (1.6%)
/CARBASALATE CALCIUM		
/CHLORPHENAMINE MALEATE		
/DEXTROPROPOXYPHENE		
/PARACETAMOL		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CAFFEINE	0	1 (0.2%)
/CODEINE PHOSPHATE		
/PARACETAMOL		
CARBAMOYLPHENOXYACETIC ACID	0	1 (0.2%)
/CYANOCOBALAMIN		
/LIDOCAINE		
/SODIUM CHLORIDE		
CARBASALATE CALCIUM	0	1 (0.2%)
CLONIDINE HYDROCHLORIDE	0	3 (0.7%)
CODEINE	0	1 (0.2%)
CODEINE PHOSPHATE	2 (0.9%)	2 (0.5%)
CODEINE PHOSPHATE	10 (4.4%)	20 (4.7%)
/PARACETAMOL		
DEXAMETHASONE ACETATE	0	3 (0.7%)
/GLYCOL SALICYLATE		
/METHYL NICOTINATE		
/SALICYLAMIDE		
DEXTROPROPOXYPHENE	0	2 (0.5%)
/PARACETAMOL		
DEXTROPROPOXYPHENE HYDROCHLORIDE	21 (9.2%)	36 (8.4%)
/PARACETAMOL		
DEXTROPROPOXYPHENE NAPSILATE	0	1 (0.2%)
DIHYDROCODEINE	2 (0.9%)	0
DIHYDROCODEINE BITARTRATE	0	4 (0.9%)
DIHYDROCODEINE BITARTRATE	6 (2.6%)	4 (0.9%)
/PARACETAMOL		
DIHYDROERGOTAMINE MESILATE	2 (0.9%)	2 (0.5%)
FENTANYL	0	1 (0.2%)
GUAIFENESIN	1 (0.4%)	3 (0.7%)
/OXOMEMAZINE		
/PARACETAMOL		
/SODIUM BENZOATE		
HEROIN	1 (0.4%)	0

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
KETOBEMIDONE HYDROCHLORIDE	0	1 (0.2%)
/N,N-DIMETHYL-3,3-DIPHENYL-1-METHYLALLYLAMINE		
HYDROCHLOR		
METAMIZOLE SODIUM	5 (2.2%)	2 (0.5%)
MORPHINE	1 (0.4%)	2 (0.5%)
MORPHINE SULFATE	0	2 (0.5%)
NALBUPHINE HYDROCHLORIDE	1 (0.4%)	0
NALOXONE HYDROCHLORIDE	0	1 (0.2%)
/TILIDINE HYDROCHLORIDE		
PARACETAMOL	38 (16.6%)	84 (19.5%)
PETHIDINE	0	1 (0.2%)
PIZOTIFEN	0	1 (0.2%)
PROPACETAMOL HYDROCHLORIDE	0	1 (0.2%)
SODIUM ACETYLSALICYLATE	0	1 (0.2%)
TRAMADOL	1 (0.4%)	1 (0.2%)
TRAMADOL HYDROCHLORIDE	3 (1.3%)	8 (1.9%)
ZOLMITRIPTAN	0	1 (0.2%)
ANTI-PARKINSON DRUGS	0	5 (1.2%)
BENZHEXOL HYDROCHLORIDE	0	1 (0.2%)
/DEMELVERINUM HYDROCHLORICUM		
DEXETIMIDE	0	1 (0.2%)
ORPHENADRINE CITRATE	0	2 (0.5%)
TRIHXYPHENIDYL HYDROCHLORIDE	0	1 (0.2%)
ANTIEPILEPTICS	5 (2.2%)	6 (1.4%)
CARBAMAZEPINE	2 (0.9%)	3 (0.7%)
CLONAZEPAM	3 (1.3%)	2 (0.5%)
DIFEBARBAMATE	0	1 (0.2%)
/FEBARBAMATE		
/PHENOBARBITAL		
GABAPENTIN	1 (0.4%)	0
VALPROATE SODIUM	0	1 (0.2%)
VALPROATE SODIUM	0	1 (0.2%)
/VALPROIC ACID		
OTHER	1 (0.4%)	6 (1.4%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CALCIUM LACTATE	1 (0.4%)	0
/CIMICIFUGA		
/MAGNESIUM HYPOSULFITE		
/OLEOSACCHARUM OF MARJOLAIN		
PILOCARPINE	0	5 (1.2%)
PILOCARPINE HYDROCHLORIDE	0	1 (0.2%)
/TIMOLOL MALEATE		
PSYCHOANALEPTICS	18 (7.9%)	39 (9.1%)
AMFEBUTAMONE	1 (0.4%)	0
AMITRIPTYLINE	4 (1.7%)	1 (0.2%)
AMITRIPTYLINE HYDROCHLORIDE	2 (0.9%)	3 (0.7%)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.4%)	0
/MEDAZEPAM		
AMITRIPTYLINE HYDROCHLORIDE	1 (0.4%)	0
/PERPHENAZINE		
CITALOPRAM	1 (0.4%)	7 (1.6%)
CLOMIPRAMINE HYDROCHLORIDE	0	4 (0.9%)
DEANOL PIDOLATE	1 (0.4%)	0
/HEPTAMINOL HYDROCHLORIDE		
DOSULEPIN	0	2 (0.5%)
DOXEPIN HYDROCHLORIDE	0	1 (0.2%)
FLUOXETINE	5 (2.2%)	8 (1.9%)
FLUVOXAMINE MALEATE	0	2 (0.5%)
HYPERICUM EXTRACT	0	1 (0.2%)
IMIPRAMINE	1 (0.4%)	0
IMIPRAMINE HYDROCHLORIDE	0	2 (0.5%)
LEVOCARNITINE	0	1 (0.2%)
/MAGNESIUM ASPARTATE		
MAPROTILINE HYDROCHLORIDE	1 (0.4%)	0
MIANSERIN HYDROCHLORIDE	0	3 (0.7%)
MILNACIPRAN HYDROCHLORIDE	0	2 (0.5%)
PIRACETAM	2 (0.9%)	5 (1.2%)
SERTRALINE	0	1 (0.2%)
SERTRALINE HYDROCHLORIDE	3 (1.3%)	0
TRIMIPRAMINE MALEATE	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
VENLAFAXINE HYDROCHLORIDE	0	1 (0.2%)
VILOXAZINE HYDROCHLORIDE	0	2 (0.5%)
PSYCHOLEPTICS	31 (13.5%)	89 (20.7%)
ACEPROMAZINE	0	1 (0.2%)
/ACEPROMETAZINE		
/DIPOTASSIUM CLORAZEPATE		
ALPRAZOLAM	3 (1.3%)	7 (1.6%)
ASPARAGINE	0	1 (0.2%)
/DIAZEPAM		
/LEVONGLUTAMIDE		
/PYRIDOXINE		
/SERINE PHOSPHATE		
/THIAMINE		
BALLOTA	3 (1.3%)	3 (0.7%)
/COLA		
/CRATAEGUS EXTRACT		
/PASSIFLORA EXTRACT		
/PAULLINIA		
/VALERIAN ROOT		
BROMAZEPAM	5 (2.2%)	9 (2.1%)
BROMPERIDOL	0	1 (0.2%)
CHLORPROTHIXENE HYDROCHLORIDE	0	1 (0.2%)
CLOMETHIAZOLE EDISILATE	0	1 (0.2%)
CLOTIAZEPAM	0	1 (0.2%)
CRATAEGUS	0	2 (0.5%)
/VALERIAN ROOT		
CRATAEGUS EXTRACT	0	1 (0.2%)
/VALERIAN EXTRACT		
CYAMEMAZINE	0	2 (0.5%)
DELORAZEPAM	1 (0.4%)	0
DIAZEPAM	1 (0.4%)	10 (2.3%)
DIAZEPAM	1 (0.4%)	0
/SULPIRIDE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DIFEBARBAMATE	0	1 (0.2%)
/FEBARBAMATE		
/PHENOBARBITAL		
DIPOTASSIUM CLORAZEPATE	2 (0.9%)	2 (0.5%)
ETHYL LOFLAZEPATE	0	1 (0.2%)
FLUNITRAZEPAM	1 (0.4%)	4 (0.9%)
FLUPENTIXOL DIHYDROCHLORIDE	0	1 (0.2%)
FLUPHENAZINE	0	1 (0.2%)
HALOPERIDOL	0	1 (0.2%)
HERBAL EXTRACTS NOS	0	1 (0.2%)
/PHENOBARBITAL		
HYDROXYZINE HYDROCHLORIDE	2 (0.9%)	1 (0.2%)
HYPERICUM EXTRACT	0	1 (0.2%)
LEVOMEPRIMAZINE HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
LITHIUM CARBONATE	0	1 (0.2%)
LOPRAZOLAM	1 (0.4%)	0
LOPRAZOLAM MESILATE	0	1 (0.2%)
LORAZEPAM	1 (0.4%)	7 (1.6%)
LORMETAZEPAM	1 (0.4%)	4 (0.9%)
NITRAZEPAM	1 (0.4%)	0
NORDAZEPAM	0	1 (0.2%)
OXAZEPAM	1 (0.4%)	5 (1.2%)
PAROXETINE	2 (0.9%)	6 (1.4%)
PRAZEPAM	4 (1.7%)	2 (0.5%)
PROCHLORPERAZINE	2 (0.9%)	4 (0.9%)
PROCHLORPERAZINE MALEATE	1 (0.4%)	1 (0.2%)
PROMETHAZINE HYDROCHLORIDE	0	1 (0.2%)
PROXIBARBAL	0	1 (0.2%)
RISPERIDONE	0	1 (0.2%)
SULPIRIDE	0	2 (0.5%)
TEMAZEPAM	1 (0.4%)	2 (0.5%)
TETRAZEPAM	3 (1.3%)	13 (3.0%)
THIORIDAZINE HYDROCHLORIDE	0	1 (0.2%)
TRIAZOLAM	0	2 (0.5%)
ZOLPIDEM HEMITARTRATE	3 (1.3%)	10 (2.3%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ZOPICLONE	0	13 (3.0%)
DERMATOLOGICALS		
ANTI-ACNE PREP	4 (1.7%)	2 (0.5%)
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
RETINOL	1 (0.4%)	0
ANTIBIOTIC&CHEMOTHERAPEUT	26 (11.4%)	26 (6.0%)
BACITRACIN	0	1 (0.2%)
/NEOMYCIN SULFATE		
BETAMETHASONE	0	1 (0.2%)
/CLOTRIMAZOLE		
/GENTAMICIN		
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
ERYTHROMYCIN	11 (4.8%)	6 (1.4%)
FRAMYCETIN SULFATE	0	1 (0.2%)
/TRYPSIN		
FUSIDATE SODIUM	3 (1.3%)	2 (0.5%)
FUSIDATE SODIUM	0	1 (0.2%)
/HYDROCORTISONE ACETATE		
FUSIDIC ACID	2 (0.9%)	4 (0.9%)
GENTAMICIN SULFATE	1 (0.4%)	3 (0.7%)
METRONIDAZOLE	6 (2.6%)	5 (1.2%)
MUPIROCI	1 (0.4%)	0
OXYTETRACYCLINE	3 (1.3%)	1 (0.2%)
OXYTETRACYCLINE DIHYDRATE	1 (0.4%)	0
SULFADIAZINE SILVER	1 (0.4%)	1 (0.2%)
TETRACYCLINE	2 (0.9%)	1 (0.2%)
ANTIFUNGALS	18 (7.9%)	26 (6.0%)
AMOROLFINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
BETAMETHASONE	0	1 (0.2%)
/CLOTRIMAZOLE		
/GENTAMICIN		
BETAMETHASONE DIPROPIONATE	0	1 (0.2%)
/CLOTRIMAZOLE		
BIFONAZOLE	1 (0.4%)	3 (0.7%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
BIFONAZOLE	0	2 (0.5%)
/UREA		
BUTOCONAZOLE NITRATE	0	1 (0.2%)
CLOTRIMAZOLE	6 (2.6%)	7 (1.6%)
CLOTRIMAZOLE	1 (0.4%)	1 (0.2%)
/HYDROCORTISONE		
ECONAZOLE NITRATE	1 (0.4%)	3 (0.7%)
FENTICONAZOLE NITRATE	0	1 (0.2%)
GRISEOFULVIN	2 (0.9%)	0
HEXETIDINE	0	1 (0.2%)
HYDROCORTISONE	0	1 (0.2%)
/MICONAZOLE		
HYDROCORTISONE	3 (1.3%)	3 (0.7%)
/MICONAZOLE NITRATE		
ISOCONAZOLE NITRATE	1 (0.4%)	1 (0.2%)
KETOCONAZOLE	2 (0.9%)	2 (0.5%)
MICONAZOLE	0	1 (0.2%)
MICONAZOLE NITRATE	0	1 (0.2%)
NYSTATIN	2 (0.9%)	0
TERBINAFINE	2 (0.9%)	4 (0.9%)
TIOCONAZOLE	1 (0.4%)	0
ANTIPRURITICS	1 (0.4%)	10 (2.3%)
CINCHOCAINE HYDROCHLORIDE	0	1 (0.2%)
CINCHOCAINE HYDROCHLORIDE	0	1 (0.2%)
/CLOCORTOLONE HEXANOATE		
/CLOCORTOLONE PIVALATE		
DIPHENHYDRAMINE HYDROCHLORIDE	0	2 (0.5%)
DOXEPIN HYDROCHLORIDE	0	1 (0.2%)
LIDOCAINE	0	1 (0.2%)
LIDOCAINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
NOSCAPINE	0	1 (0.2%)
/POLYSORBATE 85 (TWEEN 85)		
/PROMETHAZINE		
PROMETHAZINE HYDROCHLORIDE	0	1 (0.2%)
ANTISEPTICS & DISINFECTANTS	11 (4.8%)	12 (2.8%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ALLANTOIN	1 (0.4%)	0
/CETRIMONIUM BROMIDE		
/DICHLOOROBENZYL ALCOHOL		
CETRIMONIUM BROMIDE	1 (0.4%)	0
CETYLPRIDINIUM CHLORIDE	0	2 (0.5%)
/CHLOROBUTANOL		
/EUGENOL		
/VERATROLE		
CHLORHEXIDINE GLUCONATE	0	1 (0.2%)
CHLOROQUINE	2 (0.9%)	0
ESSENTIAL OILS NOS	0	1 (0.2%)
/ETHANOL		
/GLYCEROL		
/METHYL SALICYLATE		
/SALICYLATE SODIUM		
/SODIUM BICARBONATE		
/SODIUM TETRABORATE		
/THYMOL		
ETHACRIDINE	0	1 (0.2%)
HEXAMIDINE ISETHIONATE	2 (0.9%)	1 (0.2%)
HEXAMIDINE ISETHIONATE	1 (0.4%)	0
/TETRACAINE HYDROCHLORIDE		
HYDROCORTISONE	1 (0.4%)	0
/ICHTHAMMOL		
NIFUROXAZIDE	2 (0.9%)	5 (1.2%)
POVIDONE-IODINE	3 (1.3%)	1 (0.2%)
SODIUM HYPOCHLORITE	0	1 (0.2%)
TRICLOCARBAN	0	1 (0.2%)
CICATRIZANTS	0	3 (0.7%)
ALLANTOIN	0	1 (0.2%)
/CADE OIL		
/SALICYLIC ACID		
ASIATIC ACID	0	1 (0.2%)
/ASIATICOSIDE		
/MADECASSIC ACID		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DEXPANTHENOL	0	1 (0.2%)
COAL TAR,SULPH,RESORCIN PROD	0	4 (0.9%)
ALLANTOIN	0	1 (0.2%)
/COAL TAR SOLUTION		
CADE OIL	0	1 (0.2%)
/COAL TAR		
/COAL TAR SOLUTION		
/OLEYL ALCOHOL		
COAL TAR EXTRACT	0	1 (0.2%)
/HYDROCORTISONE		
TAZAROTENE	0	1 (0.2%)
CORTICOSTEROIDS	25 (10.9%)	58 (13.5%)
BETAMETHASONE	1 (0.4%)	10 (2.3%)
BETAMETHASONE	0	1 (0.2%)
/CLOTRIMAZOLE		
/GENTAMICIN		
BETAMETHASONE	0	1 (0.2%)
/NEOMYCIN		
BETAMETHASONE ACETATE	1 (0.4%)	2 (0.5%)
/BETAMETHASONE SODIUM PHOSPHATE		
BETAMETHASONE DIPROPIONATE	1 (0.4%)	3 (0.7%)
BETAMETHASONE DIPROPIONATE	0	1 (0.2%)
/CLOTRIMAZOLE		
BETAMETHASONE DIPROPIONATE	0	2 (0.5%)
/SALICYLIC ACID		
BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.2%)
BETAMETHASONE VALERATE	5 (2.2%)	0
BETAMETHASONE VALERATE	0	1 (0.2%)
/CLIOQUINOL		
BETAMETHASONE VALERATE	2 (0.9%)	1 (0.2%)
/FUSIDIC ACID		
BUDESONIDE	0	9 (2.1%)
CINCHOCAINE HYDROCHLORIDE	0	1 (0.2%)
/CLOCORTOLONE HEXANOATE		
/CLOCORTOLONE PIVALATE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CLIOQUINOL	1 (0.4%)	0
/HYDROCORTISONE		
CLIOQUINOL	1 (0.4%)	0
/HYDROCORTISONE		
/NYSTATIN		
CLOBETASOL PROPIONATE	0	1 (0.2%)
CLOCORTOLONE HEXANOATE	0	1 (0.2%)
/CLOCORTOLONE PIVALATE		
CLOTRIMAZOLE	1 (0.4%)	1 (0.2%)
/HYDROCORTISONE		
COAL TAR EXTRACT	0	1 (0.2%)
/HYDROCORTISONE		
DESONIDE	1 (0.4%)	0
DESOXIMETASONE	1 (0.4%)	1 (0.2%)
DEXAMETHASONE ACETATE	0	3 (0.7%)
/GLYCOL SALICYLATE		
/METHYL NICOTINATE		
/SALICYLAMIDE		
DEXAMETHASONE SODIUM PHOSPHATE	0	2 (0.5%)
/NEOMYCIN SULFATE		
DIFLUCORTOLONE VALERATE	0	1 (0.2%)
FLUOCINOLONE ACETONIDE	1 (0.4%)	1 (0.2%)
/NEOMYCIN SULFATE		
/POLYMYXIN B SULFATE		
FLUOCINONIDE	1 (0.4%)	0
FLUOCORTIN BUTYL	0	1 (0.2%)
FLUTICASONE PROPIONATE	1 (0.4%)	5 (1.2%)
FRAMYCETIN SULFATE	1 (0.4%)	0
/HYDROCORTISONE		
FUSIDATE SODIUM	0	1 (0.2%)
/HYDROCORTISONE ACETATE		
HYDROCORTISONE	4 (1.7%)	2 (0.5%)
HYDROCORTISONE	1 (0.4%)	0
/ICHTHAMMOL		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
HYDROCORTISONE ACETATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
HYDROCORTISONE BUTYRATE	2 (0.9%)	7 (1.6%)
METHYLPREDNISOLONE	3 (1.3%)	1 (0.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
MOMETASONE FUROATE	0	4 (0.9%)
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.4%)	2 (0.5%)
SALICYLIC ACID	0	1 (0.2%)
/TRIAMCINOLONE ACETONIDE		
TRIAMCINOLONE ACETONIDE	1 (0.4%)	3 (0.7%)
TRIAMCINOLONE HEXACETONIDE	0	1 (0.2%)
EMOLLIENTS & PROTECTIVES	14 (6.1%)	23 (5.3%)
ALGIN	2 (0.9%)	0
/CETYL PALMITATE		
/ETHYLENE GLYCOL MONOSTEARATE		
/PARAFFIN		
/PARAFFIN, LIQUID		
/PROPYLENE GLYCOL		
/STEARYL ALCOHOL		
/TROLAMINE		
ALOES	0	1 (0.2%)
BEESWAX WHITE	0	1 (0.2%)
/PARAFFIN		
/WHITE VASELINE		
/ZINC OXIDE		
BETAINE	1 (0.4%)	0
/LACTIC ACID		
/UREA		
BIFONAZOLE	0	2 (0.5%)
/UREA		
CALCIPOTRIOL	1 (0.4%)	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CETOSTEARYL ALCOHOL	1 (0.4%)	0
/GLYCERYL MONOSTEARATE		
/PARAFFIN, LIQUID		
/PARAFFIN, SOFT		
/POLYSORBATE 40		
/PROPYLENE GLYCOL		
/SILICIC ACID		
/SORBIC ACID		
COD-LIVER OIL	2 (0.9%)	3 (0.7%)
CYCLOMETHICONE	1 (0.4%)	0
/SOFT PARAFFIN		
EMULSIFYING WAX	1 (0.4%)	1 (0.2%)
/PARAFFIN, LIQUID		
/PARAFFIN, SOFT		
GLYCERYL MONOSTEARATE	1 (0.4%)	0
/METHYLPARABEN		
/PARAFFIN, LIQUID		
/PARAFFIN, SOFT		
/STEARIC ACID		
/TROLAMINE		
/WOOL FAT		
LACTULOSE	0	1 (0.2%)
/PARAFFIN		
/PARAFFIN, SOFT		
LYCOPENE	0	1 (0.2%)
/RETINOL		
/TOCOPHEROL		
PARAFFIN, LIQUID	1 (0.4%)	1 (0.2%)
PARAFFIN, LIQUID	1 (0.4%)	0
/WOOL ALCOHOLS		
PARAFFIN, SOFT	2 (0.9%)	2 (0.5%)
PIAS	3 (1.3%)	5 (1.2%)
TOCOPHEROL	0	1 (0.2%)
UREA	0	2 (0.5%)
WHEAT GERM	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
MEDICATED DRESSINGS	5 (2.2%)	10 (2.3%)
CALCIUM ALGINATE	1 (0.4%)	0
ETHANOLAMINE TENOATE /FRAMYCETIN SULFATE	0	1 (0.2%)
FRAMYCETIN SULFATE	0	2 (0.5%)
FUSIDATE SODIUM	3 (1.3%)	2 (0.5%)
FUSIDIC ACID	2 (0.9%)	4 (0.9%)
MEDICATED DRESSINGS NOS	0	1 (0.2%)
OTHER	6 (2.6%)	14 (3.3%)
ACITRETIN	0	1 (0.2%)
ALLANTOIN	0	1 (0.2%)
/CADE OIL		
/SALICYLIC ACID		
ALUMINIUM CHLOROHYDRATE	0	1 (0.2%)
ARNICA	0	1 (0.2%)
/HORSE CHESTNUT EXTRACT		
/HYOSCYAMUS DRY EXTRACT		
/SCOPARIUM		
CALCIPOTRIOL	1 (0.4%)	2 (0.5%)
CYSTEINE HYDROCHLORIDE /METHIONINE	0	1 (0.2%)
DERMATOLOGICALS NOS	1 (0.4%)	1 (0.2%)
FRAMYCETIN SULFATE /TRYPSIN	0	1 (0.2%)
LIQUID NITROGEN	1 (0.4%)	3 (0.7%)
POVIDONE-IODINE	3 (1.3%)	1 (0.2%)
SALICYLIC ACID	0	2 (0.5%)
SERRAPEPTASE	0	3 (0.7%)
GU SYSTEM/SEX HORMONES		
ANTIINFECTIVES/ANTISEPTICS	27 (11.8%)	21 (4.9%)
ACETARSOL	1 (0.4%)	0
/NEOMYCIN		
/NYSTATIN		
/POLYMYXIN B SULFATE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ANTIBIOTIC NOS	3 (1.3%)	1 (0.2%)
BUTOCONAZOLE NITRATE	0	1 (0.2%)
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
CICLOPIROX OLAMINE	1 (0.4%)	1 (0.2%)
CLOTRIMAZOLE	6 (2.6%)	7 (1.6%)
ECONAZOLE NITRATE	1 (0.4%)	3 (0.7%)
METRONIDAZOLE	6 (2.6%)	5 (1.2%)
MICONAZOLE	0	1 (0.2%)
MICONAZOLE NITRATE	0	1 (0.2%)
NEOMYCIN SULFATE	1 (0.4%)	0
/NYSTATIN		
/PREDNISOLONE SODIUM SULFOBENZOATE		
/TERNIDAZOLE		
NYSTATIN	2 (0.9%)	0
OXYTETRACYCLINE	3 (1.3%)	1 (0.2%)
OXYTETRACYCLINE DIHYDRATE	1 (0.4%)	0
POVIDONE-IODINE	3 (1.3%)	1 (0.2%)
OTHER	3 (1.3%)	6 (1.4%)
ALPROSTADIL	3 (1.3%)	3 (0.7%)
HYPERICUM EXTRACT	0	1 (0.2%)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (0.2%)
QUINAGOLIDE HYDROCHLORIDE	0	1 (0.2%)
SEX HORMONES/STIMULANTS	8 (3.5%)	32 (7.4%)
BOVINE TESTICULAR EXTRACT	0	1 (0.2%)
CHLORMADINONE ACETATE	0	1 (0.2%)
DESOGESTREL	0	1 (0.2%)
/ETHINYLESTRADIOL		
DIENESTROL	0	1 (0.2%)
DYDROGESTERONE	0	1 (0.2%)
DYDROGESTERONE	2 (0.9%)	0
/ESTRADIOL		
ESTRADIOL	0	4 (0.9%)
ESTRADIOL	0	1 (0.2%)
/ESTRIOL		
/NORETHISTERONE ACETATE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ESTRADIOL	1 (0.4%)	3 (0.7%)
/NORETHISTERONE ACETATE		
ESTRADIOL VALERATE	0	2 (0.5%)
ESTRADIOL VALERATE	0	1 (0.2%)
/MEDROXYPROGESTERONE ACETATE		
ESTRIOL	0	3 (0.7%)
ESTRIOL	0	1 (0.2%)
/LACTOBACILLUS ACIDOPHILUS		
/PROGESTERONE		
ESTRIOL DISODIUM SUCCINATE	0	1 (0.2%)
ESTROGEN NOS	0	3 (0.7%)
ESTROGEN NOS	0	1 (0.2%)
/MEDROXYPROGESTERONE		
ESTROGENS CONJUGATED	1 (0.4%)	2 (0.5%)
ESTROGENS CONJUGATED	0	1 (0.2%)
/NORGESTREL		
FINASTERIDE	2 (0.9%)	5 (1.2%)
LYNESTRENOL	0	1 (0.2%)
MEDROGESTONE	0	1 (0.2%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.2%)
NOMEGESTROL ACETATE	1 (0.4%)	2 (0.5%)
NORETHISTERONE	0	1 (0.2%)
NORETHISTERONE ACETATE	0	1 (0.2%)
PROGESTERONE	1 (0.4%)	0
PROMEGESTONE	0	2 (0.5%)
PROMESTRIENE	0	4 (0.9%)
TESTOSTERONE ENANTATE	1 (0.4%)	0
UROLOGICALS	17 (7.4%)	57 (13.3%)
ALFUZOSIN	0	4 (0.9%)
ALFUZOSIN HYDROCHLORIDE	1 (0.4%)	5 (1.2%)
AMINOACETIC ACID	1 (0.4%)	0
/GLUTAMIC ACID		
/PRUNUS AFRICANA		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CAMPBOR MONOBROMIDE	0	1 (0.2%)
/HERBAL EXTRACTS NOS		
/METHENAMINE		
CANDESARTAN CILEXETIL	0	2 (0.5%)
CIPROFLOXACIN	4 (1.7%)	1 (0.2%)
CIPROFLOXACIN HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
DOXAZOSIN MESYLATE	0	5 (1.2%)
ECHINACEA EXTRACT	0	2 (0.5%)
/SABAL EXTRACT		
ECHINACEA EXTRACT	0	3 (0.7%)
/SABAL EXTRACT		
/TROSPIUM CHLORIDE		
ENOXACIN	0	4 (0.9%)
FLAVOXATE HYDROCHLORIDE	0	1 (0.2%)
FLUMEQUINE	0	1 (0.2%)
LIPOPHILER EXTRACT	0	1 (0.2%)
/SABAL EXTRACT		
NIFURTOINOL	0	1 (0.2%)
NITROFURANTOIN	1 (0.4%)	2 (0.5%)
NITROXOLINE	0	1 (0.2%)
NORFLOXACIN	4 (1.7%)	10 (2.3%)
OFLOXACIN	2 (0.9%)	11 (2.6%)
OXYBUTYNIN	3 (1.3%)	4 (0.9%)
OXYBUTYNIN HYDROCHLORIDE	1 (0.4%)	0
PRAZOSIN	0	6 (1.4%)
PYGEUM AFRICANUM	0	1 (0.2%)
SERENOA REPENS	3 (1.3%)	4 (0.9%)
SILDENAFIL CITRATE	3 (1.3%)	1 (0.2%)
SOLIDAGO	0	1 (0.2%)
TAMSULOSIN	0	1 (0.2%)
TAMSULOSIN HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
TERAZOSIN	0	1 (0.2%)
TERAZOSIN HYDROCHLORIDE	0	3 (0.7%)
TOLTERODINE	1 (0.4%)	0

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
MUSCULO-SKELETAL		
ANTIGOUT PREP	5 (2.2%)	29 (6.7%)
ALLOPURINOL	5 (2.2%)	25 (5.8%)
ALLOPURINOL	0	1 (0.2%)
/BENZBROMARONE		
BENZBROMARONE	0	1 (0.2%)
COLCHICINE	0	3 (0.7%)
COLCHICINE	0	1 (0.2%)
/DICYCLOVERINE HYDROCHLORIDE		
COLCHICINE	0	1 (0.2%)
/OPIUM		
/TIEMONIUM METHYLSULFATE		
PROBENECID	0	1 (0.2%)
ANTIINFLAM/ANTIRHEU PROD	61 (26.6%)	149 (34.7%)
ACECLOFENAC	5 (2.2%)	1 (0.2%)
ACOMETACIN	1 (0.4%)	0
ALMINOPROFEN	0	2 (0.5%)
AMINOPHENAZONE	0	1 (0.2%)
/CYANOCOBALAMIN		
/DEXAMETHASONE SODIUM METASULFOBENZOATE		
/LIDOCAINE HYDROCHLORIDE		
/PHENYL BUTAZONE SODIUM		
BETA CYCLODEXTRIN	0	1 (0.2%)
/NIMESULIDE		
CELECOXIB	0	1 (0.2%)
CHONDROITIN SULFATE SODIUM	1 (0.4%)	1 (0.2%)
CHYMOTRYPSINOGEN	1 (0.4%)	1 (0.2%)
/RIBONUCLEASE		
/TRYPSIN		
DEKXETOPROFEN TROMETAMOL	2 (0.9%)	0
DEXTRAN SULPHATE	0	1 (0.2%)
/PHENYL BUTAZONE		
DIACEREIN	0	5 (1.2%)
DICLOFENAC	7 (3.1%)	17 (4.0%)
DICLOFENAC DIETHYLAMINE	1 (0.4%)	5 (1.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DICLOFENAC POTASSIUM	0	2 (0.5%)
DICLOFENAC SODIUM	21 (9.2%)	38 (8.8%)
DICLOFENAC SODIUM /MISOPROSTOL	3 (1.3%)	9 (2.1%)
ETODOLAC	1 (0.4%)	3 (0.7%)
FLURBIPROFEN	0	3 (0.7%)
IBUPROFEN	18 (7.9%)	34 (7.9%)
IBUPROFEN /PSEUDOEPHEDRINE HYDROCHLORIDE	3 (1.3%)	9 (2.1%)
IBUPROFEN LYSINATE	0	1 (0.2%)
INDOMETACIN	2 (0.9%)	10 (2.3%)
INDOMETACIN /METAMIZOLE SODIUM	1 (0.4%)	0
/THIAMINE		
KETOPROFEN	8 (3.5%)	28 (6.5%)
KETOPROFEN LYSINE	0	1 (0.2%)
KETOROLAC TROMETHAMINE	0	1 (0.2%)
LIDOCAINE HYDROCHLORIDE	0	1 (0.2%)
/PHENYL BUTAZONE SODIUM		
MELOXICAM	6 (2.6%)	4 (0.9%)
MISOPROSTOL	0	1 (0.2%)
/NAPROXEN		
NABUMETONE	1 (0.4%)	1 (0.2%)
NAPROXEN	5 (2.2%)	8 (1.9%)
NAPROXEN SODIUM	1 (0.4%)	3 (0.7%)
NIFLUMIC ACID	1 (0.4%)	10 (2.3%)
NIMESULIDE	2 (0.9%)	9 (2.1%)
OXACEPROL	0	1 (0.2%)
PIROXICAM	5 (2.2%)	27 (6.3%)
PIROXICAM BETA CYCLODEXTRIN	1 (0.4%)	4 (0.9%)
PRANOPROFEN	0	1 (0.2%)
PROGLUMETACIN MALEATE	0	2 (0.5%)
SERRAPEPTASE	0	3 (0.7%)
SUPROFEN	1 (0.4%)	6 (1.4%)
TENOXICAM	3 (1.3%)	8 (1.9%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
TIAPROFENIC ACID	1 (0.4%)	3 (0.7%)
MUSCLE RELAXANTS	2 (0.9%)	17 (4.0%)
CHLORMEZANONE	0	2 (0.5%)
IDROCILAMIDE	0	2 (0.5%)
ORPHENADRINE CITRATE	0	2 (0.5%)
THIOLCHICOSIDE	2 (0.9%)	11 (2.6%)
OTHER	3 (1.3%)	16 (3.7%)
AMINOHYDROXYPROPYLIDENEDIPHOSPHONATE DISODIUM	1 (0.4%)	0
AMINOPHYLLINE	0	1 (0.2%)
/QUININE SULFATE		
AMTOLMETIN GUACIL SODIUM	0	1 (0.2%)
HARPAGOPHYTUM PROCUMBENS	0	1 (0.2%)
NIAOULI OIL	0	7 (1.6%)
/QUININE BENZOATE		
/THIAMINE HYDROCHLORIDE		
QUININE	0	2 (0.5%)
QUININE HYDROCHLORIDE	0	1 (0.2%)
QUININE SULFATE	1 (0.4%)	2 (0.5%)
URIDINE TRIPHOSPHATE SODIUM	1 (0.4%)	2 (0.5%)
TOPICAL ANTIRHEU PROD	4 (1.7%)	5 (1.2%)
ADRENAL CORTICAL EXTRACT	2 (0.9%)	1 (0.2%)
/MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER		
/SALICYLIC ACID		
BENZYL NICOTINATE	0	1 (0.2%)
/ECHINACEA EXTRACT		
/GLYCOL SALICYLATE		
/HEPARIN SODIUM		
/HESPERIDIN METHYL CHALCONE		
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	2 (0.9%)	0
/SALICYLIC ACID		
OXACEPROL	0	1 (0.2%)
SALICYLIC ACID	0	2 (0.5%)
PARASITOLOGY		
ANTHELMINTICS	1 (0.4%)	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
MEBENDAZOLE	1 (0.4%)	0
NICLOSAMIDE	0	1 (0.2%)
ANTIPROTOZOALS	13 (5.7%)	14 (3.3%)
CHLOROQUINE	2 (0.9%)	0
CHLOROQUINE	1 (0.4%)	0
/PROGUANIL		
CHLOROQUINE SULFATE	2 (0.9%)	1 (0.2%)
MEFLOQUINE	2 (0.9%)	0
METRONIDAZOLE	6 (2.6%)	5 (1.2%)
PROGUANIL HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
QUININE	0	2 (0.5%)
QUININE HYDROCHLORIDE	0	1 (0.2%)
QUININE HYDROCHLORIDE	0	3 (0.7%)
/SULFATE		
QUININE SULFATE	1 (0.4%)	2 (0.5%)
RESPIRATORY		
ANTI-ASTHMATICS	12 (5.2%)	55 (12.8%)
AMINOPHYLLINE	2 (0.9%)	1 (0.2%)
AZELASTINE	0	1 (0.2%)
BAMBUETEROL HYDROCHLORIDE	0	3 (0.7%)
BECLOMETASONE	0	6 (1.4%)
BECLOMETASONE DIPROPIONATE	2 (0.9%)	16 (3.7%)
BUDESONIDE	0	9 (2.1%)
CETIRIZINE	0	1 (0.2%)
/PSEUDOEPHEDRINE		
CROMOGLICATE SODIUM	0	6 (1.4%)
CROMOGLICATE SODIUM	0	1 (0.2%)
/REPROTEROL HYDROCHLORIDE		
DIPROPHYLLINE	0	1 (0.2%)
/TURPENTINE OIL		
EPHEDRINE	0	1 (0.2%)
FENOTEROL HYDROBROMIDE	0	2 (0.5%)
/IPRATROPIUM BROMIDE		
FENSPIRIDE HYDROCHLORIDE	2 (0.9%)	6 (1.4%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
FLUTICASONE	0	3 (0.7%)
/SALMETEROL		
FORMOTEROL FUMARATE	0	5 (1.2%)
IPRATROPIUM	0	1 (0.2%)
IPRATROPIUM BROMIDE	1 (0.4%)	3 (0.7%)
ISOPRENALINE HYDROCHLORIDE	0	2 (0.5%)
LORATADINE	0	1 (0.2%)
/PSEUDOEPHEDRINE SULFATE		
MONTELUKAST SODIUM	0	2 (0.5%)
NEDOCROMIL	0	1 (0.2%)
NEDOCROMIL SODIUM	0	1 (0.2%)
PSEUDOEPHEDRINE	1 (0.4%)	0
REPROTEROL HYDROCHLORIDE	0	1 (0.2%)
SALBUTAMOL	4 (1.7%)	17 (4.0%)
SALBUTAMOL SULFATE	1 (0.4%)	2 (0.5%)
SALMETEROL HYDROXYNAPHTHOATE	0	4 (0.9%)
SALMETEROL XINAFOATE	1 (0.4%)	0
TERBUTALINE	1 (0.4%)	0
TERBUTALINE SULFATE	1 (0.4%)	2 (0.5%)
THEOPHYLLINE	0	9 (2.1%)
COUGH AND COLD PREP	34 (14.8%)	100 (23.3%)
ACETYLCYSTEINE	10 (4.4%)	38 (8.8%)
ACETYLSALICYLIC ACID	1 (0.4%)	0
/ASCORBIC ACID		
/CHLORPHENAMINE MALEATE		
/MOROXDYNE HYDROCHLORIDE		
/PHENYLEPHRINE HYDROCHLORIDE		
ACETYLSALICYLIC ACID	1 (0.4%)	0
/CAFFEINE		
/CHLORPHENAMINE MALEATE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ACONITE TINCTURE	0	1 (0.2%)
/BELLADONNA TINCTURE		
/CODEINE		
/ETHYLMORPHINE		
/POLYGALA AMARA TINCTURE		
/SODIUM BENZOATE		
/SODIUM BROMIDE		
ACONITE TINCTURE	0	3 (0.7%)
/CHERRY-LAUREL		
/CODEINE PHOSPHATE		
/SODIUM BENZOATE		
AMARANTH SOLUTION	2 (0.9%)	1 (0.2%)
/ANISE WATER		
/CHLOROFORM		
/CITRIC ACID		
AMBROXOL	3 (1.3%)	0
AMBROXOL HYDROCHLORIDE	1 (0.4%)	15 (3.5%)
AMBROXOL HYDROCHLORIDE	0	1 (0.2%)
/DOXYCYCLINE HYDROCHLORIDE		
ASCORBIC ACID	0	1 (0.2%)
/CHLORPHENAMINE MALEATE		
/PARACETAMOL		
ASCORBIC ACID	1 (0.4%)	0
/CODEINE PHOSPHATE		
/DIPROPHYLLINE		
/METAMIZOLE SODIUM		
/PARACETAMOL		
ASCORBIC ACID	1 (0.4%)	0
/PARACETAMOL		
/PHENYLEPHRINE HYDROCHLORIDE		
/SODIUM CITRATE		
BICLOTYMOL	1 (0.4%)	0
/CHLORPHENAMINE MALEATE		
/GUAIFENESIN		
/PHOLCODINE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
BROMHEXINE	0	1 (0.2%)
BROMHEXINE HYDROCHLORIDE	1 (0.4%)	3 (0.7%)
BROMPHENIRAMINE MALEATE	0	1 (0.2%)
/GUAIFENESIN		
/PHENYLEPHRINE HYDROCHLORIDE		
/PHENYLPROPANOLAMINE HYDROCHLORIDE		
BUPHENINE HYDROCHLORIDE	0	1 (0.2%)
/ESCIN		
CAFFEINE	0	1 (0.2%)
/CODEINE PHOSPHATE		
/DIPHENHYDRAMINE HYDROCHLORIDE		
/PARACETAMOL		
/PHENYLEPHRINE HYDROCHLORIDE		
CARBAMIDE	0	1 (0.2%)
/GUETHOL		
CARBINOXAMINE MALEATE	0	5 (1.2%)
/GUAIFENESIN		
/PSEUDOEPHEDRINE HYDROCHLORIDE		
CARBOCISTEINE	3 (1.3%)	19 (4.4%)
CINEOLE	0	1 (0.2%)
/ETHYLMORPHINE		
CLOBUTINOL	0	1 (0.2%)
CLOBUTINOL HYDROCHLORIDE	1 (0.4%)	8 (1.9%)
CLOPERASTINE FENDIZOATE	0	1 (0.2%)
CODEINE	0	1 (0.2%)
CODEINE	0	2 (0.5%)
/ERYSIMUM EXTRACT		
/ETHYLMORPHINE CAMSILATE		
/GRINDELIA LIQUID EXTRACT		
/MARRUBE EXTRACT		
/SULFOGAIACOL		
CODEINE	1 (0.4%)	0
/GUAIACOL		
CODEINE	1 (0.4%)	5 (1.2%)
/PHENYLTOLOXAMINE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CODEINE HYDROCHLORIDE	0	1 (0.2%)
/PHENOBARBITAL		
CODEINE PHOSPHATE	2 (0.9%)	2 (0.5%)
DEXTROMETHORPHAN	0	1 (0.2%)
DEXTROMETHORPHAN HYDROBROMIDE	0	2 (0.5%)
/METHOXYPHENAMINE HYDROCHLORIDE		
/SODIUM CITRATE		
DIHYDROCODEINE	2 (0.9%)	0
DIHYDROCODEINE BITARTRATE	0	4 (0.9%)
DIHYDROCODEINE THIOCYANATE	0	2 (0.5%)
/LIQUORICE LIQUID EXTRACT		
/PRIMULA FLUID EXTRACT		
/THYME EXTRACT		
ERDOSTEINE	0	6 (1.4%)
EUCALYPTUS OIL	0	1 (0.2%)
/PINUS SILVESTRIIS OIL		
/ROSEMARY OIL		
/TERPINEOL		
/THYME OIL		
FUSAFUNGINE	4 (1.7%)	6 (1.4%)
GUAIFENESIN	1 (0.4%)	0
GUAIFENESIN	1 (0.4%)	3 (0.7%)
/OXOMEMAZINE		
/PARACETAMOL		
/SODIUM BENZOATE		
HELICIDINE	0	2 (0.5%)
HERBAL EXTRACTS NOS	1 (0.4%)	0
IPECACUANHA	0	1 (0.2%)
/SQUILL		
LETOSTEINE	0	1 (0.2%)
MYRTOL	0	1 (0.2%)
NOSCAPINE	0	1 (0.2%)
NOSCAPINE	0	1 (0.2%)
/POLYSORBATE 85 (TWEEN 85)		
/PROMETHAZINE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
NOSCAPINE HYDROCHLORIDE	0	1 (0.2%)
PHOLCODINE	4 (1.7%)	2 (0.5%)
POTASSIUM IODIDE	0	1 (0.2%)
ZIPEPROL DIHYDROCHLORIDE	1 (0.4%)	0
NASAL PREP	19 (8.3%)	70 (16.3%)
ACETYLCYSTEINE	1 (0.4%)	8 (1.9%)
/BENZALKONIUM CHLORIDE		
/TUAMINOHEPTANE SULFATE		
AMYLEINE HYDROCHLORIDE	2 (0.9%)	0
/FRAMYCETIN SULFATE		
/NAPHAZOLINE NITRATE		
ANTAZOLINE SULFATE	0	1 (0.2%)
/XYLOMETAZOLINE HYDROCHLORIDE		
BECLOMETASONE	0	6 (1.4%)
BECLOMETASONE DIPROPIONATE	2 (0.9%)	16 (3.7%)
BUDESONIDE	0	9 (2.1%)
CETRIMONIUM BROMIDE	2 (0.9%)	4 (0.9%)
/NAPHAZOLINE NITRATE		
/PHENYLEPHRINE HYDROCHLORIDE		
/PREDNISOLONE		
CHLORHEXIDINE DIACETATE	0	2 (0.5%)
/TIXOCORTOL PIVALATE		
CROMOGLICATE SODIUM	0	6 (1.4%)
CROMOGLICATE SODIUM	0	1 (0.2%)
/REPROTEROL HYDROCHLORIDE		
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
/PHENYLEPHRINE HYDROCHLORIDE		
/POLYMYXIN B SULFATE		
EPHEDRINE	0	1 (0.2%)
ETHANOLAMINE TENOATE	0	1 (0.2%)
/FRAMYCETIN SULFATE		
FENOXAZOLINE HYDROCHLORIDE	0	1 (0.2%)
FLUNISOLIDE	2 (0.9%)	2 (0.5%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
FLUTICASONE	0	3 (0.7%)
/SALMETEROL		
FLUTICASONE PROPIONATE	1 (0.4%)	5 (1.2%)
FRAMYCETIN SULFATE	0	2 (0.5%)
FRAMYCETIN SULFATE	1 (0.4%)	0
/HYDROCORTISONE		
FRAMYCETIN SULFATE	0	1 (0.2%)
/NAPHAZOLINE NITRATE		
/PREDNISOLONE ACETATE		
IBUPROFEN	3 (1.3%)	9 (2.1%)
/PSEUDOEPHEDRINE HYDROCHLORIDE		
MOMETASONE FUROATE	0	4 (0.9%)
NASAL SPRAY	0	1 (0.2%)
NEOMYCIN SULFATE	0	1 (0.2%)
/TIXOCORTOL PIVALATE		
PARACETAMOL	1 (0.4%)	0
/PHENYLPROPANOLAMINE HYDROCHLORIDE		
/PHENYLTOLOXAMINE CITRATE		
PHENYLEPHRINE	0	1 (0.2%)
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE-FENOXAZOLINE COMPOUND	0	1 (0.2%)
PREDNISON	1 (0.4%)	5 (1.2%)
PSEUDOEPHEDRINE	1 (0.4%)	0
PSEUDOEPHEDRINE HYDROCHLORIDE	4 (1.7%)	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.2%)
/TRIPROLIDINE HYDROCHLORIDE		
SODIUM CHLORIDE	1 (0.4%)	1 (0.2%)
TIXOCORTOL PIVALATE	0	2 (0.5%)
TRIAMCINOLONE ACETONIDE	1 (0.4%)	3 (0.7%)
OTHER	0	2 (0.5%)
OXYGEN	0	2 (0.5%)
SYSTEMIC ANTIHISTAMINES	12 (5.2%)	38 (8.8%)
ALIMEMAZINE TARTRATE	1 (0.4%)	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
ASCORBIC ACID	0	1 (0.2%)
/CHLORPHENAMINE MALEATE		
/PARACETAMOL		
AZELASTINE	0	1 (0.2%)
BROMPHENIRAMINE MALEATE	0	1 (0.2%)
BUCLIZINE HYDROCHLORIDE	1 (0.4%)	1 (0.2%)
/CODEINE PHOSPHATE		
/PARACETAMOL		
BUZEPIDE METIODIDE	0	1 (0.2%)
/CLOCINIZINE HYDROCHLORIDE		
/PHENYLPROPANOLAMINE HYDROCHLORIDE		
CETIRIZINE	0	1 (0.2%)
/PSEUDOEPHEDRINE		
CETIRIZINE HYDROCHLORIDE	3 (1.3%)	9 (2.1%)
CHLORPHENAMINE MALEATE	1 (0.4%)	2 (0.5%)
CLEMASTINE	0	1 (0.2%)
CLEMASTINE FUMARATE	0	1 (0.2%)
CYCLIZINE	2 (0.9%)	0
DEXCHLORPHENIRAMINE MALEATE	1 (0.4%)	0
DIMENHYDRINATE	0	1 (0.2%)
DIMETINDENE MALEATE	0	1 (0.2%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	2 (0.5%)
FEXOFENADINE HYDROCHLORIDE	0	2 (0.5%)
LORATADINE	4 (1.7%)	13 (3.0%)
LORATADINE	0	1 (0.2%)
/PSEUDOEPHEDRINE SULFATE		
MIZOLASTINE	0	1 (0.2%)
NOSCAPINE	0	1 (0.2%)
/POLYSORBATE 85 (TWEEN 85)		
/PROMETHAZINE		
OXATOMIDE	0	1 (0.2%)
PHENIRAMINE AMINOSALICYLATE	1 (0.4%)	0
PROMETHAZINE HYDROCHLORIDE	0	1 (0.2%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.2%)
/TRIPROLIDINE HYDROCHLORIDE		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
TERFENADINE	0	1 (0.2%)
THROAT PREP	4 (1.7%)	13 (3.0%)
ALUMINIUM POTASSIUM SULFATE	0	2 (0.5%)
/LIDOCAINE HYDROCHLORIDE		
/PROPYLPARABEN		
AMYLMETACRESOL	1 (0.4%)	0
/DICHLOBENZYL ALCOHOL		
BACITRACIN ZINC	0	3 (0.7%)
/CHLORMETHINE HYDROCHLORIDE		
/PENTOSAN POLYSULFATE		
/TIXOCORTOL PIVALATE		
/TRIENTINE		
BACITRACIN ZINC	0	2 (0.5%)
/TIXOCORTOL PIVALATE		
BICLOTYMOL	0	2 (0.5%)
CETYLPRIDINIUM CHLORIDE	0	2 (0.5%)
/CHLOROBUTANOL		
/EUGENOL		
/VERATROLE		
CHLOROQUINE	2 (0.9%)	0
LIDOCAINE	0	1 (0.2%)
LIDOCAINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
SENSORY ORGANS		
OPHTALMOL/OTOLOGICAL PREP	18 (7.9%)	27 (6.3%)
BACITRACIN	0	1 (0.2%)
/NEOMYCIN SULFATE		
BENZALKONIUM CHLORIDE	1 (0.4%)	0
/DICHLORALPHENAZONE		
/DIMETICONE, ACTIVATED		
/HYDROCORTISONE		
/ISOMETHEPTENE		
/NYSTATIN		
/PARACETAMOL		

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
CHLORAMPHENICOL	1 (0.4%)	0
/COLISTIN MESILATE SODIUM		
/HYDROCORTISONE ACETATE		
DEXAMETHASONE	0	2 (0.5%)
DEXAMETHASONE	0	1 (0.2%)
/FRAMYCETIN		
DEXAMETHASONE	0	1 (0.2%)
/FRAMYCETIN SULFATE		
/GRAMICIDIN		
DEXAMETHASONE SODIUM PHOSPHATE	0	4 (0.9%)
DEXAMETHASONE SODIUM PHOSPHATE	0	2 (0.5%)
/NEOMYCIN SULFATE		
ERYTHROMYCIN	11 (4.8%)	6 (1.4%)
HEXAMIDINE ISETHIONATE	2 (0.9%)	1 (0.2%)
HYDROCORTISONE ACETATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
HYDROCORTISONE ACETATE	0	1 (0.2%)
/OXYTETRACYCLINE HYDROCHLORIDE		
/POLYMYXIN B SULFATE		
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.4%)	2 (0.5%)
TETRACYCLINE	2 (0.9%)	1 (0.2%)
OPHTHALMOLOGICALS	59 (25.8%)	126 (29.3%)
ACETAZOLAMIDE	1 (0.4%)	0
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	1 (0.2%)
/AMINO ACIDS NOS		
/PYRIDOXINE HYDROCHLORIDE		
ATROPINE	0	1 (0.2%)
BENZALKONIUM CHLORIDE	0	1 (0.2%)
/TRIMAGNESIUM SPAGLUMATE		
BETAMETHASONE	1 (0.4%)	10 (2.3%)
BETAXOLOL	2 (0.9%)	3 (0.7%)
BETAXOLOL HYDROCHLORIDE	2 (0.9%)	4 (0.9%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
BORIC ACID	0	1 (0.2%)
/CAMPHOR		
/EPHEDRINE HYDROCHLORIDE		
/PEPPERMINT OIL		
/RETINOL PALMITATE		
/SODIUM BORATE		
/SODIUM CITRATE		
/ZINC SULFATE		
BORIC ACID	0	1 (0.2%)
/PHENYLEPHRINE HYDROCHLORIDE		
/SODIUM BORATE		
BORIC ACID	0	1 (0.2%)
/SODIUM BORATE		
/SODIUM CHLORIDE		
/TETRYZOLINE HYDROCHLORIDE		
BRIMONIDINE TARTRATE	1 (0.4%)	2 (0.5%)
CARTEOLOL HYDROCHLORIDE	0	2 (0.5%)
CETHEXONIUM CHLORIDE	0	2 (0.5%)
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
CHLORAMPHENICOL	0	1 (0.2%)
/DEXAMETHASONE SODIUM PHOSPHATE		
CINCHOCAINE HYDROCHLORIDE	0	1 (0.2%)
CIPROFLOXACIN	4 (1.7%)	1 (0.2%)
CIPROFLOXACIN HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
CLONIDINE HYDROCHLORIDE	0	3 (0.7%)
CROMOGLICATE SODIUM	0	6 (1.4%)
DEXAMETHASONE	0	2 (0.5%)
DEXAMETHASONE	1 (0.4%)	3 (0.7%)
/NEOMYCIN SULFATE		
/POLYMYXIN B SULFATE		
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
/POLYMYXIN B SULFATE		
DEXAMETHASONE SODIUM PHOSPHATE	0	4 (0.9%)
DEXPANTHENOL	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
DEXTRAN	0	1 (0.2%)
/HYPROMELLOSE		
DICLOFENAC SODIUM	21 (9.2%)	38 (8.8%)
DORZOLAMIDE HYDROCHLORIDE	3 (1.3%)	4 (0.9%)
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.2%)
/TIMOLOL MALEATE		
EPHEDRINE	0	1 (0.2%)
ETHANOLAMINE TENOATE	0	1 (0.2%)
/FRAMYCETIN SULFATE		
EYE DROPS, NOS	1 (0.4%)	0
FLUORESCEIN	0	1 (0.2%)
FRAMYCETIN SULFATE	0	2 (0.5%)
FUSIDIC ACID	2 (0.9%)	4 (0.9%)
GENTAMICIN SULFATE	1 (0.4%)	3 (0.7%)
HEPARIN	2 (0.9%)	4 (0.9%)
HYDROCORTISONE	4 (1.7%)	2 (0.5%)
HYDROCORTISONE BUTYRATE	2 (0.9%)	7 (1.6%)
INDOMETACIN	2 (0.9%)	10 (2.3%)
ISOSORBIDE	0	1 (0.2%)
KETOROLAC TROMETHAMINE	0	1 (0.2%)
LATANOPROST	2 (0.9%)	2 (0.5%)
LEVOBUNOLOL HYDROCHLORIDE	0	1 (0.2%)
LIDOCAINE	0	1 (0.2%)
LIDOCAINE HYDROCHLORIDE	1 (0.4%)	2 (0.5%)
METHYLPREDNISOLONE	3 (1.3%)	1 (0.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
MYRTILLUS	0	1 (0.2%)
/TOCOPHEROL		
OFLOXACIN	2 (0.9%)	11 (2.6%)
OXYTETRACYCLINE	3 (1.3%)	1 (0.2%)
OXYTETRACYCLINE DIHYDRATE	1 (0.4%)	0
PILOCARPINE	0	5 (1.2%)
PILOCARPINE HYDROCHLORIDE	0	1 (0.2%)
/TIMOLOL MALEATE		
POTASSIUM IODIDE	0	1 (0.2%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.4%)	2 (0.5%)
SODIUM CHLORIDE	1 (0.4%)	1 (0.2%)
TETRACYCLINE	2 (0.9%)	1 (0.2%)
TIMOLOL	1 (0.4%)	1 (0.2%)
TIMOLOL MALEATE	4 (1.7%)	7 (1.6%)
TRIAMCINOLONE ACETONIDE	1 (0.4%)	3 (0.7%)
TRIAMCINOLONE HEXACETONIDE	0	1 (0.2%)
TROPICAMIDE	0	2 (0.5%)
ZINC SULFATE	0	1 (0.2%)
OTOLOGICALS	5 (2.2%)	15 (3.5%)
CAPRYLIC ACID	0	1 (0.2%)
/TROLAMINE CAPRYLATE		
CHLORAMPHENICOL	3 (1.3%)	2 (0.5%)
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	1 (0.2%)
/NEOMYCIN SULFATE		
/POLYMYXIN B SULFATE		
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (0.2%)
/NYSTATIN		
/OXYTETRACYCLINE HYDROCHLORIDE		
/POLYMYXIN B SULFATE		
GENTAMICIN SULFATE	0	1 (0.2%)
/PREDNISOLONE ACETATE		
HYDROCORTISONE	0	1 (0.2%)
/NEOMYCIN SULFATE		
/POLYMYXIN B SULFATE		
HYDROCORTISONE BUTYRATE	2 (0.9%)	7 (1.6%)
SODIUM BICARBONATE	0	1 (0.2%)
SYSTEMIC HORMONAL		
CALCIUM HOMEOSTASIS	0	2 (0.5%)
CALCITONIN	0	1 (0.2%)
CALCITONIN ACETATE	0	1 (0.2%)
CORTICOSTEROIDS	19 (8.3%)	42 (9.8%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
AMCINONIDE	0	1 (0.2%)
BETAMETHASONE	1 (0.4%)	10 (2.3%)
BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.2%)
BETAMETHASONE SODIUM PHOSPHATE /NEOMYCIN SULFATE	1 (0.4%)	0
CORTICOSTEROIDS	2 (0.9%)	2 (0.5%)
CORTIVAZOL	0	4 (0.9%)
DEXAMETHASONE	0	2 (0.5%)
DEXAMETHASONE SODIUM PHOSPHATE	0	4 (0.9%)
HYDROCORTISONE	4 (1.7%)	2 (0.5%)
HYDROCORTISONE BUTYRATE	2 (0.9%)	7 (1.6%)
LIDOCAINE	3 (1.3%)	0
/METHYLPREDNISOLONE ACETATE		
METHYLPREDNISOLONE	3 (1.3%)	1 (0.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE	1 (0.4%)	6 (1.4%)
PREDNISOLONE SODIUM SUCCINATE	0	1 (0.2%)
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.4%)	2 (0.5%)
PREDNISONE	1 (0.4%)	5 (1.2%)
TRIAMCINOLONE ACETONIDE	1 (0.4%)	3 (0.7%)
TRIAMCINOLONE HEXACETONIDE	0	1 (0.2%)
THYROID THERAPY	9 (3.9%)	27 (6.3%)
CARBIMAZOLE	1 (0.4%)	1 (0.2%)
LEVOTHYROXINE	0	1 (0.2%)
LEVOTHYROXINE	0	1 (0.2%)
/LIOETHYRONINE		
/POTASSIUM IODIDE		
LEVOTHYROXINE SODIUM	4 (1.7%)	18 (4.2%)
LEVOTHYROXINE SODIUM	1 (0.4%)	0
/LIOETHYRONINE SODIUM		
LEVOTHYROXINE SODIUM	0	4 (0.9%)
/POTASSIUM IODIDE		
POTASSIUM IODIDE	0	1 (0.2%)
THYROXINE	3 (1.3%)	3 (0.7%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
UNCLASSIFIABLE	0	1 (0.2%)
UNCLASSIFIABLE		
UNKNOWN MEDICATION	0	1 (0.2%)
VARIOUS		
ALL OTHER NON-THERAP PROD	3 (1.3%)	4 (0.9%)
BLOOD CELLS, PACKED HUMAN	1 (0.4%)	1 (0.2%)
BLOOD, WHOLE	1 (0.4%)	0
HYPROMELLOSE	1 (0.4%)	1 (0.2%)
MACROGOL	0	1 (0.2%)
POLOXAMER	0	1 (0.2%)
ALL OTHER THERAP PROD	4 (1.7%)	23 (5.3%)
ACONITUM	0	1 (0.2%)
/BRYONIA		
/EUPATORIUM PERFOLIATUM		
/LACHESIS		
/PHOSPHORUS		
ADENOSINE PHOSPHATE, SODIUM SALT	1 (0.4%)	1 (0.2%)
/DEOXYRIBONUCLEIC ACID		
ALENDRONATE	1 (0.4%)	4 (0.9%)
ALUMINIUM CHLOROHYDRATE	0	1 (0.2%)
ARNICA	0	1 (0.2%)
/HORSE CHESTNUT EXTRACT		
/HYOSCYAMUS DRY EXTRACT		
/SCOPARIUM		
CALCIUM LACTATE	1 (0.4%)	0
/CIMICIFUGA		
/MAGNESIUM HYPOSULFITE		
/OLEOSACCHARUM OF MARJOLAINAINE		
CHONDROITIN SULFURIC ACID	0	2 (0.5%)
COPPER GLUCONATE	0	1 (0.2%)
/GOLD GLUCONATE		
/SILVER GLUCONATE		
DISODIUM INOSINATE	0	1 (0.2%)
ETIDRONATE DISODIUM	0	3 (0.7%)

Data Source Table 13.5.2a

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Concomitant Medications	210 (91.7%)	401 (93.3%)
ATC Classification Level 1		
ATC Classification Level 2		
Generic Term		
GARLIC	1 (0.4%)	1 (0.2%)
HOMEOPATHIC PREPARATIONS	0	1 (0.2%)
HOMEOPATICS NOS	0	2 (0.5%)
HYPERICUM EXTRACT	0	1 (0.2%)
IPECACUANHA	0	1 (0.2%)
/SQUILL		
NICOTINE RESIN	0	1 (0.2%)
OXYGEN	0	2 (0.5%)
POTASSIUM IODIDE	0	1 (0.2%)
ALLERGENS	0	1 (0.2%)
POISON IVY EXTRACT	0	1 (0.2%)
DIAGNOSTIC AGENTS	1 (0.4%)	0
GLUCOSE	1 (0.4%)	0
GENERAL NUTRIENTS	1 (0.4%)	2 (0.5%)
BETA-ALANINE	0	1 (0.2%)
GLUCOSE	1 (0.4%)	0
WHEAT GERM	0	1 (0.2%)
INVESTIGATIONAL DRUG	0	1 (0.2%)
HEPATITIS A VACCINE	0	1 (0.2%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ALIMENTARY TRACT/METAB			
ANABOLICS, SYSTEMIC	1 (1.6%)	0	0
COBAMAMIDE	1 (1.6%)	0	0
ANTACID/ANTIPLAT/ANTIPEPTIC	12 (19.7%)	14 (17.9%)	21 (23.3%)
ACETYSALICYLIC ACID	0	1 (1.3%)	2 (2.2%)
/ALUMINIUM HYDROXIDE			
/MAGNESIUM HYDROXIDE			
ALGIN	1 (1.6%)	2 (2.6%)	1 (1.1%)
/ALGINIC ACID			
/ALUMINIUM HYDROXIDE			
/MAGNESIUM TRISILICATE			
/SODIUM BICARBONATE			
ALMAGATE	0	0	1 (1.1%)
/CALCIUM SACCHARATE			
ALUMINIUM HYDROXIDE	1 (1.6%)	1 (1.3%)	0
ALUMINIUM HYDROXIDE	0	1 (1.3%)	1 (1.1%)
/MAGNESIUM HYDROXIDE			
ALUMINIUM HYDROXIDE	0	0	0
/MAGNESIUM TRISILICATE			
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE	1 (1.6%)	2 (2.6%)	0
/LIQUORICE LIQUID EXTRACT			
/SACCHARIN SODIUM			
/SMECTITE			
/VANILLINE			
ALUMINIUM OXIDE	0	0	0
/MAGNESIUM OXIDE			
ALVERINE CITRATE	0	1 (1.3%)	1 (1.1%)
/DIMETICONE, ACTIVATED			
ANTACID NOS	0	1 (1.3%)	0
CALCIUM CARBONATE	1 (1.6%)	0	0
CALCIUM CARBONATE	0	0	0
/COLECALCIFEROL			
CALCIUM CARBONATE	0	0	0
/MAGNESIUM CARBONATE			
CIMETIDINE	0	3 (3.8%)	1 (1.1%)
DICLOFENAC SODIUM	0	0	3 (3.3%)
/MISOPROSTOL			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
DIMETICONE	0	0	0
/GUAIAZULENE			
FAMOTIDINE	0	1 (1.3%)	2 (2.2%)
LANSOPRAZOLE	2 (3.3%)	1 (1.3%)	1 (1.1%)
MAGNESIUM TRISILICATE	1 (1.6%)	0	0
MISOPROSTOL	0	0	1 (1.1%)
MISOPROSTOL	0	0	0
/NAPROXEN			
OMEPRAZOLE	7 (11.5%)	4 (5.1%)	6 (6.7%)
OMEPRAZOLE MAGNESIUM	0	0	0
PANTOPRAZOL	0	0	0
PANTOPRAZOLE	0	0	0
RANITIDINE	1 (1.6%)	0	4 (4.4%)
RANITIDINE HYDROCHLORIDE	1 (1.6%)	1 (1.3%)	5 (5.6%)
SODIUM BICARBONATE	0	0	0
SUCRALFATE	1 (1.6%)	0	1 (1.1%)
ANTIDIABETIC THERAPY	11 (18.0%)	11 (14.1%)	14 (15.6%)
ACARBOSE	0	1 (1.3%)	0
CHLORPROPAMIDE	1 (1.6%)	0	0
GLIBENCLAMIDE	1 (1.6%)	0	3 (3.3%)
GLICLAZIDE	1 (1.6%)	1 (1.3%)	4 (4.4%)
GLIMEPIRIDE	0	0	0
GLIPIZIDE	2 (3.3%)	2 (2.6%)	0
INSULIN	0	4 (5.1%)	0
INSULIN	0	0	2 (2.2%)
/INSULIN INJECTION, ISOPHANE			
INSULIN HUMAN	1 (1.6%)	0	1 (1.1%)
INSULIN HUMAN INJECTION, ISOPHANE	0	0	1 (1.1%)
INSULIN INJECTION, BIPHASIC	2 (3.3%)	1 (1.3%)	0
INSULIN INJECTION, ISOPHANE	0	1 (1.3%)	0
METFORMIN	4 (6.6%)	3 (3.8%)	2 (2.2%)
METFORMIN HYDROCHLORIDE	0	0	2 (2.2%)
ANTIDIARRHEA/GI ANTIBIOTICS	4 (6.6%)	8 (10.3%)	5 (5.6%)
ACETORPHAN	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ALBUMIN TANNATE	1 (1.6%)	0	0
/CODEINE PHOSPHATE			
/DIHYDROSTREPTOMYCIN SULFATE			
/MORPHINE			
/NEOMYCIN SULFATE			
/PAPAVERINE HYDROCHLORIDE			
ANTI-DIARRHEAL, NOS	0	0	0
ATROPINE SULFATE	1 (1.6%)	2 (2.6%)	0
/DIPHENOXYLATE HYDROCHLORIDE			
ATTAPULGITE	0	1 (1.3%)	0
BACITRACIN	0	0	0
/NEOMYCIN SULFATE			
BACTERIA NOS	0	0	0
CHARCOAL, ACTIVATED	0	0	0
CHARCOAL, ACTIVATED	0	0	0
/YEAST DRIED			
CHLOROQUINE	0	0	2 (2.2%)
LACTOBACILLUS ACIDOPHILUS	0	0	0
LOPERAMIDE	0	0	0
LOPERAMIDE HYDROCHLORIDE	0	3 (3.8%)	2 (2.2%)
LOPERAMIDE OXIDE	0	1 (1.3%)	0
MONTMORILLONITE BEIDELLITIQUE	0	1 (1.3%)	0
NIFUROXAZIDE	1 (1.6%)	1 (1.3%)	0
NIFURZIDE	0	0	0
NYSTATIN	0	1 (1.3%)	1 (1.1%)
POLYVIDONE	0	0	0
/STERCULIA			
SACCHAROMYCES BOULARDII	2 (3.3%)	0	1 (1.1%)
STREPTOMYCIN	0	1 (1.3%)	0
SULFASALAZINE	0	0	0
ANTIEMETICS & ANTINAUSEANTS	3 (4.9%)	1 (1.3%)	2 (2.2%)
DOMPERIDONE	2 (3.3%)	1 (1.3%)	0
ETHANOLAMINE ACETYLLAUCINATE	1 (1.6%)	0	0
HYOSCINE	0	0	1 (1.1%)
METOPIMAZINE	0	0	1 (1.1%)
PROMETHAZINE HYDROCHLORIDE	0	0	0
ANTIOWESITY PREP	0	1 (1.3%)	1 (1.1%)
AMFEPRAMONE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ORLISTAT	0	1 (1.3%)	1 (1.1%)
CHOLAG & HEPATIC PROTECTORS	1 (1.6%)	0	1 (1.1%)
ANETHOLE TRITHIONE	0	0	0
CHOLINE DIHYDROGEN CITRATE	1 (1.6%)	0	0
/SORBITOL			
CYSTEINE HYDROCHLORIDE	0	0	0
/METHIONINE			
ERYTHROMYCIN	0	0	0
/METHIONINE			
/MULTIVITAMINS, NOS			
/RUTOSIDE			
/SULFAFURAZOLE			
FUMARIA EXTRACT	0	0	0
HYMECROMONE	0	0	0
SILYMARIN	0	0	1 (1.1%)
THIOCTIC ACID	0	0	0
THIOCTIC ACID	0	0	0
/TROMETHAMINE SALT			
URSODEOXYCHOLIC ACID	0	0	0
DIGESTIVES	1 (1.6%)	1 (1.3%)	2 (2.2%)
AMYLASE	1 (1.6%)	0	0
BETAINE CITRATE	0	0	0
BROMELAINS	0	0	0
DIMETICONE	0	0	1 (1.1%)
/ENZYMES NOS			
GLUTAMIC ACID HYDROCHLORIDE	0	0	0
PANCREATIN	0	1 (1.3%)	1 (1.1%)
GI ANTISPAS/ANTICHOLIN	3 (4.9%)	11 (14.1%)	8 (8.9%)
ALLOBARBITAL	0	0	0
/AMINOPHENAZONE			
/DROFENINE HYDROCHLORIDE			
ALVERINE CITRATE	0	1 (1.3%)	1 (1.1%)
/DIMETICONE, ACTIVATED			
AMOBARBITAL	0	0	1 (1.1%)
/ATROPINE			
/DIMETICONE			
/HYOSCYAMINE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ARNICA	0	0	0
/HORSE CHESTNUT EXTRACT			
/HYOSCYAMUS DRY EXTRACT			
/SCOPARIUM			
ATROPINE	0	0	0
BENZHEXOL HYDROCHLORIDE	0	0	0
/DEMELVERINUM HYDROCHLORICUM			
CHARCOAL, ACTIVATED	0	0	0
/PAPAVERINE HYDROCHLORIDE			
CHLORDIAZEPOXIDE HYDROCHLORIDE	0	0	0
/CLIDINIUM BROMIDE			
CISAPRIDE	0	0	1 (1.1%)
CISAPRIDE MONOHYDRATE	0	0	0
CLEBOPRIDE	0	1 (1.3%)	0
/DIMETICONE			
ECHINACEA EXTRACT	0	0	0
/SABAL EXTRACT			
/TROPPIUM CHLORIDE			
FENPIVERINIUM BROMIDE	0	0	0
/METAMIZOLE SODIUM			
/PITOFENONE HYDROCHLORIDE			
HYOSCINE BUTYLBROMIDE	0	0	1 (1.1%)
HYOSCINE BUTYLBROMIDE	0	0	0
/PARACETAMOL			
MEBEVERINE	0	2 (2.6%)	0
MEBEVERINE HYDROCHLORIDE	0	0	2 (2.2%)
METOCLOPRAMIDE	0	0	2 (2.2%)
METOCLOPRAMIDE DIHYDROCHLORIDE	0	0	0
METOCLOPRAMIDE HYDROCHLORIDE	1 (1.6%)	2 (2.6%)	0
OTILONIUM BROMIDE	0	1 (1.3%)	0
OXYBUTYNIN	1 (1.6%)	1 (1.3%)	1 (1.1%)
OXYBUTYNIN HYDROCHLORIDE	0	0	1 (1.1%)
PHLOROGLUCINOL	1 (1.6%)	1 (1.3%)	0
PHLOROGLUCINOL	0	0	0
/TRIMETHYLPHLOROGLUCINOL			
PINAVERIUM BROMIDE	0	1 (1.3%)	0
RUSCOGENIN	0	0	0
/TRIMEBUTINE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
TIEMONIUM IODIDE	0	2 (2.6%)	0
TRIMEBUTINE	0	0	0
TRIMEBUTINE MALEATE	0	1 (1.3%)	0
LAXATIVES	2 (3.3%)	8 (10.3%)	6 (6.7%)
ALOES	0	0	0
BEE SWAX WHITE	0	0	0
/PARAFFIN			
/WHITE VASELINE			
/ZINC OXIDE			
BISACODYL	0	3 (3.8%)	0
DANTRON	0	2 (2.6%)	0
/DOCUSATE SODIUM			
DANTRON	0	1 (1.3%)	0
/POLOXAMER			
ISPA GHULA	0	2 (2.6%)	1 (1.1%)
ISPA GHULA	0	0	0
/SENNOSIDE A+B			
ISPA GHULA HUSKS	0	0	0
/PARAFFIN, LIQUID			
LACTITOL MONOHYDRATE	0	0	0
LACTULOSE	2 (3.3%)	2 (2.6%)	4 (4.4%)
LACTULOSE	0	0	0
/PARAFFIN			
/PARAFFIN, SOFT			
PARAFFIN, LIQUID	0	0	1 (1.1%)
PICOSULFURIC ACID	0	1 (1.3%)	0
POLOXAMER	0	0	0
POTASSIUM TARTRATE	0	0	0
/SODIUM BICARBONATE			
SENNA	1 (1.6%)	0	0
SENNA FRUIT	0	0	1 (1.1%)
SODIUM PICOSULFATE	0	0	0
STERCULIA	0	0	0
MINERAL SUPPLEMENTS	3 (4.9%)	7 (9.0%)	1 (1.1%)
ALBUMEN	0	0	0
/SACCHAROMYCES CEREVISIAE			
CALCIUM	1 (1.6%)	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CALCIUM	0	1 (1.3%)	1 (1.1%)
/COLECALCIFEROL			
CALCIUM	0	1 (1.3%)	0
/ERGOCALCIFEROL			
CALCIUM CARBONATE	1 (1.6%)	0	0
CALCIUM CARBONATE	0	0	0
/CITRIC ACID			
CALCIUM CARBONATE	0	0	0
/COLECALCIFEROL			
CALCIUM CITRATE	0	0	0
/CALCIUM GLUCONATE			
/SODIUM FLUOROPHOSPHATE			
CALCIUM GLUBIONATE	0	1 (1.3%)	0
CALCIUM GLUCONATE	0	0	0
/CALCIUM PHOSPHATE			
/COLECALCIFEROL			
COPPER	0	0	0
DURAPATITE	0	0	0
LEVOCARNITINE	0	0	0
/MAGNESIUM ASPARTATE			
MAGNESIUM GLUTAMATE	0	0	0
MAGNESIUM LACTATE	0	2 (2.6%)	0
/PYRIDOXINE			
MAGNESIUM NOS	0	0	0
MAGNESIUM NOS	0	1 (1.3%)	0
/POTASSIUM			
/SODIUM CHLORIDE			
PHOSPHORUS	0	0	0
/SODIUM			
POTASSIUM	0	1 (1.3%)	0
POTASSIUM ASCORBATE	0	1 (1.3%)	0
POTASSIUM BICARBONATE	0	0	0
/POTASSIUM CITRATE			
POTASSIUM CHLORIDE	1 (1.6%)	0	0
SODIUM CHLORIDE	0	1 (1.3%)	0
SODIUM CHLORIDE COMPOUND INJECTION	0	0	0
ZINC	0	0	0
ZINC SULFATE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
MOUTH PREP	16 (26.2%)	24 (30.8%)	22 (24.4%)
ACETYLSALICYLIC ACID	16 (26.2%)	22 (28.2%)	22 (24.4%)
BACITRACIN	0	0	0
/LYSOZYME			
/PAPAIN			
BICLOTYMOLOL	0	0	0
/DEQUALINIUM CHLORIDE			
/ENOXOLONE			
/LYSOZYME			
/PAPAIN			
CETYLPRIDINIUM CHLORIDE	0	0	0
/CHLOROBUTANOL			
/EUGENOL			
/VERATROLE			
CHLORHEXIDINE DIACETATE	0	0	0
/TIXOCORTOL PIVALATE			
CHLORHEXIDINE GLUCONATE	0	0	0
CHLORHEXIDINE GLUCONATE	0	0	0
/CHLOROBUTANOL			
DOMIPHEN BROMIDE	0	0	0
METRONIDAZOLE	0	5 (6.4%)	1 (1.1%)
SODIUM CHLORIDE	0	1 (1.3%)	0
TRIAMCINOLONE ACETONIDE	0	0	1 (1.1%)
VITAMINS	3 (4.9%)	2 (2.6%)	7 (7.8%)
ASCORBIC ACID	0	0	1 (1.1%)
ASCORBIC ACID	0	0	0
/CYANOCOBALAMIN			
/FOLATE SODIUM			
/HYDROXOCOBALAMIN			
/LIDOCAINE HYDROCHLORIDE			
/NICOTINAMIDE			
/PYRIDOXINE HYDROCHLORIDE			
/THIAMINE HYDROCHLORIDE			
BISBUTIAMINE	0	0	1 (1.1%)
CALCIUM	0	1 (1.3%)	1 (1.1%)
/COLECALCIFEROL			
COD-LIVER OIL	1 (1.6%)	0	1 (1.1%)
COLECALCIFEROL	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CYANOCOBALAMIN	0	0	0
/PYRIDOXINE HYDROCHLORIDE			
/THIAMINE DISULFIDE			
CYANOCOBALAMIN	1 (1.6%)	0	0
/PYRIDOXINE HYDROCHLORIDE			
/THIAMINE HYDROCHLORIDE			
CYSTINE	0	1 (1.3%)	0
/PYRIDOXINE			
DEXPANTHENOL	0	0	0
ERGOCALCIFEROL	0	0	0
ERGOCALCIFEROL	0	0	0
/HYDROQUINONE			
ERYTHROMYCIN	0	0	0
/METHIONINE			
/MULTIVITAMINS, NOS			
/RUTOSIDE			
/SULFAFURAZOLE			
HYDROXOCOBALAMIN	0	0	1 (1.1%)
/PYRIDOXINE HYDROCHLORIDE			
/THIAMINE HYDROCHLORIDE			
LYCOPENE	0	0	0
/RETINOL			
/TOCOPHEROL			
MAGNESIUM LACTATE	0	2 (2.6%)	0
/PYRIDOXINE			
PYRIDOXINE	0	0	0
PYRIDOXINE HYDROCHLORIDE	0	0	0
PYRIDOXINE HYDROCHLORIDE	0	1 (1.3%)	1 (1.1%)
/THIAMINE HYDROCHLORIDE			
RETINOL	1 (1.6%)	0	0
RIBOFLAVIN	0	0	0
THIAMINE HYDROCHLORIDE	0	0	0
TOCOPHEROL	0	0	0
TOCOPHERYL ACETATE	0	0	0
VITAMIN B	0	0	2 (2.2%)
VITAMINS NOS	0	0	1 (1.1%)
YEAST DRIED	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ANTIINFECTIVES,SYSTEMIC			
ANTIBIOTICS	26 (42.6%)	26 (33.3%)	29 (32.2%)
ACETYLCYSTEINE	0	0	0
/THIAMPHENICOL AMINOACETATE HYDROCHLORIDE			
AMBROXOL HYDROCHLORIDE	0	0	0
/DOXYCYCLINE HYDROCHLORIDE			
AMOXICILLIN	8 (13.1%)	5 (6.4%)	11 (12.2%)
AMOXICILLIN TRIHYDRATE	5 (8.2%)	3 (3.8%)	2 (2.2%)
AMOXICILLIN TRIHYDRATE	1 (1.6%)	4 (5.1%)	1 (1.1%)
/CLAVULANATE POTASSIUM			
AMOXICILLIN TRIHYDRATE	3 (4.9%)	4 (5.1%)	5 (5.6%)
/CLAVULANIC ACID			
AMPICILLIN	0	1 (1.3%)	1 (1.1%)
AMPICILLIN	0	0	1 (1.1%)
/FLUCLOXACILLIN			
ANTIBIOTIC NOS	2 (3.3%)	1 (1.3%)	0
AZITHROMYCIN	0	2 (2.6%)	0
BACAMPICILLIN HYDROCHLORIDE	0	0	0
BENZYL PENICILLIN	0	0	1 (1.1%)
BETAMETHASONE	0	0	0
/CLOTRIMAZOLE			
/GENTAMICIN			
BETAMETHASONE	0	0	0
/NEOMYCIN			
BROMELAINS	0	0	0
/TETRACYCLINE HYDROCHLORIDE			
CEFACLOR	0	0	1 (1.1%)
CEFADROXIL	0	0	0
CEFADROXIL MONOHYDRATE	0	0	0
CEFALEXIN	0	1 (1.3%)	1 (1.1%)
CEFALEXIN MONOHYDRATE	0	0	0
CEFALORIDINE	0	0	0
CEFATRIZINE	0	0	0
CEFAZOLIN SODIUM	0	0	0
CEFIXIME	0	0	1 (1.1%)
CEFODIZIME	0	0	0
CEFONICID DISODIUM	0	0	0
CEFOTAXIME	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CEFOTIAM HEXETIL HYDROCHLORIDE	0	0	0
CEFPODOXIME PROXETIL	0	1 (1.3%)	1 (1.1%)
CEFRADINE	0	0	1 (1.1%)
CEFTRIAXONE SODIUM	0	1 (1.3%)	1 (1.1%)
CEFUROXIME	0	0	0
CEFUROXIME AXETIL	1 (1.6%)	1 (1.3%)	0
CEFUROXIME SODIUM	0	0	0
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)
CHYMOTRYPSIN	0	0	1 (1.1%)
/TETRACYCLINE HYDROCHLORIDE			
CLARITHROMYCIN	3 (4.9%)	2 (2.6%)	0
CLINDAMYCIN	0	0	0
CLINDAMYCIN HYDROCHLORIDE	0	0	0
CLOFOCTOL	0	2 (2.6%)	0
CLOXACILLIN SODIUM	0	0	0
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	0
/NEOMYCIN SULFATE			
/PHENYLEPHRINE HYDROCHLORIDE			
/POLYMYXIN B SULFATE			
DICLOXACILLIN SODIUM MONOHYDRATE	0	0	0
DOXYCYCLINE	0	1 (1.3%)	0
DOXYCYCLINE HYCLATE	0	1 (1.3%)	0
DOXYCYCLINE HYDROCHLORIDE	0	0	0
ERYTHROMYCIN	4 (6.6%)	4 (5.1%)	3 (3.3%)
ERYTHROMYCIN	0	0	0
/METHIONINE			
/MULTIVITAMINS, NOS			
/RUTOSIDE			
/SULFAFURAZOLE			
FLUCLOXACILLIN	2 (3.3%)	4 (5.1%)	2 (2.2%)
FLUCLOXACILLIN SODIUM	0	0	0
FOSFOMYCIN	0	0	0
FUSIDATE SODIUM	2 (3.3%)	1 (1.3%)	0
FUSIDIC ACID	0	1 (1.3%)	1 (1.1%)
GENTAMICIN SULFATE	1 (1.6%)	0	0
JOSAMYCIN	0	0	0
LOMEFLOXACIN	0	0	0
LYMECYCLINE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
MEPARTRICIN	0	0	0
METRONIDAZOLE	1 (1.6%)	0	0
/SPIRAMYCIN			
MIDECAMYCIN	0	0	1 (1.1%)
MINOCYCLINE HYDROCHLORIDE	0	0	0
MUPIROCIN	0	0	1 (1.1%)
OXACILLIN	0	0	0
OXYTETRACYCLINE	2 (3.3%)	1 (1.3%)	0
OXYTETRACYCLINE DIHYDRATE	1 (1.6%)	0	0
PENICILLIN NOS	1 (1.6%)	0	0
PHENOXYMETHYLPENICILLIN	0	1 (1.3%)	1 (1.1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	0	0
PIPEMIDIC ACID	0	0	0
PIVMECILLINAM HYDROCHLORIDE	0	0	0
PRISTINAMYCIN	1 (1.6%)	0	0
ROXITHROMYCIN	0	1 (1.3%)	0
SPIRAMYCIN	0	0	0
STREPTOMYCIN	0	1 (1.3%)	0
SULFAMETHOXAZOLE	1 (1.6%)	0	1 (1.1%)
/TRIMETHOPRIM			
SULTAMICILLIN	0	0	0
TETRACYCLINE	0	0	2 (2.2%)
THIAMPHENICOL	0	0	0
TRIMETHOPRIM	2 (3.3%)	5 (6.4%)	3 (3.3%)
VANCOMYCIN HYDROCHLORIDE	0	0	0
ANTIMYCOTICS	2 (3.3%)	1 (1.3%)	4 (4.4%)
FLUCONAZOLE	1 (1.6%)	0	3 (3.3%)
ITRACONAZOLE	0	0	1 (1.1%)
KETOCONAZOLE	1 (1.6%)	1 (1.3%)	0
MICONAZOLE	0	0	0
MICONAZOLE NITRATE	0	0	0
ANTIVIRALS	1 (1.6%)	4 (5.1%)	1 (1.1%)
ACICLOVIR	1 (1.6%)	3 (3.8%)	1 (1.1%)
BIOSTIM	0	0	0
FAMCICLOVIR	0	1 (1.3%)	1 (1.1%)
VALACYCLOVIR HYDROCHLORIDE	0	0	0
CHEMOTHERAPEUTICS	1 (1.6%)	9 (11.5%)	4 (4.4%)
CIPROFLOXACIN	0	3 (3.8%)	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CIPROFLOXACIN HYDROCHLORIDE	0	0	1 (1.1%)
ERYTHROMYCIN	0	0	0
/METHIONINE			
/MULTIVITAMINS, NOS			
/RUTOSIDE			
/SULFAFURAZOLE			
METRONIDAZOLE	0	5 (6.4%)	1 (1.1%)
METRONIDAZOLE	1 (1.6%)	0	0
/SPIRAMYCIN			
OFLOXACIN	1 (1.6%)	1 (1.3%)	0
SULFAMETHOXAZOLE	1 (1.6%)	0	1 (1.1%)
/TRIMETHOPRIM			
IMMUNE SERA & IMMUNOGLOB	0	0	0
IMMUNOGLOBULIN HUMAN ANTI-TETANUS	0	0	0
TETANUS ANTITOXIN	0	0	0
TUBERCULOSTATICS	0	2 (2.6%)	1 (1.1%)
ETHAMBUTOL	0	1 (1.3%)	0
RIFAMPICIN	0	2 (2.6%)	0
RIFAMYCIN SODIUM	0	0	1 (1.1%)
VACCINES	13 (21.3%)	5 (6.4%)	11 (12.2%)
BACTERIA NOS	0	0	0
DIPHTHERIA AND TETANUS TOXOIDS	0	0	0
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS	0	0	1 (1.1%)
DIPHTHERIA,TETANUS AND POLIOMYELITIS VAC	0	0	2 (2.2%)
HEPATITIS A VACCINE	0	0	0
HEPATITIS B VACCINE	0	0	1 (1.1%)
HEPATITIS VACCINE, NOS	1 (1.6%)	0	0
INACTIVATED HEPATITIS A VACCINE	1 (1.6%)	0	0
INFLUENZA VIRUS VACCINE POLYVALENT	11 (18.0%)	5 (6.4%)	8 (8.9%)
MENINGOCOCCAL POLYSACCHARIDE, GROUP A VA	0	0	0
PNEUMOCOCCAL VACCINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
POLIOMYELITIS VACCINE	1 (1.6%)	0	1 (1.1%)
POLIOMYELITIS VACCINE INACTIVATED	0	0	0
TETANUS TOXOID	0	0	1 (1.1%)
TYPHOID VACCINE	2 (3.3%)	0	0
YELLOW FEVER VACCINE	0	0	1 (1.1%)
ANTINEOPLASTIC & IMMUNOSUP			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ANTINEOPLASTIC, HORMONES	0	2 (2.6%)	1 (1.1%)
BICALUTAMIDE	0	1 (1.3%)	0
ESTRADIOL	0	0	0
ESTRADIOL VALERATE	0	0	0
ESTROGENS CONJUGATED	0	1 (1.3%)	0
FLUTAMIDE	0	0	0
GOSERELIN	0	1 (1.3%)	0
GOSERELIN ACETATE	0	0	0
LEUPRORELIN	0	0	0
MEDROXYPROGESTERONE ACETATE	0	0	0
TAMOXIFEN CITRATE	0	0	1 (1.1%)
CYTOSTATIC DRUGS	2 (3.3%)	1 (1.3%)	0
CISPLATIN	0	0	0
GEMCITABINE HYDROCHLORIDE	0	0	0
LEUPRORELIN	0	0	0
SERENOA REPENS	2 (3.3%)	1 (1.3%)	0
BLOOD/BLOOD FORM ORGANS			
ANTIANAEMIC PREP	5 (8.2%)	0	4 (4.4%)
AMINOACETIC ACID	0	0	0
/FERROUS SULFATE			
CALCIUM PHOSPHATE TRIBASIC	0	0	0
/FOLIC ACID			
CYANOCOBALAMIN	0	0	0
FERROUS FUMARATE	1 (1.6%)	0	0
FERROUS GLUCONATE	0	0	0
FERROUS SULFATE	3 (4.9%)	0	3 (3.3%)
FERROUS SULFATE EXSICCATED	0	0	1 (1.1%)
FOLIC ACID	0	0	0
HYDROXOCOBALAMIN	1 (1.6%)	0	0
IRON FERRIC	0	0	0
ANTICOAGULANTS	20 (32.8%)	25 (32.1%)	26 (28.9%)
ACENOCOUMAROL	1 (1.6%)	0	2 (2.2%)
ACETYLSALICYLATE LYSINE	1 (1.6%)	0	1 (1.1%)
ACETYLSALICYLIC ACID	16 (26.2%)	22 (28.2%)	22 (24.4%)
ACETYLSALICYLIC ACID	0	0	1 (1.1%)
/DIPYRIDAMOLE			
CLOPIDOGREL	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CLORICROMEN HYDROCHLORIDE	0	1 (1.3%)	0
DALTEPARIN SODIUM	0	1 (1.3%)	0
DICOUMAROL	0	0	0
DIPYRIDAMOLE	0	1 (1.3%)	2 (2.2%)
ENOXAPARIN	0	2 (2.6%)	0
FLUINDIONE	0	0	0
GLYCOL SALICYLATE	0	0	0
/HEPARIN SODIUM			
HEPARIN	1 (1.6%)	0	1 (1.1%)
HEPARIN SODIUM	0	0	0
HEPARIN-FRACTION	0	0	0
HEPARIN-FRACTION, CALCIUM SALT	1 (1.6%)	0	0
HEPARIN-FRACTION, SODIUM SALT	0	0	1 (1.1%)
HIRUDIN	0	0	0
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	0	0
TICLOPIDINE HYDROCHLORIDE	0	0	0
WARFARIN	1 (1.6%)	0	1 (1.1%)
WARFARIN SODIUM	0	1 (1.3%)	0
ANTIHAEMORRHAGICS	0	0	1 (1.1%)
ETAMSILATE	0	0	0
TRANEXAMIC ACID	0	0	1 (1.1%)
CHOLESTEROL REDUCERS	26 (42.6%)	29 (37.2%)	41 (45.6%)
ACIPIMOX	0	2 (2.6%)	0
ATORVASTATIN	2 (3.3%)	4 (5.1%)	3 (3.3%)
ATORVASTATIN CALCIUM	6 (9.8%)	7 (9.0%)	3 (3.3%)
BENFLUOREX HYDROCHLORIDE	1 (1.6%)	0	0
BEZAFIBRATE	2 (3.3%)	4 (5.1%)	3 (3.3%)
CARNITINE HYDROCHLORIDE	0	0	0
CERIVASTATIN	1 (1.6%)	0	3 (3.3%)
CHONDROITIN SULFATE	0	0	0
CIPROFIBRATE	0	1 (1.3%)	2 (2.2%)
DUCOSAHEXAENOIC ACID	1 (1.6%)	1 (1.3%)	0
/EICOSAPENTAENOIC ACID			
ETOFIBRATE	0	0	0
EVENING PRIMROSE OIL	0	0	1 (1.1%)
FENOFIBRATE	3 (4.9%)	4 (5.1%)	9 (10.0%)
FLUVASTATIN SODIUM	2 (3.3%)	0	0
GEMFIBROZIL	2 (3.3%)	0	3 (3.3%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
L-PROPYONIL CARNITINE HYDROCHLORIDE	0	0	0
LOVASTATIN	2 (3.3%)	2 (2.6%)	2 (2.2%)
PRAVASTATIN	2 (3.3%)	2 (2.6%)	7 (7.8%)
PRAVASTATIN SODIUM	1 (1.6%)	1 (1.3%)	2 (2.2%)
SIMVASTATIN	8 (13.1%)	11 (14.1%)	15 (16.7%)
HEMORRHEOLOGIC AGENTS	0	2 (2.6%)	3 (3.3%)
PENTOXIFYLLINE	0	2 (2.6%)	3 (3.3%)
OTHER HAEMAT AGNTS	0	0	0
DEOXYRIBOUNCLEASE	0	0	0
/FIBRINOLYSIN			
PLASMA SUBSTIT/PERF SOLUT	0	2 (2.6%)	0
ALBUMEN	0	0	0
/SACCHAROMYCES CEREVISIAE			
CHLORHEXIDINE GLUCONATE	0	0	0
DEXTRAN SULPHATE	0	0	0
/PHENYL BUTAZONE			
GLUCOSE	0	1 (1.3%)	0
GLUCOSE	0	0	0
/SODIUM CHLORIDE			
I.V. FLUIDS	0	0	0
SODIUM BICARBONATE	0	0	0
SODIUM CHLORIDE	0	1 (1.3%)	0
SODIUM CHLORIDE COMPOUND INJECTION	0	0	0
SOYA OIL	0	0	0
UREA	0	0	0
CARDIOVASCULAR			
BETA BLOCKING AGENTS	13 (21.3%)	22 (28.2%)	13 (14.4%)
ACEBUTOLOL HYDROCHLORIDE	0	1 (1.3%)	1 (1.1%)
ATENOLOL	3 (4.9%)	9 (11.5%)	5 (5.6%)
ATENOLOL	0	0	0
/CHLORTALIDONE			
ATENOLOL	0	0	0
/NIFEDIPINE			
BETAXOLOL	0	1 (1.3%)	1 (1.1%)
BETAXOLOL HYDROCHLORIDE	0	0	2 (2.2%)
BISOPROLOL	2 (3.3%)	2 (2.6%)	1 (1.1%)
BISOPROLOL FUMARATE	1 (1.6%)	1 (1.3%)	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BISOPROLOL FUMARATE	0	0	0
/HYDROCHLOROTHIAZIDE			
CARTEOLOL	0	0	0
CARTEOLOL HYDROCHLORIDE	0	0	0
CARVEDILOL	0	0	0
CELIPROLOL	2 (3.3%)	1 (1.3%)	1 (1.1%)
CLOPAMIDE	0	0	0
/PINDOLOL			
DORZOLAMIDE HYDROCHLORIDE	0	0	0
/TIMOLOL MALEATE			
FELODIPINE	0	0	0
/METOPROLOL			
METOPROLOL	1 (1.6%)	2 (2.6%)	1 (1.1%)
METOPROLOL SUCCINATE	0	0	0
METOPROLOL TARTRATE	1 (1.6%)	0	0
METOPROLOL TARTRATE	0	0	0
/NIFEDIPINE			
NEBIVOLOL	0	1 (1.3%)	0
NEBIVOLOL HYDROCHLORIDE	0	0	0
OXPRENOLOL HYDROCHLORIDE	1 (1.6%)	0	0
PROPRANOLOL	0	1 (1.3%)	1 (1.1%)
PROPRANOLOL HYDROCHLORIDE	1 (1.6%)	1 (1.3%)	0
SOTALOL	0	1 (1.3%)	1 (1.1%)
SOTALOL HYDROCHLORIDE	0	0	0
TERTATOLOL	0	0	0
TIMOLOL	0	1 (1.3%)	0
TIMOLOL MALEATE	3 (4.9%)	0	1 (1.1%)
CARDIAC THERAPY	10 (16.4%)	16 (20.5%)	21 (23.3%)
ACETYLDIGOXIN	0	0	0
ACETYLSALICYLIC ACID	0	0	1 (1.1%)
/DIPYRIDAMOLE			
ADENOSINE PHOSPHATE, SODIUM SALT	0	0	1 (1.1%)
/DEOXYRIBONUCLEIC ACID			
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	0	0
/AMINO ACIDS NOS			
/PYRIDOXINE HYDROCHLORIDE			
ALPROSTADIL	1 (1.6%)	0	2 (2.2%)
AMIODARONE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
AMIODARONE HYDROCHLORIDE	0	1 (1.3%)	1 (1.1%)
ASPARTATE MAGNESIUM	0	0	0
/ASPARTATE POTASSIUM			
BISOPROLOL PUMARATE	1 (1.6%)	1 (1.3%)	0
CALCIUM LACTATE	0	0	1 (1.1%)
/CIMICIFUGA			
/MAGNESIUM HYPOSULFITE			
/OLEOSACCHARUM OF MARJOLAIN			
CAMPBOR	0	0	0
/CONVALLARIA TINCTURE			
/CRATAEGUS EXTRACT			
/MENTHOL			
/VALERIAN TINCTURE			
CANDESARTAN CILEXETIL	0	0	0
CARVEDILOL	0	0	0
DIGITOXIN	0	0	0
DIGOXIN	2 (3.3%)	3 (3.8%)	2 (2.2%)
DIPYRIDAMOLE	0	1 (1.3%)	2 (2.2%)
DOPAMINE HYDROCHLORIDE	0	0	0
GLYCERYL TRINITRATE	5 (8.2%)	6 (7.7%)	9 (10.0%)
HEPTAMINOL HYDROCHLORIDE	0	0	0
HYDROQUINIDINE HYDROCHLORIDE	0	0	0
ISOSORBIDE DINITRATE	2 (3.3%)	1 (1.3%)	0
ISOSORBIDE MONONITRATE	3 (4.9%)	5 (6.4%)	6 (6.7%)
LIDOCAINE	0	0	0
LIDOCAINE HYDROCHLORIDE	0	1 (1.3%)	0
MAGNESIUM HYDROGEN ASPARTATE	0	0	0
/POTASSIUM HYDROGEN ASPARTATE			
MEXILETINE HYDROCHLORIDE	0	0	0
MOLSIDOMINE	1 (1.6%)	1 (1.3%)	0
NICORANDIL	0	4 (5.1%)	1 (1.1%)
QUININE SULFATE	0	0	1 (1.1%)
TRIMETAZIDINE DIHYDROCHLORIDE	1 (1.6%)	1 (1.3%)	1 (1.1%)
DIURETICS	15 (24.6%)	15 (19.2%)	24 (26.7%)
ACETAZOLAMIDE	1 (1.6%)	0	0
ALTIZIDE	2 (3.3%)	2 (2.6%)	1 (1.1%)
/SPIRONOLACTONE			
AMILORIDE	1 (1.6%)	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
AMILORIDE HYDROCHLORIDE	0	0	0
AMILORIDE HYDROCHLORIDE /FUROSEMIDE	1 (1.6%)	1 (1.3%)	1 (1.1%)
AMILORIDE HYDROCHLORIDE /HYDROCHLOROTHIAZIDE	4 (6.6%)	0	3 (3.3%)
AZOSEMIDE	0	0	0
BEMETIZIDE	0	0	0
/HESPERIDIN COMPLEX			
/THIAMINE MONONITRATE			
/TRIAMTERENE			
BENDROFLUMETHIAZIDE	1 (1.6%)	0	2 (2.2%)
BENDROFLUMETHIAZIDE /POTASSIUM CHLORIDE	0	0	0
BENZTHIAZIDE	0	0	0
/TRIAMTERENE			
BISOPROLOL PUMARATE	0	0	0
/HYDROCHLOROTHIAZIDE			
BUMETANIDE	3 (4.9%)	1 (1.3%)	0
CAPTOPRIL	0	1 (1.3%)	0
/HYDROCHLOROTHIAZIDE			
CYCLOTHIAZIDE	0	0	0
/TRIAMTERENE			
DORZOLAMIDE HYDROCHLORIDE	1 (1.6%)	0	2 (2.2%)
DORZOLAMIDE HYDROCHLORIDE /TIMOLOL MALEATE	0	0	0
ENALAPRIL MALEATE	0	0	2 (2.2%)
/HYDROCHLOROTHIAZIDE			
ETACRYNIC ACID	0	0	0
FOSINOPRIL SODIUM	0	0	0
/HYDROCHLOROTHIAZIDE			
FUROSEMIDE	4 (6.6%)	8 (10.3%)	8 (8.9%)
FUROSEMIDE /SPIRONOLACTONE	0	0	0
FUROSEMIDE	0	2 (2.6%)	0
/TRIAMTERENE			
HYDROCHLOROTHIAZIDE	0	0	1 (1.1%)
HYDROCHLOROTHIAZIDE /LISINOPRIL	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
HYDROCHLOROTHIAZIDE	0	0	0
/LOSARTAN POTASSIUM			
HYDROCHLOROTHIAZIDE	0	0	0
/QUINAPRIL			
HYDROCHLOROTHIAZIDE	0	1 (1.3%)	0
/QUINAPRIL HYDROCHLORIDE			
HYDROCHLOROTHIAZIDE	0	0	0
/RAMIPRIL			
HYDROCHLOROTHIAZIDE	0	0	1 (1.1%)
/TRIAMTERENE			
HYDROCHLOROTHIAZIDE	0	0	0
/VALSARTAN			
HYDROFLUMETHIAZIDE	0	0	1 (1.1%)
/SPIRONOLACTONE			
HYPERICUM EXTRACT	0	0	0
INDAPAMIDE	2 (3.3%)	0	1 (1.1%)
INDAPAMIDE	0	0	0
/PERINDOPRIL ERBUMINE			
INDAPAMIDE HEMIHYDRATE	0	0	0
ISOSORBIDE	0	0	0
METOLAZONE	1 (1.6%)	0	0
PIRETANIDE	0	0	1 (1.1%)
POTASSIUM CANRENOATE	0	0	0
SOLIDAGO	0	0	0
SPIRONOLACTONE	0	1 (1.3%)	1 (1.1%)
THEOPHYLLINE	0	0	0
TORASEMID	0	0	0
HYPOTENSIVES	23 (37.7%)	33 (42.3%)	47 (52.2%)
ALFUZOSIN	0	0	0
ALFUZOSIN HYDROCHLORIDE	0	1 (1.3%)	0
ALMITRINE DIMESILATE	0	0	0
/RAUBASINE			
AMLODIPINE	2 (3.3%)	6 (7.7%)	3 (3.3%)
AMLODIPINE BESYLATE	2 (3.3%)	2 (2.6%)	2 (2.2%)
ATENOLOL	0	0	0
/NIFEDIPINE			
BENAZEPRIL	1 (1.6%)	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BENAZEPRIL	0	0	0
/CHLOROTHIAZIDE			
BENAZEPRIL HYDROCHLORIDE	0	0	1 (1.1%)
BEPRIDIL HYDROCHLORIDE MONOHYDRATE	0	0	0
BETULA LEAF	0	1 (1.3%)	0
/OLIVE LEAVES EXTRACT			
CANDESARTAN CILEXETIL	0	0	0
CAPTOPRIL	1 (1.6%)	3 (3.8%)	0
CAPTOPRIL	0	1 (1.3%)	0
/HYDROCHLOROTHIAZIDE			
CARVEDILOL	0	0	0
CICLETANINE HYDROCHLORIDE	0	0	1 (1.1%)
CILAZAPRIL	0	0	0
CLONIDINE HYDROCHLORIDE	0	0	0
DIHYDROERGOCRISTINE MESILATE	0	0	1 (1.1%)
/RAUBASINE			
DILTIAZEM	0	1 (1.3%)	3 (3.3%)
DILTIAZEM HYDROCHLORIDE	2 (3.3%)	3 (3.8%)	3 (3.3%)
DOXAZOSIN	0	1 (1.3%)	2 (2.2%)
DOXAZOSIN MESYLATE	0	0	0
ENALAPRIL	2 (3.3%)	2 (2.6%)	3 (3.3%)
ENALAPRIL MALEATE	5 (8.2%)	5 (6.4%)	8 (8.9%)
ENALAPRIL MALEATE	0	0	2 (2.2%)
/HYDROCHLOROTHIAZIDE			
EPROSARTAN	0	0	0
FELODIPINE	0	1 (1.3%)	2 (2.2%)
FELODIPINE	0	0	0
/METOPROLOL			
FELODIPINE	0	0	0
/RAMIPRIL			
POSINOPRIL	0	1 (1.3%)	1 (1.1%)
POSINOPRIL SODIUM	1 (1.6%)	0	0
POSINOPRIL SODIUM	0	0	0
/HYDROCHLOROTHIAZIDE			
HYDRALAZINE	0	1 (1.3%)	0
HYDROCHLOROTHIAZIDE	0	0	0
/LISINOPRIL			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
HYDROCHLOROTHIAZIDE	0	0	0
/LOSARTAN POTASSIUM			
HYDROCHLOROTHIAZIDE	0	0	0
/QUINAPRIL			
HYDROCHLOROTHIAZIDE	0	1 (1.3%)	0
/QUINAPRIL HYDROCHLORIDE			
HYDROCHLOROTHIAZIDE	0	0	0
/RAMIPRIL			
HYDROCHLOROTHIAZIDE	0	0	0
/VALSARTAN			
INDAPAMIDE	2 (3.3%)	0	1 (1.1%)
INDAPAMIDE	0	0	0
/PERINDOPRIL ERBUMINE			
INDORAMIN	1 (1.6%)	0	0
IRBESARTAN	2 (3.3%)	0	1 (1.1%)
ISRODIPINE	0	0	0
LACIDIPINE	0	1 (1.3%)	1 (1.1%)
LISINOPRIL	4 (6.6%)	3 (3.8%)	4 (4.4%)
LOSARTAN	0	2 (2.6%)	0
LOSARTAN POTASSIUM	3 (4.9%)	0	2 (2.2%)
METHYLDOPA	0	0	0
METOPROLOL TARTRATE	0	0	0
/NIFEDIPINE			
MISTLETOE EXTRACT	0	0	0
MOXONIDINE	1 (1.6%)	0	0
NICARDIPINE HYDROCHLORIDE	0	0	0
NIFEDIPINE	4 (6.6%)	3 (3.8%)	8 (8.9%)
NISOLDIPINE	0	1 (1.3%)	0
NITRENDIPINE	0	1 (1.3%)	0
PERINDOPRIL	1 (1.6%)	3 (3.8%)	1 (1.1%)
PRAZOSIN	0	0	0
QUINAPRIL	0	1 (1.3%)	3 (3.3%)
QUINAPRIL HYDROCHLORIDE	0	2 (2.6%)	2 (2.2%)
RAMIPRIL	1 (1.6%)	1 (1.3%)	2 (2.2%)
RILMENIDINE PHOSPHATE	1 (1.6%)	0	2 (2.2%)
SPIRAPRIL HYDROCHLORIDE	0	0	0
TERAZOSIN	0	0	0
TERAZOSIN HYDROCHLORIDE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
TRANOLAPRILAT	0	1 (1.3%)	3 (3.3%)
TRANOLAPRILAT /VERAPAMIL	0	0	1 (1.1%)
URAPIDIL	1 (1.6%)	0	0
VALSARTAN	0	0	1 (1.1%)
VERAPAMIL	0	0	1 (1.1%)
VERAPAMIL HYDROCHLORIDE	0	1 (1.3%)	2 (2.2%)
PERIPHERAL VASODILATORS	3 (4.9%)	7 (9.0%)	10 (11.1%)
BETAHISTINE	0	0	1 (1.1%)
BETAHISTINE HYDROCHLORIDE	1 (1.6%)	1 (1.3%)	2 (2.2%)
BETAHISTINE MESILATE	0	0	0
BUFLOMEDIL HYDROCHLORIDE	0	0	1 (1.1%)
BUPHENINE HYDROCHLORIDE /ESCI	0	0	0
CAFFEINE	0	0	0
/DIHYDROERGOCRYPTINE MESILATE			
DIHYDROERGOCORNINE MESILATE	0	0	0
/DIHYDROERGOCRISTINE MESILATE			
/DIHYDROERGOCRYPTINE MESILATE			
DIHYDROERGOCRISTINE MESILATE	0	1 (1.3%)	0
/PIRACETAM			
DIHYDROERGOCRISTINE MESILATE	0	0	1 (1.1%)
/RAUBASINE			
FLUNARIZINE DIHYDROCHLORIDE	1 (1.6%)	0	1 (1.1%)
GINKGO TREE LEAVES EXTRACT	1 (1.6%)	0	0
IFENPRODIL TARTRATE	0	0	1 (1.1%)
INOSITOL NICOTINATE	0	0	0
MOXISYLYTE HYDROCHLORIDE	0	0	0
NAFTIDROFURYL OXALATE	1 (1.6%)	3 (3.8%)	3 (3.3%)
NICERGOLINE	0	0	1 (1.1%)
NICOTINYL TARTRATE	0	0	1 (1.1%)
PENTOXIFYLLINE	0	2 (2.6%)	3 (3.3%)
PIRIBEDIL	0	0	0
VINBURNINE	0	0	0
VASOPROTECTIVES	10 (16.4%)	9 (11.5%)	12 (13.3%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
AESCLUS (OLD CODE)	0	0	0
/CRATAEGUS EXTRACT			
/METESCULETOL SODIUM			
/PASSIFLORA EXTRACT			
ARNICA	0	0	0
/HORSE CHESTNUT EXTRACT			
/HYOSCYAMUS DRY EXTRACT			
/SCOPARIUM			
ASCORBIC ACID	1 (1.6%)	0	0
/HERBAL EXTRACTS NOS			
/HESPERIDIN METHYL CHALCONE			
/PANCREAS EXTRACT			
ASCORBIC ACID	1 (1.6%)	1 (1.3%)	2 (2.2%)
/HESPERIDIN METHYL CHALCONE			
/RUSCUS ACULEATUS			
ASCORBIC ACID	0	0	0
/RUSCUS ACULEATUS RHIZOME			
BENZQUERCIN	0	1 (1.3%)	0
BETACAROTENE	0	1 (1.3%)	0
/MYRTILLUS			
BETAMETHASONE	1 (1.6%)	0	0
BETAMETHASONE	0	0	0
/CLOTRIMAZOLE			
/GENTAMICIN			
BISMUTH SUBGALLATE	0	0	0
/CARRAGHENATE			
/TALC			
/ZINC OXIDE			
BUPHENINE HYDROCHLORIDE	0	0	0
/ESCIN			
CALCIUM DOBESILATE	1 (1.6%)	1 (1.3%)	2 (2.2%)
CHROMOCARB DIETHYLAMINE	0	0	0
COUMARIN	0	0	0
/TROXERUTIN			
DIOSMIN	4 (6.6%)	3 (3.8%)	4 (4.4%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ERYTHROMYCIN	0	0	0
/METHIONINE			
/MULTIVITAMINS, NOS			
/RUTOSIDE			
/SULFAFURAZOLE			
FLAVODATE DISODIUM	0	0	0
GINKGO TREE LEAVES EXTRACT	0	2 (2.6%)	1 (1.1%)
/HEPTAMINOL HYDROCHLORIDE			
/TROXERUTIN			
GLYCOL SALICYLATE	0	0	0
/HEPARIN SODIUM			
HEPARIN	1 (1.6%)	0	1 (1.1%)
HEPARIN SODIUM	0	0	0
HEPARIN SODIUM, TOPICAL	0	0	0
HERBAL EXTRACTS NOS	1 (1.6%)	0	1 (1.1%)
/VITIS VINIFERA			
HEXAMIDINE ISETHIONATE	0	1 (1.3%)	0
/TETRACAINE HYDROCHLORIDE			
HIRUDIN	0	0	0
HORSE CHESTNUT EXTRACT	0	0	0
/THIAMINE HYDROCHLORIDE			
HYDROCORTISONE BUTYRATE	1 (1.6%)	0	1 (1.1%)
MELILOT	1 (1.6%)	2 (2.6%)	1 (1.1%)
/RUTOSIDE			
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	0	0
NAFTAZONE	1 (1.6%)	0	0
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (1.6%)	0	0
RUTOSIDE	0	0	0
TROXERUTIN	1 (1.6%)	1 (1.3%)	1 (1.1%)
CENTRAL NERVOUS SYSTEM			
ANAESTHETICS	2 (3.3%)	3 (3.8%)	1 (1.1%)
ARTICAINE HYDROCHLORIDE	0	0	0
/EPINEPHRINE HYDROCHLORIDE			
BUPIVACAINE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CETYLPRIDINIUM CHLORIDE	0	0	0
/CHLOROBUTANOL			
/EUGENOL			
/VERATROLE			
FENTANYL	0	0	0
HEXAMIDINE ISETHIONATE	0	1 (1.3%)	0
/TETRACAINE HYDROCHLORIDE			
KETAMINE	0	0	0
LIDOCAINE	0	0	0
LIDOCAINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
/METHYLPREDNISOLONE ACETATE			
LIDOCAINE HYDROCHLORIDE	0	1 (1.3%)	0
LOCAL ANESTHESIA	1 (1.6%)	0	0
MIDAZOLAM MALEATE	0	0	0
PRILOCAINE HYDROCHLORIDE	0	0	0
PROCAINE	0	0	0
PROPOFOL	0	0	0
ROPIVACAINE HYDROCHLORIDE	0	0	0
ANALGESICS	24 (39.3%)	41 (52.6%)	45 (50.0%)
ACETYLSALICYLATE CALCIUM	1 (1.6%)	1 (1.3%)	0
ACETYLSALICYLATE LYSINE	1 (1.6%)	0	1 (1.1%)
ACETYLSALICYLIC ACID	16 (26.2%)	22 (28.2%)	22 (24.4%)
ACETYLSALICYLIC ACID	0	1 (1.3%)	2 (2.2%)
/ALUMINIUM HYDROXIDE			
/MAGNESIUM HYDROXIDE			
ACETYLSALICYLIC ACID	0	0	1 (1.1%)
/ASCORBIC ACID			
ACETYLSALICYLIC ACID	0	0	0
/CAFFEINE			
ACETYLSALICYLIC ACID	0	0	0
/CAFFEINE			
/PHENACETIN			
ACETYLSALICYLIC ACID	0	0	1 (1.1%)
/CAFFEINE			
/QUININE SULFATE			
ACETYLSALICYLIC ACID	0	0	0
/LITHIUM CITRATE			
/QUININE CITRATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
AMYLASE	0	0	0
/PARACETAMOL			
ASCORBIC ACID	1 (1.6%)	1 (1.3%)	0
/PARACETAMOL			
BELLADONNA EXTRACT	0	0	0
/CAFFEINE			
/OPIUM TINCTURE			
/PARACETAMOL			
BENZALKONIUM CHLORIDE	0	0	1 (1.1%)
/DICHLORALPHENAZONE			
/DIMETICONE, ACTIVATED			
/HYDROCORTISONE			
/ISOMETHEPTENE			
/NYSTATIN			
/PARACETAMOL			
BENZOCAINE	0	1 (1.3%)	0
/SALICYLAMIDE			
BUCLIZINE HYDROCHLORIDE	1 (1.6%)	0	0
/CODEINE PHOSPHATE			
/PARACETAMOL			
BUPRENORPHINE	0	0	0
BUTALBITAL	0	1 (1.3%)	0
/CAFFEINE			
/DIHYDROERGOTAMINE MESILATE			
/PROPYPHENAZONE			
BUTALBITAL	0	0	0
/CAFFEINE			
/PROPYPHENAZONE			
CAFFEINE	0	1 (1.3%)	1 (1.1%)
/CARBASALATE CALCIUM			
/CHLORPHENAMINE MALEATE			
/DEXTROPROPOXYPHENE			
/PARACETAMOL			
CAFFEINE	0	0	0
/CODEINE PHOSPHATE			
/PARACETAMOL			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CARBAMOYLPHENOXYACETIC ACID	0	0	0
/CYANOCOBALAMIN			
/LIDOCAINE			
/SODIUM CHLORIDE			
CARBASALATE CALCIUM	0	0	0
CLONIDINE HYDROCHLORIDE	0	0	0
CODEINE	0	0	0
CODEINE PHOSPHATE	0	2 (2.6%)	0
CODEINE PHOSPHATE	3 (4.9%)	4 (5.1%)	3 (3.3%)
/PARACETAMOL			
DEXAMETHASONE ACETATE	0	0	0
/GLYCOL SALICYLATE			
/METHYL NICOTINATE			
/SALICYLAMIDE			
DEXTROPROPOXYPHENE	0	0	0
/PARACETAMOL			
DEXTROPROPOXYPHENE HYDROCHLORIDE	6 (9.8%)	10 (12.8%)	5 (5.6%)
/PARACETAMOL			
DEXTROPROPOXYPHENE NAPSILATE	0	0	0
DIHYDROCODEINE	0	2 (2.6%)	0
DIHYDROCODEINE BITARTRATE	0	0	0
DIHYDROCODEINE BITARTRATE	0	2 (2.6%)	4 (4.4%)
/PARACETAMOL			
DIHYDROERGOTAMINE MESILATE	0	1 (1.3%)	1 (1.1%)
FENTANYL	0	0	0
GUAIFENESIN	0	1 (1.3%)	0
/OXOMEMAZINE			
/PARACETAMOL			
/SODIUM BENZOATE			
HEROIN	0	0	1 (1.1%)
KETOBEMIDONE HYDROCHLORIDE	0	0	0
/N,N-DIMETHYL-3,3-DIPHENYL-1-METHYLALLYLAMINE			
HYDROCHLOR			
METAMIZOLE SODIUM	1 (1.6%)	3 (3.8%)	1 (1.1%)
MORPHINE	0	0	1 (1.1%)
MORPHINE SULFATE	0	0	0
NALBUPHINE HYDROCHLORIDE	0	0	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
NALOXONE HYDROCHLORIDE	0	0	0
/TILIDINE HYDROCHLORIDE			
PARACETAMOL	7 (11.5%)	14 (17.9%)	17 (18.9%)
PETHIDINE	0	0	0
PIZOTIFEN	0	0	0
PROPACETAMOL HYDROCHLORIDE	0	0	0
SODIUM ACETYLSALICYLATE	0	0	0
TRAMADOL	0	1 (1.3%)	0
TRAMADOL HYDROCHLORIDE	0	1 (1.3%)	2 (2.2%)
ZOLMITRIPTAN	0	0	0
ANTI-PARKINSON DRUGS	0	0	0
BENZHEXOL HYDROCHLORIDE	0	0	0
/DEMELVERINUM HYDROCHLORICUM			
DEXETIMIDE	0	0	0
ORPHENADRINE CITRATE	0	0	0
TRIHXYPHENIDYL HYDROCHLORIDE	0	0	0
ANTIEPILEPTICS	2 (3.3%)	1 (1.3%)	2 (2.2%)
CARBAMAZEPINE	1 (1.6%)	0	1 (1.1%)
CLONAZEPAM	1 (1.6%)	1 (1.3%)	1 (1.1%)
DIFEBARBAMATE	0	0	0
/FEBARBAMATE			
/PHENOBARBITAL			
GABAPENTIN	0	1 (1.3%)	0
VALPROATE SODIUM	0	0	0
VALPROATE SODIUM	0	0	0
/VALPROIC ACID			
OTHER	0	0	1 (1.1%)
CALCIUM LACTATE	0	0	1 (1.1%)
/CIMICIFUGA			
/MAGNESIUM HYPOSULFITE			
/OLEOSACCHARUM OF MARJOLAIN			
PILOCARPINE	0	0	0
PILOCARPINE HYDROCHLORIDE	0	0	0
/TIMOLOL MALEATE			
PSYCHOANALEPTICS	6 (9.8%)	6 (7.7%)	6 (6.7%)
AMFEBUTAMONE	0	1 (1.3%)	0
AMITRIPTYLINE	0	3 (3.8%)	1 (1.1%)
AMITRIPTYLINE HYDROCHLORIDE	0	2 (2.6%)	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
AMITRIPTYLINE HYDROCHLORIDE	0	0	1 (1.1%)
/MEDAZEPAM			
AMITRIPTYLINE HYDROCHLORIDE	1 (1.6%)	0	0
/PERPHENAZINE			
CITALOPRAM	1 (1.6%)	0	0
CLOMIPRAMINE HYDROCHLORIDE	0	0	0
DEANOL PIDOLATE	0	0	1 (1.1%)
/HEPTAMINOL HYDROCHLORIDE			
DOSULEPIN	0	0	0
DOXEPIN HYDROCHLORIDE	0	0	0
FLUOXETINE	1 (1.6%)	2 (2.6%)	2 (2.2%)
FLUVOXAMINE MALEATE	0	0	0
HYPERICUM EXTRACT	0	0	0
IMIPRAMINE	0	0	1 (1.1%)
IMIPRAMINE HYDROCHLORIDE	0	0	0
LEVOCARNITINE	0	0	0
/MAGNESIUM ASPARTATE			
MAPROTILINE HYDROCHLORIDE	0	0	1 (1.1%)
MIANSERIN HYDROCHLORIDE	0	0	0
MILNACIPRAN HYDROCHLORIDE	0	0	0
PIRACETAM	2 (3.3%)	0	0
SERTRALINE	0	0	0
SERTRALINE HYDROCHLORIDE	2 (3.3%)	0	1 (1.1%)
TRIMIPRAMINE MALEATE	0	0	0
VENLAFAXINE HYDROCHLORIDE	0	0	0
VILOXAZINE HYDROCHLORIDE	0	0	0
PSYCHOLEPTICS	8 (13.1%)	9 (11.5%)	14 (15.6%)
ACEPROMAZINE	0	0	0
/ACEPROMETAZINE			
/DIPOTASSIUM CLORAZEPATE			
ALPRAZOLAM	2 (3.3%)	0	1 (1.1%)
ASPARAGINE	0	0	0
/DIAZEPAM			
/LEVOTRUTHAMIDE			
/PYRIDOXINE			
/SERINE PHOSPHATE			
/THIAMINE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BALLOTA	0	0	3 (3.3%)
/COLA			
/CRATAEGUS EXTRACT			
/PASSIFLORA EXTRACT			
/PAULLINIA			
/VALERIAN ROOT			
BROMAZEPAM	0	2 (2.6%)	3 (3.3%)
BROMPERIDOL	0	0	0
CHLORPROTHIXENE HYDROCHLORIDE	0	0	0
CLOMETHIAZOLE EDISILATE	0	0	0
CLOTIAZEPAM	0	0	0
CRATAEGUS	0	0	0
/VALERIAN ROOT			
CRATAEGUS EXTRACT	0	0	0
/VALERIAN EXTRACT			
CYAMEMAZINE	0	0	0
DELORAZEPAM	1 (1.6%)	0	0
DIAZEPAM	0	0	1 (1.1%)
DIAZEPAM	0	0	1 (1.1%)
/SULPIRIDE			
DIFEBARBAMATE	0	0	0
/FEBARBAMATE			
/PHENOBARBITAL			
DIPOTASSIUM CLORAZEPATE	1 (1.6%)	1 (1.3%)	0
ETHYL LOFLAZEPATE	0	0	0
FLUNITRAZEPAM	0	0	1 (1.1%)
FLUPENTIXOL DIHYDROCHLORIDE	0	0	0
FLUPHENAZINE	0	0	0
HALOPERIDOL	0	0	0
HERBAL EXTRACTS NOS	0	0	0
/PHENOBARBITAL			
HYDROXYZINE HYDROCHLORIDE	0	1 (1.3%)	1 (1.1%)
HYPERICUM EXTRACT	0	0	0
LEVOMEPRMAZINE HYDROCHLORIDE	0	1 (1.3%)	0
LITHIUM CARBONATE	0	0	0
LOPRAZOLAM	0	1 (1.3%)	0
LOPRAZOLAM MESILATE	0	0	0
LORAZEPAM	0	1 (1.3%)	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
LORMETAZEPAM	0	0	1 (1.1%)
NITRAZEPAM	0	1 (1.3%)	0
NORDAZEPAM	0	0	0
OXAZEPAM	1 (1.6%)	0	0
PAROXETINE	2 (3.3%)	0	0
PRAZEPAM	0	1 (1.3%)	3 (3.3%)
PROCHLORPERAZINE	1 (1.6%)	0	1 (1.1%)
PROCHLORPERAZINE MALEATE	1 (1.6%)	0	0
PROMETHAZINE HYDROCHLORIDE	0	0	0
PROXIBARBAL	0	0	0
RISPERIDONE	0	0	0
SULPIRIDE	0	0	0
TEMAZEPAM	0	1 (1.3%)	0
TETRAZEPAM	1 (1.6%)	2 (2.6%)	0
THIORIDAZINE HYDROCHLORIDE	0	0	0
TRIAZOLAM	0	0	0
ZOLPIDEM HEMITARTRATE	1 (1.6%)	0	2 (2.2%)
ZOPICLONE	0	0	0
DERMATOLOGICALS			
ANTI-ACNE PREP	3 (4.9%)	0	1 (1.1%)
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)
RETINOL	1 (1.6%)	0	0
ANTIBIOTIC&CHEMOTHERAPEUT	9 (14.8%)	9 (11.5%)	8 (8.9%)
BACITRACIN	0	0	0
/NEOMYCIN SULFATE			
BETAMETHASONE	0	0	0
/CLOTRIMAZOLE			
/GENTAMICIN			
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)
ERYTHROMYCIN	4 (6.6%)	4 (5.1%)	3 (3.3%)
FRAMYCETIN SULFATE	0	0	0
/TRYPSIN			
FUSIDATE SODIUM	2 (3.3%)	1 (1.3%)	0
FUSIDATE SODIUM	0	0	0
/HYDROCORTISONE ACETATE			
FUSIDIC ACID	0	1 (1.3%)	1 (1.1%)
GENTAMICIN SULFATE	1 (1.6%)	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
METRONIDAZOLE	0	5 (6.4%)	1 (1.1%)
MUPIROCIN	0	0	1 (1.1%)
OXYTETRACYCLINE	2 (3.3%)	1 (1.3%)	0
OXYTETRACYCLINE DIHYDRATE	1 (1.6%)	0	0
SULFADIAZINE SILVER	0	0	1 (1.1%)
TETRACYCLINE	0	0	2 (2.2%)
ANTIFUNGALS	6 (9.8%)	4 (5.1%)	8 (8.9%)
AMOROLFINE HYDROCHLORIDE	0	1 (1.3%)	0
BETAMETHASONE	0	0	0
/CLOTRIMAZOLE			
/GENTAMICIN			
BETAMETHASONE DIPROPIONATE	0	0	0
/CLOTRIMAZOLE			
BIFONAZOLE	0	0	1 (1.1%)
BIFONAZOLE	0	0	0
/UREA			
BUTOCONAZOLE NITRATE	0	0	0
CLOTRIMAZOLE	2 (3.3%)	2 (2.6%)	2 (2.2%)
CLOTRIMAZOLE	0	1 (1.3%)	0
/HYDROCORTISONE			
ECONAZOLE NITRATE	0	0	1 (1.1%)
FENTICONAZOLE NITRATE	0	0	0
GRISEOFULVIN	1 (1.6%)	0	1 (1.1%)
HEXETIDINE	0	0	0
HYDROCORTISONE	0	0	0
/MICONAZOLE			
HYDROCORTISONE	1 (1.6%)	0	2 (2.2%)
/MICONAZOLE NITRATE			
ISOCONAZOLE NITRATE	1 (1.6%)	0	0
KETOCONAZOLE	1 (1.6%)	1 (1.3%)	0
MICONAZOLE	0	0	0
MICONAZOLE NITRATE	0	0	0
NYSTATIN	0	1 (1.3%)	1 (1.1%)
TERBINAFINE	1 (1.6%)	0	1 (1.1%)
TIOCONAZOLE	0	0	1 (1.1%)
ANTIPRURITICS	0	1 (1.3%)	0
CINCHOCAINE HYDROCHLORIDE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CINCHOCAINE HYDROCHLORIDE	0	0	0
/CLOCORTOLONE HEXANOATE			
/CLOCORTOLONE PIVALATE			
DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0
DOXEPIN HYDROCHLORIDE	0	0	0
LIDOCAINE	0	0	0
LIDOCAINE HYDROCHLORIDE	0	1 (1.3%)	0
NOSCAPINE	0	0	0
/POLYSORBATE 85 (TWEEN 85)			
/PROMETHAZINE			
PROMETHAZINE HYDROCHLORIDE	0	0	0
ANTISEPTICS & DISINFECTANTS	4 (6.6%)	2 (2.6%)	5 (5.6%)
ALLANTOIN	0	0	1 (1.1%)
/CETRIMONIUM BROMIDE			
/DICHLOOROBENZYL ALCOHOL			
CETRIMONIUM BROMIDE	1 (1.6%)	0	0
CETYLPRIDINIUM CHLORIDE	0	0	0
/CHLOROBUTANOL			
/EUGENOL			
/VERATROLE			
CHLORHEXIDINE GLUCONATE	0	0	0
CHLOROQUINE	0	0	2 (2.2%)
ESSENTIAL OILS NOS	0	0	0
/ETHANOL			
/GLYCEROL			
/METHYL SALICYLATE			
/SALICYLATE SODIUM			
/SODIUM BICARBONATE			
/SODIUM TETRABORATE			
/THYMOL			
ETHACRIDINE	0	0	0
HEXAMIDINE ISETHIONATE	0	1 (1.3%)	1 (1.1%)
HEXAMIDINE ISETHIONATE	0	1 (1.3%)	0
/TETRACAINE HYDROCHLORIDE			
HYDROCORTISONE	1 (1.6%)	0	0
/ICHTHAMMOL			
NIFUROXAZIDE	1 (1.6%)	1 (1.3%)	0
POVIDONE-IODINE	1 (1.6%)	1 (1.3%)	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
SODIUM HYPOCHLORITE	0	0	0
TRICLOCARBAN	0	0	0
CICATRIZANTS	0	0	0
ALLANTOIN	0	0	0
/CADE OIL			
/SALICYLIC ACID			
ASIATIC ACID	0	0	0
/ASIATICOSIDE			
/MADECASSIC ACID			
DEXPANTHENOL	0	0	0
COAL TAR,SULPH,RESORCIN PROD	0	0	0
ALLANTOIN	0	0	0
/COAL TAR SOLUTION			
CADE OIL	0	0	0
/COAL TAR			
/COAL TAR SOLUTION			
/OLEYL ALCOHOL			
COAL TAR EXTRACT	0	0	0
/HYDROCORTISONE			
TAZAROTENE	0	0	0
CORTICOSTEROIDS	9 (14.8%)	6 (7.7%)	10 (11.1%)
BETAMETHASONE	1 (1.6%)	0	0
BETAMETHASONE	0	0	0
/CLOTRIMAZOLE			
/GENTAMICIN			
BETAMETHASONE	0	0	0
/NEOMYCIN			
BETAMETHASONE ACETATE	0	0	1 (1.1%)
/BETAMETHASONE SODIUM PHOSPHATE			
BETAMETHASONE DIPROPIONATE	0	1 (1.3%)	0
BETAMETHASONE DIPROPIONATE	0	0	0
/CLOTRIMAZOLE			
BETAMETHASONE DIPROPIONATE	0	0	0
/SALICYLIC ACID			
BETAMETHASONE SODIUM PHOSPHATE	0	0	0
BETAMETHASONE VALERATE	1 (1.6%)	1 (1.3%)	3 (3.3%)
BETAMETHASONE VALERATE	0	0	0
/CLIOQUINOL			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BETAMETHASONE VALERATE	1 (1.6%)	1 (1.3%)	0
/FUSIDIC ACID			
BUDESONIDE	0	0	0
CINCHOCAINE HYDROCHLORIDE	0	0	0
/CLOCORTOLONE HEXANOATE			
/CLOCORTOLONE PIVALATE			
CLIOQUINOL	0	0	1 (1.1%)
/HYDROCORTISONE			
CLIOQUINOL	1 (1.6%)	0	0
/HYDROCORTISONE			
/NYSTATIN			
CLOBETASOL PROPIONATE	0	0	0
CLOCORTOLONE HEXANOATE	0	0	0
/CLOCORTOLONE PIVALATE			
CLOTRIMAZOLE	0	1 (1.3%)	0
/HYDROCORTISONE			
COAL TAR EXTRACT	0	0	0
/HYDROCORTISONE			
DESONIDE	1 (1.6%)	0	0
DESOXIMETASONE	0	0	1 (1.1%)
DEXAMETHASONE ACETATE	0	0	0
/GLYCOL SALICYLATE			
/METHYL NICOTINATE			
/SALICYLAMIDE			
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
/NEOMYCIN SULFATE			
DIFLUCORTOLONE VALERATE	0	0	0
FLUOCINOLONE ACETONIDE	0	1 (1.3%)	0
/NEOMYCIN SULFATE			
/POLYMYXIN B SULFATE			
FLUOCINONIDE	0	0	1 (1.1%)
FLUOCORTIN BUTYL	0	0	0
FLUTICASONE PROPIONATE	0	1 (1.3%)	0
FRAMYCETIN SULFATE	0	0	1 (1.1%)
/HYDROCORTISONE			
FUSIDATE SODIUM	0	0	0
/HYDROCORTISONE ACETATE			
HYDROCORTISONE	2 (3.3%)	0	2 (2.2%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
HYDROCORTISONE	1 (1.6%)	0	0
/ICHTHAMMOL			
HYDROCORTISONE ACETATE	0	0	0
/NEOMYCIN SULFATE			
HYDROCORTISONE BUTYRATE	1 (1.6%)	0	1 (1.1%)
METHYLPREDNISOLONE	1 (1.6%)	0	2 (2.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	0
MOMETASONE FUROATE	0	0	0
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (1.6%)	0	0
SALICYLIC ACID	0	0	0
/TRIAMCINOLONE ACETONIDE			
TRIAMCINOLONE ACETONIDE	0	0	1 (1.1%)
TRIAMCINOLONE HEXACETONIDE	0	0	0
EMOLLIENTS & PROTECTIVES	5 (8.2%)	2 (2.6%)	7 (7.8%)
ALGIN	1 (1.6%)	0	1 (1.1%)
/CETYL PALMITATE			
/ETHYLENE GLYCOL MONOSTEARATE			
/PARAFFIN			
/PARAFFIN, LIQUID			
/PROPYLENE GLYCOL			
/STEARYL ALCOHOL			
/TROLAMINE			
ALOES	0	0	0
BEEWAX WHITE	0	0	0
/PARAFFIN			
/WHITE VASELINE			
/ZINC OXIDE			
BETAINE	1 (1.6%)	0	0
/LACTIC ACID			
/UREA			
BIFONAZOLE	0	0	0
/UREA			
CALCIPOTRIOL	0	0	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CETOSTEARYL ALCOHOL	1 (1.6%)	0	0
/GLYCERYL MONOSTEARATE			
/PARAFFIN, LIQUID			
/PARAFFIN, SOFT			
/POLYSORBATE 40			
/PROPYLENE GLYCOL			
/SILICIC ACID			
/SORBIC ACID			
COD-LIVER OIL	1 (1.6%)	0	1 (1.1%)
CYCLOMETHICONE	0	1 (1.3%)	0
/SOFT PARAFFIN			
EMULSIFYING WAX	0	0	1 (1.1%)
/PARAFFIN, LIQUID			
/PARAFFIN, SOFT			
GLYCERYL MONOSTEARATE	0	1 (1.3%)	0
/METHYLPARABEN			
/PARAFFIN, LIQUID			
/PARAFFIN, SOFT			
/STEARIC ACID			
/TROLAMINE			
/WOOL FAT			
LACTULOSE	0	0	0
/PARAFFIN			
/PARAFFIN, SOFT			
LYCOPENE	0	0	0
/RETINOL			
/TOCOPHEROL			
PARAFFIN, LIQUID	0	0	1 (1.1%)
PARAFFIN, LIQUID	0	0	1 (1.1%)
/WOOL ALCOHOLS			
PARAFFIN, SOFT	1 (1.6%)	0	1 (1.1%)
PIAS	2 (3.3%)	0	1 (1.1%)
TOCOPHEROL	0	0	0
UREA	0	0	0
WHEAT GERM	0	0	0
MEDICATED DRESSINGS	2 (3.3%)	2 (2.6%)	1 (1.1%)
CALCIUM ALGINATE	0	0	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ETHANOLAMINE TENOATE	0	0	0
/FRAMYCETIN SULFATE			
FRAMYCETIN SULFATE	0	0	0
FUSIDATE SODIUM	2 (3.3%)	1 (1.3%)	0
FUSIDIC ACID	0	1 (1.3%)	1 (1.1%)
MEDICATED DRESSINGS NOS	0	0	0
OTHER	2 (3.3%)	1 (1.3%)	3 (3.3%)
ACITRETIN	0	0	0
ALLANTOIN	0	0	0
/CADE OIL			
/SALICYLIC ACID			
ALUMINIUM CHLOROHYDRATE	0	0	0
ARNICA	0	0	0
/HORSE CHESTNUT EXTRACT			
/HYOSCYAMUS DRY EXTRACT			
/SCOPARIUM			
CALCIPOTRIOL	0	0	1 (1.1%)
CYSTEINE HYDROCHLORIDE	0	0	0
/METHIONINE			
DERMATOLOGICALS NOS	0	0	1 (1.1%)
FRAMYCETIN SULFATE	0	0	0
/TRYPSIN			
LIQUID NITROGEN	1 (1.6%)	0	0
POVIDONE-IODINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
SALICYLIC ACID	0	0	0
SERRAPEPTASE	0	0	0
GU SYSTEM/SEX HORMONES			
ANTIINFECTIVES/ANTISEPTICS	9 (14.8%)	10 (12.8%)	8 (8.9%)
ACETARSOL	1 (1.6%)	0	0
/NEOMYCIN			
/NYSTATIN			
/POLYMYXIN B SULFATE			
ANTIBIOTIC NOS	2 (3.3%)	1 (1.3%)	0
BUTOCONAZOLE NITRATE	0	0	0
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)
CICLOPIROX OLAMINE	0	0	1 (1.1%)
CLOTRIMAZOLE	2 (3.3%)	2 (2.6%)	2 (2.2%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ECONAZOLE NITRATE	0	0	1 (1.1%)
METRONIDAZOLE	0	5 (6.4%)	1 (1.1%)
MICONAZOLE	0	0	0
MICONAZOLE NITRATE	0	0	0
NEOMYCIN SULFATE	1 (1.6%)	0	0
/NYSTATIN			
/PREDNISOLONE SODIUM SULFOBENZOATE			
/TERNIDAZOLE			
NYSTATIN	0	1 (1.3%)	1 (1.1%)
OXYTETRACYCLINE	2 (3.3%)	1 (1.3%)	0
OXYTETRACYCLINE DIHYDRATE	1 (1.6%)	0	0
POVIDONE-IODINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
OTHER	1 (1.6%)	0	2 (2.2%)
ALPROSTADIL	1 (1.6%)	0	2 (2.2%)
HYPERICUM EXTRACT	0	0	0
INTRAUTERINE CONTRACEPTIVE DEVICE	0	0	0
QUINAGOLIDE HYDROCHLORIDE	0	0	0
SEX HORMONES/STIMULANTS	3 (4.9%)	2 (2.6%)	3 (3.3%)
BOVINE TESTICULAR EXTRACT	0	0	0
CHLORMADINONE ACETATE	0	0	0
DESOGESTREL	0	0	0
/ETHINYLESTRADIOL			
DIENESTROL	0	0	0
DYDROGESTERONE	0	0	0
DYDROGESTERONE	0	0	2 (2.2%)
/ESTRADIOL			
ESTRADIOL	0	0	0
ESTRADIOL	0	0	0
/ESTRIOL			
/NORETHISTERONE ACETATE			
ESTRADIOL	1 (1.6%)	0	0
/NORETHISTERONE ACETATE			
ESTRADIOL VALERATE	0	0	0
ESTRADIOL VALERATE	0	0	0
/MEDROXYPROGESTERONE ACETATE			
ESTRIOL	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ESTRIOL	0	0	0
/LACTOBACILLUS ACIDOPHILUS			
/PROGESTERONE			
ESTRIOL DISODIUM SUCCINATE	0	0	0
ESTROGEN NOS	0	0	0
ESTROGEN NOS	0	0	0
/MEDROXYPROGESTERONE			
ESTROGENS CONJUGATED	0	1 (1.3%)	0
ESTROGENS CONJUGATED	0	0	0
/NORGESTREL			
FINASTERIDE	1 (1.6%)	1 (1.3%)	0
LYNESTRENOL	0	0	0
MEDROGESTONE	0	0	0
MEDROXYPROGESTERONE ACETATE	0	0	0
NOMEGESTROL ACETATE	0	0	1 (1.1%)
NORETHISTERONE	0	0	0
NORETHISTERONE ACETATE	0	0	0
PROGESTERONE	0	0	1 (1.1%)
PROMEGESTONE	0	0	0
PROMESTRIENE	0	0	0
TESTOSTERONE ENANTATE	1 (1.6%)	0	0
UROLOGICALS	4 (6.6%)	8 (10.3%)	5 (5.6%)
ALFUZOSIN	0	0	0
ALFUZOSIN HYDROCHLORIDE	0	1 (1.3%)	0
AMINOACETIC ACID	1 (1.6%)	0	0
/GLUTAMIC ACID			
/PRUNUS AFRICANA			
CAMPHOR MONOBROMIDE	0	0	0
/HERBAL EXTRACTS NOS			
/METHENAMINE			
CANDESARTAN CILEXETIL	0	0	0
CIPROFLOXACIN	0	3 (3.8%)	1 (1.1%)
CIPROFLOXACIN HYDROCHLORIDE	0	0	1 (1.1%)
DOXAZOSIN MESYLATE	0	0	0
ECHINACEA EXTRACT	0	0	0
/SABAL EXTRACT			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ECHINACEA EXTRACT	0	0	0
/SABAL EXTRACT			
/TROSPIMUM CHLORIDE			
ENOXACIN	0	0	0
FLAVOXATE HYDROCHLORIDE	0	0	0
FLUMEQUINE	0	0	0
LIPOPHILER EXTRACT	0	0	0
/SABAL EXTRACT			
NIFURTOINOL	0	0	0
NITROFURANTOIN	0	1 (1.3%)	0
NITROXOLINE	0	0	0
NORFLOXACIN	2 (3.3%)	2 (2.6%)	0
OFLOXACIN	1 (1.6%)	1 (1.3%)	0
OXYBUTYNIN	1 (1.6%)	1 (1.3%)	1 (1.1%)
OXYBUTYNIN HYDROCHLORIDE	0	0	1 (1.1%)
PRazosin	0	0	0
PYGEUM AFRICANUM	0	0	0
SERENOA REPENS	2 (3.3%)	1 (1.3%)	0
SILDENAFIL CITRATE	1 (1.6%)	1 (1.3%)	1 (1.1%)
SOLIDAGO	0	0	0
TAMSULOSIN	0	0	0
TAMSULOSIN HYDROCHLORIDE	1 (1.6%)	0	0
TERAZOSIN	0	0	0
TERAZOSIN HYDROCHLORIDE	0	0	0
TOLTERODINE	0	1 (1.3%)	0
MUSCULO-SKELETAL			
ANTIGOUT PREP	1 (1.6%)	1 (1.3%)	3 (3.3%)
ALLOPURINOL	1 (1.6%)	1 (1.3%)	3 (3.3%)
ALLOPURINOL	0	0	0
/BENZBROMARONE			
BENZBROMARONE	0	0	0
COLCHICINE	0	0	0
COLCHICINE	0	0	0
/DICYCLOVERINE HYDROCHLORIDE			
COLCHICINE	0	0	0
/OPIUM			
/TIEMONIUM METHYLSULFATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
PROBENECID	0	0	0
ANTIINFLAM/ANTIRHEU PROD	16 (26.2%)	16 (20.5%)	29 (32.2%)
ACECLOFENAC	0	2 (2.6%)	3 (3.3%)
ACEMETACIN	0	0	1 (1.1%)
ALMINOPROFEN	0	0	0
AMINOPHENAZONE	0	0	0
/CYANOCOBALAMIN			
/DEXAMETHASONE SODIUM METASULFOBENZOATE			
/LIDOCAINE HYDROCHLORIDE			
/PHENYL BUTAZONE SODIUM			
BETA CYCLODEXTRIN	0	0	0
/NIMESULIDE			
CELECOXIB	0	0	0
CHONDROITIN SULFATE SODIUM	1 (1.6%)	0	0
CHYMOTRYPSINOGEN	0	0	1 (1.1%)
/RIBONUCLEASE			
/TRYPSIN			
DEKKETOPROFEN TROMETAMOL	0	1 (1.3%)	1 (1.1%)
DEXTRAN SULPHATE	0	0	0
/PHENYL BUTAZONE			
DIACEREIN	0	0	0
DICLOFENAC	1 (1.6%)	3 (3.8%)	3 (3.3%)
DICLOFENAC DIETHYLAMINE	0	0	1 (1.1%)
DICLOFENAC POTASSIUM	0	0	0
DICLOFENAC SODIUM	3 (4.9%)	7 (9.0%)	11 (12.2%)
DICLOFENAC SODIUM	0	0	3 (3.3%)
/MISOPROSTOL			
ETODOLAC	0	1 (1.3%)	0
FLURBIPROFEN	0	0	0
IBUPROFEN	5 (8.2%)	7 (9.0%)	6 (6.7%)
IBUPROFEN	0	2 (2.6%)	1 (1.1%)
/PSEUDOEPHEDRINE HYDROCHLORIDE			
IBUPROFEN LYSINATE	0	0	0
INDOMETACIN	0	1 (1.3%)	1 (1.1%)
INDOMETACIN	0	0	1 (1.1%)
/METAMIZOLE SODIUM			
/THIAMINE			
KETOPROFEN	4 (6.6%)	2 (2.6%)	2 (2.2%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
KETOPROFEN LYSINE	0	0	0
KETOROLAC TROMETHAMINE	0	0	0
LIDOCAINE HYDROCHLORIDE	0	0	0
/PHENYLBUZAZONE SODIUM			
MELOXICAM	1 (1.6%)	2 (2.6%)	3 (3.3%)
MISOPROSTOL	0	0	0
/NAPROXEN			
NABUMETONE	0	0	1 (1.1%)
NAPROXEN	2 (3.3%)	1 (1.3%)	2 (2.2%)
NAPROXEN SODIUM	0	0	1 (1.1%)
NIFLUMIC ACID	0	0	1 (1.1%)
NIMESULIDE	1 (1.6%)	0	1 (1.1%)
OXACEPROL	0	0	0
PIROXICAM	2 (3.3%)	0	3 (3.3%)
PIROXICAM BETA CYCLODEXTRIN	0	0	1 (1.1%)
PRANOPROFEN	0	0	0
PROGLUMETACIN MALEATE	0	0	0
SERRAPEPTASE	0	0	0
SUPROFEN	0	0	1 (1.1%)
TENOXICAM	1 (1.6%)	1 (1.3%)	1 (1.1%)
TIAPROFENIC ACID	0	0	1 (1.1%)
MUSCLE RELAXANTS	0	0	2 (2.2%)
CHLORMEZANONE	0	0	0
IDROCILAMIDE	0	0	0
ORPHENADRINE CITRATE	0	0	0
THIOLCHICOSIDE	0	0	2 (2.2%)
OTHER	0	1 (1.3%)	2 (2.2%)
AMINOHYDROXYPROPYLIDENEDIPHOSPHONATE DISODIUM	0	1 (1.3%)	0
AMINOPHYLLINE	0	0	0
/QUININE SULFATE			
AMTOLMETIN GUACIL SODIUM	0	0	0
HARPAGOPHYTUM PROCUMBENS	0	0	0
NIAOULI OIL	0	0	0
/QUININE BENZOATE			
/THIAMINE HYDROCHLORIDE			
QUININE	0	0	0
QUININE HYDROCHLORIDE	0	0	0
QUININE SULFATE	0	0	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
URIDINE TRIPHOSPHATE SODIUM	0	0	1 (1.1%)
TOPICAL ANTIRHEU PROD	2 (3.3%)	2 (2.6%)	0
ADRENAL CORTICAL EXTRACT	2 (3.3%)	0	0
/MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER			
/SALICYLIC ACID			
BENZYL NICOTINATE	0	0	0
/ECHINACEA EXTRACT			
/GLYCOL SALICYLATE			
/HEPARIN SODIUM			
/HESPERIDIN METHYL CHALCONE			
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	2 (2.6%)	0
/SALICYLIC ACID			
OXACEPROL	0	0	0
SALICYLIC ACID	0	0	0
PARASITOLOGY			
ANTHELMINTICS	0	1 (1.3%)	0
MEBENDAZOLE	0	1 (1.3%)	0
NICLOSAMIDE	0	0	0
ANTIPROTOZOALS	2 (3.3%)	6 (7.7%)	5 (5.6%)
CHLOROQUINE	0	0	2 (2.2%)
CHLOROQUINE	1 (1.6%)	0	0
/PROGUANIL			
CHLOROQUINE SULFATE	0	1 (1.3%)	1 (1.1%)
MEFLOQUINE	1 (1.6%)	0	1 (1.1%)
METRONIDAZOLE	0	5 (6.4%)	1 (1.1%)
PROGUANIL HYDROCHLORIDE	0	0	1 (1.1%)
QUININE	0	0	0
QUININE HYDROCHLORIDE	0	0	0
QUININE HYDROCHLORIDE	0	0	0
/SULFATE			
QUININE SULFATE	0	0	1 (1.1%)
RESPIRATORY			
ANTI-ASTHMATICS	0	5 (6.4%)	7 (7.8%)
AMINOPHYLLINE	0	1 (1.3%)	1 (1.1%)
AZELASTINE	0	0	0
BAMBUTEROL HYDROCHLORIDE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BECLOMETASONE	0	0	0
BECLOMETASONE DIPROPIONATE	0	1 (1.3%)	1 (1.1%)
BUDESONIDE	0	0	0
CETIRIZINE	0	0	0
/PSEUDOEPHEDRINE			
CROMOGLICATE SODIUM	0	0	0
CROMOGLICATE SODIUM	0	0	0
/REPROTEROL HYDROCHLORIDE			
DIPROPHYLLINE	0	0	0
/TURPENTINE OIL			
EPHEDRINE	0	0	0
FENOTEROL HYDROBROMIDE	0	0	0
/IPRATROPIUM BROMIDE			
FENSPIRIDE HYDROCHLORIDE	0	1 (1.3%)	1 (1.1%)
FLUTICASONE	0	0	0
/SALMETEROL			
FORMOTEROL FUMARATE	0	0	0
IPRATROPIUM	0	0	0
IPRATROPIUM BROMIDE	0	0	1 (1.1%)
ISOPRENALINE HYDROCHLORIDE	0	0	0
LORATADINE	0	0	0
/PSEUDOEPHEDRINE SULFATE			
MONTELUKAST SODIUM	0	0	0
NEDOCROMIL	0	0	0
NEDOCROMIL SODIUM	0	0	0
PSEUDOEPHEDRINE	0	0	1 (1.1%)
REPROTEROL HYDROCHLORIDE	0	0	0
SALBUTAMOL	0	2 (2.6%)	2 (2.2%)
SALBUTAMOL SULFATE	0	1 (1.3%)	0
SALMETEROL HYDROXYNAPHTHOATE	0	0	0
SALMETEROL XINAFOATE	0	1 (1.3%)	0
TERBUTALINE	0	0	1 (1.1%)
TERBUTALINE SULFATE	0	0	1 (1.1%)
THEOPHYLLINE	0	0	0
COUGH AND COLD PREP	7 (11.5%)	16 (20.5%)	11 (12.2%)
ACETYLCYSTEINE	3 (4.9%)	2 (2.6%)	5 (5.6%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
ACETYSALICYLIC ACID	0	1 (1.3%)	0
/ASCORBIC ACID			
/CHLORPHENAMINE MALEATE			
/MOROXYDINE HYDROCHLORIDE			
/PHENYLEPHRINE HYDROCHLORIDE			
ACETYSALICYLIC ACID	0	0	1 (1.1%)
/CAFFEINE			
/CHLORPHENAMINE MALEATE			
ACONITE TINCTURE	0	0	0
/BELLADONNA TINCTURE			
/CODEINE			
/ETHYLMORPHINE			
/POLYGALA AMARA TINCTURE			
/SODIUM BENZOATE			
/SODIUM BROMIDE			
ACONITE TINCTURE	0	0	0
/CHERRY-LAUREL			
/CODEINE PHOSPHATE			
/SODIUM BENZOATE			
AMARANTH SOLUTION	0	2 (2.6%)	0
/ANISE WATER			
/CHLOROFORM			
/CITRIC ACID			
AMBROXOL	0	3 (3.8%)	0
AMBROXOL HYDROCHLORIDE	1 (1.6%)	0	0
AMBROXOL HYDROCHLORIDE	0	0	0
/DOXYCYCLINE HYDROCHLORIDE			
ASCORBIC ACID	0	1 (1.3%)	0
/CODEINE PHOSPHATE			
/DIPROPHYLLINE			
/METAMIZOLE SODIUM			
/PARACETAMOL			
ASCORBIC ACID	0	0	1 (1.1%)
/PARACETAMOL			
/PHENYLEPHRINE HYDROCHLORIDE			
/SODIUM CITRATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BICLOTYMOL	0	1 (1.3%)	0
/CHLORPHENAMINE MALEATE			
/GUAIFENESIN			
/PHOLCODINE			
BROMHEXINE	0	0	0
BROMHEXINE HYDROCHLORIDE	0	0	1 (1.1%)
BROMPHENIRAMINE MALEATE	0	0	0
/GUAIFENESIN			
/PHENYLEPHRINE HYDROCHLORIDE			
/PHENYLPROPANOLAMINE HYDROCHLORIDE			
BUPHENINE HYDROCHLORIDE	0	0	0
/ESCIN			
CAFFEINE	0	0	0
/CODEINE PHOSPHATE			
/DIPHENHYDRAMINE HYDROCHLORIDE			
/PARACETAMOL			
/PHENYLEPHRINE HYDROCHLORIDE			
CARBAMIDE	0	0	0
/GUETHOL			
CARBINOXAMINE MALEATE	0	0	0
/GUAIFENESIN			
/PSEUDOEPHEDRINE HYDROCHLORIDE			
CARBOCISTEINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
CINEOLE	0	0	0
/ETHYLMORPHINE			
CLOBUTINOL	0	0	0
CLOBUTINOL HYDROCHLORIDE	0	1 (1.3%)	0
CLOPERASTINE FENDIZOATE	0	0	0
CODEINE	0	0	0
CODEINE	0	0	0
/ERYSIMUM EXTRACT			
/ETHYLMORPHINE CAMSILATE			
/GRINDELIA LIQUID EXTRACT			
/MARRUBE EXTRACT			
/SULFOGAIACOL			
CODEINE	0	1 (1.3%)	0
/GUAIACOL			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CODEINE	0	0	1 (1.1%)
/PHENYLTOLOXAMINE			
CODEINE HYDROCHLORIDE	0	0	0
/PHENOBARBITAL			
CODEINE PHOSPHATE	0	2 (2.6%)	0
DEXTROMETHORPHAN	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE	0	0	0
/METHOXYPHENAMINE HYDROCHLORIDE			
/SODIUM CITRATE			
DIHYDROCODEINE	0	2 (2.6%)	0
DIHYDROCODEINE BITARTRATE	0	0	0
DIHYDROCODEINE THIOCYANATE	0	0	0
/LIQUORICE LIQUID EXTRACT			
/PRIMULA FLUID EXTRACT			
/THYME EXTRACT			
ERDOSTEINE	0	0	0
EUCALYPTUS OIL	0	0	0
/PINUS SILVESTRIS OIL			
/ROSEMARY OIL			
/TERPINEOL			
/THYME OIL			
FUSAFUNGINE	1 (1.6%)	2 (2.6%)	1 (1.1%)
GUAIFENESIN	0	0	1 (1.1%)
GUAIFENESIN	0	1 (1.3%)	0
/OXOMEMAZINE			
/PARACETAMOL			
/SODIUM BENZOATE			
HELICIDINE	0	0	0
HERBAL EXTRACTS NOS	1 (1.6%)	0	0
IPECACUANHA	0	0	0
/SQUILL			
LETOSTEINE	0	0	0
MYRTOL	0	0	0
NOSCAPINE	0	0	0
NOSCAPINE	0	0	0
/POLYSORBATE 85 (TWEEN 85)			
/PROMETHAZINE			
NOSCAPINE HYDROCHLORIDE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
PHOLCODINE	3 (4.9%)	0	1 (1.1%)
POTASSIUM IODIDE	0	0	0
ZIPEPROL DIHYDROCHLORIDE	0	0	1 (1.1%)
NASAL PREP	2 (3.3%)	8 (10.3%)	9 (10.0%)
ACETYLCYSTEINE	1 (1.6%)	0	0
/BENZALKONIUM CHLORIDE			
/TUAMINOHEPTANE SULFATE			
AMYLEINE HYDROCHLORIDE	1 (1.6%)	0	1 (1.1%)
/FRAMYCETIN SULFATE			
/NAPHAZOLINE NITRATE			
ANTAZOLINE SULFATE	0	0	0
/XYLOMETAZOLINE HYDROCHLORIDE			
BECLOMETASONE	0	0	0
BECLOMETASONE DIPROPIONATE	0	1 (1.3%)	1 (1.1%)
BUDESONIDE	0	0	0
CETRIMONIUM BROMIDE	0	1 (1.3%)	1 (1.1%)
/NAPHAZOLINE NITRATE			
/PHENYLEPHRINE HYDROCHLORIDE			
/PREDNISOLONE			
CHLORHEXIDINE DIACETATE	0	0	0
/TIXOCORTOL PIVALATE			
CROMOGLICATE SODIUM	0	0	0
CROMOGLICATE SODIUM	0	0	0
/REPROTEROL HYDROCHLORIDE			
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	0
/NEOMYCIN SULFATE			
/PHENYLEPHRINE HYDROCHLORIDE			
/POLYMYXIN B SULFATE			
EPHEDRINE	0	0	0
ETHANOLAMINE TENOATE	0	0	0
/FRAMYCETIN SULFATE			
FENOXAZOLINE HYDROCHLORIDE	0	0	0
FLUNISOLIDE	0	2 (2.6%)	0
FLUTICASONE	0	0	0
/SALMETEROL			
FLUTICASONE PROPIONATE	0	1 (1.3%)	0
FRAMYCETIN SULFATE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
FRAMYCETIN SULFATE	0	0	1 (1.1%)
/HYDROCORTISONE			
FRAMYCETIN SULFATE	0	0	0
/NAPHAZOLINE NITRATE			
/PREDNISOLONE ACETATE			
IBUPROFEN	0	2 (2.6%)	1 (1.1%)
/PSEUDOEPHEDRINE HYDROCHLORIDE			
MOMETASONE FUROATE	0	0	0
NASAL SPRAY	0	0	0
NEOMYCIN SULFATE	0	0	0
/TIXOCORTOL PIVALATE			
PARACETAMOL	1 (1.6%)	0	0
/PHENYLPROPANOLAMINE HYDROCHLORIDE			
/PHENYLTOLOXAMINE CITRATE			
PHENYLEPHRINE	0	0	0
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE-FENOXAZOLINE COMPOUND	0	0	0
PREDNISONE	0	1 (1.3%)	0
PSEUDOEPHEDRINE	0	0	1 (1.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	4 (4.4%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0
/TRIPROLIDINE HYDROCHLORIDE			
SODIUM CHLORIDE	0	1 (1.3%)	0
TIXOCORTOL PIVALATE	0	0	0
TRIAMCINOLONE ACETONIDE	0	0	1 (1.1%)
OTHER	0	0	0
OXYGEN	0	0	0
SYSTEMIC ANTIHISTAMINES	5 (8.2%)	5 (6.4%)	2 (2.2%)
ALIMEMAZINE TARTRATE	0	1 (1.3%)	0
AZELASTINE	0	0	0
BROMPHENIRAMINE MALEATE	0	0	0
BUCLIZINE HYDROCHLORIDE	1 (1.6%)	0	0
/CODEINE PHOSPHATE			
/PARACETAMOL			
BUZEPIDE METIODIDE	0	0	0
/CLOCINIZINE HYDROCHLORIDE			
/PHENYLPROPANOLAMINE HYDROCHLORIDE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CETIRIZINE	0	0	0
/PSEUDOEPHEDRINE			
CETIRIZINE HYDROCHLORIDE	1 (1.6%)	1 (1.3%)	1 (1.1%)
CHLORPHENAMINE MALEATE	0	1 (1.3%)	0
CLEMASTINE	0	0	0
CLEMASTINE FUMARATE	0	0	0
CYCLIZINE	0	2 (2.6%)	0
DEXCHLORPHENIRAMINE MALEATE	0	1 (1.3%)	0
DIMENHYDRINATE	0	0	0
DIMETINDENE MALEATE	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0
FEXOFENADINE HYDROCHLORIDE	0	0	0
LORATADINE	2 (3.3%)	1 (1.3%)	1 (1.1%)
LORATADINE	0	0	0
/PSEUDOEPHEDRINE SULFATE			
MIZOLASTINE	0	0	0
NOSCAPINE	0	0	0
/POLYSORBATE 85 (TWEEN 85)			
/PROMETHAZINE			
OXATOMIDE	0	0	0
PHENIRAMINE AMINOSALICYLATE	1 (1.6%)	0	0
PROMETHAZINE HYDROCHLORIDE	0	0	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0
/TRIPROLIDINE HYDROCHLORIDE			
TERFENADINE	0	0	0
THROAT PREP	0	1 (1.3%)	3 (3.3%)
ALUMINIUM POTASSIUM SULFATE	0	0	0
/LIDOCAINE HYDROCHLORIDE			
/PROPYLPARABEN			
AMYLMETACRESOL	0	0	1 (1.1%)
/DICHLOROBENZYL ALCOHOL			
BACITRACIN ZINC	0	0	0
/CHLORMETHINE HYDROCHLORIDE			
/PENTOSAN POLYSULFATE			
/TIXOCORTOL PIVALATE			
/TRIENTINE			
BACITRACIN ZINC	0	0	0
/TIXOCORTOL PIVALATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
BICLOTYMOL	0	0	0
CETYLPRIDINIUM CHLORIDE	0	0	0
/CHLOROBUTANOL			
/EUGENOL			
/VERATROLE			
CHLOROQUINE	0	0	2 (2.2%)
LIDOCAINE	0	0	0
LIDOCAINE HYDROCHLORIDE	0	1 (1.3%)	0
SENSORY ORGANS			
OPHTALMOL/OTOLOGICAL PREP	6 (9.8%)	5 (6.4%)	7 (7.8%)
BACITRACIN	0	0	0
/NEOMYCIN SULFATE			
BENZALKONIUM CHLORIDE	0	0	1 (1.1%)
/DICHLORALPHENAZONE			
/DIMETICONE, ACTIVATED			
/HYDROCORTISONE			
/ISOMETHEPTENE			
/NYSTATIN			
/PARACETAMOL			
CHLORAMPHENICOL	1 (1.6%)	0	0
/COLISTIN MESILATE SODIUM			
/HYDROCORTISONE ACETATE			
DEXAMETHASONE	0	0	0
DEXAMETHASONE	0	0	0
/FRAMYCETIN			
DEXAMETHASONE	0	0	0
/FRAMYCETIN SULFATE			
/GRAMICIDIN			
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
/NEOMYCIN SULFATE			
ERYTHROMYCIN	4 (6.6%)	4 (5.1%)	3 (3.3%)
HEXAMIDINE ISETHIONATE	0	1 (1.3%)	1 (1.1%)
HYDROCORTISONE ACETATE	0	0	0
/NEOMYCIN SULFATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
HYDROCORTISONE ACETATE	0	0	0
/OXYTETRACYCLINE HYDROCHLORIDE			
/POLYMYXIN B SULFATE			
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (1.6%)	0	0
TETRACYCLINE	0	0	2 (2.2%)
OPHTHALMOLOGICALS	17 (27.9%)	15 (19.2%)	27 (30.0%)
ACETAZOLAMIDE	1 (1.6%)	0	0
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	0	0
/AMINO ACIDS NOS			
/PYRIDOXINE HYDROCHLORIDE			
ATROPINE	0	0	0
BENZALKONIUM CHLORIDE	0	0	0
/TRIMAGNESIUM SPAGLUMATE			
BETAMETHASONE	1 (1.6%)	0	0
BETAXOLOL	0	1 (1.3%)	1 (1.1%)
BETAXOLOL HYDROCHLORIDE	0	0	2 (2.2%)
BORIC ACID	0	0	0
/CAMPHOR			
/EPHEDRINE HYDROCHLORIDE			
/PEPPERMINT OIL			
/RETINOL PALMITATE			
/SODIUM BORATE			
/SODIUM CITRATE			
/ZINC SULFATE			
BORIC ACID	0	0	0
/PHENYLEPHRINE HYDROCHLORIDE			
/SODIUM BORATE			
BORIC ACID	0	0	0
/SODIUM BORATE			
/SODIUM CHLORIDE			
/TETRYZOLINE HYDROCHLORIDE			
BRIMONIDINE TARTRATE	0	0	1 (1.1%)
CARTEOLOL HYDROCHLORIDE	0	0	0
CETHEXONIUM CHLORIDE	0	0	0
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
CHLORAMPHENICOL	0	0	0
/DEXAMETHASONE SODIUM PHOSPHATE			
CINCHOCAINE HYDROCHLORIDE	0	0	0
CIPROFLOXACIN	0	3 (3.8%)	1 (1.1%)
CIPROFLOXACIN HYDROCHLORIDE	0	0	1 (1.1%)
CLONIDINE HYDROCHLORIDE	0	0	0
CROMOGLICATE SODIUM	0	0	0
DEXAMETHASONE	0	0	0
DEXAMETHASONE	1 (1.6%)	0	0
/NEOMYCIN SULFATE			
/POLYMYXIN B SULFATE			
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	0
/NEOMYCIN SULFATE			
/POLYMYXIN B SULFATE			
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
DEXPANTHENOL	0	0	0
DEXTRAN	0	0	0
/HYPROMELLOSE			
DICLOFENAC SODIUM	3 (4.9%)	7 (9.0%)	11 (12.2%)
DORZOLAMIDE HYDROCHLORIDE	1 (1.6%)	0	2 (2.2%)
DORZOLAMIDE HYDROCHLORIDE	0	0	0
/TIMOLOL MALEATE			
EPHEDRINE	0	0	0
ETHANOLAMINE TENOATE	0	0	0
/FRAMYCETIN SULFATE			
EYE DROPS, NOS	0	0	1 (1.1%)
FLUORESCEIN	0	0	0
FRAMYCETIN SULFATE	0	0	0
FUSIDIC ACID	0	1 (1.3%)	1 (1.1%)
GENTAMICIN SULFATE	1 (1.6%)	0	0
HEPARIN	1 (1.6%)	0	1 (1.1%)
HYDROCORTISONE	2 (3.3%)	0	2 (2.2%)
HYDROCORTISONE BUTYRATE	1 (1.6%)	0	1 (1.1%)
INDOMETACIN	0	1 (1.3%)	1 (1.1%)
ISOSORBIDE	0	0	0
KETOROLAC TROMETHAMINE	0	0	0
LATANOPROST	1 (1.6%)	0	1 (1.1%)
LEVOBUNOLOL HYDROCHLORIDE	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
LIDOCAINE	0	0	0
LIDOCAINE HYDROCHLORIDE	0	1 (1.3%)	0
METHYLPREDNISOLONE	1 (1.6%)	0	2 (2.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	0
MYRTILLUS	0	0	0
/TOCOPHEROL			
OFLOXACIN	1 (1.6%)	1 (1.3%)	0
OXYTETRACYCLINE	2 (3.3%)	1 (1.3%)	0
OXYTETRACYCLINE DIHYDRATE	1 (1.6%)	0	0
PILOCARPINE	0	0	0
PILOCARPINE HYDROCHLORIDE	0	0	0
/TIMOLOL MALEATE			
POTASSIUM IODIDE	0	0	0
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (1.6%)	0	0
SODIUM CHLORIDE	0	1 (1.3%)	0
TETRACYCLINE	0	0	2 (2.2%)
TIMOLOL	0	1 (1.3%)	0
TIMOLOL MALEATE	3 (4.9%)	0	1 (1.1%)
TRIAMCINOLONE ACETONIDE	0	0	1 (1.1%)
TRIAMCINOLONE HEXACETONIDE	0	0	0
TROPICAMIDE	0	0	0
ZINC SULFATE	0	0	0
OTOLOGICALS	3 (4.9%)	0	2 (2.2%)
CAPRYLIC ACID	0	0	0
/TROLAMINE CAPRYLATE			
CHLORAMPHENICOL	2 (3.3%)	0	1 (1.1%)
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	0
/NEOMYCIN SULFATE			
/POLYMYXIN B SULFATE			
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
/NYSTATIN			
/OXYTETRACYCLINE HYDROCHLORIDE			
/POLYMYXIN B SULFATE			
GENTAMICIN SULFATE	0	0	0
/PREDNISOLONE ACETATE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
HYDROCORTISONE	0	0	0
/NEOMYCIN SULFATE			
/POLYMYXIN B SULFATE			
HYDROCORTISONE BUTYRATE	1 (1.6%)	0	1 (1.1%)
SODIUM BICARBONATE	0	0	0
SYSTEMIC HORMONAL			
CALCIUM HOMEOSTASIS	0	0	0
CALCITONIN	0	0	0
CALCITONIN ACETATE	0	0	0
CORTICOSTEROIDS	9 (14.8%)	2 (2.6%)	8 (8.9%)
AMCINONIDE	0	0	0
BETAMETHASONE	1 (1.6%)	0	0
BETAMETHASONE SODIUM PHOSPHATE	0	0	0
BETAMETHASONE SODIUM PHOSPHATE	0	0	1 (1.1%)
/NEOMYCIN SULFATE			
CORTICOSTEROIDS	2 (3.3%)	0	0
CORTIVAZOL	0	0	0
DEXAMETHASONE	0	0	0
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0
HYDROCORTISONE	2 (3.3%)	0	2 (2.2%)
HYDROCORTISONE BUTYRATE	1 (1.6%)	0	1 (1.1%)
LIDOCAINE	1 (1.6%)	1 (1.3%)	1 (1.1%)
/METHYLPREDNISOLONE ACETATE			
METHYLPREDNISOLONE	1 (1.6%)	0	2 (2.2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE	0	0	1 (1.1%)
PREDNISOLONE SODIUM SUCCINATE	0	0	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (1.6%)	0	0
PREDNISONE	0	1 (1.3%)	0
TRIAMCINOLONE ACETONIDE	0	0	1 (1.1%)
TRIAMCINOLONE HEXACETONIDE	0	0	0
THYROID THERAPY	4 (6.6%)	3 (3.8%)	2 (2.2%)
CARBIMAZOLE	1 (1.6%)	0	0
LEVOTHYROXINE	0	0	0
LEVOTHYROXINE	0	0	0
/LIOETHYRONINE			
/POTASSIUM IODIDE			

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
LEVOTHYROXINE SODIUM	1 (1.6%)	2 (2.6%)	1 (1.1%)
LEVOTHYROXINE SODIUM /LIOTHYRONINE SODIUM	0	0	1 (1.1%)
LEVOTHYROXINE SODIUM /POTASSIUM IODIDE	0	0	0
POTASSIUM IODIDE	0	0	0
THYROXINE	2 (3.3%)	1 (1.3%)	0
UNCLASSIFIABLE	0	0	0
UNCLASSIFIABLE UNKNOWN MEDICATION	0	0	0
VARIOUS			
ALL OTHER NON-THERAP PROD	1 (1.6%)	1 (1.3%)	1 (1.1%)
BLOOD CELLS, PACKED HUMAN	0	1 (1.3%)	0
BLOOD, WHOLE	0	0	1 (1.1%)
HYPROMELLOSE	1 (1.6%)	0	0
MACROGOL	0	0	0
POLOXAMER	0	0	0
ALL OTHER THERAP PROD	0	0	4 (4.4%)
ACONITUM	0	0	0
/BRYONIA			
/EUPATORIUM PERFOLIATUM			
/LACHESIS			
/PHOSPHORUS			
ADENOSINE PHOSPHATE, SODIUM SALT /DEOXYRIBONUCLEIC ACID	0	0	1 (1.1%)
ALENDRONATE	0	0	1 (1.1%)
ALUMINIUM CHLOROHYDRATE	0	0	0
ARNICA	0	0	0
/HORSE CHESTNUT EXTRACT			
/HYOSCYAMUS DRY EXTRACT			
/SCOPARIUM			
CALCIUM LACTATE	0	0	1 (1.1%)
/CIMICIFUGA			
/MAGNESIUM HYPOSULFITE			
/OLEOSACCHARUM OF MARJOLAIN			
CHONDROITIN SULFURIC ACID	0	0	0

Data Source Table 13.5.2b

Summary of Concomitant Medications (Continue or Start During Open Label Study)
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Concomitant Medications	55 (90.2%)	69 (88.5%)	86 (95.6%)
ATC Classification Level 1			
ATC Classification Level 2			
Generic Term			
COPPER GLUCONATE	0	0	0
/GOLD GLUCONATE			
/SILVER GLUCONATE			
DISODIUM INOSINATE	0	0	0
ETIDRONATE DISODIUM	0	0	0
GARLIC	0	0	1 (1.1%)
HOMEOPATHIC PREPARATIONS	0	0	0
HOMEOPATICS NOS	0	0	0
HYPERICUM EXTRACT	0	0	0
IPECACUANHA	0	0	0
/SQUILL			
NICOTINE RESIN	0	0	0
OXYGEN	0	0	0
POTASSIUM IODIDE	0	0	0
ALLERGENS	0	0	0
POISON IVY EXTRACT	0	0	0
DIAGNOSTIC AGENTS	0	1 (1.3%)	0
GLUCOSE	0	1 (1.3%)	0
GENERAL NUTRIENTS	0	1 (1.3%)	0
BETA-ALANINE	0	0	0
GLUCOSE	0	1 (1.3%)	0
WHEAT GERM	0	0	0
INVESTIGATIONAL DRUG	0	0	0
HEPATITIS A VACCINE	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ALIMENTARY TRACT/METAB				
ANABOLICS, SYSTEMIC	0	0	0	0
COBAMAMIDE	0	0	0	0
ANTACID/ANTIPLAT/ANTIPEPTIC	25 (20.2%)	29 (21.3%)	24 (17.3%)	4 (13.3%)
ACETYLSALICYLIC ACID	0	0	1 (0.7%)	0
/ALUMINIUM HYDROXIDE				
/MAGNESIUM HYDROXIDE				
ALGIN	2 (1.6%)	4 (2.9%)	2 (1.4%)	1 (3.3%)
/ALGINIC ACID				
/ALUMINIUM HYDROXIDE				
/MAGNESIUM TRISILICATE				
/SODIUM BICARBONATE				
ALMAGATE	0	0	0	0
/CALCIUM SACCHARATE				
ALUMINIUM HYDROXIDE	0	0	0	0
ALUMINIUM HYDROXIDE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
/MAGNESIUM HYDROXIDE				
ALUMINIUM HYDROXIDE	0	0	1 (0.7%)	0
/MAGNESIUM TRISILICATE				
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
/LIQUORICE LIQUID EXTRACT				
/SACCHARIN SODIUM				
/SMECTITE				
/VANILLINE				
ALUMINIUM OXIDE	0	0	1 (0.7%)	0
/MAGNESIUM OXIDE				
ALVERINE CITRATE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/DIMETICONE, ACTIVATED				
ANTACID NOS	0	0	0	0
CALCIUM CARBONATE	1 (0.8%)	0	1 (0.7%)	0
CALCIUM CARBONATE	1 (0.8%)	3 (2.2%)	0	0
/COLECALCIFEROL				
CALCIUM CARBONATE	1 (0.8%)	0	0	0
/MAGNESIUM CARBONATE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CIMETIDINE	2 (1.6%)	2 (1.5%)	0	0
DICLOFENAC SODIUM	1 (0.8%)	4 (2.9%)	2 (1.4%)	2 (6.7%)
/MISOPROSTOL				
DIMETICONE	0	0	1 (0.7%)	0
/GUAIAZULENE				
FAMOTIDINE	0	0	0	0
LANSOPRAZOLE	2 (1.6%)	5 (3.7%)	3 (2.2%)	1 (3.3%)
MAGNESIUM TRISILICATE	0	0	0	0
MISOPROSTOL	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
MISOPROSTOL	0	1 (0.7%)	0	0
/NAPROXEN				
OMEPRAZOLE	7 (5.6%)	12 (8.8%)	8 (5.8%)	0
OMEPRAZOLE MAGNESIUM	0	1 (0.7%)	0	0
PANTOPRAZOL	2 (1.6%)	4 (2.9%)	2 (1.4%)	0
PANTOPRAZOLE	0	0	1 (0.7%)	0
RANITIDINE	0	4 (2.9%)	1 (0.7%)	0
RANITIDINE HYDROCHLORIDE	3 (2.4%)	0	4 (2.9%)	0
SODIUM BICARBONATE	0	0	1 (0.7%)	0
SUCRALFATE	3 (2.4%)	1 (0.7%)	0	0
ANTIDIABETIC THERAPY	8 (6.5%)	12 (8.8%)	12 (8.6%)	15 (50.0%)
ACARBOSE	0	0	0	1 (3.3%)
CHLORPROPAMIDE	0	0	0	0
GLIBENCLAMIDE	1 (0.8%)	1 (0.7%)	4 (2.9%)	1 (3.3%)
GLICLAZIDE	2 (1.6%)	1 (0.7%)	3 (2.2%)	7 (23.3%)
GLIMEPIRIDE	1 (0.8%)	3 (2.2%)	0	0
GLIPIZIDE	0	0	0	0
INSULIN	1 (0.8%)	3 (2.2%)	3 (2.2%)	0
INSULIN	0	0	0	0
/INSULIN INJECTION, ISOPHANE				
INSULIN HUMAN	0	0	0	0
INSULIN HUMAN INJECTION, ISOPHANE	0	0	0	0
INSULIN INJECTION, BIPHASIC	0	0	0	0
INSULIN INJECTION, ISOPHANE	0	0	0	0
METFORMIN	2 (1.6%)	2 (1.5%)	1 (0.7%)	9 (30.0%)

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
METFORMIN HYDROCHLORIDE	1 (0.8%)	5 (3.7%)	3 (2.2%)	0
ANTIDIARRHEA/GI ANTIBIOTICS	5 (4.0%)	13 (9.6%)	6 (4.3%)	0
ACETORPHAN	1 (0.8%)	0	0	0
ALBUMIN TANNATE	0	0	0	0
/CODEINE PHOSPHATE				
/DIHYDROSTREPTOMYCIN SULFATE				
/MORPHINE				
/NEOMYCIN SULFATE				
/PAPAVERINE HYDROCHLORIDE				
ANTI-DIARRHEAL, NOS	0	0	1 (0.7%)	0
ATROPINE SULFATE	0	0	0	0
/DIPHENOXYLATE HYDROCHLORIDE				
ATTAPULGITE	0	0	1 (0.7%)	0
BACITRACIN	1 (0.8%)	0	0	0
/NEOMYCIN SULFATE				
BACTERIA NOS	1 (0.8%)	1 (0.7%)	0	0
CHARCOAL, ACTIVATED	0	1 (0.7%)	0	0
CHARCOAL, ACTIVATED	0	1 (0.7%)	0	0
/YEAST DRIED				
CHLOROQUINE	0	0	0	0
LACTOBACILLUS ACIDOPHILUS	0	2 (1.5%)	0	0
LOPERAMIDE	1 (0.8%)	4 (2.9%)	1 (0.7%)	0
LOPERAMIDE HYDROCHLORIDE	0	2 (1.5%)	0	0
LOPERAMIDE OXIDE	0	0	1 (0.7%)	0
MONTMORILLONITE BEIDELLITIQUE	0	3 (2.2%)	0	0
NIFUROXAZIDE	0	4 (2.9%)	1 (0.7%)	0
NIFURZIDE	0	0	1 (0.7%)	0
NYSTATIN	0	0	0	0
POLYVIDONE	1 (0.8%)	0	0	0
/STERCULIA				
SACCHAROMYCES BOULARDII	0	1 (0.7%)	0	0
STREPTOMYCIN	0	0	0	0
SULFASALAZINE	0	0	1 (0.7%)	0
ANTIEMETICS & ANTINAUSEANTS	3 (2.4%)	5 (3.7%)	6 (4.3%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DOMPERIDONE	1 (0.8%)	3 (2.2%)	4 (2.9%)	0
ETHANOLAMINE ACETYLLEUCINATE	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
HYOSCINE	0	0	0	0
METOPIMAZINE	1 (0.8%)	1 (0.7%)	0	0
PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
ANTI Obesity PREP	3 (2.4%)	3 (2.2%)	0	0
AMFEPRAMONE	1 (0.8%)	0	0	0
ORLISTAT	3 (2.4%)	3 (2.2%)	0	0
CHOLAG & HEPATIC PROTECTORS	3 (2.4%)	4 (2.9%)	4 (2.9%)	0
ANETHOLE TRITHIONE	0	1 (0.7%)	1 (0.7%)	0
CHOLINE DIHYDROGEN CITRATE	0	0	0	0
/SORBITOL				
CYSTEINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/METHIONINE				
ERYTHROMYCIN	2 (1.6%)	0	0	0
/METHIONINE				
/MULTIVITAMINS, NOS				
/RUTOSIDE				
/SULFAPURAZOLE				
FUMARIA EXTRACT	0	0	1 (0.7%)	0
HYMECROMONE	1 (0.8%)	0	0	0
SILYMARIN	0	0	1 (0.7%)	0
THIOCTIC ACID	0	2 (1.5%)	1 (0.7%)	0
THIOCTIC ACID	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/TROMETHAMINE SALT				
URSODEOXYCHOLIC ACID	0	1 (0.7%)	0	0
DIGESTIVES	1 (0.8%)	6 (4.4%)	6 (4.3%)	0
AMYLASE	0	0	1 (0.7%)	0
BETAINE CITRATE	0	3 (2.2%)	0	0
BROMELAINS	0	0	2 (1.4%)	0
DIMETICONE	0	0	1 (0.7%)	0
/ENZYMES NOS				
GLUTAMIC ACID HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
PANCREATIN	0	2 (1.5%)	2 (1.4%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
GI ANTISPAS/ANTICHOLIN	13 (10.5%)	20 (14.7%)	9 (6.5%)	0
ALLOBARBITAL	0	1 (0.7%)	0	0
/AMINOPHENAZONE				
/DROFENINE HYDROCHLORIDE				
ALVERINE CITRATE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/DIMETICONE, ACTIVATED				
AMOBARBITAL	0	0	0	0
/ATROPINE				
/DIMETICONE				
/HYOSCYAMINE				
ARNICA	1 (0.8%)	0	0	0
/HORSE CHESTNUT EXTRACT				
/HYOSCYAMUS DRY EXTRACT				
/SCOPARIUM				
ATROPINE	0	1 (0.7%)	0	0
BENZHEXOL HYDROCHLORIDE	0	1 (0.7%)	0	0
/DEMELVERINUM HYDROCHLORICUM				
CHARCOAL, ACTIVATED	0	1 (0.7%)	0	0
/PAPAVERINE HYDROCHLORIDE				
CHLORDIAZEPOXIDE HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	0
/CLIDINIUM BROMIDE				
CISAPRIDE	1 (0.8%)	3 (2.2%)	0	0
CISAPRIDE MONOHYDRATE	1 (0.8%)	0	0	0
CLEBOPRIDE	0	0	0	0
/DIMETICONE				
ECHINACEA EXTRACT	1 (0.8%)	0	2 (1.4%)	0
/SABAL EXTRACT				
/TROSPIDIUM CHLORIDE				
FENPIVERINIUM BROMIDE	0	1 (0.7%)	2 (1.4%)	0
/METAMIZOLE SODIUM				
/PITOFENONE HYDROCHLORIDE				
HYOSCINE BUTYLBROMIDE	0	1 (0.7%)	0	0
HYOSCINE BUTYLBROMIDE	0	1 (0.7%)	0	0
/PARACETAMOL				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
MEBEVERINE	0	0	0	0
MEBEVERINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
METOCLOPRAMIDE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
METOCLOPRAMIDE DIHYDROCHLORIDE	1 (0.8%)	0	0	0
METOCLOPRAMIDE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
OTILONIUM BROMIDE	0	0	0	0
OXYBUTYNIN	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
OXYBUTYNIN HYDROCHLORIDE	0	0	0	0
PHLOROGLUCINOL	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
PHLOROGLUCINOL	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
/TRIMETHYLPHLOROGLUCINOL				
PINAVERIUM BROMIDE	0	0	1 (0.7%)	0
RUSCOGENIN	0	1 (0.7%)	0	0
/TRIMEBUTINE				
TIEMONIUM IODIDE	0	0	0	0
TRIMEBUTINE	1 (0.8%)	0	0	0
TRIMEBUTINE MALEATE	1 (0.8%)	4 (2.9%)	2 (1.4%)	0
LAXATIVES	12 (9.7%)	7 (5.1%)	6 (4.3%)	2 (6.7%)
ALOES	1 (0.8%)	0	0	0
BEE SWAX WHITE	1 (0.8%)	0	0	0
/PARAFFIN				
/WHITE VASELINE				
/ZINC OXIDE				
BISACODYL	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
DANTRON	0	0	1 (0.7%)	0
/DOCUSATE SODIUM				
DANTRON	0	0	0	0
/POLOXAMER				
ISPAHULA	1 (0.8%)	1 (0.7%)	0	0
ISPAHULA	0	1 (0.7%)	0	0
/SENNOSIDE A+B				
ISPAHULA HUSKS	1 (0.8%)	0	0	0
/PARAFFIN, LIQUID				
LACTITOL MONOHYDRATE	0	2 (1.5%)	0	0

- 355 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
LACTULOSE	6 (4.8%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
LACTULOSE	0	0	1 (0.7%)	0
/PARAFFIN				
/PARAFFIN, SOFT				
PARAFFIN, LIQUID	0	1 (0.7%)	0	0
PICOSULFURIC ACID	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
POLOXAMER	0	0	1 (0.7%)	0
POTASSIUM TARTRATE	1 (0.8%)	0	0	0
/SODIUM BICARBONATE				
SENNA	0	0	1 (0.7%)	0
SENNA FRUIT	0	0	0	1 (3.3%)
SODIUM PICOSULFATE	2 (1.6%)	0	0	0
STERCULIA	0	0	2 (1.4%)	0
MINERAL SUPPLEMENTS	13 (10.5%)	10 (7.4%)	12 (8.6%)	0
ALBUMEN	0	1 (0.7%)	0	0
/SACCHAROMYCES CEREVISIAE				
CALCIUM	0	0	0	0
CALCIUM	2 (1.6%)	1 (0.7%)	0	0
/COLECALCIFEROL				
CALCIUM	0	0	1 (0.7%)	0
/ERGOCALCIFEROL				
CALCIUM CARBONATE	1 (0.8%)	0	1 (0.7%)	0
CALCIUM CARBONATE	0	0	2 (1.4%)	0
/CITRIC ACID				
CALCIUM CARBONATE	1 (0.8%)	3 (2.2%)	0	0
/COLECALCIFEROL				
CALCIUM CITRATE	1 (0.8%)	0	0	0
/CALCIUM GLUCONATE				
/SODIUM FLUOROPHOSPHATE				
CALCIUM GLUBIONATE	1 (0.8%)	0	0	0
CALCIUM GLUCONATE	1 (0.8%)	0	0	0
/CALCIUM PHOSPHATE				
/COLECALCIFEROL				
COPPER	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DURAPATITE	0	1 (0.7%)	0	0
LEVOCARNITINE	0	1 (0.7%)	0	0
/MAGNESIUM ASPARTATE				
MAGNESIUM GLUTAMATE	0	0	1 (0.7%)	0
MAGNESIUM LACTATE	2 (1.6%)	0	4 (2.9%)	0
/PYRIDOXINE				
MAGNESIUM NOS	1 (0.8%)	0	0	0
MAGNESIUM NOS	0	0	0	0
/POTASSIUM				
/SODIUM CHLORIDE				
PHOSPHORUS	1 (0.8%)	0	0	0
/SODIUM				
POTASSIUM	0	0	0	0
POTASSIUM ASCORBATE	0	0	0	0
POTASSIUM BICARBONATE	1 (0.8%)	0	0	0
/POTASSIUM CITRATE				
POTASSIUM CHLORIDE	3 (2.4%)	3 (2.2%)	4 (2.9%)	0
SODIUM CHLORIDE	1 (0.8%)	0	0	0
SODIUM CHLORIDE COMPOUND INJECTION	1 (0.8%)	0	0	0
ZINC	0	1 (0.7%)	0	0
ZINC SULFATE	0	0	1 (0.7%)	0
MOUTH PREP	22 (17.7%)	31 (22.8%)	27 (19.4%)	6 (20.0%)
ACETYLSALICYLIC ACID	16 (12.9%)	22 (16.2%)	24 (17.3%)	5 (16.7%)
BACITRACIN	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
/LYSOZYME				
/PAPAIN				
BICLOTYMOL	0	0	1 (0.7%)	0
/DEQUALINIUM CHLORIDE				
/ENOXOLONE				
/LYSOZYME				
/PAPAIN				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CETYLPRIDINIUM CHLORIDE	1 (0.8%)	1 (0.7%)	0	0
/CHLOROBUTANOL				
/EUGENOL				
/VERATROLE				
CHLORHEXIDINE DIACETATE	1 (0.8%)	0	1 (0.7%)	0
/TIXOCORTOL PIVALATE				
CHLORHEXIDINE GLUCONATE	0	1 (0.7%)	0	0
CHLORHEXIDINE GLUCONATE	0	1 (0.7%)	0	0
/CHLOROBUTANOL				
DOMIPHEN BROMIDE	0	0	0	1 (3.3%)
METRONIDAZOLE	2 (1.6%)	3 (2.2%)	0	0
SODIUM CHLORIDE	1 (0.8%)	0	0	0
TRIAMCINOLONE ACETONIDE	0	3 (2.2%)	0	0
VITAMINS	8 (6.5%)	9 (6.6%)	10 (7.2%)	6 (20.0%)
ASCORBIC ACID	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
ASCORBIC ACID	1 (0.8%)	0	0	0
/CYANOCOBALAMIN				
/FOLATE SODIUM				
/HYDROXOCOBALAMIN				
/LIDOCAINE HYDROCHLORIDE				
/NICOTINAMIDE				
/PYRIDOXINE HYDROCHLORIDE				
/THIAMINE HYDROC				
BISBUTIAMINE	0	2 (1.5%)	1 (0.7%)	0
CALCIUM	2 (1.6%)	1 (0.7%)	0	0
/COLECALCIFEROL				
COD-LIVER OIL	0	1 (0.7%)	0	2 (6.7%)
COLECALCIFEROL	0	1 (0.7%)	0	0
CYANOCOBALAMIN	0	1 (0.7%)	0	0
/PYRIDOXINE HYDROCHLORIDE				
/THIAMINE DISULFIDE				
CYANOCOBALAMIN	1 (0.8%)	1 (0.7%)	0	0
/PYRIDOXINE HYDROCHLORIDE				
/THIAMINE HYDROCHLORIDE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CYSTINE	0	0	0	0
/PYRIDOXINE				
DEXPANTHENOL	0	1 (0.7%)	0	0
ERGOCALCIFEROL	1 (0.8%)	0	1 (0.7%)	0
ERGOCALCIFEROL	0	1 (0.7%)	0	0
/HYDROQUINONE				
ERYTHROMYCIN	2 (1.6%)	0	0	0
/METHIONINE				
/MULTIVITAMINS, NOS				
/RUTOSIDE				
/SULFAFURAZOLE				
HYDROXOCOBALAMIN	0	0	0	0
/PYRIDOXINE HYDROCHLORIDE				
/THIAMINE HYDROCHLORIDE				
LYCOPENE	0	1 (0.7%)	0	0
/RETINOL				
/TOCOPHEROL				
MAGNESIUM LACTATE	2 (1.6%)	0	4 (2.9%)	0
/PYRIDOXINE				
PYRIDOXINE	0	0	1 (0.7%)	1 (3.3%)
PYRIDOXINE HYDROCHLORIDE	0	1 (0.7%)	0	0
PYRIDOXINE HYDROCHLORIDE	0	0	1 (0.7%)	0
/THIAMINE HYDROCHLORIDE				
RETINOL	0	0	0	0
RIBOFLAVIN	0	1 (0.7%)	0	0
THIAMINE HYDROCHLORIDE	0	0	0	1 (3.3%)
TOCOPHEROL	0	0	0	1 (3.3%)
TOCOPHERYL ACETATE	0	1 (0.7%)	1 (0.7%)	0
VITAMIN B	0	0	0	1 (3.3%)
VITAMINS NOS	0	0	0	0
YEAST DRIED	1 (0.8%)	0	0	0
ANTIINFECTIVES, SYSTEMIC				
ANTIBIOTICS	48 (38.7%)	57 (41.9%)	59 (42.4%)	6 (20.0%)

- 359 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ACETYLCYSTEINE	0	0	1 (0.7%)	0
/THIAMPHENICOL AMINOACETATE HYDROCHLORIDE				
AMBROXOL HYDROCHLORIDE	1 (0.8%)	0	0	0
/DOXYCYCLINE HYDROCHLORIDE				
AMOXICILLIN	8 (6.5%)	4 (2.9%)	11 (7.9%)	1 (3.3%)
AMOXICILLIN TRIHYDRATE	6 (4.8%)	8 (5.9%)	16 (11.5%)	1 (3.3%)
AMOXICILLIN TRIHYDRATE	0	1 (0.7%)	0	0
/CLAVULANATE POTASSIUM				
AMOXICILLIN TRIHYDRATE	6 (4.8%)	5 (3.7%)	7 (5.0%)	1 (3.3%)
/CLAVULANIC ACID				
AMPICILLIN	0	0	0	0
AMPICILLIN	0	0	0	0
/FLUCLOXACILLIN				
ANTIBIOTIC NOS	0	1 (0.7%)	0	0
AZITHROMYCIN	3 (2.4%)	3 (2.2%)	5 (3.6%)	0
BACAMPICILLIN HYDROCHLORIDE	1 (0.8%)	3 (2.2%)	0	0
BENZYL PENICILLIN	0	0	0	0
BETAMETHASONE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
/GENTAMICIN				
BETAMETHASONE	1 (0.8%)	0	0	0
/NEOMYCIN				
BROMELAINS	1 (0.8%)	0	0	0
/TETRACYCLINE HYDROCHLORIDE				
CEFACLOR	2 (1.6%)	1 (0.7%)	3 (2.2%)	0
CEFADROXIL	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
CEFADROXIL MONOHYDRATE	0	1 (0.7%)	0	0
CEFALEXIN	1 (0.8%)	2 (1.5%)	1 (0.7%)	1 (3.3%)
CEFALEXIN MONOHYDRATE	0	1 (0.7%)	1 (0.7%)	0
CEFALORIDINE	1 (0.8%)	0	0	0
CEFATRIZINE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
CEFAZOLIN SODIUM	0	0	1 (0.7%)	0
CEFIXIME	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
CEFODIZIME	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CEFONICID DISODIUM	0	1 (0.7%)	0	0
CEFOTAXIME	0	1 (0.7%)	0	0
CEFOTIAM HEXETIL HYDROCHLORIDE	0	1 (0.7%)	2 (1.4%)	0
CEFPODOXIME PROXETIL	1 (0.8%)	2 (1.5%)	4 (2.9%)	0
CEFRADINE	0	0	0	0
CEFTRIAZONE SODIUM	2 (1.6%)	0	2 (1.4%)	0
CEFUROXIME	1 (0.8%)	0	0	0
CEFUROXIME AXETIL	1 (0.8%)	0	2 (1.4%)	0
CEFUROXIME SODIUM	0	1 (0.7%)	0	0
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
CHYMOTRYPSIN	0	0	0	0
/TETRACYCLINE HYDROCHLORIDE				
CLARITHROMYCIN	4 (3.2%)	4 (2.9%)	8 (5.8%)	1 (3.3%)
CLINDAMYCIN	0	1 (0.7%)	0	0
CLINDAMYCIN HYDROCHLORIDE	0	0	1 (0.7%)	0
CLOFOCTOL	0	0	0	0
CLOXACILLIN SODIUM	0	0	2 (1.4%)	0
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	1 (0.7%)	0
/NEOMYCIN SULFATE				
/PHENYLEPHRINE HYDROCHLORIDE				
/POLYMYXIN B SULFATE				
DICLOXACILLIN SODIUM MONOHYDRATE	1 (0.8%)	1 (0.7%)	0	0
DOXYCYCLINE	2 (1.6%)	1 (0.7%)	2 (1.4%)	1 (3.3%)
DOXYCYCLINE HYCLATE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
DOXYCYCLINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
ERYTHROMYCIN	0	3 (2.2%)	3 (2.2%)	0
ERYTHROMYCIN	2 (1.6%)	0	0	0
/METHIONINE				
/MULTIVITAMINS, NOS				
/RUTOSIDE				
/SULFAFURAZOLE				
FLUCLOXACILLIN	0	2 (1.5%)	0	0
FLUCLOXACILLIN SODIUM	2 (1.6%)	2 (1.5%)	0	0
FOSFOMYCIN	2 (1.6%)	0	3 (2.2%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
FUSIDATE SODIUM	0	1 (0.7%)	1 (0.7%)	0
FUSIDIC ACID	1 (0.8%)	0	3 (2.2%)	0
GENTAMICIN SULFATE	2 (1.6%)	0	1 (0.7%)	0
JOSAMYCIN	1 (0.8%)	0	0	0
LOMEFLOXACIN	0	1 (0.7%)	1 (0.7%)	0
LYMECYCLINE	1 (0.8%)	0	0	0
MEPARTRICIN	0	1 (0.7%)	0	0
METRONIDAZOLE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
/SPIRAMYCIN				
MIDECAMYCIN	0	0	0	0
MINOCYCLINE HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
MUPIROCI	0	0	0	0
OXACILLIN	0	1 (0.7%)	0	0
OXYTETRACYCLINE	0	1 (0.7%)	0	0
OXYTETRACYCLINE DIHYDRATE	0	0	0	0
PENICILLIN NOS	2 (1.6%)	0	1 (0.7%)	0
PHENOXYMETHYLPENICILLIN	1 (0.8%)	0	0	0
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (0.8%)	5 (3.7%)	2 (1.4%)	0
PIPEMIDIC ACID	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
PIVMECILLINAM HYDROCHLORIDE	0	1 (0.7%)	2 (1.4%)	0
PRISTINAMYCIN	1 (0.8%)	0	1 (0.7%)	0
ROXITHROMYCIN	5 (4.0%)	2 (1.5%)	6 (4.3%)	0
SPIRAMYCIN	0	2 (1.5%)	0	0
STREPTOMYCIN	0	0	0	0
SULFAMETHOXAZOLE	2 (1.6%)	6 (4.4%)	3 (2.2%)	0
/TRIMETHOPRIM				
SULTAMICILLIN	0	0	1 (0.7%)	0
TETRACYCLINE	1 (0.8%)	0	0	0
THIAMPHENICOL	0	0	1 (0.7%)	0
TRIMETHOPRIM	2 (1.6%)	2 (1.5%)	5 (3.6%)	0
VANCOMYCIN HYDROCHLORIDE	0	1 (0.7%)	0	0
ANTIMYCOTICS	0	2 (1.5%)	3 (2.2%)	0
FLUCONAZOLE	0	0	1 (0.7%)	0
ITRACONAZOLE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
KETOCONAZOLE	0	1 (0.7%)	1 (0.7%)	0
MICONAZOLE	0	1 (0.7%)	0	0
MICONAZOLE NITRATE	0	0	1 (0.7%)	0
ANTIVIRALS	2 (1.6%)	0	3 (2.2%)	1 (3.3%)
ACICLOVIR	0	0	2 (1.4%)	0
BIOSTIM	1 (0.8%)	0	1 (0.7%)	0
FAMCICLOVIR	0	0	0	1 (3.3%)
VALACYCLOVIR HYDROCHLORIDE	1 (0.8%)	0	0	0
CHEMOTHERAPEUTICS	7 (5.6%)	15 (11.0%)	8 (5.8%)	0
CIPROFLOXACIN	0	1 (0.7%)	0	0
CIPROFLOXACIN HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
ERYTHROMYCIN	2 (1.6%)	0	0	0
/METHIONINE				
/MULTIVITAMINS, NOS				
/RUTOSIDE				
/SULFAPURAZOLE				
METRONIDAZOLE	2 (1.6%)	3 (2.2%)	0	0
METRONIDAZOLE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
/SPIRAMYCIN				
OFLOXACIN	1 (0.8%)	6 (4.4%)	4 (2.9%)	0
SULFAMETHOXAZOLE	2 (1.6%)	6 (4.4%)	3 (2.2%)	0
/TRIMETHOPRIM				
IMMUNE SERA & IMMUNOGLOB	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
IMMUNOGLOBULIN HUMAN ANTI-TETANUS	1 (0.8%)	2 (1.5%)	0	0
TETANUS ANTITOXIN	0	1 (0.7%)	1 (0.7%)	0
TUBERCULOSTATICS	0	0	0	0
ETHAMBUTOL	0	0	0	0
RIFAMPICIN	0	0	0	0
RIFAMYCIN SODIUM	0	0	0	0
VACCINES	23 (18.5%)	25 (18.4%)	16 (11.5%)	3 (10.0%)
BACTERIA NOS	1 (0.8%)	1 (0.7%)	0	0
DIPHTHERIA AND TETANUS TOXOIDS	0	1 (0.7%)	2 (1.4%)	0
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS	0	0	0	0
DIPHTHERIA,TETANUS AND POLIOMYELITIS VAC	1 (0.8%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
HEPATITIS A VACCINE	0	0	0	1 (3.3%)
HEPATITIS B VACCINE	0	2 (1.5%)	0	0
HEPATITIS VACCINE, NOS	0	0	0	0
INACTIVATED HEPATITIS A VACCINE	0	0	0	0
INFLUENZA VIRUS VACCINE POLYVALENT	20 (16.1%)	22 (16.2%)	16 (11.5%)	2 (6.7%)
MENINGOCOCCAL POLYSACCHARIDE, GROUP A VA	0	0	0	1 (3.3%)
PNEUMOCOCCAL VACCINE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
POLIOMYELITIS VACCINE	0	0	0	0
POLIOMYELITIS VACCINE INACTIVATED	0	0	2 (1.4%)	0
TETANUS TOXOID	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
TYPHOID VACCINE	0	0	0	0
YELLOW FEVER VACCINE	0	0	0	0
ANTINEOPLASTIC & IMMUNOSUP				
ANTINEOPLASTIC, HORMONES	4 (3.2%)	4 (2.9%)	3 (2.2%)	1 (3.3%)
BICALUTAMIDE	0	0	0	0
ESTRADIOL	2 (1.6%)	1 (0.7%)	0	1 (3.3%)
ESTRADIOL VALERATE	1 (0.8%)	0	1 (0.7%)	0
ESTROGENS CONJUGATED	0	0	1 (0.7%)	1 (3.3%)
FLUTAMIDE	1 (0.8%)	0	0	0
GOSERELIN	1 (0.8%)	0	0	0
GOSERELIN ACETATE	0	1 (0.7%)	0	0
LEUPRORELIN	0	0	1 (0.7%)	0
MEDROXYPROGESTERONE ACETATE	0	1 (0.7%)	0	0
TAMOXIFEN CITRATE	0	1 (0.7%)	0	0
CYTOSTATIC DRUGS	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
CISPLATIN	0	0	1 (0.7%)	0
GEMCITABINE HYDROCHLORIDE	0	0	1 (0.7%)	0
LEUPRORELIN	0	0	1 (0.7%)	0
SERENOVA REPENS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
BLOOD/BLOOD FORM ORGANS				
ANTIANAEMLIC PREP	9 (7.3%)	4 (2.9%)	7 (5.0%)	6 (20.0%)

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
AMINOACETIC ACID	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
/FERROUS SULFATE				
CALCIUM PHOSPHATE TRIBASIC	1 (0.8%)	0	0	0
/FOLIC ACID				
CYANOCOBALAMIN	3 (2.4%)	1 (0.7%)	0	0
FERROUS FUMARATE	0	0	0	0
FERROUS GLUCONATE	0	0	1 (0.7%)	0
FERROUS SULFATE	7 (5.6%)	1 (0.7%)	4 (2.9%)	5 (16.7%)
FERROUS SULFATE EXSICCATED	0	0	0	0
FOLIC ACID	0	1 (0.7%)	0	0
HYDROXOCOBALAMIN	0	0	0	1 (3.3%)
IRON FERRIC	0	0	1 (0.7%)	0
ANTICOAGULANTS	30 (24.2%)	35 (25.7%)	35 (25.2%)	5 (16.7%)
ACENOCOUMAROL	0	1 (0.7%)	1 (0.7%)	0
ACETYLSALICYLATE LYSINE	7 (5.6%)	5 (3.7%)	1 (0.7%)	0
ACETYLSALICYLIC ACID	16 (12.9%)	22 (16.2%)	24 (17.3%)	5 (16.7%)
ACETYLSALICYLIC ACID	0	0	0	0
/DIPYRIDAMOLE				
CLOPIDOGREL	0	0	2 (1.4%)	0
CLORICROMEN HYDROCHLORIDE	0	0	0	0
DALTEPARIN SODIUM	0	0	0	0
DICOUMAROL	0	0	1 (0.7%)	0
DIPYRIDAMOLE	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
ENOXAPARIN	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
FLUINDIONE	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
GLYCOL SALICYLATE	0	1 (0.7%)	0	0
/HEPARIN SODIUM				
HEPARIN	0	3 (2.2%)	1 (0.7%)	0
HEPARIN SODIUM	0	1 (0.7%)	0	0
HEPARIN-FRACTION	0	1 (0.7%)	0	0
HEPARIN-FRACTION, CALCIUM SALT	1 (0.8%)	3 (2.2%)	3 (2.2%)	0
HEPARIN-FRACTION, SODIUM SALT	5 (4.0%)	2 (1.5%)	0	0
HIRUDIN	1 (0.8%)	0	1 (0.7%)	0
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
TICLOPIDINE HYDROCHLORIDE	3 (2.4%)	2 (1.5%)	3 (2.2%)	0
WARFARIN	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
WARFARIN SODIUM	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ANTIHAEMORRHAGICS	1 (0.8%)	0	1 (0.7%)	0
ETAMSILATE	1 (0.8%)	0	1 (0.7%)	0
TRANEXAMIC ACID	1 (0.8%)	0	0	0
CHOLESTEROL REDUCERS	54 (43.5%)	47 (34.6%)	45 (32.4%)	7 (23.3%)
ACIPIMOX	0	0	0	0
ATORVASTATIN	3 (2.4%)	3 (2.2%)	4 (2.9%)	1 (3.3%)
ATORVASTATIN CALCIUM	9 (7.3%)	6 (4.4%)	5 (3.6%)	1 (3.3%)
BENFLUOREX HYDROCHLORIDE	0	0	1 (0.7%)	0
BEZAFIBRATE	2 (1.6%)	4 (2.9%)	4 (2.9%)	0
CARNITINE HYDROCHLORIDE	0	0	1 (0.7%)	0
CERIVASTATIN	4 (3.2%)	2 (1.5%)	3 (2.2%)	0
CHONDROITIN SULFATE	1 (0.8%)	0	0	0
CIPROFIBRATE	4 (3.2%)	1 (0.7%)	0	0
DUCOSAHEXAENOIC ACID /EICOSAPENTAENOIC ACID	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
ETOFIBRATE	1 (0.8%)	2 (1.5%)	0	0
EVENING PRIMROSE OIL	0	0	1 (0.7%)	1 (3.3%)
FENOFIBRATE	10 (8.1%)	8 (5.9%)	14 (10.1%)	0
FLUVASTATIN SODIUM	6 (4.8%)	1 (0.7%)	1 (0.7%)	0
GEMFIBROZIL	0	3 (2.2%)	1 (0.7%)	0
L-PROPYONIL CARNITINE HYDROCHLORIDE	0	0	1 (0.7%)	0
LOVASTATIN	0	0	0	0
PRAVASTATIN	8 (6.5%)	6 (4.4%)	2 (1.4%)	1 (3.3%)
PRAVASTATIN SODIUM	4 (3.2%)	5 (3.7%)	2 (1.4%)	0
SIMVASTATIN	13 (10.5%)	17 (12.5%)	10 (7.2%)	3 (10.0%)
HEMORRHEOLOGIC AGENTS	3 (2.4%)	1 (0.7%)	0	0
PENTOXIFYLLINE	3 (2.4%)	1 (0.7%)	0	0
OTHER HAEMAT AGNTS	2 (1.6%)	0	0	0
DEOXYRIBOUNCLEASE /FIBRINOLYSIN	2 (1.6%)	0	0	0
PLASMA SUBSTIT/PERF SOLUT	5 (4.0%)	2 (1.5%)	4 (2.9%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ALBUMEN	0	1 (0.7%)	0	0
/SACCHAROMYCES CEREVISIAE				
CHLORHEXIDINE GLUCONATE	0	1 (0.7%)	0	0
DEXTRAN SULPHATE	1 (0.8%)	0	0	0
/PHENYL BUTAZONE				
GLUCOSE	0	0	0	0
GLUCOSE	0	0	1 (0.7%)	0
/SODIUM CHLORIDE				
I. V. FLUIDS	1 (0.8%)	0	0	0
SODIUM BICARBONATE	0	0	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.8%)	0	0	0
SODIUM CHLORIDE COMPOUND INJECTION	1 (0.8%)	0	0	0
SOYA OIL	0	0	1 (0.7%)	0
UREA	1 (0.8%)	0	1 (0.7%)	0
CARDIOVASCULAR				
BETA BLOCKING AGENTS	32 (25.8%)	28 (20.6%)	29 (20.9%)	5 (16.7%)
ACEBUTOLOL HYDROCHLORIDE	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
ATENOLOL	8 (6.5%)	10 (7.4%)	7 (5.0%)	5 (16.7%)
ATENOLOL	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
/CHLORTALIDONE				
ATENOLOL	0	2 (1.5%)	0	0
/NIFEDIPINE				
BETAXOLOL	1 (0.8%)	0	2 (1.4%)	0
BETAXOLOL HYDROCHLORIDE	3 (2.4%)	0	1 (0.7%)	0
BISOPROLOL	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
BISOPROLOL FUMARATE	0	2 (1.5%)	1 (0.7%)	0
BISOPROLOL FUMARATE	1 (0.8%)	0	0	0
/HYDROCHLOROTHIAZIDE				
CARTEOLOL	1 (0.8%)	0	1 (0.7%)	0
CARTEOLOL HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
CARVEDILOL	3 (2.4%)	3 (2.2%)	1 (0.7%)	0
CELIPROLOL	1 (0.8%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CLOPAMIDE	0	0	1 (0.7%)	0
/PINDOLOL				
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TIMOLOL MALEATE				
FELODIPINE	0	0	2 (1.4%)	0
/METOPROLOL				
METOPROLOL	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
METOPROLOL SUCCINATE	5 (4.0%)	2 (1.5%)	0	0
METOPROLOL TARTRATE	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
METOPROLOL TARTRATE	1 (0.8%)	0	0	0
/NIFEDIPINE				
NEBIVOLOL	0	0	0	0
NEBIVOLOL HYDROCHLORIDE	1 (0.8%)	0	0	0
OXPRENOLOL HYDROCHLORIDE	0	0	0	0
PROPRANOLOL	0	1 (0.7%)	1 (0.7%)	0
PROPRANOLOL HYDROCHLORIDE	0	1 (0.7%)	0	0
SOTALOL	0	2 (1.5%)	1 (0.7%)	0
SOTALOL HYDROCHLORIDE	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
TERTATOLOL	0	0	1 (0.7%)	0
TIMOLOL	0	0	1 (0.7%)	0
TIMOLOL MALEATE	3 (2.4%)	2 (1.5%)	2 (1.4%)	0
CARDIAC THERAPY	27 (21.8%)	35 (25.7%)	28 (20.1%)	2 (6.7%)
ACETYLDIGOXIN	4 (3.2%)	1 (0.7%)	0	0
ACETYLSALICYLIC ACID	0	0	0	0
/DIPYRIDAMOLE				
ADENOSINE PHOSPHATE, SODIUM SALT	0	0	1 (0.7%)	0
/DEOXYRIBONUCLEIC ACID				
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	0	1 (0.7%)	0
/AMINO ACIDS NOS				
/PYRIDOXINE HYDROCHLORIDE				
ALPROSTADIL	2 (1.6%)	1 (0.7%)	0	0
AMIODARONE	0	0	1 (0.7%)	0
AMIODARONE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ASPARTATE MAGNESIUM	0	1 (0.7%)	1 (0.7%)	0
/ASPARTATE POTASSIUM				
BISOPROLOL FUMARATE	0	2 (1.5%)	1 (0.7%)	0
CALCIUM LACTATE	0	0	0	0
/CIMICIFUGA				
/MAGNESIUM HYPOSULFITE				
/OLEOSACCHARUM OF MARJOLAIN				
CAMPBOR	0	0	1 (0.7%)	0
/CONVALLARIA TINCTURE				
/CRATAEGUS EXTRACT				
/MENTHOL				
/VALERIAN TINCTURE				
CANDESARTAN CILEXETIL	0	1 (0.7%)	1 (0.7%)	0
CARVEDILOL	3 (2.4%)	3 (2.2%)	1 (0.7%)	0
DIGITOXIN	1 (0.8%)	0	0	0
DIGOXIN	1 (0.8%)	7 (5.1%)	3 (2.2%)	0
DIPYRIDAMOLE	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
DOPAMINE HYDROCHLORIDE	0	1 (0.7%)	0	0
GLYCERYL TRINITRATE	6 (4.8%)	12 (8.8%)	7 (5.0%)	1 (3.3%)
HEPTAMINOL HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
HYDROQUINIDINE HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
ISOSORBIDE DINITRATE	0	1 (0.7%)	2 (1.4%)	0
ISOSORBIDE MONONITRATE	7 (5.6%)	6 (4.4%)	6 (4.3%)	0
LIDOCAINE	0	1 (0.7%)	0	0
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
MAGNESIUM HYDROGEN ASPARTATE	1 (0.8%)	0	0	0
/POTASSIUM HYDROGEN ASPARTATE				
MEXILETINE HYDROCHLORIDE	1 (0.8%)	0	0	0
MOLSIDOMINE	1 (0.8%)	4 (2.9%)	4 (2.9%)	0
NICORANDIL	2 (1.6%)	0	0	0
QUININE SULFATE	0	0	1 (0.7%)	1 (3.3%)
TRIMETAZIDINE DIHYDROCHLORIDE	5 (4.0%)	4 (2.9%)	2 (1.4%)	0
DIURETICS	44 (35.5%)	43 (31.6%)	34 (24.5%)	4 (13.3%)
ACETAZOLAMIDE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ALTIZIDE	4 (3.2%)	5 (3.7%)	5 (3.6%)	0
/SPIRONOLACTONE				
AMILORIDE	0	0	0	0
AMILORIDE HYDROCHLORIDE	0	1 (0.7%)	0	0
AMILORIDE HYDROCHLORIDE	2 (1.6%)	0	1 (0.7%)	0
/FUROSEMIDE				
AMILORIDE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
/HYDROCHLOROTHIAZIDE				
AZOSEMIDE	0	1 (0.7%)	0	0
BEMETIZIDE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
/HESPERIDIN COMPLEX				
/THIAMINE MONONITRATE				
/TRIAMTERENE				
BENDROFLUMETHIAZIDE	0	1 (0.7%)	0	1 (3.3%)
BENDROFLUMETHIAZIDE	0	1 (0.7%)	0	0
/POTASSIUM CHLORIDE				
BENZTHIAZIDE	0	1 (0.7%)	0	0
/TRIAMTERENE				
BISOPROLOL FUMARATE	1 (0.8%)	0	0	0
/HYDROCHLOROTHIAZIDE				
BUMETANIDE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
CAPTAPRIL	2 (1.6%)	7 (5.1%)	5 (3.6%)	0
/HYDROCHLOROTHIAZIDE				
CYCLOTHIAZIDE	1 (0.8%)	0	0	0
/TRIAMTERENE				
DORZOLAMIDE HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	1 (3.3%)
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TIMOLOL MALEATE				
ENALAPRIL MALEATE	0	0	0	0
/HYDROCHLOROTHIAZIDE				
ETACRYNIC ACID	0	1 (0.7%)	0	0
FOSINOPRIL SODIUM	0	0	1 (0.7%)	0
/HYDROCHLOROTHIAZIDE				
FUROSEMIDE	20 (16.1%)	10 (7.4%)	11 (7.9%)	2 (6.7%)

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
FUROSEMIDE	1 (0.8%)	2 (1.5%)	0	0
/SPIRONOLACTONE				
FUROSEMIDE	0	0	0	0
/TRIAMTERENE				
HYDROCHLOROTHIAZIDE	0	1 (0.7%)	0	0
HYDROCHLOROTHIAZIDE	3 (2.4%)	1 (0.7%)	3 (2.2%)	0
/LISINAPRIL				
HYDROCHLOROTHIAZIDE	1 (0.8%)	2 (1.5%)	0	0
/LOSARTAN POTASSIUM				
HYDROCHLOROTHIAZIDE	3 (2.4%)	0	1 (0.7%)	0
/QUINAPRIL				
HYDROCHLOROTHIAZIDE	0	2 (1.5%)	0	0
/QUINAPRIL HYDROCHLORIDE				
HYDROCHLOROTHIAZIDE	1 (0.8%)	0	0	0
/RAMIPRIL				
HYDROCHLOROTHIAZIDE	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
/TRIAMTERENE				
HYDROCHLOROTHIAZIDE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/VALSARTAN				
HYDROFLUMETHIAZIDE	0	0	0	0
/SPIRONOLACTONE				
HYPERICUM EXTRACT	1 (0.8%)	0	0	0
INDAPAMIDE	1 (0.8%)	0	1 (0.7%)	0
INDAPAMIDE	0	1 (0.7%)	0	0
/PERINDOPRIL ERBUMINE				
INDAPAMIDE HEMIHYDRATE	0	1 (0.7%)	0	0
ISOSORBIDE	0	1 (0.7%)	0	0
METOLAZONE	0	0	0	0
PIRETANIDE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
POTASSIUM CANRENOATE	0	1 (0.7%)	0	0
SOLIDAGO	0	1 (0.7%)	0	0
SPIRONOLACTONE	3 (2.4%)	4 (2.9%)	1 (0.7%)	0
THEOPHYLLINE	4 (3.2%)	1 (0.7%)	4 (2.9%)	0
TORASEMID	1 (0.8%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
HYPOTENSIVES	59 (47.6%)	73 (53.7%)	66 (47.5%)	8 (26.7%)
ALFUZOSIN	3 (2.4%)	0	1 (0.7%)	0
ALFUZOSIN HYDROCHLORIDE	2 (1.6%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
ALMITRINE DIMESILATE	0	1 (0.7%)	1 (0.7%)	0
/RAUBASINE				
AMLODIPINE	1 (0.8%)	4 (2.9%)	1 (0.7%)	0
AMLODIPINE BESYLATE	1 (0.8%)	7 (5.1%)	6 (4.3%)	0
ATENOLOL	0	2 (1.5%)	0	0
/NIFEDIPINE				
BENAZEPRIL	1 (0.8%)	0	1 (0.7%)	0
BENAZEPRIL	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
/CHLOROTHIAZIDE				
BENAZEPRIL HYDROCHLORIDE	0	0	0	0
BEPRIDIL HYDROCHLORIDE MONOHYDRATE	0	0	1 (0.7%)	0
BETULA LEAF	0	0	0	0
/OLIVE LEAVES EXTRACT				
CANDESARTAN CILEXETIL	0	1 (0.7%)	1 (0.7%)	0
CAPTOPRIL	7 (5.6%)	7 (5.1%)	5 (3.6%)	1 (3.3%)
CAPTOPRIL	2 (1.6%)	7 (5.1%)	5 (3.6%)	0
/HYDROCHLOROTHIAZIDE				
CARVEDILOL	3 (2.4%)	3 (2.2%)	1 (0.7%)	0
CICLETANINE HYDROCHLORIDE	0	1 (0.7%)	0	0
CILAZAPRIL	1 (0.8%)	1 (0.7%)	0	0
CLONIDINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	0	0
DIHYDROERGOCRISTINE MESILATE	0	2 (1.5%)	1 (0.7%)	0
/RAUBASINE				
DILTIAZEM	3 (2.4%)	3 (2.2%)	0	1 (3.3%)
DILTIAZEM HYDROCHLORIDE	3 (2.4%)	2 (1.5%)	3 (2.2%)	0
DOXAZOSIN	0	1 (0.7%)	0	1 (3.3%)
DOXAZOSIN MESYLATE	2 (1.6%)	3 (2.2%)	0	0
ENALAPRIL	3 (2.4%)	0	1 (0.7%)	2 (6.7%)
ENALAPRIL MALEATE	7 (5.6%)	9 (6.6%)	7 (5.0%)	1 (3.3%)
ENALAPRIL MALEATE	0	0	0	0
/HYDROCHLOROTHIAZIDE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
EPROSARTAN	0	0	1 (0.7%)	0
FELODIPINE	5 (4.0%)	5 (3.7%)	2 (1.4%)	0
FELODIPINE	0	0	2 (1.4%)	0
/METOPROLOL				
FELODIPINE	0	1 (0.7%)	0	0
/RAMIPRIL				
FOSINOPRIL	0	0	1 (0.7%)	0
FOSINOPRIL SODIUM	0	0	0	0
FOSINOPRIL SODIUM	0	0	1 (0.7%)	0
/HYDROCHLOROTHIAZIDE				
HYDRALAZINE	0	0	0	0
HYDROCHLOROTHIAZIDE	3 (2.4%)	1 (0.7%)	3 (2.2%)	0
/LISINOPRIL				
HYDROCHLOROTHIAZIDE	1 (0.8%)	2 (1.5%)	0	0
/LOSARTAN POTASSIUM				
HYDROCHLOROTHIAZIDE	3 (2.4%)	0	1 (0.7%)	0
/QUINAPRIL				
HYDROCHLOROTHIAZIDE	0	2 (1.5%)	0	0
/QUINAPRIL HYDROCHLORIDE				
HYDROCHLOROTHIAZIDE	1 (0.8%)	0	0	0
/RAMIPRIL				
HYDROCHLOROTHIAZIDE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/VALSARTAN				
INDAPAMIDE	1 (0.8%)	0	1 (0.7%)	0
INDAPAMIDE	0	1 (0.7%)	0	0
/PERINDOPRIL ERBUMINE				
INDORAMIN	0	0	0	0
IRBESARTAN	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
ISRODIPINE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
LACIDIPINE	0	0	2 (1.4%)	0
LISINOPRIL	5 (4.0%)	3 (2.2%)	4 (2.9%)	2 (6.7%)
LOSARTAN	0	0	1 (0.7%)	1 (3.3%)
LOSARTAN POTASSIUM	3 (2.4%)	4 (2.9%)	1 (0.7%)	0
METHYLDOPA	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
METOPROLOL TARTRATE	1 (0.8%)	0	0	0
/NIFEDIPINE				
MISTLETOE EXTRACT	0	0	1 (0.7%)	0
MOXONIDINE	1 (0.8%)	0	1 (0.7%)	0
NICARDIPINE HYDROCHLORIDE	2 (1.6%)	0	3 (2.2%)	0
NIFEDIPINE	7 (5.6%)	9 (6.6%)	6 (4.3%)	0
NISOLDIPINE	0	0	0	0
NITRENDIPINE	1 (0.8%)	1 (0.7%)	0	0
PERINDOPRIL	1 (0.8%)	2 (1.5%)	5 (3.6%)	0
PRazosin	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
QUINAPRIL	0	0	1 (0.7%)	0
QUINAPRIL HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
RAMIPRIL	3 (2.4%)	8 (5.9%)	3 (2.2%)	0
RILMENIDINE PHOSPHATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
SPIRAPRIL HYDROCHLORIDE	0	1 (0.7%)	0	0
TERAZOSIN	1 (0.8%)	0	0	0
TERAZOSIN HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	0
TRANDOLAPRILAT	0	1 (0.7%)	0	0
TRANDOLAPRILAT	0	0	0	0
/VERAPAMIL				
URAPIDIL	1 (0.8%)	1 (0.7%)	3 (2.2%)	0
VALSARTAN	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
VERAPAMIL	0	1 (0.7%)	0	0
VERAPAMIL HYDROCHLORIDE	0	3 (2.2%)	1 (0.7%)	0
PERIPHERAL VASODILATORS	13 (10.5%)	13 (9.6%)	13 (9.4%)	0
BETAHISTINE	0	0	0	0
BETAHISTINE HYDROCHLORIDE	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
BETAHISTINE MESILATE	0	1 (0.7%)	0	0
BUFLOMEDIL HYDROCHLORIDE	3 (2.4%)	0	4 (2.9%)	0
BUPHENINE HYDROCHLORIDE	0	0	1 (0.7%)	0
/ESCIN				
CAFFEINE	0	1 (0.7%)	0	0
/DIHYDROERGOCRYPTINE MESILATE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DIHYDROERGOCORNINE MESILATE	1 (0.8%)	1 (0.7%)	0	0
/DIHYDROERGOCRISTINE MESILATE				
/DIHYDROERGOCRYPTINE MESILATE				
DIHYDROERGOCRISTINE MESILATE	0	0	0	0
/PIRACETAM				
DIHYDROERGOCRISTINE MESILATE	0	2 (1.5%)	1 (0.7%)	0
/RAUBASINE				
FLUNARIZINE DIHYDROCHLORIDE	1 (0.8%)	0	1 (0.7%)	0
GINKGO TREE LEAVES EXTRACT	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
IFENPRODIL TARTRATE	1 (0.8%)	0	2 (1.4%)	0
INOSITOL NICOTINATE	0	1 (0.7%)	0	0
MOXISYLYTE HYDROCHLORIDE	1 (0.8%)	0	1 (0.7%)	0
NAFTIDROFURYL OXALATE	3 (2.4%)	4 (2.9%)	5 (3.6%)	0
NICERGOLINE	2 (1.6%)	0	0	0
NICOTINYL TARTRATE	0	0	0	0
PENTOXIFYLLINE	3 (2.4%)	1 (0.7%)	0	0
PIRIBEDIL	0	1 (0.7%)	0	0
VINBURNINE	0	2 (1.5%)	0	0
VASOPROTECTIVES	26 (21.0%)	29 (21.3%)	19 (13.7%)	0
AESCULUS (OLD CODE)	0	1 (0.7%)	0	0
/CRATAEGUS EXTRACT				
/METESCULETOL SODIUM				
/PASSIFLORA EXTRACT				
ARNICA	1 (0.8%)	0	0	0
/HORSE CHESTNUT EXTRACT				
/HYOSCYAMUS DRY EXTRACT				
/SCOPARIUM				
ASCORBIC ACID	2 (1.6%)	0	0	0
/HERBAL EXTRACTS NOS				
/HESPERIDIN METHYL CHALCONE				
/PANCREAS EXTRACT				
ASCORBIC ACID	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/HESPERIDIN METHYL CHALCONE				
/RUSCUS ACULEATUS				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ASCORBIC ACID	0	1 (0.7%)	0	0
/RUSCUS ACULEATUS RHIZOME				
BENZQUERCIN	0	0	0	0
BETACAROTENE	0	1 (0.7%)	2 (1.4%)	0
/MYRTILLUS				
BETAMETHASONE	2 (1.6%)	2 (1.5%)	6 (4.3%)	0
BETAMETHASONE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
/GENTAMICIN				
BISMUTH SUBGALLATE	0	1 (0.7%)	0	0
/CARRAGHENATE				
/TALC				
/ZINC OXIDE				
BUPHENINE HYDROCHLORIDE	0	0	1 (0.7%)	0
/ESCIN				
CALCIUM DOBESILATE	0	1 (0.7%)	0	0
CHROMOCARB DIETHYLAMINE	0	0	1 (0.7%)	0
COUMARIN	1 (0.8%)	0	0	0
/TROXERUTIN				
DIOSMIN	13 (10.5%)	3 (2.2%)	3 (2.2%)	0
ERYTHROMYCIN	2 (1.6%)	0	0	0
/METHIONINE				
/MULTIVITAMINS, NOS				
/RUTOSIDE				
/SULFAFURAZOLE				
FLAVODATE DISODIUM	1 (0.8%)	1 (0.7%)	0	0
GINKGO TREE LEAVES EXTRACT	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
/HEPTAMINOL HYDROCHLORIDE				
/TROXERUTIN				
GLYCOL SALICYLATE	0	1 (0.7%)	0	0
/HEPARIN SODIUM				
HEPARIN	0	3 (2.2%)	1 (0.7%)	0
HEPARIN SODIUM	0	1 (0.7%)	0	0
HEPARIN SODIUM, TOPICAL	0	0	1 (0.7%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
HERBAL EXTRACTS NOS	2 (1.6%)	1 (0.7%)	3 (2.2%)	0
/VITIS VINIFERA	0	0	0	0
HEXAMIDINE ISETHIONATE	0	0	0	0
/TETRACAINE HYDROCHLORIDE	1 (0.8%)	0	1 (0.7%)	0
HIRUDIN	0	1 (0.7%)	0	0
HORSE CHESTNUT EXTRACT	0	0	0	0
/THIAMINE HYDROCHLORIDE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
HYDROCORTISONE BUTYRATE	1 (0.8%)	3 (2.2%)	2 (1.4%)	0
MELILOL	0	0	0	0
/RUTOSIDE	0	1 (0.7%)	0	0
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	0	0	0
NAFTAZONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE	0	0	1 (0.7%)	0
PREDNISOLONE SODIUM SUCCINATE	1 (0.8%)	0	1 (0.7%)	0
PREDNISOLONE SODIUM SULFOBENZOATE	0	2 (1.5%)	1 (0.7%)	0
RUTOSIDE	0	2 (1.5%)	1 (0.7%)	0
TROXERUTIN	3 (2.4%)	2 (1.5%)	1 (0.7%)	0
CENTRAL NERVOUS SYSTEM				
ANAESTHETICS	6 (4.8%)	3 (2.2%)	2 (1.4%)	0
ARTICAINE HYDROCHLORIDE	1 (0.8%)	0	0	0
/EPINEPHRINE HYDROCHLORIDE	1 (0.8%)	0	0	0
BUPIVACAINE	1 (0.8%)	1 (0.7%)	0	0
CETYLPRIDINIUM CHLORIDE	0	0	0	0
/CHLOROBUTANOL	0	0	0	0
/EUGENOL	0	0	0	0
/VERATROLE	0	0	0	0
FENTANYL	1 (0.8%)	0	0	0
HEXAMIDINE ISETHIONATE	0	0	0	0
/TETRACAINE HYDROCHLORIDE	0	0	0	0
KETAMINE	1 (0.8%)	0	0	0
LIDOCAINE	0	1 (0.7%)	0	0
LIDOCAINE	0	0	0	0
/METHYLPREDNISOLONE ACETATE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
LOCAL ANESTHESIA	0	0	0	0
MIDAZOLAM MALEATE	1 (0.8%)	0	1 (0.7%)	0
PRILOCAINE HYDROCHLORIDE	1 (0.8%)	0	0	0
PROCAINE	0	1 (0.7%)	1 (0.7%)	0
PROPOFOL	0	0	1 (0.7%)	0
ROPIVACAINE HYDROCHLORIDE	1 (0.8%)	0	0	0
ANALGESICS	52 (41.9%)	68 (50.0%)	70 (50.4%)	8 (26.7%)
ACETYLSALICYLATE CALCIUM	0	1 (0.7%)	0	0
ACETYLSALICYLATE LYSINE	7 (5.6%)	5 (3.7%)	1 (0.7%)	0
ACETYLSALICYLIC ACID	16 (12.9%)	22 (16.2%)	24 (17.3%)	5 (16.7%)
ACETYLSALICYLIC ACID /ALUMINIUM HYDROXIDE	0	0	1 (0.7%)	0
ACETYLSALICYLIC ACID /MAGNESIUM HYDROXIDE	0	1 (0.7%)	1 (0.7%)	0
ACETYLSALICYLIC ACID /ASCORBIC ACID	1 (0.8%)	1 (0.7%)	0	0
ACETYLSALICYLIC ACID /CAFFEINE	1 (0.8%)	0	0	0
ACETYLSALICYLIC ACID /PHENACETIN	0	0	0	0
ACETYLSALICYLIC ACID /CAFFEINE	1 (0.8%)	1 (0.7%)	0	0
ACETYLSALICYLIC ACID /QUININE SULFATE	1 (0.8%)	1 (0.7%)	0	0
ACETYLSALICYLIC ACID /LITHIUM CITRATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ACETYLSALICYLIC ACID /QUININE CITRATE	0	1 (0.7%)	3 (2.2%)	0
AMYLASE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
/PARACETAMOL	0	1 (0.7%)	3 (2.2%)	0
ASCORBIC ACID	0	1 (0.7%)	3 (2.2%)	0
/PARACETAMOL	0	1 (0.7%)	3 (2.2%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BELLADONNA EXTRACT	1 (0.8%)	3 (2.2%)	0	0
/CAFFEINE				
/OPIUM TINCTURE				
/PARACETAMOL				
BENZALKONIUM CHLORIDE	0	0	0	0
/DICHLORALPHENAZONE				
/DIMETICONE, ACTIVATED				
/HYDROCORTISONE				
/ISOMETHEPTENE				
/NYSTATIN				
/PARACETAMOL				
BENZOCAINE	0	1 (0.7%)	0	0
/SALICYLAMIDE				
BUCLIZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
/CODEINE PHOSPHATE				
/PARACETAMOL				
BUPRENORPHINE	0	1 (0.7%)	0	0
BUTALBITAL	0	0	0	0
/CAFFEINE				
/DIHYDROERGOTAMINE MESILATE				
/PROPYPHENAZONE				
BUTALBITAL	0	0	1 (0.7%)	0
/CAFFEINE				
/PROPYPHENAZONE				
CAFFEINE	0	4 (2.9%)	3 (2.2%)	0
/CARBASALATE CALCIUM				
/CHLORPHENAMINE MALEATE				
/DEXTROPROPOXYPHENE				
/PARACETAMOL				
CAFFEINE	0	0	1 (0.7%)	0
/CODEINE PHOSPHATE				
/PARACETAMOL				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CARBAMOYLPHENOXYACETIC ACID	0	1 (0.7%)	0	0
/CYANOCOBALAMIN				
/LIDOCAINE				
/SODIUM CHLORIDE				
CARBASALATE CALCIUM	0	1 (0.7%)	0	0
CLONIDINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	0	0
CODEINE	0	1 (0.7%)	0	0
CODEINE PHOSPHATE	1 (0.8%)	0	1 (0.7%)	0
CODEINE PHOSPHATE	8 (6.5%)	9 (6.6%)	2 (1.4%)	1 (3.3%)
/PARACETAMOL				
DEXAMETHASONE ACETATE	0	0	3 (2.2%)	0
/GLYCOL SALICYLATE				
/METHYL NICOTINATE				
/SALICYLAMIDE				
DEXTROPROPOXYPHENE	1 (0.8%)	1 (0.7%)	0	0
/PARACETAMOL				
DEXTROPROPOXYPHENE HYDROCHLORIDE	8 (6.5%)	11 (8.1%)	15 (10.8%)	1 (3.3%)
/PARACETAMOL				
DEXTROPROPOXYPHENE NAPSILATE	1 (0.8%)	0	0	0
DIHYDROCODEINE	0	0	0	0
DIHYDROCODEINE BITARTRATE	2 (1.6%)	2 (1.5%)	0	0
DIHYDROCODEINE BITARTRATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
/PARACETAMOL				
DIHYDROERGOTAMINE MESILATE	1 (0.8%)	1 (0.7%)	0	0
FENTANYL	1 (0.8%)	0	0	0
GUAIFENESIN	2 (1.6%)	0	1 (0.7%)	0
/OXOMEMAZINE				
/PARACETAMOL				
/SODIUM BENZOATE				
HEROIN	0	0	0	0
KETOBEMIDONE HYDROCHLORIDE	1 (0.8%)	0	0	0
/N,N-DIMETHYL-3,3-DIPHENYL-1-METHYLALLYLAMINE				
HYDROCHLOR				
METAMIZOLE SODIUM	1 (0.8%)	0	1 (0.7%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
MORPHINE	1 (0.8%)	0	1 (0.7%)	0
MORPHINE SULFATE	1 (0.8%)	1 (0.7%)	0	0
NALBUPHINE HYDROCHLORIDE	0	0	0	0
NALOXONE HYDROCHLORIDE	0	0	1 (0.7%)	0
/TILIDINE HYDROCHLORIDE				
PARACETAMOL	24 (19.4%)	25 (18.4%)	32 (23.0%)	3 (10.0%)
PETHIDINE	0	0	1 (0.7%)	0
PIZOTIFEN	0	0	1 (0.7%)	0
PROPACETAMOL HYDROCHLORIDE	0	0	1 (0.7%)	0
SODIUM ACETYLSALICYLATE	0	0	1 (0.7%)	0
TRAMADOL	0	1 (0.7%)	0	0
TRAMADOL HYDROCHLORIDE	1 (0.8%)	4 (2.9%)	3 (2.2%)	0
ZOLMITRIPTAN	1 (0.8%)	0	0	0
ANTI-PARKINSON DRUGS	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
BENZHEXOL HYDROCHLORIDE	0	1 (0.7%)	0	0
/DEMELVERINUM HYDROCHLORICUM				
DEXETIMIDE	1 (0.8%)	0	0	0
ORPHENADRINE CITRATE	0	1 (0.7%)	1 (0.7%)	0
TRIHXYPHENIDYL HYDROCHLORIDE	1 (0.8%)	0	0	0
ANTIEPILEPTICS	2 (1.6%)	1 (0.7%)	3 (2.2%)	0
CARBAMAZEPINE	0	0	3 (2.2%)	0
CLONAZEPAM	0	1 (0.7%)	1 (0.7%)	0
DIFEBARBAMATE	1 (0.8%)	0	0	0
/FEBARBAMATE				
/PHENOBARBITAL				
GABAPENTIN	0	0	0	0
VALPROATE SODIUM	1 (0.8%)	0	0	0
VALPROATE SODIUM	1 (0.8%)	0	0	0
/VALPROIC ACID				
OTHER	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
CALCIUM LACTATE	0	0	0	0
/CIMICIFUGA				
/MAGNESIUM HYPOSULFITE				
/OLEOSACCHARUM OF MARJOLAIN				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
PILOCARPINE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
PILOCARPINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TIMOLOL MALEATE				
PSYCHOANALEPTICS	17 (13.7%)	12 (8.8%)	9 (6.5%)	1 (3.3%)
AMFEBUTAMONE	0	0	0	0
AMITRIPTYLINE	0	0	0	1 (3.3%)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0
/MEDAZEPAM				
AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0
/PERPHENAZINE				
CITALOPRAM	3 (2.4%)	2 (1.5%)	2 (1.4%)	0
CLOMIPRAMINE HYDROCHLORIDE	2 (1.6%)	0	2 (1.4%)	0
DEANOL PIDOLATE	0	0	0	0
/HEPTAMINOL HYDROCHLORIDE				
DOSULEPIN	1 (0.8%)	1 (0.7%)	0	0
DOXEPIN HYDROCHLORIDE	0	1 (0.7%)	0	0
FLUOXETINE	3 (2.4%)	3 (2.2%)	2 (1.4%)	0
FLUVOXAMINE MALEATE	1 (0.8%)	1 (0.7%)	0	0
HYPERICUM EXTRACT	1 (0.8%)	0	0	0
IMIPRAMINE	0	0	0	0
IMIPRAMINE HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
LEVOCARNITINE	0	1 (0.7%)	0	0
/MAGNESIUM ASPARTATE				
MAPROTILINE HYDROCHLORIDE	0	0	0	0
MIANSERIN HYDROCHLORIDE	2 (1.6%)	0	1 (0.7%)	0
MILNACIPRAN HYDROCHLORIDE	2 (1.6%)	0	0	0
PIRACETAM	2 (1.6%)	3 (2.2%)	0	0
SERTRALINE	1 (0.8%)	0	0	0
SERTRALINE HYDROCHLORIDE	0	0	0	0
TRIMIPRAMINE MALEATE	0	0	1 (0.7%)	0
VENLAFAXINE HYDROCHLORIDE	0	1 (0.7%)	0	0
VILOXAZINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
PSYCHOLEPTICS	30 (24.2%)	30 (22.1%)	27 (19.4%)	1 (3.3%)

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ACEPROMAZINE	0	1 (0.7%)	0	0
/ACEPROMETAZINE				
/DIPOTASSIUM CLORAZEPATE				
ALPRAZOLAM	3 (2.4%)	4 (2.9%)	0	0
ASPARAGINE	1 (0.8%)	0	0	0
/DIAZEPAM				
/LEVOGLUTAMIDE				
/PYRIDOXINE				
/SERINE PHOSPHATE				
/THIAMINE				
BALLOTA	2 (1.6%)	0	1 (0.7%)	0
/COLA				
/CRATAEGUS EXTRACT				
/PASSIFLORA EXTRACT				
/PAULLINIA				
/VALERIAN ROOT				
BROMAZEPAM	3 (2.4%)	3 (2.2%)	2 (1.4%)	0
BROMPERIDOL	1 (0.8%)	0	0	0
CHLORPROTHIXENE HYDROCHLORIDE	0	1 (0.7%)	0	0
CLOMETHIAZOLE EDISILATE	1 (0.8%)	0	0	0
CLOTIAZEPAM	0	1 (0.7%)	0	0
CRATAEGUS	0	1 (0.7%)	1 (0.7%)	0
/VALERIAN ROOT				
CRATAEGUS EXTRACT	0	1 (0.7%)	0	0
/VALERIAN EXTRACT				
CYAMEMAZINE	1 (0.8%)	0	1 (0.7%)	0
DELORAZEPAM	0	0	0	0
DIAZEPAM	2 (1.6%)	1 (0.7%)	7 (5.0%)	0
DIAZEPAM	0	0	0	0
/SULPIRIDE				
DIFEBARBAMATE	1 (0.8%)	0	0	0
/FEBARBAMATE				
/PHENOBARBITAL				
DIPOTASSIUM CLORAZEPATE	2 (1.6%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ETHYL LOFLAZEPATE	0	1 (0.7%)	0	0
FLUNITRAZEPAM	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
FLUPENTIXOL DIHYDROCHLORIDE	0	0	1 (0.7%)	0
FLUPHENAZINE	0	0	1 (0.7%)	0
HALOPERIDOL	1 (0.8%)	0	0	0
HERBAL EXTRACTS NOS	0	1 (0.7%)	0	0
/PHENOBARBITAL				
HYDROXYZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
HYPERICUM EXTRACT	1 (0.8%)	0	0	0
LEVOMEPRMAZINE HYDROCHLORIDE	0	1 (0.7%)	0	0
LITHIUM CARBONATE	0	0	1 (0.7%)	0
LOPRAZOLAM	0	0	0	0
LOPRAZOLAM MESILATE	0	1 (0.7%)	0	0
LORAZEPAM	5 (4.0%)	0	2 (1.4%)	0
LORMETAZEPAM	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
NITRAZEPAM	0	0	0	0
NORDAZEPAM	0	0	1 (0.7%)	0
OXAZEPAM	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
PAROXETINE	1 (0.8%)	1 (0.7%)	3 (2.2%)	1 (3.3%)
PRAZEPAM	0	1 (0.7%)	1 (0.7%)	0
PROCHLORPERAZINE	2 (1.6%)	0	2 (1.4%)	0
PROCHLORPERAZINE MALEATE	0	0	1 (0.7%)	0
PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
PROXIBARBAL	1 (0.8%)	0	0	0
RISPERIDONE	1 (0.8%)	0	0	0
SULPIRIDE	0	2 (1.5%)	0	0
TEMAZEPAM	1 (0.8%)	0	1 (0.7%)	0
TETRAZEPAM	3 (2.4%)	6 (4.4%)	4 (2.9%)	0
THIORIDAZINE HYDROCHLORIDE	0	0	1 (0.7%)	0
TRIAZOLAM	1 (0.8%)	0	1 (0.7%)	0
ZOLPIDEM HEMITARTRATE	4 (3.2%)	4 (2.9%)	2 (1.4%)	0
ZOPICLONE	4 (3.2%)	8 (5.9%)	1 (0.7%)	0

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Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ANTI-ACNE PREP	1 (0.8%)	0	1 (0.7%)	0
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
RETINOL	0	0	0	0
ANTIBIOTIC&CHEMOTHERAPEUT	8 (6.5%)	10 (7.4%)	8 (5.8%)	0
BACITRACIN	1 (0.8%)	0	0	0
/NEOMYCIN SULFATE				
BETAMETHASONE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
/GENTAMICIN				
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
ERYTHROMYCIN	0	3 (2.2%)	3 (2.2%)	0
FRAMYCETIN SULFATE	1 (0.8%)	0	0	0
/TRYPSIN				
FUSIDATE SODIUM	0	1 (0.7%)	1 (0.7%)	0
FUSIDATE SODIUM	0	1 (0.7%)	0	0
/HYDROCORTISONE ACETATE				
FUSIDIC ACID	1 (0.8%)	0	3 (2.2%)	0
GENTAMICIN SULFATE	2 (1.6%)	0	1 (0.7%)	0
METRONIDAZOLE	2 (1.6%)	3 (2.2%)	0	0
MUPIROCIN	0	0	0	0
OXYTETRACYCLINE	0	1 (0.7%)	0	0
OXYTETRACYCLINE DIHYDRATE	0	0	0	0
SULFADIAZINE SILVER	0	1 (0.7%)	0	0
TETRACYCLINE	1 (0.8%)	0	0	0
ANTIFUNGALS	5 (4.0%)	9 (6.6%)	9 (6.5%)	3 (10.0%)
AMOROLFINE HYDROCHLORIDE	1 (0.8%)	0	1 (0.7%)	0
BETAMETHASONE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
/GENTAMICIN				
BETAMETHASONE DIPROPIONATE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
BIFONAZOLE	0	2 (1.5%)	1 (0.7%)	0
BIFONAZOLE	0	1 (0.7%)	1 (0.7%)	0
/UREA				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BUTOCONAZOLE NITRATE	0	0	1 (0.7%)	0
CLOTRIMAZOLE	1 (0.8%)	2 (1.5%)	3 (2.2%)	1 (3.3%)
CLOTRIMAZOLE	0	0	1 (0.7%)	0
/HYDROCORTISONE				
ECONAZOLE NITRATE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
FENTICONAZOLE NITRATE	0	0	1 (0.7%)	0
GRISEOFULVIN	0	0	0	0
HEXETIDINE	0	0	1 (0.7%)	0
HYDROCORTISONE	1 (0.8%)	0	0	0
/MICONAZOLE				
HYDROCORTISONE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/MICONAZOLE NITRATE				
ISOCONAZOLE NITRATE	0	0	1 (0.7%)	0
KETOCONAZOLE	0	1 (0.7%)	1 (0.7%)	0
MICONAZOLE	0	1 (0.7%)	0	0
MICONAZOLE NITRATE	0	0	1 (0.7%)	0
NYSTATIN	0	0	0	0
TERBINAFINE	2 (1.6%)	0	0	2 (6.7%)
TIOCONAZOLE	0	0	0	0
ANTIPRURITICS	3 (2.4%)	5 (3.7%)	1 (0.7%)	1 (3.3%)
CINCHOCAINE HYDROCHLORIDE	0	1 (0.7%)	0	0
CINCHOCAINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/CLOCORTOLONE HEXANOATE				
/CLOCORTOLONE PIVALATE				
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.8%)	0	0	1 (3.3%)
DOXEPIN HYDROCHLORIDE	0	1 (0.7%)	0	0
LIDOCAINE	0	1 (0.7%)	0	0
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
NOSCAPINE	0	0	1 (0.7%)	0
/POLYSORBATE 85 (TWEEN 85)				
/PROMETHAZINE				
PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
ANTISEPTICS & DISINFECTANTS	2 (1.6%)	7 (5.1%)	3 (2.2%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ALLANTOIN	0	0	0	0
/CETRIMONIUM BROMIDE				
/DICHLOROBENZYL ALCOHOL				
CETRIMONIUM BROMIDE	0	0	0	0
CETYLPYRIDINIUM CHLORIDE	1 (0.8%)	1 (0.7%)	0	0
/CHLOROBUTANOL				
/EUGENOL				
/VERATROLE				
CHLORHEXIDINE GLUCONATE	0	1 (0.7%)	0	0
CHLOROQUINE	0	0	0	0
ESSENTIAL OILS NOS	0	0	1 (0.7%)	0
/ETHANOL				
/GLYCEROL				
/METHYL SALICYLATE				
/SALICYLATE SODIUM				
/SODIUM BICARBONATE				
/SODIUM TETRABORATE				
/THYMOL				
ETHACRIDINE	0	1 (0.7%)	0	0
HEXAMIDINE ISETHIONATE	0	0	1 (0.7%)	0
HEXAMIDINE ISETHIONATE	0	0	0	0
/TETRACAINES HYDROCHLORIDE				
HYDROCORTISONE	0	0	0	0
/ICHTHAMMOL				
NIFUROXAZIDE	0	4 (2.9%)	1 (0.7%)	0
POVIDONE- IODINE	0	1 (0.7%)	0	0
SODIUM HYPOCHLORITE	1 (0.8%)	0	0	0
TRICLOCARBAN	0	0	1 (0.7%)	0
CICATRIZANTS	0	2 (1.5%)	1 (0.7%)	0
ALLANTOIN	0	1 (0.7%)	0	0
/CAFE OIL				
/SALICYLIC ACID				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ASIATIC ACID	0	0	1 (0.7%)	0
/ASIATICOSIDE				
/MADECASSIC ACID				
DEXPANTHENOL	0	1 (0.7%)	0	0
COAL TAR,SULPH,RESORCIN PROD	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ALLANTOIN	0	0	1 (0.7%)	0
/COAL TAR SOLUTION				
CADE OIL	0	0	1 (0.7%)	0
/COAL TAR				
/COAL TAR SOLUTION				
/OLEYL ALCOHOL				
COAL TAR EXTRACT	1 (0.8%)	0	0	0
/HYDROCORTISONE				
TAZAROTENE	0	1 (0.7%)	0	0
CORTICOSTEROIDS	15 (12.1%)	23 (16.9%)	20 (14.4%)	0
BETAMETHASONE	2 (1.6%)	2 (1.5%)	6 (4.3%)	0
BETAMETHASONE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
/GENTAMICIN				
BETAMETHASONE	1 (0.8%)	0	0	0
/NEOMYCIN				
BETAMETHASONE ACETATE	1 (0.8%)	0	1 (0.7%)	0
/BETAMETHASONE SODIUM PHOSPHATE				
BETAMETHASONE DIPROPIONATE	0	1 (0.7%)	2 (1.4%)	0
BETAMETHASONE DIPROPIONATE	0	1 (0.7%)	0	0
/CLOTRIMAZOLE				
BETAMETHASONE DIPROPIONATE	0	0	2 (1.4%)	0
/SALICYLIC ACID				
BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.7%)	0	0
BETAMETHASONE VALERATE	0	0	0	0
BETAMETHASONE VALERATE	1 (0.8%)	0	0	0
/CLIOQUINOL				
BETAMETHASONE VALERATE	0	0	1 (0.7%)	0
/FUSIDIC ACID				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BUDESONIDE	2 (1.6%)	5 (3.7%)	2 (1.4%)	0
CINCHOCAINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/CLOCORTOLONE HEXANOATE				
/CLOCORTOLONE PIVALATE				
CLIOQUINOL	0	0	0	0
/HYDROCORTISONE				
CLIOQUINOL	0	0	0	0
/HYDROCORTISONE				
/NYSTATIN				
CLOBETASOL PROPIONATE	1 (0.8%)	0	0	0
CLOCORTOLONE HEXANOATE	0	0	1 (0.7%)	0
/CLOCORTOLONE PIVALATE				
CLOTRIMAZOLE	0	0	1 (0.7%)	0
/HYDROCORTISONE				
COAL TAR EXTRACT	1 (0.8%)	0	0	0
/HYDROCORTISONE				
DESONIDE	0	0	0	0
DESOXIMETASONE	0	0	1 (0.7%)	0
DEXAMETHASONE ACETATE	0	0	3 (2.2%)	0
/GLYCOL SALICYLATE				
/METHYL NICOTINATE				
/SALICYLAMIDE				
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (0.7%)	1 (0.7%)	0
/NEOMYCIN SULFATE				
DIFLUCORTOLONE VALERATE	0	0	1 (0.7%)	0
FLUOCINOLONE ACETONIDE	0	0	1 (0.7%)	0
/NEOMYCIN SULFATE				
/POLYMYXIN B SULFATE				
FLUOCINONIDE	0	0	0	0
FLUOCORTIN BUTYL	0	1 (0.7%)	0	0
FLUTICASONE PROPIONATE	0	4 (2.9%)	1 (0.7%)	0
FRAMYCETIN SULFATE	0	0	0	0
/HYDROCORTISONE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
FUSIDATE SODIUM	0	1 (0.7%)	0	0
/HYDROCORTISONE ACETATE				
HYDROCORTISONE	2 (1.6%)	0	0	0
HYDROCORTISONE	0	0	0	0
/ICHTHAMMOL				
HYDROCORTISONE ACETATE	0	1 (0.7%)	0	0
/NEOMYCIN SULFATE				
HYDROCORTISONE BUTYRATE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
METHYLPREDNISOLONE	1 (0.8%)	0	0	0
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
MOMETASONE FUROATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
PREDNISOLONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.8%)	0	1 (0.7%)	0
SALICYLIC ACID	0	1 (0.7%)	0	0
/TRIAMCINOLONE ACETONIDE				
TRIAMCINOLONE ACETONIDE	0	3 (2.2%)	0	0
TRIAMCINOLONE HEXACETONIDE	0	0	1 (0.7%)	0
EMOLLIENTS & PROTECTIVES	7 (5.6%)	6 (4.4%)	7 (5.0%)	3 (10.0%)
ALGIN	0	0	0	0
/CETYL PALMITATE				
/ETHYLENE GLYCOL MONOSTEARATE				
/PARAFFIN				
/PARAFFIN, LIQUID				
/PROPYLENE GLYCOL				
/STEARYL ALCOHOL				
/TROLAMINE				
ALOES	1 (0.8%)	0	0	0
BEEWAX WHITE	1 (0.8%)	0	0	0
/PARAFFIN				
/WHITE VASELINE				
/ZINC OXIDE				

- 390 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BETAINE	0	0	0	0
/LACTIC ACID				
/UREA				
BIFONAZOLE	0	1 (0.7%)	1 (0.7%)	0
/UREA				
CALCIPOTRIOL	1 (0.8%)	1 (0.7%)	0	0
CETOSTEARYL ALCOHOL	0	0	0	0
/GLYCERYL MONOSTEARATE				
/PARAFFIN, LIQUID				
/PARAFFIN, SOFT				
/POLYSORBATE 40				
/PROPYLENE GLYCOL				
/SILICIC ACID				
/SORBIC ACID				
COD-LIVER OIL	0	1 (0.7%)	0	2 (6.7%)
CYCLOMETHICONE	0	0	0	0
/SOFT PARAFFIN				
EMULSIFYING WAX	0	0	1 (0.7%)	0
/PARAFFIN, LIQUID				
/PARAFFIN, SOFT				
GLYCERYL MONOSTEARATE	0	0	0	0
/METHYLPARABEN				
/PARAFFIN, LIQUID				
/PARAFFIN, SOFT				
/STEARIC ACID				
/TROLAMINE				
/WOOL FAT				
LACTULOSE	0	0	1 (0.7%)	0
/PARAFFIN				
/PARAFFIN, SOFT				
LYCOPENE	0	1 (0.7%)	0	0
/RETINOL				
/TOCOPHEROL				
PARAFFIN, LIQUID	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
PARAFFIN, LIQUID	0	0	0	0
/WOOL ALCOHOLS				
PARAFFIN, SOFT	1 (0.8%)	0	1 (0.7%)	0
PIAS	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
TOCOPHEROL	0	0	0	1 (3.3%)
UREA	1 (0.8%)	0	1 (0.7%)	0
WHEAT GERM	1 (0.8%)	0	0	0
MEDICATED DRESSINGS	3 (2.4%)	2 (1.5%)	5 (3.6%)	0
CALCIUM ALGINATE	0	0	0	0
ETHANOLAMINE TENOATE	1 (0.8%)	0	0	0
/FRAMYCETIN SULFATE				
FRAMYCETIN SULFATE	1 (0.8%)	0	1 (0.7%)	0
FUSIDATE SODIUM	0	1 (0.7%)	1 (0.7%)	0
FUSIDIC ACID	1 (0.8%)	0	3 (2.2%)	0
MEDICATED DRESSINGS NOS	0	1 (0.7%)	0	0
OTHER	4 (3.2%)	7 (5.1%)	3 (2.2%)	0
ACITRETIN	0	1 (0.7%)	0	0
ALLANTOIN	0	1 (0.7%)	0	0
/CADE OIL				
/SALICYLIC ACID				
ALUMINIUM CHLOROHYDRATE	1 (0.8%)	0	0	0
ARNICA	1 (0.8%)	0	0	0
/HORSE CHESTNUT EXTRACT				
/HYOSCYAMUS DRY EXTRACT				
/SCOPARIUM				
CALCIPOTRIOL	1 (0.8%)	1 (0.7%)	0	0
CYSTEINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/METHIONINE				
DERMATOLOGICALS NOS	0	1 (0.7%)	0	0
FRAMYCETIN SULFATE	1 (0.8%)	0	0	0
/TRYPSIN				
LIQUID NITROGEN	1 (0.8%)	0	2 (1.4%)	0
POVIDONE-IODINE	0	1 (0.7%)	0	0
SALICYLIC ACID	1 (0.8%)	1 (0.7%)	0	0

- 392 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
SERRAPEPTASE	0	2 (1.5%)	1 (0.7%)	0
GU SYSTEM/SEX HORMONES				
ANTIINFECTIVES/ANTISEPTICS	5 (4.0%)	9 (6.6%)	6 (4.3%)	1 (3.3%)
ACETARSOL	0	0	0	0
/NEOMYCIN				
/NYSTATIN				
/POLYMYXIN B SULFATE				
ANTIBIOTIC NOS	0	1 (0.7%)	0	0
BUTOCONAZOLE NITRATE	0	0	1 (0.7%)	0
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
CICLOPIROX OLAMINE	1 (0.8%)	0	0	0
CLOTRIMAZOLE	1 (0.8%)	2 (1.5%)	3 (2.2%)	1 (3.3%)
ECONAZOLE NITRATE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
METRONIDAZOLE	2 (1.6%)	3 (2.2%)	0	0
MICONAZOLE	0	1 (0.7%)	0	0
MICONAZOLE NITRATE	0	0	1 (0.7%)	0
NEOMYCIN SULFATE	0	0	0	0
/NYSTATIN				
/PREDNISOLONE SODIUM SULFOBENZOATE				
/TERNIDAZOLE				
NYSTATIN	0	0	0	0
OXYTETRACYCLINE	0	1 (0.7%)	0	0
OXYTETRACYCLINE DIHYDRATE	0	0	0	0
POVIDONE- IODINE	0	1 (0.7%)	0	0
OTHER	4 (3.2%)	1 (0.7%)	0	1 (3.3%)
ALPROSTADIL	2 (1.6%)	1 (0.7%)	0	0
HYPERICUM EXTRACT	1 (0.8%)	0	0	0
INTRAUTERINE CONTRACEPTIVE DEVICE	1 (0.8%)	0	0	0
QUINAGOLIDE HYDROCHLORIDE	0	0	0	1 (3.3%)
SEX HORMONES/STIMULANTS	10 (8.1%)	8 (5.9%)	12 (8.6%)	1 (3.3%)
BOVINE TESTICULAR EXTRACT	1 (0.8%)	0	0	0
CHLORMADINONE ACETATE	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DESOGESTREL	1 (0.8%)	0	0	0
/ETHINYLESTRADIOL				
DIENESTROL	0	1 (0.7%)	0	0
DYDROGESTERONE	0	0	1 (0.7%)	0
DYDROGESTERONE	0	0	0	0
/ESTRADIOL				
ESTRADIOL	2 (1.6%)	1 (0.7%)	0	1 (3.3%)
ESTRADIOL	0	1 (0.7%)	0	0
/ESTRIOL				
/NORETHISTERONE ACETATE				
ESTRADIOL	1 (0.8%)	0	2 (1.4%)	0
/NORETHISTERONE ACETATE				
ESTRADIOL VALERATE	1 (0.8%)	0	1 (0.7%)	0
ESTRADIOL VALERATE	0	0	1 (0.7%)	0
/MEDROXYPROGESTERONE ACETATE				
ESTRIOL	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
ESTRIOL	0	0	1 (0.7%)	0
/LACTOBACILLUS ACIDOPHILUS				
/PROGESTERONE				
ESTRIOL DISODIUM SUCCINATE	0	1 (0.7%)	0	0
ESTROGEN NOS	1 (0.8%)	0	2 (1.4%)	0
ESTROGEN NOS	0	0	1 (0.7%)	0
/MEDROXYPROGESTERONE				
ESTROGENS CONJUGATED	0	0	1 (0.7%)	1 (3.3%)
ESTROGENS CONJUGATED	0	0	1 (0.7%)	0
/NORGESTREL				
FINASTERIDE	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
LYNESTRENOL	0	0	1 (0.7%)	0
MEDROGESTONE	0	0	1 (0.7%)	0
MEDROXYPROGESTERONE ACETATE	0	1 (0.7%)	0	0
NOMEGESTROL ACETATE	0	1 (0.7%)	1 (0.7%)	0
NORETHISTERONE	0	0	1 (0.7%)	0
NORETHISTERONE ACETATE	0	0	1 (0.7%)	0
PROGESTERONE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
PROMEGESTONE	1 (0.8%)	0	0	0
PROMESTRIENE	0	3 (2.2%)	1 (0.7%)	0
TESTOSTERONE ENANTATE	0	0	0	0
UROLOGICALS	18 (14.5%)	20 (14.7%)	18 (12.9%)	1 (3.3%)
ALFUZOSIN	3 (2.4%)	0	1 (0.7%)	0
ALFUZOSIN HYDROCHLORIDE	2 (1.6%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
AMINOACETIC ACID	0	0	0	0
/GLUTAMIC ACID				
/PRUNUS AFRICANA				
CAMPHOR MONOBROMIDE	0	0	1 (0.7%)	0
/HERBAL EXTRACTS NOS				
/METHENAMINE				
CANDESARTAN CILEXETIL	0	1 (0.7%)	1 (0.7%)	0
CIPROFLOXACIN	0	1 (0.7%)	0	0
CIPROFLOXACIN HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
DOXAZOSIN MESYLATE	2 (1.6%)	3 (2.2%)	0	0
ECHINACEA EXTRACT	0	2 (1.5%)	0	0
/SABAL EXTRACT				
ECHINACEA EXTRACT	1 (0.8%)	0	2 (1.4%)	0
/SABAL EXTRACT				
/TROSPIMUM CHLORIDE				
ENOXACIN	3 (2.4%)	0	1 (0.7%)	0
FLAVOXATE HYDROCHLORIDE	0	1 (0.7%)	0	0
FLUMEQUINE	1 (0.8%)	0	0	0
LIPOPHILER EXTRACT	0	1 (0.7%)	0	0
/SABAL EXTRACT				
NIFURTOINOL	0	1 (0.7%)	0	0
NITROFURANTOIN	0	1 (0.7%)	1 (0.7%)	0
NITROXOLINE	0	0	1 (0.7%)	0
NORFLOXACIN	2 (1.6%)	4 (2.9%)	4 (2.9%)	0
OFLOXACIN	1 (0.8%)	6 (4.4%)	4 (2.9%)	0
OXYBUTYNIN	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
OXYBUTYNIN HYDROCHLORIDE	0	0	0	0
PRAZOSIN	1 (0.8%)	2 (1.5%)	3 (2.2%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
PYGEUM AFRICANUM	0	0	1 (0.7%)	0
SERENOA REPENS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
SILDENAFIL CITRATE	1 (0.8%)	0	0	0
SOLIDAGO	0	1 (0.7%)	0	0
TAMSULOSIN	1 (0.8%)	0	0	0
TAMSULOSIN HYDROCHLORIDE	0	0	2 (1.4%)	0
TERAZOSIN	1 (0.8%)	0	0	0
TERAZOSIN HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	0
TOLTERODINE	0	0	0	0
MUSCULO-SKELETAL				
ANTIGOUT PREP	5 (4.0%)	11 (8.1%)	12 (8.6%)	1 (3.3%)
ALLOPURINOL	4 (3.2%)	10 (7.4%)	10 (7.2%)	1 (3.3%)
ALLOPURINOL	1 (0.8%)	0	0	0
/BENZBROMARONE				
BENZBROMARONE	1 (0.8%)	0	0	0
COLCHICINE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
COLCHICINE	0	1 (0.7%)	0	0
/DICYCLOVERINE HYDROCHLORIDE				
COLCHICINE	0	0	1 (0.7%)	0
/OPIUM				
/TIEMONIUM METHYLSULFATE				
PROBENECID	0	0	1 (0.7%)	0
ANTIINFLAM/ANTIRHEU PROD	46 (37.1%)	56 (41.2%)	42 (30.2%)	4 (13.3%)
ACECLOFENAC	0	1 (0.7%)	0	0
ACOMETACIN	0	0	0	0
ALMINOPROFEN	1 (0.8%)	0	1 (0.7%)	0
AMINOPHENAZONE	1 (0.8%)	0	0	0
/CYANOCOBALAMIN				
/DEXAMETHASONE SODIUM METASULFOBENZOATE				
/LIDOCAINE HYDROCHLORIDE				
/PHENYLBUTAZONE SODIUM				
BETA CYCLODEXTRIN	0	1 (0.7%)	0	0
/NIMESULIDE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CELECOXIB	0	0	1 (0.7%)	0
CHONDROITIN SULFATE SODIUM	1 (0.8%)	0	0	0
CHYMOTRYPSINOGEN	1 (0.8%)	0	0	0
/RIBONUCLEASE				
/TRYPSIN				
DEKKETOPROFEN TROMETAMOL	0	0	0	0
DEXTRAN SULPHATE	1 (0.8%)	0	0	0
/PHENYL BUTAZONE				
DIACEREIN	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
DICLOFENAC	4 (3.2%)	7 (5.1%)	5 (3.6%)	1 (3.3%)
DICLOFENAC DIETHYLAMINE	3 (2.4%)	2 (1.5%)	0	0
DICLOFENAC POTASSIUM	0	2 (1.5%)	0	0
DICLOFENAC SODIUM	10 (8.1%)	17 (12.5%)	10 (7.2%)	0
DICLOFENAC SODIUM	1 (0.8%)	4 (2.9%)	2 (1.4%)	2 (6.7%)
/MISOPROSTOL				
ETODOLAC	2 (1.6%)	1 (0.7%)	0	0
FLURBIPROFEN	0	2 (1.5%)	1 (0.7%)	0
IBUPROFEN	9 (7.3%)	15 (11.0%)	10 (7.2%)	0
IBUPROFEN	3 (2.4%)	3 (2.2%)	3 (2.2%)	0
/PSEUDOEPHEDRINE HYDROCHLORIDE				
IBUPROFEN LYSINATE	1 (0.8%)	0	0	0
INDOMETACIN	0	7 (5.1%)	3 (2.2%)	0
INDOMETACIN	0	0	0	0
/METAMIZOLE SODIUM				
/THIAMINE				
KETOPROFEN	10 (8.1%)	8 (5.9%)	9 (6.5%)	1 (3.3%)
KETOPROFEN LYSINE	0	0	1 (0.7%)	0
KETOROLAC TROMETHAMINE	0	1 (0.7%)	0	0
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	0	0	0
/PHENYL BUTAZONE SODIUM				
MELOXICAM	0	3 (2.2%)	1 (0.7%)	0
MISOPROSTOL	0	1 (0.7%)	0	0
/NAPROXEN				
NABUMETONE	0	1 (0.7%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
NAPROXEN	1 (0.8%)	4 (2.9%)	3 (2.2%)	0
NAPROXEN SODIUM	0	2 (1.5%)	1 (0.7%)	0
NIFLUMIC ACID	4 (3.2%)	2 (1.5%)	3 (2.2%)	0
NIMESULIDE	3 (2.4%)	3 (2.2%)	3 (2.2%)	0
OXACEPROL	1 (0.8%)	0	0	0
PIROXICAM	8 (6.5%)	11 (8.1%)	8 (5.8%)	0
PIROXICAM BETA CYCLODEXTRIN	2 (1.6%)	2 (1.5%)	0	0
PRANOPROFEN	0	0	1 (0.7%)	0
PROGLUMETACIN MALEATE	1 (0.8%)	1 (0.7%)	0	0
SERRAPEPTASE	0	2 (1.5%)	1 (0.7%)	0
SUPROFEN	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
TENOXICAM	1 (0.8%)	6 (4.4%)	1 (0.7%)	0
TIAPROFENIC ACID	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
MUSCLE RELAXANTS	5 (4.0%)	6 (4.4%)	5 (3.6%)	0
CHLORMEZANONE	1 (0.8%)	0	0	0
IDROCILAMIDE	0	0	2 (1.4%)	0
ORPHENADRINE CITRATE	0	1 (0.7%)	1 (0.7%)	0
THIOLCHICOSIDE	4 (3.2%)	5 (3.7%)	2 (1.4%)	0
OTHER	2 (1.6%)	8 (5.9%)	5 (3.6%)	1 (3.3%)
AMINOHYDROXYPROPYLIDENEDIPHOSPHONATE DISODIUM	0	0	0	0
AMINOPHYLLINE	0	1 (0.7%)	0	0
/QUININE SULFATE				
AMTOLMETIN GUACIL SODIUM	0	1 (0.7%)	0	0
HARPAGOPHYTUM PROCUMBENS	0	1 (0.7%)	0	0
NIAOULI OIL	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
/QUININE BENZOATE				
/THIAMINE HYDROCHLORIDE				
QUININE	0	0	2 (1.4%)	0
QUININE HYDROCHLORIDE	0	1 (0.7%)	0	0
QUININE SULFATE	0	0	1 (0.7%)	1 (3.3%)
URIDINE TRIPHOSPHATE SODIUM	0	2 (1.5%)	0	0
TOPICAL ANTIRHEU PROD	3 (2.4%)	1 (0.7%)	0	1 (3.3%)

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ADRENAL CORTICAL EXTRACT	0	0	0	1 (3.3%)
/MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER				
/SALICYLIC ACID				
BENZYL NICOTINATE	1 (0.8%)	0	0	0
/ECHINACEA EXTRACT				
/GLYCOL SALICYLATE				
/HEPARIN SODIUM				
/HESPERIDIN METHYL CHALCONE				
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	0	0	0
/SALICYLIC ACID				
OXACEPROL	1 (0.8%)	0	0	0
SALICYLIC ACID	1 (0.8%)	1 (0.7%)	0	0
PARASITOLOGY				
ANTHELMINTICS	1 (0.8%)	0	0	0
MEBENDAZOLE	0	0	0	0
NICLOSAMIDE	1 (0.8%)	0	0	0
ANTIPROTOZOALS	2 (1.6%)	6 (4.4%)	4 (2.9%)	2 (6.7%)
CHLOROQUINE	0	0	0	0
CHLOROQUINE	0	0	0	0
/PROGUANIL				
CHLOROQUINE SULFATE	0	0	0	1 (3.3%)
MEFLOQUINE	0	0	0	0
METRONIDAZOLE	2 (1.6%)	3 (2.2%)	0	0
PROGUANIL HYDROCHLORIDE	0	0	0	1 (3.3%)
QUININE	0	0	2 (1.4%)	0
QUININE HYDROCHLORIDE	0	1 (0.7%)	0	0
QUININE HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	0
/SULFATE				
QUININE SULFATE	0	0	1 (0.7%)	1 (3.3%)
RESPIRATORY				
ANTI-ASTHMATICS	17 (13.7%)	19 (14.0%)	18 (12.9%)	1 (3.3%)
AMINOPHYLLINE	1 (0.8%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
AZELASTINE	0	0	1 (0.7%)	0
BAMBUTEROL HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	0
BECLOMETASONE	3 (2.4%)	0	3 (2.2%)	0
BECLOMETASONE DIPROPIONATE	5 (4.0%)	6 (4.4%)	4 (2.9%)	1 (3.3%)
BUDESONIDE	2 (1.6%)	5 (3.7%)	2 (1.4%)	0
CETIRIZINE	0	0	1 (0.7%)	0
/PSEUDOEPHEDRINE				
CROMOGLICATE SODIUM	1 (0.8%)	3 (2.2%)	2 (1.4%)	0
CROMOGLICATE SODIUM	0	1 (0.7%)	0	0
/REPROTEROL HYDROCHLORIDE				
DIPROPHYLLINE	0	1 (0.7%)	0	0
/TURPENTINE OIL				
EPHEDRINE	0	0	1 (0.7%)	0
FENOTEROL HYDROBROMIDE	0	0	2 (1.4%)	0
/IPRATROPIUM BROMIDE				
FENSPIRIDE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
FLUTICASONE	0	1 (0.7%)	2 (1.4%)	0
/SALMETEROL				
FORMOTEROL FUMARATE	1 (0.8%)	4 (2.9%)	0	0
IPRATROPIUM	0	0	1 (0.7%)	0
IPRATROPIUM BROMIDE	3 (2.4%)	0	0	0
ISOPRENALINE HYDROCHLORIDE	0	2 (1.5%)	0	0
LORATADINE	0	0	1 (0.7%)	0
/PSEUDOEPHEDRINE SULFATE				
MONTELUKAST SODIUM	0	1 (0.7%)	1 (0.7%)	0
NEDOCROMIL	0	1 (0.7%)	0	0
NEDOCROMIL SODIUM	0	1 (0.7%)	0	0
PSEUDOEPHEDRINE	0	0	0	0
REPROTEROL HYDROCHLORIDE	0	1 (0.7%)	0	0
SALBUTAMOL	9 (7.3%)	4 (2.9%)	4 (2.9%)	0
SALBUTAMOL SULFATE	0	1 (0.7%)	1 (0.7%)	0
SALMETEROL HYDROXYNAPHTHOATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
SALMETEROL XINAFOATE	0	0	0	0
TERBUTALINE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
TERBUTALINE SULFATE	0	1 (0.7%)	1 (0.7%)	0
THEOPHYLLINE	4 (3.2%)	1 (0.7%)	4 (2.9%)	0
COUGH AND COLD PREP	31 (25.0%)	34 (25.0%)	32 (23.0%)	2 (6.7%)
ACETYLCYSTEINE	13 (10.5%)	12 (8.8%)	13 (9.4%)	0
ACETYLSALICYLIC ACID	0	0	0	0
/ASCORBIC ACID				
/CHLORPHENAMINE MALEATE				
/MOROXDYNE HYDROCHLORIDE				
/PHENYLEPHRINE HYDROCHLORIDE				
ACETYLSALICYLIC ACID	0	0	0	0
/CAFFEINE				
/CHLORPHENAMINE MALEATE				
ACONITE TINCTURE	0	1 (0.7%)	0	0
/BELLADONNA TINCTURE				
/CODEINE				
/ETHYLMORPHINE				
/POLYGALA AMARA TINCTURE				
/SODIUM BENZOATE				
/SODIUM BROMIDE				
ACONITE TINCTURE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
/CHERRY-LAUREL				
/CODEINE PHOSPHATE				
/SODIUM BENZOATE				
AMARANTH SOLUTION	0	0	1 (0.7%)	0
/ANISE WATER				
/CHLOROFORM				
/CITRIC ACID				
AMBROXOL	0	0	0	0
AMBROXOL HYDROCHLORIDE	3 (2.4%)	4 (2.9%)	7 (5.0%)	0
AMBROXOL HYDROCHLORIDE	1 (0.8%)	0	0	0
/DOXYCYCLINE HYDROCHLORIDE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
ASCORBIC ACID	0	0	0	0
/CODEINE PHOSPHATE				
/DIPROPHYLLINE				
/METAMIZOLE SODIUM				
/PARACETAMOL				
ASCORBIC ACID	0	0	0	0
/PARACETAMOL				
/PHENYLEPHRINE HYDROCHLORIDE				
/SODIUM CITRATE				
BICLOTYMOL	0	0	0	0
/CHLORPHENAMINE MALEATE				
/GUAIFENESIN				
/PHOLCODINE				
BROMHEXINE	1 (0.8%)	0	0	0
BROMHEXINE HYDROCHLORIDE	2 (1.6%)	1 (0.7%)	0	0
BROMPHENIRAMINE MALEATE	0	0	1 (0.7%)	0
/GUAIFENESIN				
/PHENYLEPHRINE HYDROCHLORIDE				
/PHENYLPROPANOLAMINE HYDROCHLORIDE				
BUPHENINE HYDROCHLORIDE	0	0	1 (0.7%)	0
/ESCIN				
CAFFEINE	0	0	1 (0.7%)	0
/CODEINE PHOSPHATE				
/DIPHENHYDRAMINE HYDROCHLORIDE				
/PARACETAMOL				
/PHENYLEPHRINE HYDROCHLORIDE				
CARBAMIDE	0	0	1 (0.7%)	0
/GUETHOL				
CARBINOXAMINE MALEATE	1 (0.8%)	2 (1.5%)	2 (1.4%)	0
/GUAIFENESIN				
/PSEUDOEPHEDRINE HYDROCHLORIDE				
CARBOCISTEINE	8 (6.5%)	4 (2.9%)	7 (5.0%)	0
CINEOLE	0	0	1 (0.7%)	0
/ETHYLMORPHINE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CLOBUTINOL	0	1 (0.7%)	0	0
CLOBUTINOL HYDROCHLORIDE	1 (0.8%)	4 (2.9%)	3 (2.2%)	0
CLOPERASTINE FENDIZOATE	0	0	1 (0.7%)	0
CODEINE	0	1 (0.7%)	0	0
CODEINE	1 (0.8%)	0	1 (0.7%)	0
/ERYSIMUM EXTRACT				
/ETHYLMORPHINE CAMSILATE				
/GRINDELIA LIQUID EXTRACT				
/MARRUBE EXTRACT				
/SULFOGAIACOL				
CODEINE	0	0	0	0
/GUAIACOL				
CODEINE	0	3 (2.2%)	2 (1.4%)	0
/PHENYLTOLOXAMINE				
CODEINE HYDROCHLORIDE	0	0	0	1 (3.3%)
/PHENOBARBITAL				
CODEINE PHOSPHATE	1 (0.8%)	0	1 (0.7%)	0
DEXTROMETHORPHAN	0	1 (0.7%)	0	0
DEXTROMETHORPHAN HYDROBROMIDE	2 (1.6%)	0	0	0
/METHOXYPHENAMINE HYDROCHLORIDE				
/SODIUM CITRATE				
DIHYDROCODEINE	0	0	0	0
DIHYDROCODEINE BITARTRATE	2 (1.6%)	2 (1.5%)	0	0
DIHYDROCODEINE THIOCYANATE	0	2 (1.5%)	0	0
/LIQUORICE LIQUID EXTRACT				
/PRIMULA FLUID EXTRACT				
/THYME EXTRACT				
ERDOSTEINE	4 (3.2%)	1 (0.7%)	1 (0.7%)	0
EUCALYPTUS OIL	0	0	1 (0.7%)	0
/PINUS SILVESTRIS OIL				
/ROSEMARY OIL				
/TERPINEOL				
/THYME OIL				
FUSAFUNGINE	3 (2.4%)	3 (2.2%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
GUAIFENESIN	0	0	0	0
GUAIFENESIN /OXOMEMAZINE	2 (1.6%)	0	1 (0.7%)	0
/PARACETAMOL				
/SODIUM BENZOATE				
HELICIDINE	1 (0.8%)	1 (0.7%)	0	0
HERBAL EXTRACTS NOS	0	0	0	0
IPECACUANHA	0	0	0	1 (3.3%)
/SQUILL				
LETOSTEINE	0	0	1 (0.7%)	0
MYRTOL	0	1 (0.7%)	0	0
NOSCAPINE	1 (0.8%)	0	0	0
NOSCAPINE	0	0	1 (0.7%)	0
/POLYSORBATE 85 (TWEEN 85)				
/PROMETHAZINE				
NOSCAPINE HYDROCHLORIDE	1 (0.8%)	0	0	0
PHOLCODINE	0	1 (0.7%)	0	1 (3.3%)
POTASSIUM IODIDE	1 (0.8%)	0	0	0
ZIPEPROL DIHYDROCHLORIDE	0	0	0	0
NASAL PREP	21 (16.9%)	27 (19.9%)	19 (13.7%)	2 (6.7%)
ACETYLCYSTEINE	1 (0.8%)	1 (0.7%)	6 (4.3%)	0
/BENZALKONIUM CHLORIDE				
/TUAMINOHEPTANE SULFATE				
AMYLEINE HYDROCHLORIDE	0	0	0	0
/FRAMYCETIN SULFATE				
/NAPHAZOLINE NITRATE				
ANTAZOLINE SULFATE	0	0	0	1 (3.3%)
/XYLOMETAZOLINE HYDROCHLORIDE				
BECLOMETASONE	3 (2.4%)	0	3 (2.2%)	0
BECLOMETASONE DIPROPIONATE	5 (4.0%)	6 (4.4%)	4 (2.9%)	1 (3.3%)
BUDESONIDE	2 (1.6%)	5 (3.7%)	2 (1.4%)	0

- 404 -

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BRL-049653/RSD-
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Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CETRIMONIUM BROMIDE	2 (1.6%)	0	1 (0.7%)	0
/NAPHAZOLINE NITRATE				
/PHENYLEPHRINE HYDROCHLORIDE				
/PREDNISOLONE				
CHLORHEXIDINE DIACETATE	1 (0.8%)	0	1 (0.7%)	0
/TIXOCORTOL PIVALATE				
CROMOGLICATE SODIUM	1 (0.8%)	3 (2.2%)	2 (1.4%)	0
CROMOGLICATE SODIUM	0	1 (0.7%)	0	0
/REPROTEROL HYDROCHLORIDE				
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	1 (0.7%)	0
/NEOMYCIN SULFATE				
/PHENYLEPHRINE HYDROCHLORIDE				
/POLYMYXIN B SULFATE				
EPHEDRINE	0	0	1 (0.7%)	0
ETHANOLAMINE TENOATE	1 (0.8%)	0	0	0
/FRAMYCETIN SULFATE				
FENOXAZOLINE HYDROCHLORIDE	0	0	1 (0.7%)	0
FLUNISOLIDE	1 (0.8%)	0	1 (0.7%)	0
FLUTICASONE	0	1 (0.7%)	2 (1.4%)	0
/SALMETEROL				
FLUTICASONE PROPIONATE	0	4 (2.9%)	1 (0.7%)	0
FRAMYCETIN SULFATE	1 (0.8%)	0	1 (0.7%)	0
FRAMYCETIN SULFATE	0	0	0	0
/HYDROCORTISONE				
FRAMYCETIN SULFATE	1 (0.8%)	0	0	0
/NAPHAZOLINE NITRATE				
/PREDNISOLONE ACETATE				
IBUPROFEN	3 (2.4%)	3 (2.2%)	3 (2.2%)	0
/PSEUDOEPHEDRINE HYDROCHLORIDE				
MOMETASONE FUROATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
NASAL SPRAY	1 (0.8%)	0	0	0
NEOMYCIN SULFATE	1 (0.8%)	0	0	0
/TIXOCORTOL PIVALATE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
PARACETAMOL	0	0	0	0
/PHENYLPROPANOLAMINE HYDROCHLORIDE				
/PHENYLTOLOXAMINE CITRATE				
PHENYLEPHRINE	0	0	1 (0.7%)	0
PREDNISOLONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE-FENOXAZOLINE COMPOUND	0	0	1 (0.7%)	0
PREDNISONE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
PSEUDOEPHEDRINE	0	0	0	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TRIPROLIDINE HYDROCHLORIDE				
SODIUM CHLORIDE	1 (0.8%)	0	0	0
TIXOCORTOL PIVALATE	1 (0.8%)	1 (0.7%)	0	0
TRIAMCINOLONE ACETONIDE	0	3 (2.2%)	0	0
OTHER	1 (0.8%)	1 (0.7%)	0	0
OXYGEN	1 (0.8%)	1 (0.7%)	0	0
SYSTEMIC ANTIHISTAMINES	9 (7.3%)	10 (7.4%)	15 (10.8%)	3 (10.0%)
ALIMEMAZINE TARTRATE	0	1 (0.7%)	0	0
AZELASTINE	0	0	1 (0.7%)	0
BROMPHENIRAMINE MALEATE	1 (0.8%)	0	0	0
BUCLIZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
/CODEINE PHOSPHATE				
/PARACETAMOL				
BUZEPIDE METIODIDE	0	0	1 (0.7%)	0
/CLOCINIZINE HYDROCHLORIDE				
/PHENYLPROPANOLAMINE HYDROCHLORIDE				
CETIRIZINE	0	0	1 (0.7%)	0
/PSEUDOEPHEDRINE				
CETIRIZINE HYDROCHLORIDE	3 (2.4%)	2 (1.5%)	4 (2.9%)	0
CHLORPHENAMINE MALEATE	0	0	1 (0.7%)	1 (3.3%)
CLEMASTINE	0	0	1 (0.7%)	0
CLEMASTINE FUMARATE	1 (0.8%)	0	0	0
CYCLIZINE	0	0	0	0
DEXCHLORPHENIRAMINE MALEATE	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DIMENHYDRINATE	0	1 (0.7%)	0	0
DIMETINDENE MALEATE	0	0	1 (0.7%)	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.8%)	0	0	1 (3.3%)
FEXOFENADINE HYDROCHLORIDE	0	0	2 (1.4%)	0
LORATADINE	2 (1.6%)	7 (5.1%)	3 (2.2%)	1 (3.3%)
LORATADINE	0	0	1 (0.7%)	0
/PSEUDOEPHEDRINE SULFATE				
MIZOLASTINE	0	0	1 (0.7%)	0
NOSCAPINE	0	0	1 (0.7%)	0
/POLYSORBATE 85 (TWEEN 85)				
/PROMETHAZINE				
OXATOMIDE	1 (0.8%)	0	0	0
PHENIRAMINE AMINOSALICYLATE	0	0	0	0
PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	0	0	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TRIPROLIDINE HYDROCHLORIDE				
TERFENADINE	0	0	1 (0.7%)	0
THROAT PREP	4 (3.2%)	5 (3.7%)	3 (2.2%)	0
ALUMINIUM POTASSIUM SULFATE	1 (0.8%)	0	1 (0.7%)	0
/LIDOCAINE HYDROCHLORIDE				
/PROPYLPARABEN				
AMYLMETACRESOL	0	0	0	0
/DICHLOROBENZYL ALCOHOL				
BACITRACIN ZINC	1 (0.8%)	2 (1.5%)	0	0
/CHLORMETHINE HYDROCHLORIDE				
/PENTOSAN POLYSULFATE				
/TIXOCORTOL PIVALATE				
/TRIENTINE				
BACITRACIN ZINC	1 (0.8%)	0	0	0
/TIXOCORTOL PIVALATE				
BICLOTYMOL	0	0	2 (1.4%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
CETYLPRIDINIUM CHLORIDE	1 (0.8%)	1 (0.7%)	0	0
/CHLOROBUTANOL				
/EUGENOL				
/VERATROLE				
CHLOROQUINE	0	0	0	0
LIDOCAINE	0	1 (0.7%)	0	0
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
SENSORY ORGANS				
OPHTALMOL/OTOLOGICAL PREP	5 (4.0%)	12 (8.8%)	9 (6.5%)	1 (3.3%)
BACITRACIN	1 (0.8%)	0	0	0
/NEOMYCIN SULFATE				
BENZALKONIUM CHLORIDE	0	0	0	0
/DICHLORALPHENAZONE				
/DIMETICONE, ACTIVATED				
/HYDROCORTISONE				
/ISOMETHEPTENE				
/NYSTATIN				
/PARACETAMOL				
CHLORAMPHENICOL	0	0	0	0
/COLISTIN MESILATE SODIUM				
/HYDROCORTISONE ACETATE				
DEXAMETHASONE	0	2 (1.5%)	0	0
DEXAMETHASONE	0	0	1 (0.7%)	0
/FRAMYCETIN				
DEXAMETHASONE	0	0	0	1 (3.3%)
/FRAMYCETIN SULFATE				
/GRAMICIDIN				
DEXAMETHASONE SODIUM PHOSPHATE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (0.7%)	1 (0.7%)	0
/NEOMYCIN SULFATE				
ERYTHROMYCIN	0	3 (2.2%)	3 (2.2%)	0
HEXAMIDINE ISETHIONATE	0	0	1 (0.7%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
HYDROCORTISONE ACETATE	0	1 (0.7%)	0	0
/NEOMYCIN SULFATE				
HYDROCORTISONE ACETATE	0	1 (0.7%)	0	0
/OXYTETRACYCLINE HYDROCHLORIDE				
/POLYMYXIN B SULFATE				
PREDNISOLONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.8%)	0	1 (0.7%)	0
TETRACYCLINE	1 (0.8%)	0	0	0
OPHTHALMOLOGICALS	36 (29.0%)	44 (32.4%)	43 (30.9%)	2 (6.7%)
ACETAZOLAMIDE	0	0	0	0
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	0	0	1 (0.7%)	0
/AMINO ACIDS NOS				
/PYRIDOXINE HYDROCHLORIDE				
ATROPINE	0	1 (0.7%)	0	0
BENZALKONIUM CHLORIDE	0	0	1 (0.7%)	0
/TRIMAGNESIUM SPAGLUMATE				
BETAMETHASONE	2 (1.6%)	2 (1.5%)	6 (4.3%)	0
BETAXOLOL	1 (0.8%)	0	2 (1.4%)	0
BETAXOLOL HYDROCHLORIDE	3 (2.4%)	0	1 (0.7%)	0
BORIC ACID	0	1 (0.7%)	0	0
/CAMPHOR				
/EPHEDRINE HYDROCHLORIDE				
/PEPPERMINT OIL				
/RETINOL PALMITATE				
/SODIUM BORATE				
/SODIUM CITRATE				
/ZINC SULFATE				
BORIC ACID	1 (0.8%)	0	0	0
/PHENYLEPHRINE HYDROCHLORIDE				
/SODIUM BORATE				

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BORIC ACID	0	1 (0.7%)	0	0
/SODIUM BORATE				
/SODIUM CHLORIDE				
/TETRYZOLINE HYDROCHLORIDE				
BRIMONIDINE TARTRATE	0	0	2 (1.4%)	0
CARTEOLOL HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
CETHEXONIUM CHLORIDE	0	0	2 (1.4%)	0
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
CHLORAMPHENICOL	1 (0.8%)	0	0	0
/DEXAMETHASONE SODIUM PHOSPHATE				
CINCHOCAINE HYDROCHLORIDE	0	1 (0.7%)	0	0
CIPROFLOXACIN	0	1 (0.7%)	0	0
CIPROFLOXACIN HYDROCHLORIDE	0	1 (0.7%)	1 (0.7%)	0
CLONIDINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	0	0
CROMOGLICATE SODIUM	1 (0.8%)	3 (2.2%)	2 (1.4%)	0
DEXAMETHASONE	0	2 (1.5%)	0	0
DEXAMETHASONE	0	1 (0.7%)	0	2 (6.7%)
/NEOMYCIN SULFATE				
/POLYMYXIN B SULFATE				
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	1 (0.7%)	0
/NEOMYCIN SULFATE				
/POLYMYXIN B SULFATE				
DEXAMETHASONE SODIUM PHOSPHATE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
DEXPANTHENOL	0	1 (0.7%)	0	0
DEXTRAN	1 (0.8%)	0	0	0
/HYPROMELLOSE				
DICLOFENAC SODIUM	10 (8.1%)	17 (12.5%)	10 (7.2%)	0
DORZOLAMIDE HYDROCHLORIDE	0	2 (1.5%)	1 (0.7%)	1 (3.3%)
DORZOLAMIDE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TIMOLOL MALEATE				
EPHEDRINE	0	0	1 (0.7%)	0
ETHANOLAMINE TENOATE	1 (0.8%)	0	0	0
/FRAMYCETIN SULFATE				
EYE DROPS, NOS	0	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
FLUORESCEIN	0	1 (0.7%)	0	0
FRAMYCETIN SULFATE	1 (0.8%)	0	1 (0.7%)	0
FUSIDIC ACID	1 (0.8%)	0	3 (2.2%)	0
GENTAMICIN SULFATE	2 (1.6%)	0	1 (0.7%)	0
HEPARIN	0	3 (2.2%)	1 (0.7%)	0
HYDROCORTISONE	2 (1.6%)	0	0	0
HYDROCORTISONE BUTYRATE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
INDOMETACIN	0	7 (5.1%)	3 (2.2%)	0
ISOSORBIDE	0	1 (0.7%)	0	0
KETOROLAC TROMETHAMINE	0	1 (0.7%)	0	0
LATANOPROST	1 (0.8%)	0	1 (0.7%)	0
LEVOBUNOLOL HYDROCHLORIDE	0	0	1 (0.7%)	0
LIDOCAINE	0	1 (0.7%)	0	0
LIDOCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.7%)	0	0
METHYLPREDNISOLONE	1 (0.8%)	0	0	0
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
MYRTILLUS	0	1 (0.7%)	0	0
/TOCOPHEROL				
OFLOXACIN	1 (0.8%)	6 (4.4%)	4 (2.9%)	0
OXYTETRACYCLINE	0	1 (0.7%)	0	0
OXYTETRACYCLINE DIHYDRATE	0	0	0	0
PILOCARPINE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
PILOCARPINE HYDROCHLORIDE	0	1 (0.7%)	0	0
/TIMOLOL MALEATE				
POTASSIUM IODIDE	1 (0.8%)	0	0	0
PREDNISOLONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.8%)	0	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.8%)	0	0	0
TETRACYCLINE	1 (0.8%)	0	0	0
TIMOLOL	0	0	1 (0.7%)	0
TIMOLOL MALEATE	3 (2.4%)	2 (1.5%)	2 (1.4%)	0
TRIAMCINOLONE ACETONIDE	0	3 (2.2%)	0	0
TRIAMCINOLONE HEXACETONIDE	0	0	1 (0.7%)	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
TROPICAMIDE	0	1 (0.7%)	1 (0.7%)	0
ZINC SULFATE	0	0	1 (0.7%)	0
OTOLOGICALS	5 (4.0%)	5 (3.7%)	5 (3.6%)	0
CAPRYLIC ACID	1 (0.8%)	0	0	0
/TROLAMINE CAPRYLATE				
CHLORAMPHENICOL	1 (0.8%)	0	1 (0.7%)	0
DEXAMETHASONE SODIUM METASULFOBENZOATE	0	0	1 (0.7%)	0
/NEOMYCIN SULFATE				
/POLYMYXIN B SULFATE				
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (0.7%)	0	0
/NYSTATIN				
/OXYTETRACYCLINE HYDROCHLORIDE				
/POLYMYXIN B SULFATE				
GENTAMICIN SULFATE	0	1 (0.7%)	0	0
/PREDNISOLONE ACETATE				
HYDROCORTISONE	1 (0.8%)	0	0	0
/NEOMYCIN SULFATE				
/POLYMYXIN B SULFATE				
HYDROCORTISONE BUTYRATE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
SODIUM BICARBONATE	0	0	1 (0.7%)	0
SYSTEMIC HORMONAL				
CALCIUM HOMEOSTASIS	1 (0.8%)	1 (0.7%)	0	0
CALCITONIN	1 (0.8%)	0	0	0
CALCITONIN ACETATE	0	1 (0.7%)	0	0
CORTICOSTEROIDS	12 (9.7%)	17 (12.5%)	13 (9.4%)	0
AMCINONIDE	1 (0.8%)	0	0	0
BETAMETHASONE	2 (1.6%)	2 (1.5%)	6 (4.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.7%)	0	0
BETAMETHASONE SODIUM PHOSPHATE	0	0	0	0
/NEOMYCIN SULFATE				
CORTICOSTEROIDS	1 (0.8%)	0	1 (0.7%)	0
CORTIVAZOL	0	2 (1.5%)	2 (1.4%)	0
DEXAMETHASONE	0	2 (1.5%)	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
DEXAMETHASONE SODIUM PHOSPHATE	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
HYDROCORTISONE	2 (1.6%)	0	0	0
HYDROCORTISONE BUTYRATE	2 (1.6%)	3 (2.2%)	2 (1.4%)	0
LIDOCAINE	0	0	0	0
/METHYLPREDNISOLONE ACETATE				
METHYLPREDNISOLONE	1 (0.8%)	0	0	0
METHYLPREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
PREDNISOLONE	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
PREDNISOLONE SODIUM SUCCINATE	0	0	1 (0.7%)	0
PREDNISOLONE SODIUM SULFOBENZOATE	1 (0.8%)	0	1 (0.7%)	0
PREDNISONE	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
TRIAMCINOLONE ACETONIDE	0	3 (2.2%)	0	0
TRIAMCINOLONE HEXACETONIDE	0	0	1 (0.7%)	0
THYROID THERAPY	11 (8.9%)	10 (7.4%)	6 (4.3%)	0
CARBIMAZOLE	0	1 (0.7%)	0	0
LEVOTHYROXINE	0	0	1 (0.7%)	0
LEVOTHYROXINE	0	1 (0.7%)	0	0
/LIOETHYRONINE				
/POTASSIUM IODIDE				
LEVOTHYROXINE SODIUM	8 (6.5%)	6 (4.4%)	4 (2.9%)	0
LEVOTHYROXINE SODIUM	0	0	0	0
/LIOETHYRONINE SODIUM				
LEVOTHYROXINE SODIUM	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
/POTASSIUM IODIDE				
POTASSIUM IODIDE	1 (0.8%)	0	0	0
THYROXINE	2 (1.6%)	1 (0.7%)	0	0
UNCLASSIFIABLE	0	1 (0.7%)	0	0
UNCLASSIFIABLE				
UNKNOWN MEDICATION	0	1 (0.7%)	0	0
VARIOUS				
ALL OTHER NON-THERAP PROD	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
BLOOD CELLS, PACKED HUMAN	1 (0.8%)	0	0	0

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
BLOOD, WHOLE	0	0	0	0
HYPROMELLOSE	0	0	1 (0.7%)	0
MACROGOL	0	1 (0.7%)	0	0
POLOXAMER	0	0	1 (0.7%)	0
ALL OTHER THERAP PROD	12 (9.7%)	6 (4.4%)	3 (2.2%)	2 (6.7%)
ACONITUM	0	1 (0.7%)	0	0
/BRYONIA				
/EUPATORIUM PERFOLIATUM				
/LACHESIS				
/PHOSPHORUS				
ADENOSINE PHOSPHATE, SODIUM SALT	0	0	1 (0.7%)	0
/DEOXYRIBONUCLEIC ACID				
ALENDRONATE	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ALUMINIUM CHLOROHYDRATE	1 (0.8%)	0	0	0
ARNICA	1 (0.8%)	0	0	0
/HORSE CHESTNUT EXTRACT				
/HYOSCYAMUS DRY EXTRACT				
/SCOPARIUM				
CALCIUM LACTATE	0	0	0	0
/CIMICIFUGA				
/MAGNESIUM HYPOSULFITE				
/OLEOSACCHARUM OF MARJOLAIN				
CHONDROITIN SULFURIC ACID	1 (0.8%)	1 (0.7%)	0	0
COPPER GLUCONATE	1 (0.8%)	0	0	0
/GOLD GLUCONATE				
/SILVER GLUCONATE				
DISODIUM INOSINATE	0	1 (0.7%)	0	0
ETIDRONATE DISODIUM	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
GARLIC	0	0	0	1 (3.3%)
HOMEOPATHIC PREPARATIONS	1 (0.8%)	0	0	0
HOMEOPATHICS NOS	2 (1.6%)	0	0	0
HYPERICUM EXTRACT	1 (0.8%)	0	0	0
IPECACUANHA	0	0	0	1 (3.3%)
/SQUILL				

- 414 -

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100TV9/1/CPMS-009

Data Source Table 13.5.2c

Summary of Concomitant Medications (Continue or Start During Open Label Study)
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Concomitant Medications	114 (91.9%)	129 (94.9%)	128 (92.1%)	29 (96.7%)
ATC Classification Level 1				
ATC Classification Level 2				
Generic Term				
NICOTINE RESIN	1 (0.8%)	0	0	0
OXYGEN	1 (0.8%)	1 (0.7%)	0	0
POTASSIUM IODIDE	1 (0.8%)	0	0	0
ALLERGENS	1 (0.8%)	0	0	0
POISON IVY EXTRACT	1 (0.8%)	0	0	0
DIAGNOSTIC AGENTS	0	0	0	0
GLUCOSE	0	0	0	0
GENERAL NUTRIENTS	2 (1.6%)	0	0	0
BETA-ALANINE	1 (0.8%)	0	0	0
GLUCOSE	0	0	0	0
WHEAT GERM	1 (0.8%)	0	0	0
INVESTIGATIONAL DRUG	0	0	0	1 (3.3%)
HEPATITIS A VACCINE	0	0	0	1 (3.3%)

Data Source Table 13.6.1a

Summary of Patient Exposure to Study Treatment During the Open Label Study
All Patients Who Entered Study 009

Patient Exposure (days)	2bd Comb Total (N=229)	4bd Mono Total (N=430)
<=28	2 (0.9%)	11 (2.6%)
29 - 90	9 (3.9%)	19 (4.4%)
91 - 180	6 (2.6%)	14 (3.3%)
181 - 270	13 (5.7%)	18 (4.2%)
271 - 360	19 (8.3%)	28 (6.5%)
361 - 450	15 (6.6%)	32 (7.4%)
451 - 540	8 (3.5%)	15 (3.5%)
541 - 630	14 (6.1%)	15 (3.5%)
631 - 720	12 (5.2%)	27 (6.3%)
721 - 810	16 (7.0%)	20 (4.7%)
811 - 900	9 (3.9%)	46 (10.7%)
901 - 990	11 (4.8%)	87 (20.2%)
991 - 1080	31 (13.5%)	81 (18.8%)
1081 - 1170	20 (8.7%)	17 (4.0%)
1171 - 1260	23 (10.0%)	0
1261 - 1350	19 (8.3%)	0
1351 - 1440	2 (0.9%)	0
>1440	0	0
Mean Duration	772.50	710.08
SD	392.19	337.39
Median	819.00	864.00
Minimum	2.00	1.00
Maximum	1373.00	1134.00

Data Source Table 13.6.1b

Summary of Patient Exposure to Study Treatment During the Open Label Study
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Patient Exposure (days)	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
<=28	1 (1.6%)	1 (1.3%)	0
29 - 90	2 (3.3%)	1 (1.3%)	6 (6.7%)
91 - 180	2 (3.3%)	1 (1.3%)	3 (3.3%)
181 - 270	1 (1.6%)	5 (6.4%)	7 (7.8%)
271 - 360	3 (4.9%)	11 (14.1%)	5 (5.6%)
361 - 450	4 (6.6%)	6 (7.7%)	5 (5.6%)
451 - 540	3 (4.9%)	2 (2.6%)	3 (3.3%)
541 - 630	4 (6.6%)	4 (5.1%)	6 (6.7%)
631 - 720	2 (3.3%)	5 (6.4%)	5 (5.6%)
721 - 810	7 (11.5%)	5 (6.4%)	4 (4.4%)
811 - 900	2 (3.3%)	2 (2.6%)	5 (5.6%)
901 - 990	1 (1.6%)	6 (7.7%)	4 (4.4%)
991 - 1080	10 (16.4%)	7 (9.0%)	14 (15.6%)
1081 - 1170	5 (8.2%)	5 (6.4%)	10 (11.1%)
1171 - 1260	6 (9.8%)	12 (15.4%)	5 (5.6%)
1261 - 1350	8 (13.1%)	4 (5.1%)	7 (7.8%)
1351 - 1440	0	1 (1.3%)	1 (1.1%)
>1440	0	0	0
Mean Duration	818.7	758.6	753.2
SD	387.88	390.97	397.93
Median	824.0	769.5	822.5
Minimum	2	17	32
Maximum	1345	1373	1351

Data Source Table 13.6.1c

Summary of Patient Exposure to Study Treatment During the Open Label Study
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Patient Exposure (days)	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
<=28	4 (3.2%)	2 (1.5%)	4 (2.9%)	1 (3.3%)
29 - 90	3 (2.4%)	3 (2.2%)	5 (3.6%)	8 (26.7%)
91 - 180	0	1 (0.7%)	11 (7.9%)	2 (6.7%)
181 - 270	5 (4.0%)	6 (4.4%)	5 (3.6%)	2 (6.7%)
271 - 360	5 (4.0%)	8 (5.9%)	9 (6.5%)	5 (16.7%)
361 - 450	7 (5.6%)	11 (8.1%)	13 (9.4%)	1 (3.3%)
451 - 540	4 (3.2%)	6 (4.4%)	3 (2.2%)	2 (6.7%)
541 - 630	2 (1.6%)	5 (3.7%)	7 (5.0%)	1 (3.3%)
631 - 720	12 (9.7%)	10 (7.4%)	3 (2.2%)	2 (6.7%)
721 - 810	6 (4.8%)	5 (3.7%)	8 (5.8%)	1 (3.3%)
811 - 900	15 (12.1%)	21 (15.4%)	8 (5.8%)	2 (6.7%)
901 - 990	34 (27.4%)	24 (17.6%)	28 (20.1%)	1 (3.3%)
991 - 1080	25 (20.2%)	27 (19.9%)	28 (20.1%)	1 (3.3%)
1081 - 1170	2 (1.6%)	7 (5.1%)	7 (5.0%)	1 (3.3%)
1171 - 1260	0	0	0	0
1261 - 1350	0	0	0	0
1351 - 1440	0	0	0	0
>1440	0	0	0	0
Mean Duration	769.6	752.9	686.9	391.7
SD	301.55	305.56	358.86	336.82
Median	896.0	874.0	849.0	346.5
Minimum	6	1	19	21
Maximum	1088	1134	1120	1098

BRL 49653C/009

Data Source Table 13.6.2

First and Last Date of Study Medication During the Open Label Study

Date	PIDs for Patients Taking Study Medication on This Day

This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the Sponsor Clinical Study Register.

BRL 49653C/009

Data Source Table 13.6.3a

Summary of Overall Compliance During the Open Label Study
All Patients Who Entered Study 009

Drug	Percentage Compliance	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Study Medication	< 50	0	2 (0.5%)
	50 - < 80	1 (0.4%)	13 (3.0%)
	80 - < 100	179 (78.2%)	325 (75.6%)
	100 - 120	48 (21.0%)	81 (18.8%)
	> 120	0	1 (0.2%)
	Missing	1 (0.4%)	8 (1.9%)

Data Source Table 13.6.3b

Summary of Overall Compliance During the Open Label Study
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Drug	Percentage Compliance	2bd Comb Total		
		015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Study Medication	< 50	0	0	0
	50 - < 80	1 (1.6%)	0	0
	80 - < 100	48 (78.7%)	61 (78.2%)	70 (77.8%)
	100 - 120	12 (19.7%)	16 (20.5%)	20 (22.2%)
	> 120	0	0	0
	Missing	0	1 (1.3%)	0

Data Source Table 13.6.3c

Summary of Overall Compliance During the Open Label Study
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Drug	Percentage Compliance	4bd Mono Total			
		020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Study Medication	< 50	1 (0.8%)	0	0	1 (3.3%)
	50 - < 80	1 (0.8%)	4 (2.9%)	3 (2.2%)	5 (16.7%)
	80 - < 100	92 (74.2%)	109 (80.1%)	107 (77.0%)	16 (53.3%)
	100 - 120	27 (21.8%)	21 (15.4%)	28 (20.1%)	5 (16.7%)
	> 120	1 (0.8%)	0	0	0
	Missing	2 (1.6%)	2 (1.5%)	1 (0.7%)	3 (10.0%)

14 Source Tables: Efficacy Results

	Page
Table 14.1Aa Summary Statistics for Efficacy Variables at Each Visit, All Patients Who Entered Study 009	424
Table 14.1Ab Summary Statistics for Efficacy Variables at Each Visit, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension.	479
Table 14.1Ac Summary Statistics for Efficacy Variables at Each Visit, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension.	534

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	229	430
Mean	9.07	7.98
SD	1.091	1.274
Median	8.80	7.90
Minimum	7.3	4.8
Maximum	13.0	13.8
Open Label Baseline		
Number of patients with values	229	428
Mean	8.42	7.38
SD	1.221	1.301
Median	8.30	7.10
Minimum	5.4	3.9
Maximum	12.7	11.5
Month 0		
Number of patients with values	23	22
Mean	8.33	7.29
SD	1.237	1.170
Median	8.00	7.05
Minimum	6.8	6.0
Maximum	10.8	10.6
Month 1		
Number of patients with values	220	410
Mean	8.47	7.57
SD	1.228	1.354
Median	8.40	7.40
Minimum	5.3	4.4
Maximum	12.4	13.9
Month 2		
Number of patients with values	220	401
Mean	8.31	7.57
SD	1.192	1.327
Median	8.20	7.30
Minimum	5.3	4.5
Maximum	12.1	12.4

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	217	397
Mean	8.18	7.55
SD	1.092	1.338
Median	8.00	7.30
Minimum	5.6	5.0
Maximum	11.5	15.8
Month 6		
Number of patients with values	209	384
Mean	8.24	7.41
SD	1.143	1.225
Median	8.30	7.20
Minimum	5.2	4.8
Maximum	12.6	12.5
Month 9		
Number of patients with values	202	375
Mean	8.35	7.38
SD	1.228	1.148
Median	8.20	7.20
Minimum	5.6	4.9
Maximum	11.7	11.6
Month 12		
Number of patients with values	184	342
Mean	8.36	7.42
SD	1.270	1.226
Median	8.20	7.20
Minimum	5.7	4.9
Maximum	11.9	11.6

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	173	314
Mean	8.42	7.38
SD	1.303	1.224
Median	8.40	7.10
Minimum	5.6	4.8
Maximum	12.2	12.0
Month 18		
Number of patients with values	157	293
Mean	8.31	7.32
SD	1.239	1.205
Median	8.30	7.00
Minimum	5.8	4.6
Maximum	12.0	12.2
Month 21		
Number of patients with values	153	279
Mean	8.39	7.28
SD	1.278	1.143
Median	8.20	7.10
Minimum	5.9	4.4
Maximum	12.5	10.5
Month 24		
Number of patients with values	129	252
Mean	8.36	7.39
SD	1.277	1.187
Median	8.30	7.15
Minimum	5.7	4.7
Maximum	12.3	12.1

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	122	226
Mean	8.37	7.39
SD	1.359	1.200
Median	8.30	7.10
Minimum	6.1	4.9
Maximum	14.0	12.6
Month 30		
Number of patients with values	107	180
Mean	8.43	7.34
SD	1.471	1.072
Median	8.30	7.10
Minimum	5.1	5.3
Maximum	12.6	10.9
Month 33		
Number of patients with values	94	156
Mean	8.44	7.23
SD	1.320	1.159
Median	8.25	7.00
Minimum	6.1	4.8
Maximum	11.9	11.1
Month 36		
Number of patients with values	84	78
Mean	8.31	7.23
SD	1.264	1.172
Median	8.20	6.95
Minimum	6.1	5.4
Maximum	12.9	11.0

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	50	16
Mean	8.37	6.82
SD	1.326	0.947
Median	8.25	6.75
Minimum	6.2	5.6
Maximum	12.2	9.4
Month 42		
Number of patients with values	32	0
Mean	8.42	
SD	1.264	
Median	8.30	
Minimum	6.6	
Maximum	12.1	
Month 45		
Number of patients with values	20	0
Mean	7.74	
SD	0.861	
Median	7.45	
Minimum	6.6	
Maximum	9.1	
Month 48		
Number of patients with values	2	0
Mean	8.35	
SD	2.192	
Median	8.35	
Minimum	6.8	
Maximum	9.9	

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	229	430
Mean	197.1	184.6
SD	37.42	47.96
Median	198.0	173.0
Minimum	93	102
Maximum	307	407
Open Label Baseline		
Number of patients with values	229	430
Mean	170.6	152.8
SD	41.59	40.46
Median	171.0	146.0
Minimum	66	61
Maximum	280	292
Month 0		
Number of patients with values	22	21
Mean	182.0	153.0
SD	43.65	45.89
Median	184.5	137.0
Minimum	104	89
Maximum	280	252
Month 1		
Number of patients with values	220	411
Mean	163.8	157.1
SD	40.91	47.88
Median	164.0	145.0
Minimum	71	80
Maximum	341	521
Month 2		
Number of patients with values	218	402
Mean	158.9	149.6
SD	39.90	38.73
Median	157.0	141.0
Minimum	71	73
Maximum	287	284

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	217	397
Mean	161.2	148.3
SD	37.69	39.72
Median	162.0	139.0
Minimum	68	79
Maximum	250	298
Month 6		
Number of patients with values	208	381
Mean	160.9	141.5
SD	37.55	36.67
Median	160.0	132.0
Minimum	70	80
Maximum	307	312
Month 9		
Number of patients with values	200	374
Mean	165.8	140.8
SD	39.18	34.51
Median	169.0	136.0
Minimum	80	64
Maximum	271	291
Month 12		
Number of patients with values	182	343
Mean	164.2	141.9
SD	43.39	35.39
Median	164.0	136.0
Minimum	71	79
Maximum	320	304

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	171	320
Mean	161.8	140.0
SD	43.94	36.11
Median	161.0	132.0
Minimum	75	30
Maximum	286	277
Month 18		
Number of patients with values	154	295
Mean	161.2	142.1
SD	39.57	39.15
Median	160.0	134.0
Minimum	61	61
Maximum	271	280
Month 21		
Number of patients with values	151	279
Mean	160.7	141.3
SD	41.88	37.83
Median	161.0	134.0
Minimum	62	68
Maximum	327	318
Month 24		
Number of patients with values	128	250
Mean	161.8	141.9
SD	48.85	37.92
Median	161.0	134.0
Minimum	50	70
Maximum	384	291

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	119	229
Mean	167.8	139.5
SD	50.12	35.94
Median	170.0	130.0
Minimum	20	61
Maximum	327	295
Month 30		
Number of patients with values	107	180
Mean	164.5	139.2
SD	44.93	34.16
Median	161.0	132.0
Minimum	68	82
Maximum	296	282
Month 33		
Number of patients with values	94	157
Mean	163.0	139.1
SD	40.15	36.55
Median	164.0	130.0
Minimum	66	71
Maximum	266	250
Month 36		
Number of patients with values	83	77
Mean	160.0	137.8
SD	40.05	38.49
Median	162.0	127.0
Minimum	82	82
Maximum	270	320

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	49	16
Mean	168.4	130.4
SD	44.90	24.49
Median	166.0	125.0
Minimum	86	95
Maximum	275	179
Month 42		
Number of patients with values	32	0
Mean	160.8	
SD	48.07	
Median	149.0	
Minimum	82	
Maximum	271	
Month 45		
Number of patients with values	18	0
Mean	145.9	
SD	45.42	
Median	146.0	
Minimum	73	
Maximum	245	
Month 48		
Number of patients with values	2	0
Mean	167.5	
SD	65.76	
Median	167.5	
Minimum	121	
Maximum	214	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	229	366
Mean	57.18	67.24
SD	35.504	49.969
Median	48.00	53.00
Minimum	7.0	8.0
Maximum	199.0	535.0
Open Label Baseline		
Number of patients with values	229	381
Mean	52.10	65.37
SD	32.033	63.112
Median	46.00	52.00
Minimum	6.6	3.6
Maximum	191.0	722.0
Month 0		
Number of patients with values	20	18
Mean	58.20	54.11
SD	29.237	28.419
Median	47.50	55.50
Minimum	27.0	17.0
Maximum	133.0	126.0
Month 1		
Number of patients with values	1	7
Mean	4.00	43.57
SD		16.652
Median	4.00	37.00
Minimum	4.0	25.0
Maximum	4.0	66.0
Month 2		
Number of patients with values	3	2
Mean	37.00	31.50
SD	17.059	9.192
Median	42.00	31.50
Minimum	18.0	25.0
Maximum	51.0	38.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	2	5
Mean	48.50	34.80
SD	10.607	10.402
Median	48.50	37.00
Minimum	41.0	23.0
Maximum	56.0	46.0
Month 6		
Number of patients with values	189	354
Mean	54.12	50.37
SD	32.764	39.435
Median	45.00	40.00
Minimum	9.3	3.9
Maximum	224.0	439.0
Month 9		
Number of patients with values	4	15
Mean	44.00	48.00
SD	21.182	38.389
Median	38.00	34.00
Minimum	26.0	13.0
Maximum	74.0	163.0
Month 12		
Number of patients with values	172	299
Mean	53.53	53.62
SD	29.420	44.876
Median	51.50	41.00
Minimum	6.9	9.6
Maximum	170.0	388.0

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	19	23
Mean	43.53	44.43
SD	29.058	30.846
Median	34.00	39.00
Minimum	12.0	7.9
Maximum	136.0	152.0
Month 18		
Number of patients with values	140	249
Mean	55.49	49.78
SD	38.462	38.443
Median	46.00	41.00
Minimum	10.0	9.3
Maximum	272.0	453.0
Month 21		
Number of patients with values	9	7
Mean	31.22	40.57
SD	8.829	12.381
Median	29.00	42.00
Minimum	22.0	24.0
Maximum	44.0	61.0
Month 24		
Number of patients with values	123	208
Mean	49.92	52.21
SD	32.390	52.061
Median	46.00	39.00
Minimum	3.0	1.7
Maximum	240.0	546.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	17	13
Mean	55.41	42.15
SD	34.455	21.866
Median	43.00	44.00
Minimum	20.0	10.0
Maximum	147.0	82.0
Month 30		
Number of patients with values	93	133
Mean	48.40	45.82
SD	26.121	26.866
Median	45.00	39.00
Minimum	11.0	10.0
Maximum	122.0	192.0
Month 33		
Number of patients with values	9	51
Mean	57.78	54.78
SD	19.117	79.590
Median	56.00	39.00
Minimum	35.0	15.0
Maximum	88.0	580.0
Month 36		
Number of patients with values	72	58
Mean	47.89	51.26
SD	24.513	37.374
Median	46.50	38.00
Minimum	2.3	11.0
Maximum	117.0	184.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	13
Mean	46.71	43.77
SD	27.402	26.449
Median	41.00	33.00
Minimum	18.0	14.0
Maximum	112.0	113.0
Month 42		
Number of patients with values	27	0
Mean	49.59	
SD	25.114	
Median	46.00	
Minimum	14.0	
Maximum	135.0	
Month 45		
Number of patients with values	14	0
Mean	52.50	
SD	22.762	
Median	46.00	
Minimum	23.0	
Maximum	95.0	
Month 48		
Number of patients with values	1	0
Mean	23.00	
SD		
Median	23.00	
Minimum	23.0	
Maximum	23.0	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	206	359
Mean	33.54	25.85
SD	100.175	88.047
Median	9.00	6.00
Minimum	2.0	1.0
Maximum	940.0	1390.0
Open Label Baseline		
Number of patients with values	228	397
Mean	34.78	30.30
SD	125.110	116.750
Median	7.00	6.00
Minimum	2.0	1.0
Maximum	1480.0	1880.0
Month 0		
Number of patients with values	23	26
Mean	112.04	100.35
SD	313.285	366.628
Median	19.00	12.50
Minimum	3.0	2.0
Maximum	1480.0	1880.0
Month 1		
Number of patients with values	2	16
Mean	25.50	23.81
SD	10.607	29.584
Median	25.50	11.00
Minimum	18.0	2.0
Maximum	33.0	94.0
Month 2		
Number of patients with values	3	2
Mean	40.67	11.00
SD	60.078	1.414
Median	8.00	11.00
Minimum	4.0	10.0
Maximum	110.0	12.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	1	4
Mean	68.00	21.25
SD		33.210
Median	68.00	5.50
Minimum	68.0	3.0
Maximum	68.0	71.0
Month 6		
Number of patients with values	174	333
Mean	55.64	33.12
SD	162.674	90.370
Median	12.00	6.00
Minimum	2.0	2.0
Maximum	1350.0	1120.0
Month 9		
Number of patients with values	6	13
Mean	11.83	22.15
SD	9.283	36.941
Median	9.50	6.00
Minimum	3.0	3.0
Maximum	25.0	127.0
Month 12		
Number of patients with values	155	306
Mean	49.01	104.88
SD	152.610	694.153
Median	12.00	8.00
Minimum	2.0	2.0
Maximum	1610.0	8640.0

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	15	25
Mean	59.80	36.40
SD	181.917	81.020
Median	8.00	6.00
Minimum	2.0	2.0
Maximum	715.0	380.0
Month 18		
Number of patients with values	132	247
Mean	41.68	52.87
SD	103.849	199.767
Median	13.00	8.00
Minimum	2.0	2.0
Maximum	943.0	2170.0
Month 21		
Number of patients with values	6	10
Mean	25.00	157.20
SD	33.347	468.356
Median	13.00	7.00
Minimum	3.0	2.0
Maximum	91.0	1490.0
Month 24		
Number of patients with values	108	211
Mean	45.65	51.49
SD	96.245	249.986
Median	13.00	9.00
Minimum	2.0	2.0
Maximum	544.0	3480.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	13	18
Mean	14.69	51.56
SD	15.724	158.693
Median	8.00	8.50
Minimum	3.0	2.0
Maximum	60.0	685.0
Month 30		
Number of patients with values	90	150
Mean	48.27	28.48
SD	99.955	70.669
Median	13.50	7.00
Minimum	2.0	2.0
Maximum	669.0	515.0
Month 33		
Number of patients with values	8	54
Mean	22.88	62.87
SD	21.616	135.244
Median	11.50	9.00
Minimum	3.0	2.0
Maximum	50.0	604.0
Month 36		
Number of patients with values	72	62
Mean	55.29	22.16
SD	113.850	39.531
Median	14.00	7.00
Minimum	2.0	2.0
Maximum	647.0	188.0

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	13	11
Mean	16.15	38.73
SD	29.955	86.810
Median	6.00	3.00
Minimum	2.0	2.0
Maximum	113.0	291.0
Month 42		
Number of patients with values	27	0
Mean	70.89	
SD	147.539	
Median	21.00	
Minimum	2.0	
Maximum	692.0	
Month 45		
Number of patients with values	16	0
Mean	65.69	
SD	115.395	
Median	18.50	
Minimum	4.0	
Maximum	449.0	
Month 48		
Number of patients with values	2	0
Mean	25.00	
SD	4.243	
Median	25.00	
Minimum	22.0	
Maximum	28.0	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	228	429
Mean	212.0	221.1
SD	36.83	42.36
Median	214.0	220.0
Minimum	106	114
Maximum	335	437
Open Label Baseline		
Number of patients with values	229	426
Mean	223.3	234.7
SD	42.02	49.59
Median	223.0	230.0
Minimum	73	126
Maximum	350	491
Month 0		
Number of patients with values	21	21
Mean	230.1	225.7
SD	37.44	58.24
Median	233.0	207.0
Minimum	149	143
Maximum	321	434
Month 1		
Number of patients with values	3	11
Mean	212.7	235.4
SD	25.77	44.24
Median	217.0	245.0
Minimum	185	157
Maximum	236	312
Month 2		
Number of patients with values	6	5
Mean	233.5	279.6
SD	53.82	30.15
Median	225.0	266.0
Minimum	178	246
Maximum	332	314

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	13	26
Mean	235.2	249.2
SD	44.43	51.23
Median	215.0	247.5
Minimum	191	120
Maximum	326	334
Month 6		
Number of patients with values	196	358
Mean	225.8	243.2
SD	45.27	51.99
Median	224.0	240.5
Minimum	95	121
Maximum	395	540
Month 9		
Number of patients with values	9	29
Mean	220.8	242.7
SD	27.62	58.03
Median	222.0	233.0
Minimum	181	123
Maximum	263	376
Month 12		
Number of patients with values	175	320
Mean	225.4	240.0
SD	42.12	49.30
Median	223.0	237.0
Minimum	81	122
Maximum	333	436

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	21	30
Mean	221.1	244.2
SD	39.09	60.03
Median	229.0	247.5
Minimum	107	136
Maximum	286	369
Month 18		
Number of patients with values	149	274
Mean	220.9	234.7
SD	43.67	49.13
Median	218.0	232.0
Minimum	90	128
Maximum	356	442
Month 21		
Number of patients with values	13	13
Mean	210.4	230.5
SD	48.19	44.22
Median	201.0	234.0
Minimum	143	153
Maximum	311	301
Month 24		
Number of patients with values	121	222
Mean	217.3	227.2
SD	44.30	43.28
Median	213.0	225.5
Minimum	90	128
Maximum	338	368

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	18	22
Mean	227.2	242.6
SD	40.73	53.47
Median	232.0	245.0
Minimum	125	163
Maximum	289	369
Month 30		
Number of patients with values	99	156
Mean	215.0	227.5
SD	51.84	49.94
Median	210.0	221.0
Minimum	88	112
Maximum	395	428
Month 33		
Number of patients with values	12	54
Mean	242.5	224.9
SD	40.60	42.86
Median	243.0	225.0
Minimum	182	136
Maximum	313	340
Month 36		
Number of patients with values	71	61
Mean	216.5	218.5
SD	41.87	41.38
Median	213.0	215.0
Minimum	92	134
Maximum	314	317

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	11
Mean	202.3	228.5
SD	38.59	52.39
Median	212.0	204.0
Minimum	139	159
Maximum	279	330
Month 42		
Number of patients with values	28	0
Mean	217.2	
SD	41.20	
Median	214.0	
Minimum	146	
Maximum	306	
Month 45		
Number of patients with values	14	0
Mean	211.6	
SD	35.62	
Median	199.5	
Minimum	148	
Maximum	263	
Month 48		
Number of patients with values	2	0
Mean	234.5	
SD	16.26	
Median	234.5	
Minimum	223	
Maximum	246	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	229	430
Mean	44.2	47.9
SD	13.13	15.11
Median	42.0	45.0
Minimum	24	17
Maximum	108	123
Open Label Baseline		
Number of patients with values	229	426
Mean	46.9	52.6
SD	13.42	14.88
Median	45.0	50.0
Minimum	24	18
Maximum	100	115
Month 0		
Number of patients with values	21	22
Mean	46.4	53.7
SD	14.73	12.17
Median	43.0	55.5
Minimum	24	29
Maximum	78	76
Month 1		
Number of patients with values	3	11
Mean	44.3	50.5
SD	15.37	16.35
Median	37.0	48.0
Minimum	34	25
Maximum	62	71
Month 2		
Number of patients with values	6	5
Mean	44.2	62.6
SD	6.71	22.35
Median	46.0	53.0
Minimum	34	45
Maximum	53	100

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	13	25
Mean	48.7	58.2
SD	10.11	17.99
Median	48.0	54.0
Minimum	30	37
Maximum	73	124
Month 6		
Number of patients with values	197	353
Mean	49.0	54.8
SD	13.50	15.54
Median	47.0	53.0
Minimum	16	15
Maximum	97	112
Month 9		
Number of patients with values	9	28
Mean	45.9	54.6
SD	11.35	11.67
Median	43.0	54.5
Minimum	36	32
Maximum	72	82
Month 12		
Number of patients with values	174	321
Mean	50.1	55.6
SD	13.33	15.60
Median	47.5	53.0
Minimum	28	17
Maximum	99	112

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	20	30
Mean	52.6	54.4
SD	13.79	17.88
Median	53.5	51.0
Minimum	25	20
Maximum	86	92
Month 18		
Number of patients with values	148	275
Mean	51.3	57.7
SD	14.43	16.61
Median	48.0	56.0
Minimum	29	22
Maximum	98	111
Month 21		
Number of patients with values	13	13
Mean	48.8	56.0
SD	10.43	18.11
Median	47.0	55.0
Minimum	34	24
Maximum	65	96
Month 24		
Number of patients with values	119	221
Mean	52.3	56.6
SD	14.98	14.81
Median	51.0	55.0
Minimum	27	20
Maximum	113	112

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	18	21
Mean	49.6	57.6
SD	11.22	23.49
Median	47.5	57.0
Minimum	33	21
Maximum	77	95
Month 30		
Number of patients with values	98	155
Mean	51.7	56.9
SD	14.57	15.23
Median	50.0	57.0
Minimum	26	20
Maximum	92	113
Month 33		
Number of patients with values	12	54
Mean	51.3	54.8
SD	12.59	19.20
Median	50.5	52.0
Minimum	36	27
Maximum	72	133
Month 36		
Number of patients with values	71	61
Mean	52.6	54.7
SD	14.84	14.41
Median	50.0	53.0
Minimum	30	23
Maximum	93	95

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	11
Mean	46.0	57.3
SD	12.43	16.82
Median	43.0	59.0
Minimum	28	30
Maximum	74	75
Month 42		
Number of patients with values	28	0
Mean	52.2	
SD	12.18	
Median	53.0	
Minimum	28	
Maximum	77	
Month 45		
Number of patients with values	14	0
Mean	49.9	
SD	11.24	
Median	48.5	
Minimum	34	
Maximum	78	
Month 48		
Number of patients with values	2	0
Mean	61.5	
SD	12.02	
Median	61.5	
Minimum	53	
Maximum	70	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	225	419
Mean	133.9	140.0
SD	31.54	33.99
Median	133.0	138.0
Minimum	38	60
Maximum	221	250
Open Label Baseline		
Number of patients with values	226	424
Mean	139.0	146.7
SD	35.98	38.52
Median	138.0	142.0
Minimum	25	60
Maximum	244	287
Month 0		
Number of patients with values	19	20
Mean	144.1	125.8
SD	38.87	28.33
Median	142.0	121.0
Minimum	79	65
Maximum	244	165
Month 1		
Number of patients with values	3	10
Mean	135.3	148.1
SD	21.39	33.82
Median	140.0	156.0
Minimum	112	88
Maximum	154	196
Month 2		
Number of patients with values	6	5
Mean	152.7	190.4
SD	40.58	28.64
Median	147.5	194.0
Minimum	110	154
Maximum	221	231

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	13	25
Mean	155.3	155.4
SD	40.52	52.17
Median	135.0	160.0
Minimum	108	42
Maximum	240	252
Month 6		
Number of patients with values	182	329
Mean	137.0	152.2
SD	37.57	42.63
Median	137.5	152.0
Minimum	35	58
Maximum	281	269
Month 9		
Number of patients with values	9	24
Mean	138.1	143.4
SD	29.34	50.46
Median	138.0	135.0
Minimum	81	50
Maximum	175	277
Month 12		
Number of patients with values	164	304
Mean	136.3	149.7
SD	34.71	42.82
Median	132.0	148.0
Minimum	29	42
Maximum	225	285

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	17	29
Mean	134.1	154.6
SD	36.61	57.15
Median	129.0	160.0
Minimum	48	58
Maximum	185	267
Month 18		
Number of patients with values	142	262
Mean	132.9	142.6
SD	37.32	41.35
Median	131.0	142.0
Minimum	29	52
Maximum	225	269
Month 21		
Number of patients with values	13	12
Mean	126.6	135.7
SD	42.74	34.65
Median	125.0	142.5
Minimum	71	88
Maximum	212	185
Month 24		
Number of patients with values	110	215
Mean	129.9	138.9
SD	39.61	39.43
Median	132.0	135.0
Minimum	25	63
Maximum	219	269

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	16	20
Mean	136.3	149.2
SD	38.13	47.02
Median	130.0	140.0
Minimum	54	81
Maximum	202	254
Month 30		
Number of patients with values	91	147
Mean	122.4	138.5
SD	38.78	41.96
Median	121.0	131.0
Minimum	31	54
Maximum	227	254
Month 33		
Number of patients with values	11	52
Mean	150.6	133.7
SD	35.06	39.89
Median	140.0	131.0
Minimum	100	48
Maximum	225	265
Month 36		
Number of patients with values	69	60
Mean	129.8	137.2
SD	38.37	38.37
Median	129.0	131.0
Minimum	27	73
Maximum	225	215

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	11
Mean	121.4	144.2
SD	34.10	47.32
Median	115.0	125.0
Minimum	58	67
Maximum	173	238
Month 42		
Number of patients with values	28	0
Mean	132.9	
SD	35.55	
Median	127.0	
Minimum	87	
Maximum	206	
Month 45		
Number of patients with values	13	0
Mean	136.3	
SD	27.94	
Median	129.0	
Minimum	85	
Maximum	173	
Month 48		
Number of patients with values	2	0
Mean	138.5	
SD	7.78	
Median	138.5	
Minimum	133	
Maximum	144	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	228	429
Mean	175.1	183.4
SD	95.06	274.01
Median	152.0	139.0
Minimum	37	46
Maximum	687	5142
Open Label Baseline		
Number of patients with values	229	426
Mean	193.4	173.6
SD	119.09	108.88
Median	158.0	146.5
Minimum	35	42
Maximum	813	911
Month 0		
Number of patients with values	21	22
Mean	220.6	193.3
SD	134.92	118.32
Median	182.0	173.5
Minimum	79	67
Maximum	558	487
Month 1		
Number of patients with values	3	11
Mean	162.7	186.5
SD	87.30	125.27
Median	180.0	129.0
Minimum	68	80
Maximum	240	440
Month 2		
Number of patients with values	6	5
Mean	182.8	133.0
SD	77.91	58.89
Median	160.0	115.0
Minimum	112	64
Maximum	313	223

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	13	26
Mean	158.5	173.8
SD	55.17	90.85
Median	150.0	140.0
Minimum	73	58
Maximum	246	388
Month 6		
Number of patients with values	198	360
Mean	193.7	182.8
SD	113.41	123.32
Median	164.0	144.0
Minimum	38	37
Maximum	584	801
Month 9		
Number of patients with values	9	29
Mean	184.4	224.2
SD	52.23	156.53
Median	178.0	181.0
Minimum	94	33
Maximum	285	638
Month 12		
Number of patients with values	176	321
Mean	195.0	175.9
SD	110.54	132.89
Median	161.0	142.0
Minimum	49	40
Maximum	598	1612

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	22	30
Mean	176.1	182.0
SD	115.04	118.39
Median	150.0	150.5
Minimum	56	51
Maximum	495	604
Month 18		
Number of patients with values	150	274
Mean	183.6	173.2
SD	101.61	120.07
Median	158.5	134.5
Minimum	37	39
Maximum	558	897
Month 21		
Number of patients with values	13	13
Mean	174.4	195.8
SD	51.87	163.05
Median	183.0	135.0
Minimum	82	59
Maximum	250	684
Month 24		
Number of patients with values	122	222
Mean	184.4	156.9
SD	111.57	101.75
Median	151.0	128.5
Minimum	54	53
Maximum	622	972

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	18	22
Mean	222.9	183.2
SD	124.01	135.97
Median	213.0	130.0
Minimum	63	43
Maximum	517	658
Month 30		
Number of patients with values	99	157
Mean	197.7	159.4
SD	164.47	111.57
Median	152.0	129.0
Minimum	49	42
Maximum	1301	900
Month 33		
Number of patients with values	12	54
Mean	197.7	184.1
SD	118.94	97.77
Median	165.0	164.0
Minimum	90	40
Maximum	517	619
Month 36		
Number of patients with values	71	61
Mean	182.2	137.2
SD	114.72	83.38
Median	161.0	127.0
Minimum	48	47
Maximum	882	596

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	11
Mean	177.1	133.7
SD	81.29	86.95
Median	188.0	96.0
Minimum	73	35
Maximum	374	312
Month 42		
Number of patients with values	28	0
Mean	161.1	
SD	69.06	
Median	147.0	
Minimum	70	
Maximum	286	
Month 45		
Number of patients with values	14	0
Mean	150.2	
SD	79.60	
Median	131.0	
Minimum	81	
Maximum	403	
Month 48		
Number of patients with values	2	0
Mean	175.0	
SD	25.46	
Median	175.0	
Minimum	157	
Maximum	193	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	229	421
Mean	27.051	26.057
SD	8.6289	8.3724
Median	25.710	24.860
Minimum	6.78	7.63
Maximum	64.12	57.63
Open Label Baseline		
Number of patients with values	229	424
Mean	24.413	21.156
SD	8.1264	6.7622
Median	23.730	20.340
Minimum	7.63	5.08
Maximum	56.78	41.53
Month 0		
Number of patients with values	22	24
Mean	24.138	23.117
SD	6.3735	7.9660
Median	23.020	22.035
Minimum	15.25	11.86
Maximum	43.50	41.53
Month 1		
Number of patients with values	1	11
Mean	32.770	18.850
SD		4.9513
Median	32.770	17.230
Minimum	32.77	12.15
Maximum	32.77	29.10
Month 2		
Number of patients with values	3	4
Mean	20.053	23.658
SD	5.6713	8.2820
Median	20.620	22.175
Minimum	14.12	16.10
Maximum	25.42	34.18

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	2	6
Mean	22.740	19.775
SD	0.1980	5.0345
Median	22.740	17.940
Minimum	22.60	14.97
Maximum	22.88	27.40
Month 6		
Number of patients with values	198	362
Mean	21.627	21.123
SD	6.7787	6.5700
Median	20.900	20.340
Minimum	5.93	5.34
Maximum	42.37	70.06
Month 9		
Number of patients with values	5	15
Mean	21.470	17.720
SD	2.6743	5.6312
Median	21.190	17.800
Minimum	18.64	8.76
Maximum	24.86	30.23
Month 12		
Number of patients with values	175	302
Mean	22.775	21.721
SD	6.2572	6.6655
Median	22.030	20.620
Minimum	8.19	12.15
Maximum	42.09	79.38

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	19	24
Mean	24.264	23.256
SD	4.5688	5.5150
Median	24.010	22.740
Minimum	17.80	13.81
Maximum	36.44	31.64
Month 18		
Number of patients with values	142	257
Mean	25.056	22.270
SD	6.4975	7.0293
Median	23.450	21.190
Minimum	13.84	13.81
Maximum	47.46	58.19
Month 21		
Number of patients with values	5	7
Mean	25.648	25.461
SD	6.2759	10.0478
Median	23.450	20.900
Minimum	21.75	16.38
Maximum	36.72	40.68
Month 24		
Number of patients with values	120	208
Mean	23.625	21.953
SD	5.4950	8.7677
Median	23.020	20.060
Minimum	14.69	13.81
Maximum	40.68	113.56

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	17	14
Mean	24.974	23.788
SD	5.5947	5.6047
Median	23.730	23.870
Minimum	16.95	14.97
Maximum	36.72	33.05
Month 30		
Number of patients with values	97	137
Mean	23.963	20.866
SD	5.7814	5.3355
Median	24.010	19.770
Minimum	13.81	13.81
Maximum	42.94	40.68
Month 33		
Number of patients with values	11	51
Mean	22.985	21.029
SD	5.3073	5.7706
Median	22.320	19.210
Minimum	16.67	13.81
Maximum	31.07	38.70
Month 36		
Number of patients with values	72	57
Mean	22.753	19.959
SD	6.3148	4.8543
Median	22.030	18.640
Minimum	13.81	13.81
Maximum	43.50	33.33

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	18	14
Mean	22.409	21.264
SD	5.1741	4.9131
Median	22.035	20.620
Minimum	13.81	13.81
Maximum	31.07	28.53
Month 42		
Number of patients with values	28	0
Mean	20.750	
SD	4.3434	
Median	20.055	
Minimum	13.81	
Maximum	34.75	
Month 45		
Number of patients with values	14	0
Mean	22.436	
SD	6.3519	
Median	21.610	
Minimum	13.81	
Maximum	32.77	
Month 48		
Number of patients with values	1	0
Mean	18.930	
SD		
Median	18.930	
Minimum	18.93	
Maximum	18.93	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Double Blind Baseline		
Number of patients with values	228	429
Mean	5.112	4.989
SD	1.4426	1.6812
Median	4.930	4.680
Minimum	1.96	2.03
Maximum	9.20	15.00
Open Label Baseline		
Number of patients with values	229	426
Mean	5.099	4.762
SD	1.6558	1.5248
Median	4.880	4.410
Minimum	2.17	2.06
Maximum	11.79	11.97
Month 0		
Number of patients with values	27	27
Mean	5.470	4.477
SD	2.0200	1.4546
Median	5.440	3.960
Minimum	2.49	2.55
Maximum	11.79	7.14
Month 1		
Number of patients with values	3	11
Mean	5.147	5.263
SD	1.7247	2.4902
Median	5.000	4.290
Minimum	3.50	3.00
Maximum	6.94	10.24
Month 2		
Number of patients with values	6	5
Mean	5.330	4.824
SD	1.0982	1.3206
Median	5.340	5.020
Minimum	3.70	2.66
Maximum	7.06	5.92

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication 2bd Comb Total 4bd Mono Total

Month 3		
Number of patients with values	13	25
Mean	4.948	4.573
SD	1.0573	1.4257
Median	4.740	4.850
Minimum	3.58	1.81
Maximum	7.17	7.38
Month 6		
Number of patients with values	195	350
Mean	4.967	4.859
SD	1.8322	2.0869
Median	4.620	4.410
Minimum	1.85	1.88
Maximum	15.94	21.13
Month 9		
Number of patients with values	9	28
Mean	4.973	4.639
SD	0.9245	1.4421
Median	5.160	4.475
Minimum	3.18	2.16
Maximum	6.02	7.45
Month 12		
Number of patients with values	173	318
Mean	4.777	4.695
SD	1.5698	1.8783
Median	4.570	4.310
Minimum	1.88	1.74
Maximum	11.89	16.88

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	19	30
Mean	4.597	5.007
SD	1.9250	2.1104
Median	4.480	4.530
Minimum	2.23	1.90
Maximum	9.80	9.55
Month 18		
Number of patients with values	148	274
Mean	4.586	4.373
SD	1.4255	1.5105
Median	4.475	4.105
Minimum	1.96	2.12
Maximum	10.68	12.40
Month 21		
Number of patients with values	13	13
Mean	4.415	4.668
SD	1.0228	2.5134
Median	4.300	4.340
Minimum	2.45	2.04
Maximum	5.94	12.54
Month 24		
Number of patients with values	118	220
Mean	4.476	4.294
SD	1.4693	1.4749
Median	4.155	4.100
Minimum	1.64	2.03
Maximum	9.16	14.30

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	18	21
Mean	4.764	4.771
SD	1.2964	1.7792
Median	4.645	4.530
Minimum	3.07	2.32
Maximum	7.82	8.38
Month 30		
Number of patients with values	98	153
Mean	4.530	4.319
SD	2.0168	1.7366
Median	4.205	3.900
Minimum	1.83	2.14
Maximum	13.08	13.38
Month 33		
Number of patients with values	12	54
Mean	4.979	4.416
SD	1.5111	1.3413
Median	4.665	4.225
Minimum	3.21	1.87
Maximum	8.24	7.48
Month 36		
Number of patients with values	71	61
Mean	4.397	4.260
SD	1.3954	1.4080
Median	4.300	3.880
Minimum	1.96	1.92
Maximum	8.87	9.28

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients with values	17	11
Mean	4.655	4.536
SD	1.4351	2.4945
Median	4.540	3.590
Minimum	2.86	2.18
Maximum	7.58	11.00
Month 42		
Number of patients with values	28	0
Mean	4.400	
SD	1.4169	
Median	3.900	
Minimum	2.52	
Maximum	8.59	
Month 45		
Number of patients with values	14	0
Mean	4.329	
SD	0.6812	
Median	4.280	
Minimum	3.33	
Maximum	5.70	
Month 48		
Number of patients with values	2	0
Mean	3.860	
SD	0.4950	
Median	3.860	
Minimum	3.51	
Maximum	4.21	

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication 2bd Comb Total 4bd Mono Total

Double Blind Baseline		
Number of patients with values	225	419
Mean	3.248	3.172
SD	1.0689	1.1769
Median	3.140	3.000
Minimum	0.70	0.78
Maximum	6.25	8.62
Open Label Baseline		
Number of patients with values	226	424
Mean	3.179	2.978
SD	1.2052	1.0524
Median	3.000	2.805
Minimum	0.83	0.89
Maximum	7.54	8.70
Month 0		
Number of patients with values	26	27
Mean	3.288	2.615
SD	1.4201	0.8985
Median	3.040	2.560
Minimum	1.10	1.16
Maximum	7.54	4.46
Month 1		
Number of patients with values	3	10
Mean	3.273	3.026
SD	1.1544	1.2609
Median	3.030	2.790
Minimum	2.26	1.75
Maximum	4.53	5.93
Month 2		
Number of patients with values	6	5
Mean	3.477	3.356
SD	0.7971	1.1607
Median	3.435	3.570
Minimum	2.25	1.54
Maximum	4.70	4.36

BRL 49653C/009

Data Source Table 14.1Aa
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Entered Study 009

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients with values	13	25
Mean	3.263	2.877
SD	0.8880	1.1509
Median	3.120	2.910
Minimum	2.32	0.69
Maximum	5.00	4.89
Month 6		
Number of patients with values	182	329
Mean	2.958	2.933
SD	1.2550	1.2242
Median	2.785	2.770
Minimum	0.71	0.79
Maximum	11.56	8.25
Month 9		
Number of patients with values	9	24
Mean	3.119	2.649
SD	0.8294	0.9500
Median	3.140	2.750
Minimum	1.88	0.88
Maximum	4.11	4.45
Month 12		
Number of patients with values	164	304
Mean	2.864	2.896
SD	1.0389	1.3161
Median	2.760	2.640
Minimum	0.67	0.58
Maximum	6.45	11.41

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients with values	17	29
Mean	2.718	3.110
SD	1.3702	1.5780
Median	2.390	2.670
Minimum	1.00	0.77
Maximum	6.84	7.03
Month 18		
Number of patients with values	142	262
Mean	2.714	2.631
SD	0.9537	1.0587
Median	2.585	2.535
Minimum	0.67	0.68
Maximum	5.37	7.06
Month 21		
Number of patients with values	13	12
Mean	2.665	2.446
SD	0.9206	0.7273
Median	2.760	2.615
Minimum	1.18	0.92
Maximum	4.21	3.16
Month 24		
Number of patients with values	110	215
Mean	2.648	2.598
SD	1.0646	0.9581
Median	2.535	2.500
Minimum	0.44	0.83
Maximum	5.48	5.85

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients with values	16	20
Mean	2.820	2.899
SD	1.1163	1.3113
Median	2.410	2.730
Minimum	1.54	1.22
Maximum	5.82	5.95
Month 30		
Number of patients with values	91	147
Mean	2.491	2.553
SD	1.1072	1.0264
Median	2.350	2.380
Minimum	0.53	0.88
Maximum	6.65	6.00
Month 33		
Number of patients with values	11	52
Mean	2.985	2.632
SD	0.9034	1.0918
Median	2.810	2.425
Minimum	1.94	0.76
Maximum	4.69	5.33
Month 36		
Number of patients with values	69	60
Mean	2.659	2.634
SD	1.1002	0.9628
Median	2.520	2.455
Minimum	0.57	0.77
Maximum	6.52	5.15

BRL 49653C/009

Data Source Table 14.1Aa
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Entered Study 009

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication 2bd Comb Total 4bd Mono Total

Month 39		
Number of patients with values	17	11
Mean	2.782	2.927
SD	1.0362	1.9256
Median	2.720	2.230
Minimum	1.41	0.92
Maximum	5.24	7.93
Month 42		
Number of patients with values	28	0
Mean	2.704	
SD	1.0884	
Median	2.360	
Minimum	1.22	
Maximum	6.44	
Month 45		
Number of patients with values	13	0
Mean	2.795	
SD	0.5973	
Median	2.790	
Minimum	1.89	
Maximum	4.05	
Month 48		
Number of patients with values	2	0
Mean	2.285	
SD	0.3182	
Median	2.285	
Minimum	2.06	
Maximum	2.51	

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	8.76	9.24	9.14
SD	1.042	1.122	1.065
Median	8.50	9.10	8.90
Minimum	7.3	7.3	7.3
Maximum	13.0	12.2	12.9
Open Label Baseline			
Number of patients with values	61	78	90
Mean	8.82	8.40	8.15
SD	1.237	1.094	1.254
Median	8.60	8.45	8.00
Minimum	7.0	6.0	5.4
Maximum	12.7	10.8	12.4
Month 0			
Number of patients with values	6	9	8
Mean	9.00	8.24	7.91
SD	1.254	1.203	1.199
Median	8.95	8.30	7.60
Minimum	7.6	6.8	6.9
Maximum	10.6	10.8	10.7
Month 1			
Number of patients with values	58	76	86
Mean	8.83	8.44	8.25
SD	1.226	1.133	1.268
Median	8.60	8.55	8.05
Minimum	6.7	5.9	5.3
Maximum	12.4	11.4	11.8
Month 2			
Number of patients with values	57	76	87
Mean	8.38	8.36	8.22
SD	1.119	1.168	1.265
Median	8.30	8.15	8.00
Minimum	6.6	5.9	5.3
Maximum	11.9	11.4	12.1

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	57	76	84
Mean	8.06	8.28	8.16
SD	1.033	1.078	1.148
Median	8.00	8.20	8.00
Minimum	6.2	5.9	5.6
Maximum	11.5	11.3	11.2
Month 6			
Number of patients with values	56	73	80
Mean	7.97	8.29	8.38
SD	1.083	1.077	1.222
Median	8.00	8.30	8.30
Minimum	5.9	5.9	5.2
Maximum	11.6	10.5	12.6
Month 9			
Number of patients with values	56	70	76
Mean	8.13	8.40	8.45
SD	1.165	1.260	1.242
Median	7.95	8.45	8.40
Minimum	6.1	5.7	5.6
Maximum	11.7	11.4	11.5
Month 12			
Number of patients with values	53	61	70
Mean	8.22	8.45	8.40
SD	1.224	1.347	1.244
Median	8.00	8.40	8.35
Minimum	6.0	6.1	5.7
Maximum	11.2	11.9	11.6

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	47	58	68
Mean	8.26	8.45	8.50
SD	1.150	1.371	1.351
Median	8.20	8.35	8.40
Minimum	6.2	6.2	5.6
Maximum	11.4	12.2	12.2
Month 18			
Number of patients with values	45	52	60
Mean	8.00	8.42	8.45
SD	1.196	1.325	1.170
Median	8.00	8.25	8.45
Minimum	5.8	6.0	6.2
Maximum	11.7	11.6	12.0
Month 21			
Number of patients with values	44	50	59
Mean	8.17	8.53	8.43
SD	1.169	1.526	1.113
Median	8.15	8.50	8.20
Minimum	5.9	6.0	6.4
Maximum	10.8	12.5	12.0
Month 24			
Number of patients with values	36	41	52
Mean	8.11	8.29	8.59
SD	1.049	1.446	1.263
Median	8.30	8.20	8.45
Minimum	5.7	6.1	6.0
Maximum	9.7	12.3	12.2

Data Source Table 14.1Ab
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	37	40	45
Mean	8.26	8.27	8.55
SD	1.256	1.268	1.519
Median	8.20	8.30	8.40
Minimum	6.3	6.1	6.3
Maximum	11.3	11.3	14.0
Month 30			
Number of patients with values	28	35	44
Mean	8.14	8.30	8.71
SD	1.185	1.466	1.614
Median	8.10	8.40	8.60
Minimum	6.1	5.1	6.0
Maximum	10.6	11.2	12.6
Month 33			
Number of patients with values	26	34	34
Mean	8.15	8.51	8.60
SD	1.070	1.429	1.379
Median	8.20	8.20	8.30
Minimum	6.3	6.1	6.3
Maximum	10.3	11.3	11.9
Month 36			
Number of patients with values	27	25	32
Mean	8.25	8.33	8.34
SD	1.135	1.336	1.346
Median	8.30	8.10	8.20
Minimum	6.1	6.5	6.1
Maximum	10.1	11.1	12.9

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	15	15	20
Mean	8.07	8.31	8.63
SD	1.095	1.286	1.512
Median	8.20	8.40	8.20
Minimum	6.3	6.2	6.6
Maximum	10.1	10.2	12.2
Month 42			
Number of patients with values	8	15	9
Mean	8.60	8.23	8.59
SD	1.093	1.188	1.593
Median	8.95	7.90	8.60
Minimum	6.6	6.9	6.7
Maximum	10.3	10.8	12.1
Month 45			
Number of patients with values	8	5	7
Mean	7.35	7.48	8.36
SD	0.725	0.904	0.697
Median	7.15	7.40	8.30
Minimum	6.6	6.7	7.4
Maximum	8.7	9.0	9.1
Month 48			
Number of patients with values	0	1	1
Mean		9.90	6.80
SD			
Median		9.90	6.80
Minimum		9.9	6.8
Maximum		9.9	6.8

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	196.4	199.6	195.3
SD	35.55	37.82	38.59
Median	198.0	199.0	191.0
Minimum	125	118	93
Maximum	307	298	277
Open Label Baseline			
Number of patients with values	61	78	90
Mean	195.4	170.2	154.2
SD	36.46	36.77	40.86
Median	198.0	170.5	152.0
Minimum	116	87	66
Maximum	264	280	250
Month 0			
Number of patients with values	6	9	7
Mean	214.2	184.3	151.6
SD	23.07	49.41	29.09
Median	208.0	187.0	155.0
Minimum	182	125	104
Maximum	243	280	191
Month 1			
Number of patients with values	59	74	87
Mean	170.1	163.3	159.9
SD	41.86	36.98	43.33
Median	173.0	165.0	159.0
Minimum	91	77	71
Maximum	341	243	270
Month 2			
Number of patients with values	55	77	86
Mean	155.4	157.8	162.2
SD	36.63	38.00	43.59
Median	155.0	157.0	158.5
Minimum	71	80	80
Maximum	225	246	287

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	57	75	85
Mean	163.2	162.1	159.2
SD	36.52	39.22	37.44
Median	166.0	162.0	159.0
Minimum	77	79	68
Maximum	229	246	250
Month 6			
Number of patients with values	55	73	80
Mean	158.3	162.4	161.3
SD	36.29	37.86	38.47
Median	155.0	164.0	154.0
Minimum	70	87	79
Maximum	221	252	307
Month 9			
Number of patients with values	55	70	75
Mean	162.3	165.8	168.4
SD	34.81	41.67	40.11
Median	168.0	169.0	171.0
Minimum	82	80	100
Maximum	254	271	271
Month 12			
Number of patients with values	52	60	70
Mean	168.2	162.2	163.1
SD	37.72	45.72	45.64
Median	165.0	168.0	154.5
Minimum	105	71	77
Maximum	261	320	280

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	48	55	68
Mean	162.9	162.9	160.1
SD	42.38	36.16	50.79
Median	159.0	166.0	148.0
Minimum	77	77	75
Maximum	261	257	286
Month 18			
Number of patients with values	43	51	60
Mean	157.9	164.4	161.0
SD	38.56	40.32	40.09
Median	150.0	166.0	158.0
Minimum	71	61	64
Maximum	234	268	271
Month 21			
Number of patients with values	43	50	58
Mean	161.1	166.0	155.7
SD	36.90	39.69	46.99
Median	159.0	171.0	154.0
Minimum	98	79	62
Maximum	239	254	327
Month 24			
Number of patients with values	36	40	52
Mean	158.1	164.7	162.1
SD	36.75	56.82	50.31
Median	158.0	159.5	162.0
Minimum	73	71	50
Maximum	229	384	287

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	36	39	44
Mean	170.1	166.9	166.7
SD	43.59	46.35	58.67
Median	170.0	171.0	170.5
Minimum	64	70	20
Maximum	275	268	327
Month 30			
Number of patients with values	28	35	44
Mean	162.2	162.6	167.4
SD	37.80	42.35	51.45
Median	164.0	154.0	164.5
Minimum	68	84	70
Maximum	252	252	296
Month 33			
Number of patients with values	26	34	34
Mean	164.5	161.9	163.0
SD	33.40	39.67	46.04
Median	170.0	162.5	158.0
Minimum	95	89	66
Maximum	229	261	266
Month 36			
Number of patients with values	27	25	31
Mean	166.3	159.4	155.1
SD	36.91	45.08	38.95
Median	168.0	168.0	155.0
Minimum	91	82	86
Maximum	229	229	270

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	14	15	20
Mean	165.2	164.5	173.6
SD	36.44	45.06	51.38
Median	174.0	157.0	181.0
Minimum	98	89	86
Maximum	230	270	275
Month 42			
Number of patients with values	8	15	9
Mean	162.9	153.1	171.9
SD	31.20	46.69	63.51
Median	163.5	143.0	148.0
Minimum	109	82	91
Maximum	202	232	271
Month 45			
Number of patients with values	6	5	7
Mean	137.7	134.8	161.0
SD	49.69	46.59	43.64
Median	134.0	157.0	154.0
Minimum	89	73	109
Maximum	227	180	245
Month 48			
Number of patients with values	0	1	1
Mean		214.0	121.0
SD			
Median		214.0	121.0
Minimum		214	121
Maximum		214	121

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	56.33	59.56	55.68
SD	37.079	38.563	31.750
Median	47.00	48.00	50.50
Minimum	7.0	11.0	8.4
Maximum	173.0	199.0	163.0
Open Label Baseline			
Number of patients with values	61	78	90
Mean	50.50	56.99	48.95
SD	31.053	38.183	26.163
Median	45.00	43.50	46.50
Minimum	9.4	8.3	6.6
Maximum	174.0	191.0	168.0
Month 0			
Number of patients with values	5	8	7
Mean	63.80	59.00	53.29
SD	40.419	32.876	17.366
Median	54.00	45.00	41.00
Minimum	27.0	31.0	37.0
Maximum	133.0	119.0	81.0
Month 1			
Number of patients with values	1	0	0
Mean	4.00		
SD			
Median	4.00		
Minimum	4.0		
Maximum	4.0		
Month 2			
Number of patients with values	0	0	3
Mean			37.00
SD			17.059
Median			42.00
Minimum			18.0
Maximum			51.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	1	0	1
Mean	41.00		56.00
SD			
Median	41.00		56.00
Minimum	41.0		56.0
Maximum	41.0		56.0
Month 6			
Number of patients with values	53	65	71
Mean	50.51	58.12	53.16
SD	33.489	37.245	27.495
Median	40.00	45.00	49.00
Minimum	15.0	10.0	9.3
Maximum	161.0	224.0	136.0
Month 9			
Number of patients with values	0	2	2
Mean		53.50	34.50
SD		28.991	12.021
Median		53.50	34.50
Minimum		33.0	26.0
Maximum		74.0	43.0
Month 12			
Number of patients with values	50	58	64
Mean	50.92	55.99	53.34
SD	27.576	34.148	26.304
Median	47.00	52.00	52.00
Minimum	14.0	6.9	10.0
Maximum	170.0	161.0	138.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	7	6	6
Mean	46.43	47.17	36.50
SD	13.697	46.223	24.313
Median	52.00	30.00	28.00
Minimum	25.0	12.0	19.0
Maximum	61.0	136.0	83.0
Month 18			
Number of patients with values	38	46	56
Mean	51.87	61.74	52.80
SD	39.342	49.523	25.333
Median	37.50	48.00	49.00
Minimum	13.0	10.0	17.0
Maximum	189.0	272.0	120.0
Month 21			
Number of patients with values	3	3	3
Mean	36.33	25.67	31.67
SD	11.590	4.726	8.327
Median	42.00	24.00	29.00
Minimum	23.0	22.0	25.0
Maximum	44.0	31.0	41.0
Month 24			
Number of patients with values	35	39	49
Mean	47.17	52.19	50.08
SD	32.409	40.317	25.020
Median	43.00	43.00	54.00
Minimum	8.9	8.4	3.0
Maximum	172.0	240.0	126.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	2	6
Mean	66.33	37.00	45.17
SD	40.841	24.042	23.198
Median	68.00	37.00	37.50
Minimum	20.0	20.0	26.0
Maximum	147.0	54.0	85.0
Month 30			
Number of patients with values	26	30	37
Mean	44.92	50.87	48.84
SD	28.105	26.457	24.843
Median	39.00	50.00	47.00
Minimum	16.0	15.0	11.0
Maximum	114.0	109.0	122.0
Month 33			
Number of patients with values	2	4	3
Mean	75.50	51.00	55.00
SD	0.707	12.302	28.583
Median	75.50	52.50	39.00
Minimum	75.0	35.0	38.0
Maximum	76.0	64.0	88.0
Month 36			
Number of patients with values	24	22	26
Mean	42.63	50.77	50.32
SD	20.774	24.444	27.705
Median	44.50	49.00	48.50
Minimum	14.0	19.0	2.3
Maximum	97.0	102.0	117.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	5	8
Mean	47.50	57.60	39.50
SD	31.681	40.771	13.846
Median	38.00	45.00	41.00
Minimum	22.0	21.0	18.0
Maximum	92.0	112.0	64.0
Month 42			
Number of patients with values	8	11	8
Mean	44.63	46.55	58.75
SD	21.974	18.630	35.005
Median	45.50	39.00	57.00
Minimum	14.0	23.0	14.0
Maximum	75.0	89.0	135.0
Month 45			
Number of patients with values	6	3	5
Mean	49.50	56.33	53.80
SD	27.031	23.159	21.811
Median	42.00	50.00	50.00
Minimum	23.0	37.0	28.0
Maximum	95.0	82.0	79.0
Month 48			
Number of patients with values	0	1	0
Mean		23.00	
SD			
Median		23.00	
Minimum		23.0	
Maximum		23.0	

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	49	75	82
Mean	40.16	22.20	39.95
SD	136.663	35.158	114.076
Median	10.00	9.00	8.00
Minimum	2.0	2.0	2.0
Maximum	940.0	151.0	850.0
Open Label Baseline			
Number of patients with values	60	78	90
Mean	38.45	26.69	39.34
SD	120.523	62.041	163.938
Median	8.00	7.00	6.50
Minimum	2.0	2.0	2.0
Maximum	892.0	431.0	1480.0
Month 0			
Number of patients with values	7	10	6
Mean	15.57	81.80	275.00
SD	12.752	139.657	591.458
Median	7.00	19.00	31.50
Minimum	4.0	3.0	5.0
Maximum	31.0	431.0	1480.0
Month 1			
Number of patients with values	1	0	1
Mean	18.00		33.00
SD			
Median	18.00		33.00
Minimum	18.0		33.0
Maximum	18.0		33.0
Month 2			
Number of patients with values	0	1	2
Mean		4.00	59.00
SD			72.125
Median		4.00	59.00
Minimum		4.0	8.0
Maximum		4.0	110.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	0	0	1
Mean			68.00
SD			
Median			68.00
Minimum			68.0
Maximum			68.0
Month 6			
Number of patients with values	48	63	63
Mean	50.40	49.87	65.41
SD	141.537	147.367	191.793
Median	10.00	12.00	16.00
Minimum	2.0	2.0	2.0
Maximum	911.0	1080.0	1350.0
Month 9			
Number of patients with values	1	1	4
Mean	4.00	5.00	15.50
SD			9.469
Median	4.00	5.00	17.00
Minimum	4.0	5.0	3.0
Maximum	4.0	5.0	25.0
Month 12			
Number of patients with values	43	54	58
Mean	85.65	40.17	30.09
SD	251.450	109.479	61.148
Median	21.00	11.00	11.00
Minimum	2.0	2.0	2.0
Maximum	1610.0	753.0	326.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	3	7	5
Mean	9.67	118.86	7.20
SD	8.145	263.738	3.421
Median	6.00	18.00	8.00
Minimum	4.0	2.0	2.0
Maximum	19.0	715.0	11.0
Month 18			
Number of patients with values	36	41	55
Mean	53.17	48.29	29.24
SD	111.423	149.153	36.852
Median	17.50	12.00	11.00
Minimum	3.0	2.0	2.0
Maximum	521.0	943.0	159.0
Month 21			
Number of patients with values	1	2	3
Mean	25.00	13.00	33.00
SD		5.657	50.239
Median	25.00	13.00	5.00
Minimum	25.0	9.0	3.0
Maximum	25.0	17.0	91.0
Month 24			
Number of patients with values	28	36	44
Mean	57.07	41.39	41.86
SD	105.771	103.227	85.070
Median	17.50	9.00	19.50
Minimum	3.0	2.0	2.0
Maximum	429.0	509.0	544.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	7	2	4
Mean	20.43	5.00	9.50
SD	19.932	0.000	4.359
Median	11.00	5.00	7.50
Minimum	3.0	5.0	7.0
Maximum	60.0	5.0	16.0
Month 30			
Number of patients with values	23	30	37
Mean	54.04	56.73	37.81
SD	99.258	142.863	45.215
Median	14.00	12.50	15.00
Minimum	2.0	2.0	2.0
Maximum	439.0	669.0	152.0
Month 33			
Number of patients with values	1	3	4
Mean	5.00	33.33	19.50
SD		26.312	19.942
Median	5.00	47.00	11.50
Minimum	5.0	3.0	6.0
Maximum	5.0	50.0	49.0
Month 36			
Number of patients with values	21	24	27
Mean	67.38	57.83	43.63
SD	145.353	131.927	59.009
Median	14.00	11.00	16.00
Minimum	3.0	2.0	2.0
Maximum	647.0	605.0	205.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	2	7
Mean	11.25	5.00	22.14
SD	8.617	1.414	40.716
Median	7.50	5.00	4.00
Minimum	6.0	4.0	2.0
Maximum	24.0	6.0	113.0
Month 42			
Number of patients with values	7	12	8
Mean	128.29	41.42	64.88
SD	252.833	42.210	135.774
Median	13.00	28.50	13.50
Minimum	4.0	4.0	2.0
Maximum	692.0	148.0	399.0
Month 45			
Number of patients with values	6	4	6
Mean	128.00	38.25	21.67
SD	173.307	55.464	21.906
Median	58.50	14.00	14.50
Minimum	5.0	4.0	7.0
Maximum	449.0	121.0	65.0
Month 48			
Number of patients with values	0	1	1
Mean		28.00	22.00
SD			
Median		28.00	22.00
Minimum		28.0	22.0
Maximum		28.0	22.0

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	77	90
Mean	214.3	205.4	216.1
SD	30.13	40.39	37.37
Median	214.0	213.0	217.0
Minimum	135	106	134
Maximum	313	335	300
Open Label Baseline			
Number of patients with values	61	78	90
Mean	220.5	218.9	228.9
SD	29.65	46.13	45.12
Median	221.0	222.0	223.5
Minimum	145	73	142
Maximum	313	321	350
Month 0			
Number of patients with values	6	7	8
Mean	209.8	223.4	251.1
SD	41.96	20.29	38.64
Median	211.5	233.0	244.0
Minimum	149	193	210
Maximum	263	250	321
Month 1			
Number of patients with values	2	1	0
Mean	226.5	185.0	
SD	13.44		
Median	226.5	185.0	
Minimum	217	185	
Maximum	236	185	
Month 2			
Number of patients with values	1	2	3
Mean	196.0	200.0	268.3
SD		31.11	55.79
Median	196.0	200.0	245.0
Minimum	196	178	228
Maximum	196	222	332

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	214.3	280.0	242.4
SD	32.48	21.21	52.62
Median	205.0	280.0	221.0
Minimum	191	265	199
Maximum	278	295	326
Month 6			
Number of patients with values	51	69	76
Mean	230.8	221.6	226.3
SD	42.14	49.86	43.11
Median	226.0	224.0	220.0
Minimum	153	95	135
Maximum	395	325	359
Month 9			
Number of patients with values	1	4	4
Mean	221.0	220.3	221.3
SD		33.72	29.94
Median	221.0	217.5	225.5
Minimum	221	183	181
Maximum	221	263	253
Month 12			
Number of patients with values	49	60	66
Mean	227.7	224.3	224.8
SD	40.21	47.97	38.23
Median	223.0	222.5	223.0
Minimum	147	81	140
Maximum	333	322	321

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	6	7	8
Mean	243.5	206.9	216.8
SD	25.29	55.62	24.57
Median	249.5	217.0	223.5
Minimum	194	107	175
Maximum	262	286	246
Month 18			
Number of patients with values	41	50	58
Mean	223.2	216.1	223.4
SD	42.68	52.74	35.39
Median	227.0	209.5	217.5
Minimum	136	90	154
Maximum	308	331	356
Month 21			
Number of patients with values	4	4	5
Mean	216.0	173.8	235.2
SD	51.54	27.32	47.66
Median	208.5	175.5	212.0
Minimum	162	143	198
Maximum	285	201	311
Month 24			
Number of patients with values	35	40	46
Mean	220.6	213.8	218.0
SD	45.81	54.14	32.97
Median	210.0	214.5	213.0
Minimum	127	90	154
Maximum	338	312	285

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	4	5
Mean	230.0	230.3	219.6
SD	35.67	35.61	58.78
Median	210.0	242.5	233.0
Minimum	193	178	125
Maximum	289	258	279
Month 30			
Number of patients with values	25	33	41
Mean	216.2	208.3	219.7
SD	46.11	51.39	56.00
Median	210.0	210.0	207.0
Minimum	124	88	141
Maximum	353	325	395
Month 33			
Number of patients with values	1	5	6
Mean	260.0	271.6	215.3
SD		38.47	25.47
Median	260.0	271.0	213.0
Minimum	260	213	182
Maximum	260	313	255
Month 36			
Number of patients with values	20	23	28
Mean	220.3	206.8	221.9
SD	40.43	50.89	34.12
Median	213.5	202.0	220.0
Minimum	133	92	165
Maximum	301	314	293

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	197.8	181.8	213.4
SD	18.68	41.56	42.88
Median	199.5	178.0	220.0
Minimum	177	139	149
Maximum	215	232	279
Month 42			
Number of patients with values	8	12	8
Mean	232.8	220.3	197.0
SD	42.49	45.20	27.78
Median	220.5	220.5	199.0
Minimum	187	146	159
Maximum	306	295	241
Month 45			
Number of patients with values	5	3	6
Mean	224.2	235.7	189.2
SD	35.01	35.44	26.57
Median	228.0	252.0	193.0
Minimum	187	195	148
Maximum	263	260	225
Month 48			
Number of patients with values	0	1	1
Mean		246.0	223.0
SD			
Median		246.0	223.0
Minimum		246	223
Maximum		246	223

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	44.8	43.6	44.3
SD	12.85	12.73	13.76
Median	43.0	41.0	42.0
Minimum	26	24	27
Maximum	97	90	108
Open Label Baseline			
Number of patients with values	61	78	90
Mean	47.1	45.2	48.3
SD	11.40	12.39	15.37
Median	45.0	42.5	46.5
Minimum	31	24	24
Maximum	85	85	100
Month 0			
Number of patients with values	6	7	8
Mean	49.8	44.7	45.3
SD	20.82	10.48	14.19
Median	38.5	43.0	45.0
Minimum	34	28	24
Maximum	78	58	72
Month 1			
Number of patients with values	2	1	0
Mean	48.0	37.0	
SD	19.80		
Median	48.0	37.0	
Minimum	34	37	
Maximum	62	37	
Month 2			
Number of patients with values	1	2	3
Mean	53.0	36.5	46.3
SD		3.54	1.15
Median	53.0	36.5	47.0
Minimum	53	34	45
Maximum	53	39	47

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	44.5	53.0	52.0
SD	9.52	4.24	11.81
Median	42.5	53.0	48.0
Minimum	30	50	45
Maximum	57	56	73
Month 6			
Number of patients with values	50	71	76
Mean	49.5	48.4	49.2
SD	13.04	13.56	13.90
Median	50.0	46.0	46.5
Minimum	16	25	29
Maximum	93	97	90
Month 9			
Number of patients with values	1	4	4
Mean	37.0	44.0	50.0
SD		8.64	14.67
Median	37.0	42.0	43.0
Minimum	37	36	42
Maximum	37	56	72
Month 12			
Number of patients with values	48	60	66
Mean	49.6	48.9	51.7
SD	11.39	12.04	15.61
Median	47.0	47.0	49.0
Minimum	28	29	28
Maximum	86	84	99

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	5	8	7
Mean	42.8	57.4	54.0
SD	11.63	16.42	9.18
Median	43.0	57.5	53.0
Minimum	25	28	44
Maximum	55	86	71
Month 18			
Number of patients with values	40	50	58
Mean	51.9	51.7	50.5
SD	14.97	14.15	14.50
Median	47.5	51.0	48.0
Minimum	33	31	29
Maximum	98	88	95
Month 21			
Number of patients with values	4	4	5
Mean	46.5	44.0	54.6
SD	1.73	14.45	9.86
Median	47.0	38.5	56.0
Minimum	44	34	43
Maximum	48	65	65
Month 24			
Number of patients with values	35	40	44
Mean	52.7	53.1	51.3
SD	13.22	14.78	16.69
Median	52.0	53.0	47.0
Minimum	29	27	30
Maximum	90	84	113

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	4	5
Mean	49.1	46.3	53.0
SD	9.69	10.28	15.54
Median	47.0	47.0	54.0
Minimum	38	33	35
Maximum	67	58	77
Month 30			
Number of patients with values	25	32	41
Mean	53.0	52.0	50.6
SD	14.27	14.35	15.21
Median	50.0	53.0	49.0
Minimum	29	31	26
Maximum	92	84	90
Month 33			
Number of patients with values	1	5	6
Mean	36.0	52.2	53.2
SD		14.24	11.60
Median	36.0	51.0	53.0
Minimum	36	38	40
Maximum	36	70	72
Month 36			
Number of patients with values	20	23	28
Mean	54.2	55.1	49.3
SD	15.45	14.53	14.58
Median	50.5	56.0	45.5
Minimum	35	30	31
Maximum	93	80	84

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	50.0	38.0	47.8
SD	16.75	6.98	11.91
Median	44.0	40.0	43.0
Minimum	38	28	33
Maximum	74	44	67
Month 42			
Number of patients with values	8	12	8
Mean	50.8	52.4	53.3
SD	10.17	14.30	11.97
Median	51.0	54.0	54.5
Minimum	38	28	37
Maximum	65	77	72
Month 45			
Number of patients with values	5	3	6
Mean	47.2	60.7	46.7
SD	8.98	15.82	8.64
Median	44.0	57.0	48.5
Minimum	40	47	34
Maximum	62	78	57
Month 48			
Number of patients with values	0	1	1
Mean		70.0	53.0
SD			
Median		70.0	53.0
Minimum		70	53
Maximum		70	53

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	60	76	89
Mean	135.9	128.6	137.1
SD	27.93	32.86	32.44
Median	137.0	125.0	135.0
Minimum	46	38	81
Maximum	202	219	221
Open Label Baseline			
Number of patients with values	60	76	90
Mean	138.2	133.9	143.9
SD	27.61	38.08	38.71
Median	142.0	134.0	141.0
Minimum	42	25	79
Maximum	198	210	244
Month 0			
Number of patients with values	6	5	8
Mean	126.3	126.2	168.5
SD	32.93	29.15	38.00
Median	135.5	135.0	162.5
Minimum	79	79	135
Maximum	158	150	244
Month 1			
Number of patients with values	2	1	0
Mean	147.0	112.0	
SD	9.90		
Median	147.0	112.0	
Minimum	140	112	
Maximum	154	112	
Month 2			
Number of patients with values	1	2	3
Mean	119.0	123.5	183.3
SD		19.09	33.26
Median	119.0	123.5	171.0
Minimum	119	110	158
Maximum	119	137	221

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	142.2	191.0	156.8
SD	30.09	36.77	50.58
Median	135.0	191.0	133.0
Minimum	108	165	117
Maximum	198	217	240
Month 6			
Number of patients with values	48	60	74
Mean	141.6	129.5	140.0
SD	30.99	40.36	38.65
Median	142.0	127.0	139.5
Minimum	50	35	63
Maximum	206	223	281
Month 9			
Number of patients with values	1	4	4
Mean	152.0	142.5	130.3
SD		28.92	35.86
Median	152.0	144.5	136.5
Minimum	152	106	81
Maximum	152	175	167
Month 12			
Number of patients with values	46	55	63
Mean	138.3	136.1	135.0
SD	29.29	39.58	34.29
Median	137.0	131.0	131.0
Minimum	88	29	63
Maximum	188	221	225

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	5	6	6
Mean	163.0	117.5	126.7
SD	19.75	46.85	23.46
Median	171.0	120.0	126.0
Minimum	129	48	98
Maximum	177	185	162
Month 18			
Number of patients with values	40	47	55
Mean	138.7	125.9	134.8
SD	39.99	43.00	28.91
Median	145.0	123.0	131.0
Minimum	38	29	83
Maximum	206	225	210
Month 21			
Number of patients with values	4	4	5
Mean	127.5	101.3	146.2
SD	52.82	32.93	38.10
Median	113.5	97.0	127.0
Minimum	81	71	119
Maximum	202	140	212
Month 24			
Number of patients with values	34	35	41
Mean	134.1	125.7	130.0
SD	40.08	45.93	33.54
Median	134.0	125.0	137.0
Minimum	25	29	50
Maximum	219	215	192

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	8	4	4
Mean	137.5	149.5	120.5
SD	31.12	38.00	54.74
Median	129.0	153.0	120.5
Minimum	96	100	54
Maximum	202	192	187
Month 30			
Number of patients with values	23	30	38
Mean	122.3	118.9	125.2
SD	32.51	46.24	36.55
Median	125.0	121.0	120.0
Minimum	31	31	69
Maximum	204	219	227
Month 33			
Number of patients with values	1	4	6
Mean	169.0	175.0	131.3
SD		42.52	19.61
Median	169.0	177.0	132.5
Minimum	169	121	100
Maximum	169	225	158
Month 36			
Number of patients with values	20	22	27
Mean	135.0	121.4	132.8
SD	36.09	46.35	32.79
Median	132.0	118.0	131.0
Minimum	35	27	73
Maximum	198	225	202

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	117.8	99.0	132.9
SD	21.08	36.09	35.55
Median	111.5	96.0	144.0
Minimum	100	58	75
Maximum	148	146	173
Month 42			
Number of patients with values	8	12	8
Mean	147.8	135.9	113.4
SD	28.23	42.83	22.21
Median	142.0	131.0	111.5
Minimum	112	87	90
Maximum	188	206	156
Month 45			
Number of patients with values	5	3	5
Mean	147.8	151.3	115.8
SD	27.69	19.50	22.91
Median	162.0	160.0	115.0
Minimum	110	129	85
Maximum	173	165	148
Month 48			
Number of patients with values	0	1	1
Mean		144.0	133.0
SD			
Median		144.0	133.0
Minimum		144	133
Maximum		144	133

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	77	90
Mean	170.8	171.5	180.9
SD	96.29	98.28	92.15
Median	148.0	149.0	156.5
Minimum	53	56	37
Maximum	483	687	526
Open Label Baseline			
Number of patients with values	61	78	90
Mean	179.3	210.8	187.8
SD	127.15	132.03	99.58
Median	145.0	169.5	159.0
Minimum	37	42	35
Maximum	813	558	478
Month 0			
Number of patients with values	6	7	8
Mean	173.7	296.7	189.3
SD	83.74	178.95	103.67
Median	167.0	212.0	181.5
Minimum	89	127	79
Maximum	310	558	389
Month 1			
Number of patients with values	2	1	0
Mean	154.0	180.0	
SD	121.62		
Median	154.0	180.0	
Minimum	68	180	
Maximum	240	180	
Month 2			
Number of patients with values	1	2	3
Mean	112.0	203.5	192.7
SD		44.55	105.36
Median	112.0	203.5	148.0
Minimum	112	172	117
Maximum	112	235	313

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	140.8	179.5	171.2
SD	53.69	94.05	49.25
Median	137.0	179.5	194.0
Minimum	73	113	95
Maximum	204	246	217
Month 6			
Number of patients with values	51	70	77
Mean	185.2	205.6	188.6
SD	106.46	131.92	99.36
Median	163.0	161.5	169.0
Minimum	55	50	38
Maximum	526	584	545
Month 9			
Number of patients with values	1	4	4
Mean	162.0	172.0	202.5
SD		12.44	79.43
Median	162.0	172.0	215.5
Minimum	162	158	94
Maximum	162	186	285
Month 12			
Number of patients with values	49	60	67
Mean	186.3	205.4	192.0
SD	99.29	131.11	98.48
Median	153.0	155.0	181.0
Minimum	62	51	49
Maximum	440	598	534

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	6	8	8
Mean	184.8	163.9	181.9
SD	53.32	139.80	133.63
Median	178.0	114.0	140.0
Minimum	112	56	82
Maximum	250	481	495
Month 18			
Number of patients with values	42	50	58
Mean	169.1	192.3	186.7
SD	82.73	116.26	101.07
Median	164.0	142.5	157.0
Minimum	37	55	64
Maximum	356	514	558
Month 21			
Number of patients with values	4	4	5
Mean	210.8	143.0	170.4
SD	41.29	46.08	53.61
Median	212.5	150.5	196.0
Minimum	168	82	103
Maximum	250	189	221
Month 24			
Number of patients with values	35	40	47
Mean	161.0	193.1	194.3
SD	83.73	148.38	91.19
Median	145.0	145.0	185.0
Minimum	61	54	73
Maximum	431	622	461

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	4	5
Mean	222.8	175.5	261.2
SD	130.85	52.22	158.07
Median	218.0	182.5	218.0
Minimum	63	107	75
Maximum	517	230	482
Month 30			
Number of patients with values	25	33	41
Mean	173.6	194.7	214.8
SD	103.30	113.51	221.11
Median	160.0	174.0	140.0
Minimum	50	49	72
Maximum	432	513	1301
Month 33			
Number of patients with values	1	5	6
Mean	274.0	231.6	156.7
SD		172.37	54.94
Median	274.0	130.0	165.0
Minimum	274	118	90
Maximum	274	517	222
Month 36			
Number of patients with values	20	23	28
Mean	154.3	166.5	215.1
SD	66.93	93.00	148.37
Median	137.0	135.0	187.0
Minimum	55	48	93
Maximum	297	494	882

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	152.3	227.5	165.7
SD	58.71	115.18	72.27
Median	152.5	220.5	166.0
Minimum	94	95	73
Maximum	210	374	265
Month 42			
Number of patients with values	8	12	8
Mean	169.6	160.4	153.5
SD	72.82	71.89	69.44
Median	146.0	141.0	147.0
Minimum	89	72	70
Maximum	282	286	273
Month 45			
Number of patients with values	5	3	6
Mean	147.4	118.0	168.7
SD	36.78	47.82	115.91
Median	144.0	101.0	123.0
Minimum	94	81	101
Maximum	182	172	403
Month 48			
Number of patients with values	0	1	1
Mean		157.0	193.0
SD			
Median		157.0	193.0
Minimum		157	193
Maximum		157	193

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	26.646	26.409	27.882
SD	8.3550	8.7537	8.7304
Median	26.270	24.580	25.990
Minimum	12.99	6.78	12.99
Maximum	50.00	56.21	64.12
Open Label Baseline			
Number of patients with values	61	78	90
Mean	26.248	25.561	22.175
SD	9.0872	8.3927	6.6362
Median	24.290	25.710	22.740
Minimum	14.41	7.63	8.47
Maximum	56.78	52.82	40.11
Month 0			
Number of patients with values	6	8	8
Mean	21.278	25.775	24.646
SD	2.9553	9.4226	4.0589
Median	20.055	23.870	25.280
Minimum	18.64	15.25	16.38
Maximum	26.55	43.50	29.10
Month 1			
Number of patients with values	1	0	0
Mean	32.770		
SD			
Median	32.770		
Minimum	32.77		
Maximum	32.77		
Month 2			
Number of patients with values	0	0	3
Mean			20.053
SD			5.6713
Median			20.620
Minimum			14.12
Maximum			25.42

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	1	0	1
Mean	22.880		22.600
SD			
Median	22.880		22.600
Minimum	22.88		22.60
Maximum	22.88		22.60
Month 6			
Number of patients with values	55	69	74
Mean	21.294	22.128	21.408
SD	6.5442	7.0859	6.7220
Median	21.190	20.900	20.760
Minimum	9.32	9.89	5.93
Maximum	40.96	37.29	42.37
Month 9			
Number of patients with values	0	3	2
Mean		19.680	24.155
SD		1.3384	0.9970
Median		19.210	24.155
Minimum		18.64	23.45
Maximum		21.19	24.86
Month 12			
Number of patients with values	51	59	65
Mean	22.582	22.675	23.017
SD	6.2374	7.1227	5.4752
Median	21.750	20.900	22.880
Minimum	8.19	10.17	14.12
Maximum	38.42	42.09	37.29

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	5	8	6
Mean	22.034	23.834	26.695
SD	3.4218	3.4067	6.0969
Median	24.010	22.740	26.415
Minimum	17.80	19.77	18.08
Maximum	25.42	27.97	36.44
Month 18			
Number of patients with values	39	47	56
Mean	24.157	25.834	25.030
SD	6.0588	7.0432	6.3472
Median	23.160	24.580	23.160
Minimum	15.25	13.84	15.82
Maximum	44.92	47.46	42.37
Month 21			
Number of patients with values	2	2	1
Mean	30.505	22.600	22.030
SD	8.7893	1.2021	
Median	30.505	22.600	22.030
Minimum	24.29	21.75	22.03
Maximum	36.72	23.45	22.03
Month 24			
Number of patients with values	34	39	47
Mean	24.459	23.257	23.326
SD	6.8338	5.4132	4.4365
Median	22.880	22.880	23.160
Minimum	15.54	14.69	15.25
Maximum	40.68	33.33	32.77

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	2	6
Mean	25.392	23.020	24.998
SD	5.5396	2.9981	6.8863
Median	24.290	23.020	22.035
Minimum	16.95	20.90	19.77
Maximum	34.46	25.14	36.72
Month 30			
Number of patients with values	26	32	39
Mean	23.095	24.841	23.821
SD	6.6315	5.9040	5.0880
Median	23.870	24.715	23.730
Minimum	13.81	15.82	13.81
Maximum	35.31	42.94	33.05
Month 33			
Number of patients with values	2	4	5
Mean	23.445	21.400	24.068
SD	2.7931	5.1440	6.6737
Median	23.445	20.340	24.860
Minimum	21.47	16.67	16.67
Maximum	25.42	28.25	31.07
Month 36			
Number of patients with values	24	21	27
Mean	21.958	23.985	22.502
SD	7.1132	6.5151	5.4414
Median	20.620	23.730	22.600
Minimum	13.81	15.82	13.81
Maximum	43.50	43.50	33.62

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	5	9
Mean	21.675	25.706	20.904
SD	6.4735	4.4833	4.6384
Median	22.885	25.990	20.340
Minimum	13.81	19.21	15.54
Maximum	27.12	31.07	28.53
Month 42			
Number of patients with values	8	12	8
Mean	19.209	20.664	22.421
SD	3.0842	4.0307	5.6393
Median	18.925	20.195	21.325
Minimum	14.69	13.81	16.95
Maximum	24.58	27.12	34.75
Month 45			
Number of patients with values	6	3	5
Mean	23.542	26.553	18.638
SD	5.6023	9.8053	3.3534
Median	26.130	31.640	18.360
Minimum	15.25	15.25	13.81
Maximum	29.10	32.77	22.88
Month 48			
Number of patients with values	0	1	0
Mean		18.930	
SD			
Median		18.930	
Minimum		18.93	
Maximum		18.93	

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	61	77	90
Mean	5.053	5.025	5.227
SD	1.2111	1.5009	1.5404
Median	5.060	4.870	5.000
Minimum	2.46	1.96	2.11
Maximum	8.56	9.20	9.10
Open Label Baseline			
Number of patients with values	61	78	90
Mean	4.887	5.150	5.199
SD	1.1137	1.6337	1.9584
Median	4.910	4.900	4.845
Minimum	2.23	2.43	2.17
Maximum	7.53	9.48	11.79
Month 0			
Number of patients with values	7	10	10
Mean	4.760	5.617	5.821
SD	1.3187	1.5740	2.7565
Median	4.560	5.695	5.355
Minimum	3.04	3.88	2.49
Maximum	6.69	8.93	11.79
Month 1			
Number of patients with values	2	1	0
Mean	5.220	5.000	
SD	2.4324		
Median	5.220	5.000	
Minimum	3.50	5.00	
Maximum	6.94	5.00	
Month 2			
Number of patients with values	1	2	3
Mean	3.700	5.465	5.783
SD		0.3182	1.1443
Median	3.700	5.465	5.440
Minimum	3.70	5.24	4.85
Maximum	3.70	5.69	7.06

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	4.982	5.285	4.772
SD	1.1964	0.0212	1.2114
Median	4.655	5.285	4.420
Minimum	3.61	5.27	3.58
Maximum	7.17	5.30	6.79
Month 6			
Number of patients with values	50	69	76
Mean	5.040	4.942	4.940
SD	2.0854	1.8886	1.6134
Median	4.600	4.570	4.660
Minimum	2.43	1.85	2.02
Maximum	15.94	10.89	9.28
Month 9			
Number of patients with values	1	4	4
Mean	5.970	5.055	4.643
SD		0.5442	1.2236
Median	5.970	4.930	4.685
Minimum	5.97	4.58	3.18
Maximum	5.97	5.78	6.02
Month 12			
Number of patients with values	48	60	65
Mean	4.758	4.892	4.684
SD	1.3922	1.7547	1.5294
Median	4.600	4.685	4.380
Minimum	2.49	1.88	2.10
Maximum	11.89	10.37	9.25

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	5	7	7
Mean	6.106	4.029	4.087
SD	2.1803	2.1581	0.8442
Median	5.140	3.470	4.090
Minimum	4.51	2.23	2.92
Maximum	9.80	8.32	5.35
Month 18			
Number of patients with values	40	50	58
Mean	4.573	4.438	4.721
SD	1.2447	1.5998	1.3938
Median	4.540	4.155	4.520
Minimum	1.96	2.09	2.60
Maximum	7.64	10.68	9.41
Month 21			
Number of patients with values	4	4	5
Mean	4.643	4.255	4.362
SD	1.0599	1.4287	0.8271
Median	4.590	4.330	4.300
Minimum	3.45	2.45	3.37
Maximum	5.94	5.91	5.55
Month 24			
Number of patients with values	35	40	43
Mean	4.406	4.327	4.671
SD	1.3244	1.6765	1.3854
Median	3.960	4.000	4.520
Minimum	2.43	1.80	1.64
Maximum	8.23	9.16	8.35

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	9	4	5
Mean	4.848	5.303	4.182
SD	1.2364	1.9495	0.7110
Median	4.620	5.160	3.870
Minimum	3.42	3.07	3.57
Maximum	6.83	7.82	5.18
Month 30			
Number of patients with values	25	32	41
Mean	4.387	4.311	4.789
SD	1.6973	1.8048	2.3433
Median	4.160	4.115	4.310
Minimum	2.10	1.83	2.09
Maximum	10.41	9.56	13.08
Month 33			
Number of patients with values	1	5	6
Mean	7.220	5.516	4.158
SD		1.7356	0.7160
Median	7.220	5.460	4.110
Minimum	7.22	3.87	3.21
Maximum	7.22	8.24	4.95
Month 36			
Number of patients with values	20	23	28
Mean	4.240	3.984	4.848
SD	0.9211	1.4619	1.5283
Median	4.295	3.530	4.790
Minimum	2.66	1.96	2.46
Maximum	5.66	8.73	8.87

BRL 49653C/009

Data Source Table 14.1Ab
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	4.178	5.000	4.714
SD	0.9062	1.8044	1.5532
Median	4.465	4.770	4.560
Minimum	2.86	3.39	3.02
Maximum	4.92	7.07	7.58
Month 42			
Number of patients with values	8	12	8
Mean	4.729	4.549	3.846
SD	1.2523	1.7367	0.9611
Median	4.380	4.130	3.520
Minimum	3.72	2.52	2.80
Maximum	7.42	8.59	5.73
Month 45			
Number of patients with values	5	3	6
Mean	4.796	3.967	4.122
SD	0.6207	0.5677	0.6489
Median	4.560	4.150	3.975
Minimum	4.24	3.33	3.35
Maximum	5.70	4.42	5.06
Month 48			
Number of patients with values	0	1	1
Mean		3.510	4.210
SD			
Median		3.510	4.210
Minimum		3.51	4.21
Maximum		3.51	4.21

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Double Blind Baseline			
Number of patients with values	60	76	89
Mean	3.208	3.189	3.325
SD	0.9195	1.1161	1.1267
Median	3.225	3.160	3.120
Minimum	1.16	0.70	0.98
Maximum	5.66	6.25	6.04
Open Label Baseline			
Number of patients with values	60	76	90
Mean	3.063	3.128	3.300
SD	0.8680	1.1396	1.4327
Median	3.080	2.990	2.930
Minimum	1.12	0.83	1.04
Maximum	5.35	6.73	7.54
Month 0			
Number of patients with values	7	9	10
Mean	2.906	3.116	3.711
SD	0.9758	0.7965	2.0152
Median	2.760	3.440	3.050
Minimum	1.82	1.65	1.10
Maximum	4.46	4.00	7.54
Month 1			
Number of patients with values	2	1	0
Mean	3.395	3.030	
SD	1.6051		
Median	3.395	3.030	
Minimum	2.26	3.03	
Maximum	4.53	3.03	
Month 2			
Number of patients with values	1	2	3
Mean	2.250	3.375	3.953
SD		0.1909	0.6830
Median	2.250	3.375	3.800
Minimum	2.25	3.24	3.36
Maximum	2.25	3.51	4.70

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients with values	6	2	5
Mean	3.302	3.590	3.086
SD	0.9071	0.4101	1.0954
Median	3.130	3.590	2.780
Minimum	2.37	3.30	2.32
Maximum	4.87	3.88	5.00
Month 6			
Number of patients with values	48	60	74
Mean	3.097	2.734	3.051
SD	1.5139	1.0699	1.2009
Median	2.795	2.580	2.850
Minimum	1.30	0.71	0.81
Maximum	11.56	5.34	6.69
Month 9			
Number of patients with values	1	4	4
Mean	4.110	3.260	2.730
SD		0.4925	1.0180
Median	4.110	3.290	2.530
Minimum	4.11	2.65	1.88
Maximum	4.11	3.81	3.98
Month 12			
Number of patients with values	46	55	63
Mean	2.848	2.904	2.841
SD	0.6304	1.1956	1.1409
Median	2.890	2.700	2.590
Minimum	1.34	0.67	0.86
Maximum	4.02	6.45	5.82

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients with values	5	6	6
Mean	4.114	1.928	2.343
SD	1.5764	0.8958	0.5932
Median	3.430	1.735	2.195
Minimum	3.00	1.00	1.63
Maximum	6.84	3.43	3.24
Month 18			
Number of patients with values	40	47	55
Mean	2.842	2.482	2.820
SD	0.9919	0.9418	0.9156
Median	2.830	2.290	2.670
Minimum	0.75	0.67	1.40
Maximum	4.95	4.79	5.37
Month 21			
Number of patients with values	4	4	5
Mean	2.735	2.530	2.718
SD	1.0857	1.2474	0.6819
Median	2.505	2.410	2.760
Minimum	1.72	1.18	2.02
Maximum	4.21	4.12	3.79
Month 24			
Number of patients with values	34	35	41
Mean	2.718	2.404	2.800
SD	1.0988	1.0369	1.0482
Median	2.555	2.200	2.750
Minimum	0.48	0.58	0.44
Maximum	5.48	4.85	5.07

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients with values	8	4	4
Mean	2.830	3.513	2.108
SD	0.8868	1.7060	0.4112
Median	2.485	3.255	2.230
Minimum	2.02	1.72	1.54
Maximum	4.59	5.82	2.43
Month 30			
Number of patients with values	23	30	38
Mean	2.422	2.436	2.577
SD	0.8935	1.3567	1.0253
Median	2.410	2.260	2.420
Minimum	0.53	0.65	0.79
Maximum	4.28	6.65	5.67
Month 33			
Number of patients with values	1	4	6
Mean	4.690	3.213	2.550
SD		0.8316	0.6063
Median	4.690	2.955	2.475
Minimum	4.69	2.53	1.94
Maximum	4.69	4.41	3.50
Month 36			
Number of patients with values	20	22	27
Mean	2.593	2.361	2.950
SD	0.7364	1.1901	1.2079
Median	2.725	2.010	2.900
Minimum	0.70	0.57	1.12
Maximum	3.84	6.23	6.52

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100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 14.1Ab
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd	015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients with values	4	4	9
Mean	2.493	2.690	2.952
SD	0.6562	1.0876	1.2098
Median	2.700	2.805	2.720
Minimum	1.55	1.41	1.74
Maximum	3.02	3.74	5.24
Month 42			
Number of patients with values	8	12	8
Mean	3.014	2.829	2.208
SD	0.8890	1.3832	0.5947
Median	2.760	2.605	2.145
Minimum	2.28	1.22	1.54
Maximum	4.95	6.44	3.43
Month 45			
Number of patients with values	5	3	5
Mean	3.164	2.557	2.570
SD	0.5689	0.3798	0.6311
Median	2.890	2.740	2.320
Minimum	2.68	2.12	1.89
Maximum	4.05	2.81	3.38
Month 48			
Number of patients with values	0	1	1
Mean		2.060	2.510
SD			
Median		2.060	2.510
Minimum		2.06	2.51
Maximum		2.06	2.51

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100TV9/1/CPMS-009

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	8.08	7.88	7.96	8.02
SD	1.496	1.189	1.160	1.163
Median	8.00	7.70	7.90	8.05
Minimum	5.8	6.0	4.8	6.1
Maximum	13.8	11.6	11.3	10.2
Open Label Baseline				
Number of patients with values	124	136	139	28
Mean	7.35	7.40	7.18	8.39
SD	1.356	1.221	1.159	1.661
Median	7.00	7.10	7.00	8.05
Minimum	3.9	5.6	4.4	6.0
Maximum	11.5	11.4	11.5	11.5
Month 0				
Number of patients with values	4	11	6	1
Mean	8.10	7.08	7.33	6.00
SD	1.917	0.880	1.023	
Median	7.80	7.00	7.30	6.00
Minimum	6.2	6.1	6.3	6.0
Maximum	10.6	9.1	8.8	6.0
Month 1				
Number of patients with values	120	130	133	26
Mean	7.32	7.42	7.81	8.31
SD	1.443	1.164	1.307	1.660
Median	6.90	7.25	7.70	7.90
Minimum	4.9	4.4	4.7	6.1
Maximum	13.9	10.8	11.5	11.3
Month 2				
Number of patients with values	114	131	132	23
Mean	7.26	7.29	8.04	8.05
SD	1.319	1.129	1.359	1.405
Median	6.95	7.10	7.90	7.60
Minimum	4.7	4.5	4.8	6.1
Maximum	12.4	11.4	11.5	11.1

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	118	127	129	22
Mean	7.35	7.27	7.97	7.84
SD	1.463	1.071	1.353	1.380
Median	7.10	7.10	7.80	7.30
Minimum	5.2	5.1	5.0	6.3
Maximum	15.8	11.0	12.1	10.6
Month 6				
Number of patients with values	114	127	125	17
Mean	7.22	7.24	7.77	7.38
SD	1.142	1.114	1.347	1.153
Median	7.10	7.10	7.40	7.20
Minimum	4.9	5.4	4.8	5.9
Maximum	11.1	11.1	12.5	10.2
Month 9				
Number of patients with values	115	124	117	18
Mean	7.28	7.21	7.61	7.39
SD	1.181	0.990	1.201	1.015
Median	7.10	6.95	7.30	7.10
Minimum	4.9	5.2	5.0	6.1
Maximum	10.9	10.4	11.1	9.9
Month 12				
Number of patients with values	105	113	107	17
Mean	7.38	7.29	7.59	7.45
SD	1.313	1.146	1.225	1.174
Median	7.10	6.90	7.30	7.10
Minimum	5.0	5.0	4.9	6.1
Maximum	11.6	11.6	11.4	9.9

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	100	108	97	9
Mean	7.33	7.30	7.57	7.12
SD	1.192	1.230	1.251	1.168
Median	7.10	7.05	7.40	6.80
Minimum	5.1	5.4	4.8	5.9
Maximum	11.0	12.0	11.8	9.7
Month 18				
Number of patients with values	97	97	89	10
Mean	7.32	7.19	7.46	7.29
SD	1.307	1.133	1.196	0.905
Median	7.10	6.90	7.30	7.10
Minimum	5.0	5.4	4.6	6.1
Maximum	12.0	12.2	10.8	8.7
Month 21				
Number of patients with values	93	94	84	8
Mean	7.32	7.20	7.36	6.88
SD	1.338	1.057	1.034	0.705
Median	7.20	6.90	7.15	6.95
Minimum	4.4	5.6	4.6	6.0
Maximum	10.5	10.3	9.9	7.8
Month 24				
Number of patients with values	84	83	80	5
Mean	7.40	7.33	7.49	6.88
SD	1.334	1.172	1.058	0.773
Median	7.10	6.90	7.30	7.30
Minimum	4.7	5.2	5.6	5.9
Maximum	10.8	12.1	10.4	7.6

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	73	77	70	6
Mean	7.52	7.28	7.42	6.88
SD	1.427	1.070	1.107	0.588
Median	7.20	7.00	7.20	6.65
Minimum	5.1	5.0	4.9	6.4
Maximum	12.6	9.8	10.4	7.8
Month 30				
Number of patients with values	54	69	52	5
Mean	7.40	7.33	7.35	6.90
SD	1.216	1.064	0.973	0.495
Median	7.10	7.10	7.20	6.80
Minimum	5.7	5.3	5.7	6.3
Maximum	10.9	10.3	9.8	7.5
Month 33				
Number of patients with values	53	47	53	3
Mean	7.39	7.06	7.27	6.60
SD	1.381	1.096	0.965	0.781
Median	7.00	6.90	7.20	6.20
Minimum	4.8	5.5	5.2	6.1
Maximum	11.1	10.0	9.9	7.5
Month 36				
Number of patients with values	24	25	28	1
Mean	7.40	6.94	7.36	7.20
SD	1.470	0.945	1.077	
Median	6.80	6.80	7.05	7.20
Minimum	6.0	5.4	6.0	7.2
Maximum	11.0	8.8	10.1	7.2

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Hemoglobin A1c (%)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	6	7	1
Mean	6.80	6.72	7.04	5.90
SD	0.141	1.413	0.602	
Median	6.80	6.30	6.90	5.90
Minimum	6.7	5.6	6.3	5.9
Maximum	6.9	9.4	8.0	5.9
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	187.2	181.0	183.7	190.8
SD	48.64	52.03	43.42	42.28
Median	175.0	168.0	173.0	182.0
Minimum	121	102	114	130
Maximum	407	337	291	270
Open Label Baseline				
Number of patients with values	124	136	139	30
Mean	144.1	153.2	155.2	176.1
SD	40.68	39.56	37.23	48.82
Median	136.0	148.0	152.0	159.0
Minimum	61	86	75	106
Maximum	280	266	286	292
Month 0				
Number of patients with values	4	11	6	0
Mean	152.0	143.5	171.2	
SD	57.10	49.62	30.84	
Median	144.0	132.0	172.5	
Minimum	91	89	136	
Maximum	229	252	211	
Month 1				
Number of patients with values	120	132	133	25
Mean	144.9	147.7	175.9	166.1
SD	49.82	37.61	49.02	50.93
Median	136.5	143.0	164.0	148.0
Minimum	89	80	105	105
Maximum	521	284	366	273
Month 2				
Number of patients with values	113	131	134	23
Mean	139.9	142.9	164.9	147.8
SD	37.19	33.66	40.96	35.47
Median	130.0	136.0	155.0	139.0
Minimum	82	73	86	98
Maximum	255	246	284	223

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	117	127	130	22
Mean	139.5	141.8	162.8	149.3
SD	34.55	35.43	43.17	45.67
Median	130.0	134.0	154.0	142.0
Minimum	79	82	86	80
Maximum	250	266	298	259
Month 6				
Number of patients with values	114	127	122	17
Mean	136.9	137.8	149.7	139.3
SD	34.31	35.66	39.69	29.62
Median	129.0	130.0	141.0	125.0
Minimum	84	91	80	102
Maximum	239	312	286	204
Month 9				
Number of patients with values	114	125	116	18
Mean	138.1	136.6	148.1	131.2
SD	36.37	29.16	35.01	29.86
Median	133.0	134.0	141.0	130.5
Minimum	75	84	87	64
Maximum	246	220	268	191
Month 12				
Number of patients with values	104	114	108	17
Mean	139.0	140.6	147.5	132.3
SD	35.47	31.47	39.60	28.67
Median	132.0	135.0	141.0	125.0
Minimum	82	79	89	98
Maximum	237	243	304	182

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	104	110	98	8
Mean	137.2	138.4	145.5	130.8
SD	39.50	33.42	35.83	24.26
Median	129.5	130.0	136.5	118.0
Minimum	30	87	89	109
Maximum	248	246	277	175
Month 18				
Number of patients with values	99	98	89	9
Mean	141.5	139.2	148.1	121.6
SD	41.92	32.83	42.79	24.42
Median	136.0	132.0	134.0	109.0
Minimum	61	86	89	98
Maximum	257	266	280	162
Month 21				
Number of patients with values	94	95	82	8
Mean	139.8	141.0	145.5	120.8
SD	40.45	38.50	35.07	15.48
Median	130.0	136.0	139.0	118.0
Minimum	71	68	87	102
Maximum	241	318	257	143
Month 24				
Number of patients with values	84	83	78	5
Mean	140.2	140.5	146.4	122.6
SD	41.70	36.87	35.60	14.54
Median	133.0	132.0	138.0	120.0
Minimum	75	70	96	107
Maximum	284	279	291	145

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	74	77	72	6
Mean	142.0	137.3	140.3	126.2
SD	42.89	31.95	32.44	34.58
Median	133.0	130.0	129.5	121.5
Minimum	79	61	95	91
Maximum	295	221	237	189
Month 30				
Number of patients with values	56	69	51	4
Mean	137.6	141.7	138.9	121.8
SD	35.26	37.44	29.15	18.01
Median	131.0	132.0	134.0	116.0
Minimum	82	86	96	107
Maximum	227	282	204	148
Month 33				
Number of patients with values	52	48	54	3
Mean	145.3	134.0	138.7	119.7
SD	44.18	31.57	32.78	18.58
Median	133.0	124.0	131.0	111.0
Minimum	71	84	80	107
Maximum	250	230	248	141
Month 36				
Number of patients with values	23	26	27	1
Mean	141.4	133.7	139.1	123.0
SD	55.17	25.27	33.19	
Median	123.0	136.5	129.0	123.0
Minimum	82	96	87	123
Maximum	320	200	204	123

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	6	7	1
Mean	119.5	131.0	135.7	112.0
SD	2.12	32.83	21.70	
Median	119.5	118.0	132.0	112.0
Minimum	118	95	102	112
Maximum	121	179	173	112
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	112	126	127	0
Mean	73.85	65.59	63.13	
SD	62.997	40.184	45.558	
Median	58.00	53.00	49.00	
Minimum	9.5	16.0	8.0	
Maximum	535.0	249.0	275.0	
Open Label Baseline				
Number of patients with values	118	128	134	0
Mean	59.94	59.62	75.87	
SD	83.054	48.555	53.718	
Median	45.00	48.00	60.00	
Minimum	3.6	14.0	8.2	
Maximum	722.0	379.0	290.0	
Month 0				
Number of patients with values	4	9	5	0
Mean	57.75	52.89	53.40	
SD	25.941	21.497	44.568	
Median	59.50	60.00	50.00	
Minimum	25.0	20.0	17.0	
Maximum	87.0	84.0	126.0	
Month 1				
Number of patients with values	2	3	2	0
Mean	42.50	30.33	64.50	
SD	13.435	6.110	2.121	
Median	42.50	29.00	64.50	
Minimum	33.0	25.0	63.0	
Maximum	52.0	37.0	66.0	
Month 2				
Number of patients with values	0	0	2	0
Mean			31.50	
SD			9.192	
Median			31.50	
Minimum			25.0	
Maximum			38.0	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	1	1	3	0
Mean	46.00	37.00	30.33	
SD			11.015	
Median	46.00	37.00	25.00	
Minimum	46.0	37.0	23.0	
Maximum	46.0	37.0	43.0	
Month 6				
Number of patients with values	109	117	116	12
Mean	53.49	50.00	46.88	59.50
SD	52.703	29.212	34.422	30.518
Median	42.00	42.00	35.50	50.50
Minimum	3.9	15.0	9.9	27.0
Maximum	439.0	140.0	201.0	131.0
Month 9				
Number of patients with values	4	4	4	3
Mean	48.00	62.75	43.75	34.00
SD	41.126	66.860	13.074	7.211
Median	42.00	30.00	44.00	36.00
Minimum	13.0	28.0	31.0	26.0
Maximum	95.0	163.0	56.0	40.0
Month 12				
Number of patients with values	90	101	96	12
Mean	58.04	52.33	52.40	41.00
SD	60.768	33.572	40.118	13.094
Median	44.50	38.00	40.00	40.00
Minimum	13.0	9.6	12.0	24.0
Maximum	388.0	151.0	298.0	62.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	4	11	8	0
Mean	32.25	60.45	28.49	
SD	11.955	36.492	15.749	
Median	33.00	49.00	28.00	
Minimum	20.0	29.0	7.9	
Maximum	43.0	152.0	56.0	
Month 18				
Number of patients with values	84	82	78	5
Mean	49.71	50.82	49.39	40.00
SD	51.373	29.301	31.401	18.828
Median	40.00	41.50	44.50	37.00
Minimum	10.0	14.0	9.3	20.0
Maximum	453.0	150.0	186.0	70.0
Month 21				
Number of patients with values	1	2	4	0
Mean	42.00	38.00	41.50	
SD		5.657	17.020	
Median	42.00	38.00	40.50	
Minimum	42.0	34.0	24.0	
Maximum	42.0	42.0	61.0	
Month 24				
Number of patients with values	72	70	64	2
Mean	54.92	52.08	50.02	29.50
SD	71.661	35.934	40.875	14.849
Median	37.50	42.50	38.50	29.50
Minimum	7.2	1.7	10.0	19.0
Maximum	546.0	182.0	281.0	40.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	5	5	1	2
Mean	33.00	44.40	51.00	55.00
SD	25.020	23.126		15.556
Median	23.00	40.00	51.00	55.00
Minimum	10.0	20.0	51.0	44.0
Maximum	68.0	82.0	51.0	66.0
Month 30				
Number of patients with values	41	49	40	3
Mean	40.59	47.33	49.33	46.00
SD	17.824	26.254	34.575	23.812
Median	37.00	40.00	39.50	37.00
Minimum	12.0	13.0	10.0	28.0
Maximum	82.0	128.0	192.0	73.0
Month 33				
Number of patients with values	24	9	18	0
Mean	61.75	55.44	45.17	
SD	111.630	49.087	21.705	
Median	39.00	42.00	36.50	
Minimum	15.0	19.0	21.0	
Maximum	580.0	183.0	112.0	
Month 36				
Number of patients with values	15	21	21	1
Mean	49.33	44.52	60.67	24.00
SD	37.113	21.938	48.528	
Median	33.00	39.00	39.00	24.00
Minimum	12.0	11.0	12.0	24.0
Maximum	131.0	103.0	184.0	24.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Insulin (pmol/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	1	4	7	1
Mean	28.00	52.50	41.29	42.00
SD		40.632	21.762	
Median	28.00	35.50	30.00	42.00
Minimum	28.0	26.0	14.0	42.0
Maximum	28.0	113.0	69.0	42.0
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	112	119	127	0
Mean	17.35	21.81	37.11	
SD	33.561	48.735	136.389	
Median	7.00	5.00	8.00	
Minimum	1.0	1.0	1.0	
Maximum	256.0	393.0	1390.0	
Open Label Baseline				
Number of patients with values	124	134	138	0
Mean	13.78	28.76	46.77	
SD	25.020	81.052	178.705	
Median	5.50	6.00	7.00	
Minimum	1.0	1.0	1.0	
Maximum	194.0	618.0	1880.0	
Month 0				
Number of patients with values	7	12	7	0
Mean	32.71	17.00	310.86	
SD	34.340	16.017	698.204	
Median	15.00	14.00	10.00	
Minimum	3.0	2.0	3.0	
Maximum	94.0	55.0	1880.0	
Month 1				
Number of patients with values	3	5	4	4
Mean	63.67	7.20	26.50	12.00
SD	47.438	4.324	23.629	6.976
Median	88.00	8.00	19.00	13.50
Minimum	9.0	2.0	8.0	3.0
Maximum	94.0	13.0	60.0	18.0
Month 2				
Number of patients with values	0	0	2	0
Mean			11.00	
SD			1.414	
Median			11.00	
Minimum			10.0	
Maximum			12.0	

Data Source Table 14.1Ac
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	1	1	2	0
Mean	4.00	71.00	5.00	
SD			2.828	
Median	4.00	71.00	5.00	
Minimum	4.0	71.0	3.0	
Maximum	4.0	71.0	7.0	
Month 6				
Number of patients with values	101	113	108	11
Mean	29.75	34.93	34.31	33.82
SD	71.284	120.168	72.826	40.899
Median	6.00	6.00	6.50	15.00
Minimum	2.0	2.0	2.0	2.0
Maximum	534.0	1120.0	526.0	121.0
Month 9				
Number of patients with values	4	3	3	3
Mean	22.50	8.00	48.00	10.00
SD	35.679	6.245	68.462	5.292
Median	5.00	6.00	11.00	12.00
Minimum	4.0	3.0	6.0	4.0
Maximum	76.0	15.0	127.0	14.0
Month 12				
Number of patients with values	95	98	98	15
Mean	107.67	61.50	67.08	617.60
SD	819.632	200.971	260.796	2220.542
Median	7.00	8.00	9.50	11.00
Minimum	2.0	2.0	2.0	2.0
Maximum	8000.0	1540.0	2450.0	8640.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	9	10	5	1
Mean	15.33	68.40	16.40	6.00
SD	23.743	121.921	22.865	
Median	4.00	14.50	6.00	6.00
Minimum	2.0	2.0	2.0	6.0
Maximum	74.0	380.0	56.0	6.0
Month 18				
Number of patients with values	84	83	74	6
Mean	42.08	62.67	57.14	15.67
SD	156.693	278.149	138.827	12.388
Median	7.50	8.00	9.50	13.00
Minimum	2.0	2.0	2.0	5.0
Maximum	1070.0	2170.0	818.0	39.0
Month 21				
Number of patients with values	4	3	3	0
Mean	384.75	7.67	3.33	
SD	736.867	6.028	1.528	
Median	21.00	7.00	3.00	
Minimum	7.0	2.0	2.0	
Maximum	1490.0	14.0	5.0	
Month 24				
Number of patients with values	71	68	67	5
Mean	26.01	78.19	51.82	45.60
SD	66.953	422.468	105.117	83.083
Median	8.00	8.00	11.00	8.00
Minimum	2.0	2.0	2.0	4.0
Maximum	485.0	3480.0	644.0	194.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	7	6	3	2
Mean	14.57	120.17	31.67	5.00
SD	8.829	276.768	25.541	1.414
Median	12.00	6.00	30.00	5.00
Minimum	4.0	2.0	7.0	4.0
Maximum	27.0	685.0	58.0	6.0
Month 30				
Number of patients with values	43	57	45	5
Mean	20.79	15.18	53.13	24.40
SD	43.895	24.645	115.058	40.716
Median	7.00	6.00	13.00	7.00
Minimum	2.0	2.0	2.0	2.0
Maximum	259.0	117.0	515.0	97.0
Month 33				
Number of patients with values	22	12	20	0
Mean	42.68	75.58	77.45	
SD	128.141	146.837	139.974	
Median	7.00	12.50	23.00	
Minimum	2.0	2.0	2.0	
Maximum	604.0	489.0	572.0	
Month 36				
Number of patients with values	16	22	23	1
Mean	14.06	18.82	31.70	6.00
SD	23.345	32.834	52.597	
Median	6.00	7.00	7.00	6.00
Minimum	2.0	2.0	2.0	6.0
Maximum	93.0	144.0	188.0	6.0

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Urinary Albumin (mg/L)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	4	5	0
Mean	2.00	82.75	18.20	
SD	0.000	139.600	32.935	
Median	2.00	18.50	3.00	
Minimum	2.0	3.0	2.0	
Maximum	2.0	291.0	77.0	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	29
Mean	223.1	220.6	222.9	207.3
SD	43.56	45.45	38.78	37.65
Median	222.0	215.0	222.0	205.0
Minimum	115	133	131	114
Maximum	364	437	330	288
Open Label Baseline				
Number of patients with values	124	136	139	26
Mean	249.7	238.2	221.2	218.2
SD	62.86	45.58	36.12	37.62
Median	243.5	239.0	218.0	213.0
Minimum	126	143	143	147
Maximum	491	407	326	322
Month 0				
Number of patients with values	4	10	6	1
Mean	281.0	208.0	222.3	202.0
SD	103.35	34.64	42.39	
Median	241.5	203.5	220.0	202.0
Minimum	207	143	173	202
Maximum	434	257	281	202
Month 1				
Number of patients with values	3	6	2	0
Mean	232.0	222.2	280.0	
SD	36.06	44.41	45.25	
Median	242.0	238.0	280.0	
Minimum	192	157	248	
Maximum	262	266	312	
Month 2				
Number of patients with values	0	1	4	0
Mean		263.0	283.8	
SD			33.13	
Median		263.0	287.5	
Minimum		263	246	
Maximum		263	314	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	11	0
Mean	225.5	236.3	270.7	
SD	35.11	49.73	52.91	
Median	220.0	244.0	261.0	
Minimum	189	120	167	
Maximum	273	296	334	
Month 6				
Number of patients with values	110	120	112	15
Mean	238.4	241.8	253.2	216.5
SD	51.85	57.31	46.16	36.16
Median	236.0	237.0	249.0	219.0
Minimum	121	127	153	156
Maximum	393	540	398	290
Month 9				
Number of patients with values	6	10	9	4
Mean	224.7	225.9	283.6	219.5
SD	14.95	76.77	39.27	44.12
Median	223.0	214.5	287.0	218.0
Minimum	207	123	210	167
Maximum	245	376	341	275
Month 12				
Number of patients with values	95	107	102	16
Mean	238.7	232.1	252.1	224.3
SD	49.81	49.21	48.94	34.62
Median	233.0	230.0	242.5	222.5
Minimum	122	123	166	166
Maximum	367	374	436	288

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	7	14	8	1
Mean	223.1	242.9	272.0	189.0
SD	44.28	53.92	78.00	
Median	233.0	248.5	279.0	189.0
Minimum	154	136	175	189
Maximum	277	334	369	189
Month 18				
Number of patients with values	89	94	83	8
Mean	233.5	230.2	243.6	209.0
SD	42.87	51.65	53.28	18.49
Median	233.0	225.5	241.0	212.5
Minimum	128	138	152	178
Maximum	337	380	442	233
Month 21				
Number of patients with values	4	4	5	0
Mean	226.5	255.8	213.6	
SD	23.63	32.07	60.55	
Median	231.0	245.0	186.0	
Minimum	196	232	153	
Maximum	248	301	301	
Month 24				
Number of patients with values	76	74	68	4
Mean	226.0	225.4	230.4	226.3
SD	42.30	48.22	39.99	24.06
Median	231.0	220.0	229.5	227.5
Minimum	147	144	128	200
Maximum	342	368	321	250

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	8	8	5	1
Mean	252.3	243.0	235.6	197.0
SD	40.57	71.89	48.14	
Median	257.5	232.5	222.0	197.0
Minimum	176	163	181	197
Maximum	299	369	297	197
Month 30				
Number of patients with values	46	61	46	3
Mean	228.4	224.1	232.6	202.3
SD	36.82	63.25	42.59	4.73
Median	227.0	207.0	224.5	204.0
Minimum	137	112	156	197
Maximum	308	428	359	206
Month 33				
Number of patients with values	22	14	18	0
Mean	228.5	218.0	225.8	
SD	37.23	56.38	39.09	
Median	227.5	206.0	227.5	
Minimum	172	136	145	
Maximum	307	340	286	
Month 36				
Number of patients with values	17	22	21	1
Mean	231.1	214.5	212.6	214.0
SD	39.59	39.15	45.66	
Median	227.0	217.0	202.0	214.0
Minimum	162	134	144	214
Maximum	294	292	317	214

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	224.5	241.8	214.0	
SD	68.59	68.60	26.82	
Median	224.5	235.0	202.5	
Minimum	176	159	197	
Maximum	273	330	254	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	49.3	46.9	47.1	49.6
SD	15.03	14.74	15.75	14.20
Median	47.0	44.5	45.0	44.5
Minimum	17	20	19	32
Maximum	97	97	123	96
Open Label Baseline				
Number of patients with values	124	136	139	26
Mean	55.7	52.4	49.7	53.8
SD	16.83	14.93	12.62	13.69
Median	55.0	49.5	49.0	52.0
Minimum	18	23	20	36
Maximum	115	114	94	103
Month 0				
Number of patients with values	4	11	6	1
Mean	60.8	52.7	51.0	52.0
SD	9.03	14.55	9.96	
Median	62.0	55.0	53.0	52.0
Minimum	49	29	37	52
Maximum	70	76	63	52
Month 1				
Number of patients with values	3	6	2	0
Mean	54.0	47.5	54.5	
SD	23.64	16.43	9.19	
Median	64.0	42.5	54.5	
Minimum	27	25	48	
Maximum	71	71	61	
Month 2				
Number of patients with values	0	1	4	0
Mean		45.0	67.0	
SD			23.17	
Median		45.0	59.5	
Minimum		45	49	
Maximum		45	100	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	10	0
Mean	66.5	56.6	56.5	
SD	39.04	12.95	11.50	
Median	52.5	54.0	53.0	
Minimum	37	40	43	
Maximum	124	81	81	
Month 6				
Number of patients with values	107	117	113	15
Mean	56.5	53.6	54.3	54.5
SD	17.07	13.34	16.32	14.78
Median	55.0	53.0	53.0	53.0
Minimum	21	26	15	38
Maximum	112	88	94	98
Month 9				
Number of patients with values	6	10	8	4
Mean	55.5	55.8	51.6	56.0
SD	14.36	12.35	11.10	10.23
Median	60.0	53.0	52.0	53.5
Minimum	32	43	38	47
Maximum	70	82	68	70
Month 12				
Number of patients with values	97	106	103	15
Mean	57.2	55.4	54.2	56.6
SD	16.41	15.01	15.52	15.48
Median	55.0	53.0	53.0	50.0
Minimum	24	24	17	37
Maximum	112	100	95	98

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	7	14	8	1
Mean	57.7	49.5	60.8	48.0
SD	18.78	13.34	24.11	
Median	59.0	49.0	58.0	48.0
Minimum	29	20	33	48
Maximum	83	75	92	48
Month 18				
Number of patients with values	89	94	84	8
Mean	58.2	56.7	58.2	57.3
SD	16.51	17.55	16.23	11.78
Median	55.0	53.5	58.5	58.0
Minimum	22	24	30	37
Maximum	110	111	110	78
Month 21				
Number of patients with values	4	4	5	0
Mean	63.5	57.8	48.6	
SD	21.76	7.18	21.50	
Median	54.0	57.0	48.0	
Minimum	50	50	24	
Maximum	96	67	73	
Month 24				
Number of patients with values	75	73	69	4
Mean	57.2	56.2	56.1	60.5
SD	15.53	13.97	15.40	6.86
Median	56.0	54.0	54.0	61.5
Minimum	22	30	20	52
Maximum	112	90	85	67

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	8	8	4	1
Mean	57.1	58.0	50.8	85.0
SD	25.36	27.12	12.15	
Median	56.0	52.0	50.0	85.0
Minimum	21	23	39	85
Maximum	95	89	64	85
Month 30				
Number of patients with values	46	61	45	3
Mean	57.9	55.4	58.1	55.7
SD	15.37	13.08	18.18	4.62
Median	56.0	56.0	59.0	53.0
Minimum	34	32	20	53
Maximum	106	107	113	61
Month 33				
Number of patients with values	22	14	18	0
Mean	57.6	54.4	51.8	
SD	26.84	14.81	8.49	
Median	49.5	55.0	53.0	
Minimum	27	37	38	
Maximum	133	98	63	
Month 36				
Number of patients with values	17	22	21	1
Mean	54.7	54.9	54.5	55.0
SD	17.95	10.99	15.45	
Median	51.0	57.0	53.0	55.0
Minimum	25	35	23	55
Maximum	95	77	82	55

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: HDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	61.0	46.4	69.0	
SD	16.97	17.53	6.93	
Median	61.0	38.0	71.0	
Minimum	49	30	59	
Maximum	73	73	75	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	122	133	136	27
Mean	142.1	140.3	141.8	121.7
SD	34.54	32.93	34.76	28.19
Median	140.0	137.0	142.0	129.0
Minimum	60	60	60	62
Maximum	237	231	250	169
Open Label Baseline				
Number of patients with values	123	135	139	26
Mean	156.5	149.0	138.8	132.5
SD	45.17	36.33	32.45	34.42
Median	150.0	146.0	138.0	136.5
Minimum	60	65	62	71
Maximum	287	256	219	242
Month 0				
Number of patients with values	3	10	6	1
Mean	141.0	119.3	127.7	133.0
SD	15.72	30.36	32.46	
Median	148.0	111.0	123.0	133.0
Minimum	123	65	96	133
Maximum	152	165	165	133
Month 1				
Number of patients with values	3	5	2	0
Mean	141.3	136.0	188.5	
SD	25.72	34.37	10.61	
Median	152.0	140.0	188.5	
Minimum	112	88	181	
Maximum	160	173	196	
Month 2				
Number of patients with values	0	1	4	0
Mean		194.0	189.5	
SD			32.99	
Median		194.0	186.5	
Minimum		194	154	
Maximum		194	231	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	10	0
Mean	117.0	146.1	181.0	
SD	43.52	47.18	51.61	
Median	101.0	140.0	177.0	
Minimum	85	42	94	
Maximum	181	213	252	
Month 6				
Number of patients with values	98	112	103	15
Mean	148.3	151.8	159.9	130.5
SD	45.44	41.83	40.11	39.86
Median	144.0	149.0	160.0	138.0
Minimum	65	58	65	58
Maximum	269	256	262	198
Month 9				
Number of patients with values	6	9	5	4
Mean	138.3	129.8	181.2	134.3
SD	15.36	68.77	40.16	35.57
Median	137.5	133.0	185.0	135.0
Minimum	123	50	117	90
Maximum	165	277	227	177
Month 12				
Number of patients with values	92	103	94	15
Mean	148.0	144.4	159.8	133.7
SD	43.89	44.44	40.65	24.51
Median	148.0	140.0	157.0	125.0
Minimum	54	42	88	104
Maximum	248	269	285	179

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	6	14	8	1
Mean	130.3	155.6	176.3	112.0
SD	40.22	48.82	78.61	
Median	135.5	166.0	177.5	112.0
Minimum	83	58	71	112
Maximum	183	215	267	112
Month 18				
Number of patients with values	86	91	77	8
Mean	144.1	139.8	145.4	131.3
SD	39.76	43.76	42.08	18.74
Median	147.0	131.0	144.0	137.5
Minimum	60	52	65	104
Maximum	233	269	246	156
Month 21				
Number of patients with values	4	4	4	0
Mean	127.0	170.0	110.0	
SD	28.37	15.12	28.61	
Median	132.0	169.5	100.0	
Minimum	88	156	88	
Maximum	156	185	152	
Month 24				
Number of patients with values	73	72	66	4
Mean	136.6	138.6	141.7	140.0
SD	35.60	45.58	37.69	14.45
Median	140.0	124.0	137.0	139.5
Minimum	65	71	63	125
Maximum	225	269	237	156

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	7	8	4	1
Mean	158.9	151.6	138.8	104.0
SD	29.25	58.88	56.06	
Median	160.0	132.5	130.0	104.0
Minimum	125	81	87	104
Maximum	210	254	208	104
Month 30				
Number of patients with values	45	57	42	3
Mean	142.4	133.5	141.6	131.0
SD	36.58	49.93	36.86	7.21
Median	142.0	117.0	135.5	133.0
Minimum	54	62	87	123
Maximum	227	254	248	137
Month 33				
Number of patients with values	22	14	16	0
Mean	134.7	131.1	134.6	
SD	34.02	54.47	34.79	
Median	133.0	122.0	137.5	
Minimum	81	48	79	
Maximum	225	265	200	
Month 36				
Number of patients with values	16	22	21	1
Mean	146.9	135.2	131.9	138.0
SD	43.35	33.98	40.16	
Median	141.5	132.5	117.0	138.0
Minimum	73	73	83	138
Maximum	206	210	215	138

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	144.5	154.4	131.3	
SD	54.45	64.02	24.74	
Median	144.5	163.0	124.0	
Minimum	106	67	110	
Maximum	183	238	167	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	29
Mean	169.0	196.2	178.9	209.7
SD	130.12	442.14	118.81	241.50
Median	132.0	137.5	148.0	143.0
Minimum	50	46	46	58
Maximum	1107	5142	857	1367
Open Label Baseline				
Number of patients with values	124	136	139	26
Mean	175.8	180.3	168.4	159.0
SD	124.56	110.24	98.09	74.41
Median	142.5	156.0	144.0	137.0
Minimum	52	42	45	75
Maximum	911	837	576	364
Month 0				
Number of patients with values	4	11	6	1
Mean	231.0	174.8	220.5	82.0
SD	180.10	95.34	126.13	
Median	185.0	180.0	206.0	82.0
Minimum	67	70	96	82
Maximum	487	355	385	82
Month 1				
Number of patients with values	3	6	2	0
Mean	183.7	188.3	185.0	
SD	168.42	130.11	124.45	
Median	93.0	142.5	185.0	
Minimum	80	98	97	
Maximum	378	440	273	
Month 2				
Number of patients with values	0	1	4	0
Mean		115.0	137.5	
SD			67.00	
Median		115.0	131.5	
Minimum		115	64	
Maximum		115	223	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	11	0
Mean	213.5	168.5	164.6	
SD	124.76	98.76	73.88	
Median	213.5	146.0	135.0	
Minimum	79	58	88	
Maximum	348	388	289	
Month 6				
Number of patients with values	111	120	113	15
Mean	175.0	183.3	193.8	160.0
SD	124.72	118.44	131.34	88.60
Median	142.0	151.0	143.0	128.0
Minimum	37	42	50	47
Maximum	801	728	700	363
Month 9				
Number of patients with values	6	10	9	4
Mean	156.0	172.7	360.3	149.0
SD	95.90	128.91	166.01	93.45
Median	124.0	113.0	278.0	154.0
Minimum	69	70	148	33
Maximum	292	480	638	255
Month 12				
Number of patients with values	96	107	102	16
Mean	178.9	163.8	190.4	146.1
SD	178.84	87.89	125.84	97.47
Median	137.0	143.0	151.5	98.5
Minimum	46	48	40	66
Maximum	1612	534	719	397

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	7	14	8	1
Mean	179.7	188.3	177.1	148.0
SD	189.56	92.12	105.98	
Median	125.0	167.0	186.0	148.0
Minimum	65	58	51	148
Maximum	604	390	308	148
Month 18				
Number of patients with values	89	94	83	8
Mean	163.0	166.7	198.1	104.5
SD	111.26	98.03	149.39	53.89
Median	129.0	140.5	149.0	99.0
Minimum	50	56	42	39
Maximum	687	624	897	188
Month 21				
Number of patients with values	4	4	5	0
Mean	182.0	146.3	246.4	
SD	108.47	66.97	248.45	
Median	173.0	125.5	129.0	
Minimum	59	91	88	
Maximum	323	243	684	
Month 24				
Number of patients with values	76	74	68	4
Mean	155.5	153.8	163.3	132.8
SD	116.49	93.22	96.05	62.79
Median	126.5	133.0	134.5	110.0
Minimum	54	53	54	86
Maximum	972	702	487	225

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	8	8	5	1
Mean	221.8	168.1	173.6	43.0
SD	195.25	95.09	77.85	
Median	133.5	138.0	125.0	43.0
Minimum	90	60	111	43
Maximum	658	365	266	43
Month 30				
Number of patients with values	47	61	46	3
Mean	137.0	170.6	172.8	80.3
SD	53.93	132.99	123.64	20.50
Median	127.0	134.0	134.0	80.0
Minimum	49	50	42	60
Maximum	281	900	705	101
Month 33				
Number of patients with values	22	14	18	0
Mean	181.3	160.7	205.6	
SD	70.72	60.39	141.00	
Median	173.0	152.5	165.5	
Minimum	51	72	40	
Maximum	308	276	619	
Month 36				
Number of patients with values	17	22	21	1
Mean	165.6	122.9	130.7	108.0
SD	130.33	53.96	56.64	
Median	141.0	121.5	127.0	108.0
Minimum	50	57	47	108
Maximum	596	296	310	108

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Triglycerides (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	97.0	203.4	65.0	
SD	18.38	83.25	23.68	
Median	97.0	179.0	67.5	
Minimum	84	96	35	
Maximum	110	312	90	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	21
Mean	26.440	25.457	26.282	25.990
SD	8.5814	8.4048	8.1656	8.8122
Median	25.850	24.010	25.420	23.160
Minimum	7.63	8.76	12.15	13.56
Maximum	55.93	57.63	52.54	41.53
Open Label Baseline				
Number of patients with values	124	136	139	24
Mean	18.849	20.364	23.546	23.399
SD	6.1485	6.3296	6.7810	7.2705
Median	18.360	19.915	23.160	20.625
Minimum	5.08	7.06	9.89	12.99
Maximum	37.85	38.42	41.53	40.11
Month 0				
Number of patients with values	5	12	7	0
Mean	24.350	19.680	28.129	
SD	8.2622	6.3338	8.3664	
Median	24.010	19.495	24.010	
Minimum	16.95	11.86	20.06	
Maximum	37.85	34.46	41.53	
Month 1				
Number of patients with values	2	5	4	0
Mean	16.670	17.626	21.470	
SD	1.5981	2.8440	7.4339	
Median	16.670	16.380	22.315	
Minimum	15.54	15.54	12.15	
Maximum	17.80	22.60	29.10	
Month 2				
Number of patients with values	0	0	4	0
Mean			23.658	
SD			8.2820	
Median			22.175	
Minimum			16.10	
Maximum			34.18	

Data Source Table 14.1Ac
 Summary Statistics for Efficacy Variables at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	1	0	5	0
Mean	18.080		20.114	
SD			5.5517	
Median	18.080		17.800	
Minimum	18.08		14.97	
Maximum	18.08		27.40	
Month 6				
Number of patients with values	109	120	119	13
Mean	21.282	20.407	21.786	20.036
SD	7.6771	5.8885	6.1941	5.8840
Median	19.770	19.490	21.190	18.930
Minimum	7.63	5.34	8.19	7.63
Maximum	70.06	39.27	38.98	29.66
Month 9				
Number of patients with values	4	4	4	3
Mean	15.608	16.378	21.965	16.667
SD	4.0506	2.3883	6.4731	8.7019
Median	16.245	16.385	21.470	15.250
Minimum	10.45	13.81	14.69	8.76
Maximum	19.49	18.93	30.23	25.99
Month 12				
Number of patients with values	94	100	96	12
Mean	21.555	21.461	22.092	22.222
SD	5.9965	8.0715	5.5377	7.6296
Median	20.200	20.340	22.030	20.195
Minimum	12.15	13.81	13.81	14.69
Maximum	48.31	79.38	39.55	43.79

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	4	12	8	0
Mean	20.760	23.938	23.481	
SD	4.8407	6.5708	4.1989	
Median	20.195	25.140	22.315	
Minimum	16.10	13.81	18.36	
Maximum	26.55	31.64	29.66	
Month 18				
Number of patients with values	87	84	80	6
Mean	21.343	22.847	22.625	22.880
SD	5.5776	7.9071	7.5347	6.0757
Median	20.060	21.890	21.610	22.595
Minimum	13.81	13.81	13.81	15.25
Maximum	39.83	58.19	55.08	31.92
Month 21				
Number of patients with values	1	2	4	0
Mean	38.980	21.465	24.080	
SD		2.3971	11.2202	
Median	38.980	21.465	19.630	
Minimum	38.98	19.77	16.38	
Maximum	38.98	23.16	40.68	
Month 24				
Number of patients with values	73	69	64	2
Mean	20.550	23.399	21.948	23.445
SD	5.8262	12.6421	5.9510	8.7893
Median	18.930	20.620	20.620	23.445
Minimum	13.81	13.81	13.81	17.23
Maximum	43.79	113.56	38.98	29.66

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	6	5	1	2
Mean	24.245	22.994	23.160	24.715
SD	6.9765	6.1977		2.1991
Median	26.270	20.900	23.160	24.715
Minimum	14.97	18.08	23.16	23.16
Maximum	31.07	33.05	23.16	26.27
Month 30				
Number of patients with values	43	49	42	3
Mean	20.719	20.696	21.126	22.127
SD	5.2503	5.0897	5.8383	5.6095
Median	19.490	19.210	20.900	19.770
Minimum	13.81	13.81	13.84	18.08
Maximum	35.88	32.20	40.68	28.53
Month 33				
Number of patients with values	24	9	18	0
Mean	21.891	20.837	19.976	
SD	5.6437	7.6993	4.9707	
Median	19.770	17.510	18.925	
Minimum	14.41	13.81	13.81	
Maximum	35.59	38.70	30.51	
Month 36				
Number of patients with values	15	21	20	1
Mean	19.899	19.289	20.153	31.070
SD	5.3382	4.2115	4.7696	
Median	18.640	18.080	19.350	31.070
Minimum	13.81	14.97	13.81	31.07
Maximum	33.33	30.79	30.23	31.07

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Free Fatty Acids (mg/dL)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	4	7	1
Mean	17.370	21.248	22.154	22.880
SD	2.9981	6.7682	4.6351	
Median	17.370	21.890	21.470	22.880
Minimum	15.25	13.81	15.82	22.88
Maximum	19.49	27.40	28.53	22.88
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	124	136	139	29
Mean	4.895	5.025	5.175	4.400
SD	1.7070	1.6196	1.7686	1.2731
Median	4.655	4.880	4.770	4.510
Minimum	2.03	2.56	2.14	2.14
Maximum	12.46	15.00	11.25	8.19
Open Label Baseline				
Number of patients with values	124	136	139	26
Mean	4.818	4.876	4.712	4.230
SD	1.7536	1.5820	1.3011	1.0265
Median	4.295	4.665	4.460	4.120
Minimum	2.06	2.37	2.16	2.24
Maximum	11.59	11.97	8.34	6.39
Month 0				
Number of patients with values	6	13	7	1
Mean	4.528	4.382	4.697	3.880
SD	1.3754	1.5556	1.6168	
Median	4.505	3.880	4.200	3.880
Minimum	2.96	2.55	3.09	3.88
Maximum	6.68	7.14	6.97	3.88
Month 1				
Number of patients with values	3	6	2	0
Mean	5.370	5.250	5.140	
SD	3.7555	2.5976	0.0424	
Median	3.410	4.265	5.140	
Minimum	3.00	3.25	5.11	
Maximum	9.70	10.24	5.17	
Month 2				
Number of patients with values	0	1	4	0
Mean		5.840	4.570	
SD			1.3766	
Median		5.840	4.850	
Minimum		5.84	2.66	
Maximum		5.84	5.92	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	10	0
Mean	4.228	4.376	4.928	
SD	2.3318	1.3621	1.1429	
Median	3.860	4.760	4.980	
Minimum	1.81	2.22	2.98	
Maximum	7.38	6.28	6.29	
Month 6				
Number of patients with values	106	117	111	15
Mean	4.663	4.750	5.260	4.237
SD	1.9374	1.5440	2.6832	1.3583
Median	4.215	4.430	4.630	4.300
Minimum	1.94	2.22	1.99	1.88
Maximum	12.00	10.55	21.13	7.25
Month 9				
Number of patients with values	6	10	8	4
Mean	4.350	4.145	5.741	4.105
SD	1.4097	1.4653	0.9969	1.4297
Median	3.785	3.860	5.455	4.090
Minimum	3.14	2.16	4.36	2.39
Maximum	6.66	7.27	7.45	5.85
Month 12				
Number of patients with values	95	106	102	15
Mean	4.545	4.460	5.161	4.144
SD	1.6936	1.4251	2.3905	1.3009
Median	4.310	4.290	4.405	3.860
Minimum	1.92	1.74	2.24	2.24
Maximum	11.47	8.55	16.88	7.51

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Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	7	14	8	1
Mean	4.410	5.175	5.368	3.940
SD	2.3970	1.5374	2.9006	
Median	3.970	4.825	4.885	3.940
Minimum	2.19	3.02	1.90	3.94
Maximum	9.55	8.15	9.32	3.94
Month 18				
Number of patients with values	89	94	83	8
Mean	4.312	4.382	4.486	3.775
SD	1.4547	1.5600	1.5713	0.7154
Median	4.080	4.205	4.110	3.830
Minimum	2.12	2.15	2.12	2.49
Maximum	10.55	12.40	9.00	4.81
Month 21				
Number of patients with values	4	4	5	0
Mean	3.890	4.433	5.478	
SD	1.2860	0.1986	4.0250	
Median	4.340	4.415	3.710	
Minimum	2.04	4.22	2.78	
Maximum	4.84	4.68	12.54	
Month 24				
Number of patients with values	75	73	68	4
Mean	4.182	4.207	4.541	3.763
SD	1.2360	1.2038	1.9382	0.4387
Median	4.000	4.100	4.145	3.740
Minimum	2.03	2.21	2.14	3.26
Maximum	7.43	7.17	14.30	4.31

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	8	8	4	1
Mean	5.121	4.709	4.808	2.320
SD	1.9708	1.4890	2.1272	
Median	4.655	4.605	4.245	2.320
Minimum	3.03	2.85	3.12	2.32
Maximum	8.38	7.09	7.62	2.32
Month 30				
Number of patients with values	45	60	45	3
Mean	4.149	4.280	4.588	3.650
SD	1.1141	1.7297	2.2417	0.2816
Median	3.930	3.910	4.040	3.720
Minimum	2.54	2.14	2.25	3.34
Maximum	7.07	13.38	11.85	3.89
Month 33				
Number of patients with values	22	14	18	0
Mean	4.503	4.186	4.487	
SD	1.5313	1.3108	1.1576	
Median	4.390	3.985	4.120	
Minimum	1.87	2.43	3.02	
Maximum	7.48	6.67	7.00	
Month 36				
Number of patients with values	17	22	21	1
Mean	4.708	3.996	4.191	3.890
SD	1.8774	0.7992	1.4827	
Median	4.170	3.970	3.810	3.890
Minimum	1.92	2.64	2.21	3.89
Maximum	9.28	5.97	8.78	3.89

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: Total Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	3.665	6.026	3.110	
SD	0.1061	3.2062	0.3374	
Median	3.665	5.240	3.130	
Minimum	3.59	2.18	2.77	
Maximum	3.74	11.00	3.41	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Double Blind Baseline				
Number of patients with values	122	133	136	27
Mean	3.137	3.183	3.313	2.613
SD	1.1839	1.0356	1.3233	0.8273
Median	2.980	3.090	3.000	2.720
Minimum	0.78	1.05	0.95	0.95
Maximum	6.71	7.00	8.62	3.91
Open Label Baseline				
Number of patients with values	123	135	139	26
Mean	3.032	3.027	2.963	2.593
SD	1.2361	0.9786	0.9687	0.8642
Median	2.820	2.980	2.770	2.575
Minimum	0.92	1.16	0.89	1.04
Maximum	8.70	5.71	5.94	4.65
Month 0				
Number of patients with values	6	13	7	1
Mean	2.522	2.565	2.794	2.560
SD	0.6084	0.9625	1.1335	
Median	2.710	2.240	2.220	2.560
Minimum	1.76	1.16	1.71	2.56
Maximum	3.14	4.13	4.46	2.56
Month 1				
Number of patients with values	3	5	2	0
Mean	3.273	2.692	3.490	
SD	2.3090	0.7611	0.3960	
Median	2.140	2.790	3.490	
Minimum	1.75	1.97	3.21	
Maximum	5.93	3.86	3.77	
Month 2				
Number of patients with values	0	1	4	0
Mean		4.310	3.118	
SD			1.1904	
Median		4.310	3.285	
Minimum		4.31	1.54	
Maximum		4.31	4.36	

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients with values	4	11	10	0
Mean	2.355	2.696	3.284	
SD	1.7870	1.0309	0.9705	
Median	1.920	2.800	3.465	
Minimum	0.69	0.78	1.64	
Maximum	4.89	4.13	4.58	
Month 6				
Number of patients with values	98	112	103	15
Mean	2.779	2.929	3.144	2.577
SD	1.2516	1.0167	1.3945	1.0991
Median	2.660	2.840	2.820	2.580
Minimum	0.79	1.09	0.84	0.79
Maximum	6.83	5.94	8.25	4.95
Month 9				
Number of patients with values	6	9	5	4
Mean	2.677	2.276	3.382	2.530
SD	0.8925	1.0067	0.6232	1.0180
Median	2.435	2.130	3.230	2.530
Minimum	1.89	0.88	2.89	1.29
Maximum	4.16	3.77	4.45	3.77
Month 12				
Number of patients with values	92	103	94	15
Mean	2.822	2.745	3.192	2.528
SD	1.2313	1.0410	1.6512	0.8297
Median	2.450	2.650	2.900	2.420
Minimum	0.74	0.58	1.04	1.08
Maximum	6.67	5.11	11.41	4.32

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients with values	6	14	8	1
Mean	2.175	3.303	3.573	2.330
SD	0.7474	1.2218	2.3736	
Median	2.230	3.005	2.940	2.330
Minimum	1.00	1.29	0.77	2.33
Maximum	3.10	5.24	7.03	2.33
Month 18				
Number of patients with values	86	91	77	8
Mean	2.645	2.619	2.656	2.368
SD	1.1073	1.0094	1.1142	0.4848
Median	2.440	2.620	2.390	2.490
Minimum	0.84	0.68	0.82	1.38
Maximum	7.06	5.42	6.14	2.85
Month 21				
Number of patients with values	4	4	4	0
Mean	2.233	2.958	2.148	
SD	0.9313	0.1884	0.7128	
Median	2.445	2.955	1.955	
Minimum	0.92	2.76	1.52	
Maximum	3.12	3.16	3.16	
Month 24				
Number of patients with values	73	72	66	4
Mean	2.552	2.577	2.690	2.325
SD	0.9225	0.9433	1.0438	0.2231
Median	2.390	2.545	2.590	2.365
Minimum	0.83	0.99	1.00	2.02
Maximum	4.84	4.64	5.85	2.55

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients with values	7	8	4	1
Mean	3.057	2.891	3.055	1.220
SD	1.3898	1.0412	1.8620	
Median	2.760	2.795	2.765	1.220
Minimum	1.80	1.57	1.36	1.22
Maximum	5.95	4.91	5.33	1.22
Month 30				
Number of patients with values	45	57	42	3
Mean	2.611	2.487	2.595	2.370
SD	0.9523	0.9871	1.1952	0.3051
Median	2.360	2.330	2.440	2.510
Minimum	1.29	0.88	0.88	2.02
Maximum	5.40	5.15	6.00	2.58
Month 33				
Number of patients with values	22	14	16	0
Mean	2.736	2.527	2.581	
SD	1.2584	1.1606	0.7997	
Median	2.645	2.290	2.410	
Minimum	0.76	0.86	1.59	
Maximum	5.33	5.20	4.02	
Month 36				
Number of patients with values	16	22	21	1
Mean	2.854	2.505	2.607	2.510
SD	1.2569	0.5963	1.0573	
Median	2.455	2.500	2.310	2.510
Minimum	0.77	1.45	1.07	2.51
Maximum	5.15	4.04	5.09	2.51

Data Source Table 14.1Ac
Summary Statistics for Efficacy Variables at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter: LDL Cholesterol/HDL Cholesterol (ratio)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients with values	2	5	4	0
Mean	2.335	3.982	1.905	
SD	0.2475	2.5638	0.3073	
Median	2.335	3.290	1.920	
Minimum	2.16	0.92	1.55	
Maximum	2.51	7.93	2.23	
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 48				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

15 Source Tables: Safety Results

	Page
Table 15.0 Report Narratives for Study 49653/009 - Location Table	594
Table 15.1.1a Summary of Ongoing Adverse Experiences at Open Label Baseline, by Preferred Term All Patients Who Entered Study 009	598
Table 15.1.1b Summary of Ongoing Adverse Experiences at Open Label Baseline, by Preferred Term All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	607
Table 15.1.1c Summary of Ongoing Adverse Experiences at Open Label Baseline, by Preferred Term All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	617
Table 15.2.1a Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Entered Study 009	627
Table 15.2.1b Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	639
Table 15.2.1c Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	657
Table 15.2.2a Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity, All Patients Who Entered Study 009	681
Table 15.2.2b Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	694
Table 15.2.2c Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	714
Table 15.2.3a Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Entered Study 009	738
Table 15.2.3b Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	743
Table 15.2.3c Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	749
Table 15.2.3x Narratives for Patients with Nonfatal Serious Adverse Experiences	757

Table X15.2.3a Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Entered Study 009	932
Table X15.2.3b Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	938
Table X15.2.3c Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	944
Table 15.2.4a Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term, All Patients Who Entered Study 009	950
Table 15.2.4b Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	961
Table 15.2.4c Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	972
Table X15.2.4a Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Entered Study 009	984
Table X15.2.4b Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	1002
Table X15.2.4c Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	1021
Table 15.4 List of Fatal Adverse Experiences (During the Open Label Study)	1041
Table 15.4x Narratives for Patients with Adverse Experiences Leading to Death	1042
Table 15.5a Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience, All Patients Who Entered Study 009	1056
Table 15.5b Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	1059
Table 15.5c Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	1062
Table 15.5x Narratives for Patients Withdrawn Due to an Adverse Experience	1065

Table 15.6.2Ba Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern or Specified Change From Open Label Baseline, All Patients Who Entered Study 009	1074
Table 15.6.2Bb Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern or Specified Change From Open Label Baseline, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	1075
Table 15.6.2Bc Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern or Specified Change From Open Label Baseline, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	1076
Table 15.6.3Ba Summary Statistics for Vital Signs at Each Visit, All Patients Who Entered Study 009	1077
Table 15.6.3Bb Summary Statistics for Vital Signs at Each Visit, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	1098
Table 15.6.3Bc Summary Statistics for Vital Signs at Each Visit, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	1119
Table 15.7.1a Summary of Laboratory Data (Safety) at Each Visit, All Patients Who Entered Study 009	1140
Table 15.7.1b Summary of Laboratory Data (Safety) at Each Visit, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	1470
Table 15.7.1c Summary of Laboratory Data (Safety) at Each Visit, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	1800
Table 15.7.4a Summary of Laboratory Data Values (Safety) of Potential Clinical Concern at Any Time During the On-Therapy (During the Open Label Study) Period, All Patients Who Entered Study 009	2130
Table 15.7.4b Summary of Laboratory Data Values (Safety) of Potential Clinical Concern at Any Time During the On-Therapy (During the Open Label Study) Period, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	2133
Table 15.7.4c Summary of Laboratory Data Values (Safety) of Potential Clinical Concern at Any Time During the On-Therapy (During the Open Label Study) Period, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	2136
Table 15.8.3Ba Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline, All Patients Who Entered Study 009	2139
Table 15.8.3Bb Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	2140
Table 15.8.3Bc Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	2141

Table 15.8.5Ba Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline, All Patients Who Entered Study 009	2142
Table 15.8.5Bb Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline, All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension	2150
Table 15.8.5Bc Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline, All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension	2158
Table 15.9.1 Event Rates of On-therapy Reports of Cardiovascular AEs and Edema - Rosiglitazone Monotherapy	2166
Table 15.9.2 Event Rates of On-therapy Reports of Cardiovascular AEs and Edema - Rosiglitazone with Metformin in Combination	2168
Table 15.9.3 Event Rates of On-therapy Reports of Cardiovascular AEs and Edema - Rosiglitazone with Sulfonylurea in Combination	2170

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Rosiglitazone

BRL-049653

Report Narratives for Study 49653/009 - Location Table

009

Table 15.0

Final

SB Document Number: BRL-049653/RSD-101LPN/1

Issue Date: 24 July 2001

Location of Report Narratives

The narrative for the PID can be found in the table indicated				
PID	Deaths	Serious AEs (nonfatal)	AE leading to withdrawal	Lab values of Potential Clinical Concern
	Table 15.4x	Table 15.2.3x	Table 15.5x	NA

This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the Sponsor Clinical Study Register.

Continued

#This case was deleted as it was subsequently found that the patient had undergone elective knee surgery.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
HYPERCHOLESTEROLEMIA	7 (3.1%)	27 (6.3%)
ARTHRITIS	1 (0.4%)	14 (3.3%)
HYPERTRIGLYCERIDEMIA	3 (1.3%)	13 (3.0%)
URINARY TRACT INFECTION	4 (1.7%)	12 (2.8%)
DIABETES MELLITUS AGGRAVATED	0	10 (2.3%)
ANXIETY	1 (0.4%)	8 (1.9%)
ARTHRALGIA	1 (0.4%)	8 (1.9%)
INJURY	1 (0.4%)	8 (1.9%)
DEPRESSION	0	7 (1.6%)
DIZZINESS	0	7 (1.6%)
FATIGUE	3 (1.3%)	6 (1.4%)
HYPERLIPEMIA	2 (0.9%)	6 (1.4%)
EDEMA LEGS	1 (0.4%)	6 (1.4%)
HYPERTENSION AGGRAVATED	1 (0.4%)	6 (1.4%)
ANEMIA	0	6 (1.4%)
COUGHING	5 (2.2%)	5 (1.2%)
HYPERTENSION	4 (1.7%)	5 (1.2%)
CONSTIPATION	2 (0.9%)	5 (1.2%)
PAIN	2 (0.9%)	5 (1.2%)
EDEMA DEPENDENT	1 (0.4%)	5 (1.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
VEIN DISORDER	1 (0.4%)	5 (1.2%)
WEIGHT INCREASE	1 (0.4%)	5 (1.2%)
RHINITIS	0	5 (1.2%)
HYPERGLYCEMIA	5 (2.2%)	4 (0.9%)
ABDOMINAL PAIN	3 (1.3%)	4 (0.9%)
HEADACHE	3 (1.3%)	4 (0.9%)
CRAMPS LEGS	2 (0.9%)	4 (0.9%)
NEURALGIA	2 (0.9%)	4 (0.9%)
RESPIRATORY DISORDER	2 (0.9%)	4 (0.9%)
ALBUMINURIA	1 (0.4%)	4 (0.9%)
BRONCHITIS	0	4 (0.9%)
GAMMA-GT INCREASED	0	4 (0.9%)
SGPT INCREASED	0	4 (0.9%)
BACK PAIN	6 (2.6%)	3 (0.7%)
ARTHROSIS	3 (1.3%)	3 (0.7%)
DYSPNEA	2 (0.9%)	3 (0.7%)
GLAUCOMA	2 (0.9%)	3 (0.7%)
TENDINITIS	2 (0.9%)	3 (0.7%)
HYPOGLYCEMIA	1 (0.4%)	3 (0.7%)
INSOMNIA	1 (0.4%)	3 (0.7%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
MICTURITION FREQUENCY	1 (0.4%)	3 (0.7%)
MYOCARDIAL ISCHEMIA	1 (0.4%)	3 (0.7%)
PROSTATIC DISORDER	1 (0.4%)	3 (0.7%)
ANGINA PECTORIS	0	3 (0.7%)
CARPAL TUNNEL SYNDROME	0	3 (0.7%)
LIPOMA	0	3 (0.7%)
PRURITUS	0	3 (0.7%)
THIRST	0	3 (0.7%)
DYSPEPSIA	4 (1.7%)	2 (0.5%)
PARESTHESIA	4 (1.7%)	2 (0.5%)
INFECTION FUNGAL	3 (1.3%)	2 (0.5%)
IMPOTENCE	2 (0.9%)	2 (0.5%)
MOUTH DRY	2 (0.9%)	2 (0.5%)
THROMBOCYTOPENIA	2 (0.9%)	2 (0.5%)
ARTHRITIS AGGRAVATED	1 (0.4%)	2 (0.5%)
GOITRE	1 (0.4%)	2 (0.5%)
HYPESTHESIA	1 (0.4%)	2 (0.5%)
NAUSEA	1 (0.4%)	2 (0.5%)
TINNITUS	1 (0.4%)	2 (0.5%)
ALOPECIA	0	2 (0.5%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
APPETITE INCREASED	0	2 (0.5%)
BONE DISORDER	0	2 (0.5%)
BRADYCARDIA	0	2 (0.5%)
CLAUDICATION INTERMITTENT	0	2 (0.5%)
CONJUNCTIVITIS	0	2 (0.5%)
DEPRESSION AGGRAVATED	0	2 (0.5%)
DYSURIA	0	2 (0.5%)
ECG ABNORMAL SPECIFIC	0	2 (0.5%)
ECZEMA	0	2 (0.5%)
EXTRASYSTOLES	0	2 (0.5%)
FLATULENCE	0	2 (0.5%)
HEPATOCELLULAR DAMAGE	0	2 (0.5%)
HYPOCALCEMIA	0	2 (0.5%)
LEUKOPENIA	0	2 (0.5%)
MONILIASIS GENITAL	0	2 (0.5%)
MYALGIA	0	2 (0.5%)
NERVOUSNESS	0	2 (0.5%)
NEUROPATHY	0	2 (0.5%)
POLYURIA	0	2 (0.5%)
RETINAL DISORDER	0	2 (0.5%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
SGOT INCREASED	0	2 (0.5%)
SKIN DRY	0	2 (0.5%)
ATRIOVENTRICULAR BLOCK	3 (1.3%)	1 (0.2%)
GASTROINTESTINAL DISORDER NOS	3 (1.3%)	1 (0.2%)
PYURIA	3 (1.3%)	1 (0.2%)
EYE PAIN	2 (0.9%)	1 (0.2%)
SOMNOLENCE	2 (0.9%)	1 (0.2%)
VISION ABNORMAL	2 (0.9%)	1 (0.2%)
CATARACT	1 (0.4%)	1 (0.2%)
CEREBROVASCULAR DISORDER	1 (0.4%)	1 (0.2%)
DIVERTICULITIS	1 (0.4%)	1 (0.2%)
EDEMA	1 (0.4%)	1 (0.2%)
GRANULOCYTOPENIA	1 (0.4%)	1 (0.2%)
LYMPHEDEMA	1 (0.4%)	1 (0.2%)
PERIPHERAL ISCHEMIA	1 (0.4%)	1 (0.2%)
PSORIASIS	1 (0.4%)	1 (0.2%)
SKELETAL PAIN	1 (0.4%)	1 (0.2%)
ALCOHOL INTOLERANCE	0	1 (0.2%)
ALLERGIC REACTION	0	1 (0.2%)
ALLERGY	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
ASTHENIA	0	1 (0.2%)
ASTHMA	0	1 (0.2%)
BLEPHARITIS	0	1 (0.2%)
CARCINOMA	0	1 (0.2%)
CHEST PAIN	0	1 (0.2%)
COLITIS	0	1 (0.2%)
DEAFNESS	0	1 (0.2%)
DERMATITIS	0	1 (0.2%)
DERMATITIS CONTACT	0	1 (0.2%)
DUODENITIS	0	1 (0.2%)
EJACULATION FAILURE	0	1 (0.2%)
EMOTIONAL LABILITY	0	1 (0.2%)
ESOPHAGITIS	0	1 (0.2%)
EXOPHTHALMOS	0	1 (0.2%)
EXTRASYSTOLES SUPRAVENTRICULAR	0	1 (0.2%)
FACE EDEMA	0	1 (0.2%)
GASTRITIS	0	1 (0.2%)
GASTROESOPHAGEAL REFLUX	0	1 (0.2%)
GYNECOMASTIA	0	1 (0.2%)
HEMORRHAGE RECTUM	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
HEPATIC ENZYMES INCREASED	0	1 (0.2%)
HEPATIC FUNCTION ABNORMAL	0	1 (0.2%)
HEPATITIS	0	1 (0.2%)
HIGH DENSITY LIPOPROTEIN DECREASE	0	1 (0.2%)
HOT FLUSHES	0	1 (0.2%)
HYPERKALEMIA	0	1 (0.2%)
HYPOCHLOREMIA	0	1 (0.2%)
HYPONATREMIA	0	1 (0.2%)
HYPOTHYROIDISM	0	1 (0.2%)
INFECTION VIRAL	0	1 (0.2%)
INFLUENZA-LIKE SYMPTOMS	0	1 (0.2%)
LACRIMATION ABNORMAL	0	1 (0.2%)
LEUKORRHEA	0	1 (0.2%)
LIVER FATTY	0	1 (0.2%)
LYMPHOCYTOSIS	0	1 (0.2%)
MALAISE	0	1 (0.2%)
MELANOSIS	0	1 (0.2%)
MONILIASIS	0	1 (0.2%)
NEOPLASM NOS	0	1 (0.2%)
PANCREATITIS	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
PERIODONTITIS	0	1 (0.2%)
PHARYNGITIS	0	1 (0.2%)
PHLEBITIS	0	1 (0.2%)
RASH ERYTHEMATOUS	0	1 (0.2%)
RENAL FAILURE ACUTE	0	1 (0.2%)
SKIN DISORDER	0	1 (0.2%)
SKIN HYPERTROPHY	0	1 (0.2%)
SYNCOPE	0	1 (0.2%)
TASTE PERVERSION	0	1 (0.2%)
TENOSYNOVITIS	0	1 (0.2%)
TETANY	0	1 (0.2%)
THROMBOPHLEBITIS DEEP	0	1 (0.2%)
THYROIDITIS	0	1 (0.2%)
TRACHEITIS	0	1 (0.2%)
TREMOR	0	1 (0.2%)
UPPER RESP TRACT INFECTION	0	1 (0.2%)
VAGINITIS	0	1 (0.2%)
VASCULAR DISORDER	0	1 (0.2%)
WEIGHT DECREASE	0	1 (0.2%)
DIARRHEA	2 (0.9%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1a

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	87 (38.0%)	194 (45.1%)
Preferred Term		
NEUROPATHY PERIPHERAL	2 (0.9%)	0
RASH	2 (0.9%)	0
APHASIA	1 (0.4%)	0
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0
CARDIAC FAILURE LEFT	1 (0.4%)	0
DERMATITIS LICHENOID	1 (0.4%)	0
DYSPHAGIA	1 (0.4%)	0
HERPES SIMPLEX	1 (0.4%)	0
HERPES ZOSTER	1 (0.4%)	0
HYPERCALCEMIA	1 (0.4%)	0
HYPERPARATHYROIDISM	1 (0.4%)	0
INFECTION	1 (0.4%)	0
INFECTION BACTERIAL	1 (0.4%)	0
LEUKOCYTOSIS	1 (0.4%)	0
OCULAR HEMORRHAGE	1 (0.4%)	0
PALPITATION	1 (0.4%)	0
PHOSPHATASE ALKALINE INCREASED	1 (0.4%)	0
SINUSITIS	1 (0.4%)	0
SPUTUM INCREASED	1 (0.4%)	0
URINE ABNORMAL	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
HYPERCHOLESTEROLEMIA	1 (1.6%)	3 (3.8%)	3 (3.3%)
ATRIOVENTRICULAR BLOCK	0	1 (1.3%)	2 (2.2%)
URINARY TRACT INFECTION	2 (3.3%)	0	2 (2.2%)
CRAMPS LEGS	0	0	2 (2.2%)
GLAUCOMA	0	0	2 (2.2%)
HYPERLIPEMIA	0	0	2 (2.2%)
BACK PAIN	2 (3.3%)	3 (3.8%)	1 (1.1%)
HYPERTENSION	0	3 (3.8%)	1 (1.1%)
COUGHING	2 (3.3%)	2 (2.6%)	1 (1.1%)
PARESTHESIA	1 (1.6%)	2 (2.6%)	1 (1.1%)
ABDOMINAL PAIN	0	2 (2.6%)	1 (1.1%)
ARTHROSIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
CONSTIPATION	0	1 (1.3%)	1 (1.1%)
DIARRHEA	0	1 (1.3%)	1 (1.1%)
NEUROPATHY PERIPHERAL	0	1 (1.3%)	1 (1.1%)
PAIN	0	1 (1.3%)	1 (1.1%)
RESPIRATORY DISORDER	0	1 (1.3%)	1 (1.1%)
TENDINITIS	0	1 (1.3%)	1 (1.1%)
DYSPEPSIA	3 (4.9%)	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
INFECTION FUNGAL	2 (3.3%)	0	1 (1.1%)
EYE PAIN	1 (1.6%)	0	1 (1.1%)
MOUTH DRY	1 (1.6%)	0	1 (1.1%)
RASH	1 (1.6%)	0	1 (1.1%)
ARTHRITIS	0	0	1 (1.1%)
CATARACT	0	0	1 (1.1%)
DERMATITIS LICHENOID	0	0	1 (1.1%)
GOITRE	0	0	1 (1.1%)
GRANULOCYTOPENIA	0	0	1 (1.1%)
HERPES ZOSTER	0	0	1 (1.1%)
HYPOGLYCEMIA	0	0	1 (1.1%)
INFECTION	0	0	1 (1.1%)
LEUKOCYTOSIS	0	0	1 (1.1%)
MICTURITION FREQUENCY	0	0	1 (1.1%)
MYOCARDIAL ISCHEMIA	0	0	1 (1.1%)
NAUSEA	0	0	1 (1.1%)
PERIPHERAL ISCHEMIA	0	0	1 (1.1%)
PSORIASIS	0	0	1 (1.1%)
SINUSITIS	0	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
WEIGHT INCREASE	0	0	1 (1.1%)
PYURIA	0	3 (3.8%)	0
FATIGUE	1 (1.6%)	2 (2.6%)	0
HEADACHE	1 (1.6%)	2 (2.6%)	0
HYPERTRIGLYCERIDEMIA	1 (1.6%)	2 (2.6%)	0
DYSPNEA	0	2 (2.6%)	0
NEURALGIA	0	2 (2.6%)	0
HYPERGLYCEMIA	4 (6.6%)	1 (1.3%)	0
GASTROINTESTINAL DISORDER NOS	2 (3.3%)	1 (1.3%)	0
IMPOTENCE	1 (1.6%)	1 (1.3%)	0
THROMBOCYTOPENIA	1 (1.6%)	1 (1.3%)	0
VISION ABNORMAL	1 (1.6%)	1 (1.3%)	0
ANXIETY	0	1 (1.3%)	0
ARTHRALGIA	0	1 (1.3%)	0
ARTHRITIS AGGRAVATED	0	1 (1.3%)	0
BONE DEVELOPMENT ABNORMAL	0	1 (1.3%)	0
CARDIAC FAILURE LEFT	0	1 (1.3%)	0
DIVERTICULITIS	0	1 (1.3%)	0
EDEMA	0	1 (1.3%)	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
EDEMA DEPENDENT	0	1 (1.3%)	0
EDEMA LEGS	0	1 (1.3%)	0
HYPERTENSION AGGRAVATED	0	1 (1.3%)	0
HYPESTHESIA	0	1 (1.3%)	0
INFECTION BACTERIAL	0	1 (1.3%)	0
LYMPHEDEMA	0	1 (1.3%)	0
OCULAR HEMORRHAGE	0	1 (1.3%)	0
SKELETAL PAIN	0	1 (1.3%)	0
SPUTUM INCREASED	0	1 (1.3%)	0
TINNITUS	0	1 (1.3%)	0
SOMNOLENCE	2 (3.3%)	0	0
ALBUMINURIA	1 (1.6%)	0	0
APHASIA	1 (1.6%)	0	0
CEREBROVASCULAR DISORDER	1 (1.6%)	0	0
DYSPHAGIA	1 (1.6%)	0	0
HERPES SIMPLEX	1 (1.6%)	0	0
HYPERCALCEMIA	1 (1.6%)	0	0
HYPERPARATHYROIDISM	1 (1.6%)	0	0
INJURY	1 (1.6%)	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
INSOMNIA	1 (1.6%)	0	0
PALPITATION	1 (1.6%)	0	0
PHOSPHATASE ALKALINE INCREASED	1 (1.6%)	0	0
PROSTATIC DISORDER	1 (1.6%)	0	0
URINE ABNORMAL	1 (1.6%)	0	0
VEIN DISORDER	1 (1.6%)	0	0
ALCOHOL INTOLERANCE	0	0	0
ALLERGIC REACTION	0	0	0
ALLERGY	0	0	0
ALOPECIA	0	0	0
ANEMIA	0	0	0
ANGINA PECTORIS	0	0	0
APPETITE INCREASED	0	0	0
ASTHENIA	0	0	0
ASTHMA	0	0	0
BLEPHARITIS	0	0	0
BONE DISORDER	0	0	0
BRADYCARDIA	0	0	0
BRONCHITIS	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
CARCINOMA	0	0	0
CARPAL TUNNEL SYNDROME	0	0	0
CHEST PAIN	0	0	0
CLAUDICATION INTERMITTENT	0	0	0
COLITIS	0	0	0
CONJUNCTIVITIS	0	0	0
DEAFNESS	0	0	0
DEPRESSION	0	0	0
DEPRESSION AGGRAVATED	0	0	0
DERMATITIS	0	0	0
DERMATITIS CONTACT	0	0	0
DIABETES MELLITUS AGGRAVATED	0	0	0
DIZZINESS	0	0	0
DUODENITIS	0	0	0
DYSURIA	0	0	0
ECG ABNORMAL SPECIFIC	0	0	0
ECZEMA	0	0	0
EJACULATION FAILURE	0	0	0
EMOTIONAL LABILITY	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
ESOPHAGITIS	0	0	0
EXOPHTHALMOS	0	0	0
EXTRASYSTOLES	0	0	0
EXTRASYSTOLES SUPRAVENTRICULAR	0	0	0
FACE EDEMA	0	0	0
FLATULENCE	0	0	0
GAMMA-GT INCREASED	0	0	0
GASTRITIS	0	0	0
GASTROESOPHAGEAL REFLUX	0	0	0
GYNECOMASTIA	0	0	0
HEMORRHAGE RECTUM	0	0	0
HEPATIC ENZYMES INCREASED	0	0	0
HEPATIC FUNCTION ABNORMAL	0	0	0
HEPATITIS	0	0	0
HEPATOCELLULAR DAMAGE	0	0	0
HIGH DENSITY LIPOPROTEIN DECREASE	0	0	0
HOT FLUSHES	0	0	0
HYPERKALEMIA	0	0	0
HYPOCALCEMIA	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
HYPOCHLOREMIA	0	0	0
HYPONATREMIA	0	0	0
HYPOTHYROIDISM	0	0	0
INFECTION VIRAL	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0
LACRIMATION ABNORMAL	0	0	0
LEUKOPENIA	0	0	0
LEUKORRHEA	0	0	0
LIPOMA	0	0	0
LIVER FATTY	0	0	0
LYMPHOCYTOSIS	0	0	0
MALaise	0	0	0
MELANOSIS	0	0	0
MONILIASIS	0	0	0
MONILIASIS GENITAL	0	0	0
MYALGIA	0	0	0
NEOPLASM NOS	0	0	0
NERVOUSNESS	0	0	0
NEUROPATHY	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
PANCREATITIS	0	0	0
PERIODONTITIS	0	0	0
PHARYNGITIS	0	0	0
PHLEBITIS	0	0	0
POLYURIA	0	0	0
PRURITUS	0	0	0
RASH ERYTHEMATOUS	0	0	0
RENAL FAILURE ACUTE	0	0	0
RETINAL DISORDER	0	0	0
RHINITIS	0	0	0
SGOT INCREASED	0	0	0
SGPT INCREASED	0	0	0
SKIN DISORDER	0	0	0
SKIN DRY	0	0	0
SKIN HYPERTROPHY	0	0	0
SYNCOPE	0	0	0
TASTE PERVERSION	0	0	0
TENOSYNOVITIS	0	0	0
TETANY	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1b

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	26 (42.6%)	29 (37.2%)	32 (35.6%)
Preferred Term			
THIRST	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0
THYROIDITIS	0	0	0
TRACHEITIS	0	0	0
TREMOR	0	0	0
UPPER RESP TRACT INFECTION	0	0	0
VAGINITIS	0	0	0
VASCULAR DISORDER	0	0	0
WEIGHT DECREASE	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
HYPERCHOLESTEROLEMIA	7 (5.6%)	9 (6.6%)	3 (2.2%)	8 (26.7%)
ARTHRITIS	5 (4.0%)	5 (3.7%)	4 (2.9%)	0
HYPERTRIGLYCERIDEMIA	5 (4.0%)	3 (2.2%)	3 (2.2%)	2 (6.7%)
EDEMA LEGS	5 (4.0%)	1 (0.7%)	0	0
VEIN DISORDER	5 (4.0%)	0	0	0
RHINITIS	4 (3.2%)	1 (0.7%)	0	0
WEIGHT INCREASE	4 (3.2%)	1 (0.7%)	0	0
ARTHRALGIA	3 (2.4%)	3 (2.2%)	2 (1.4%)	0
DIZZINESS	3 (2.4%)	2 (1.5%)	2 (1.4%)	0
HYPERLIPEMIA	3 (2.4%)	1 (0.7%)	2 (1.4%)	0
PAIN	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
DYSPNEA	3 (2.4%)	0	0	0
INJURY	2 (1.6%)	4 (2.9%)	2 (1.4%)	0
HYPERTENSION AGGRAVATED	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
EDEMA DEPENDENT	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
HYPERTENSION	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
ANEMIA	2 (1.6%)	1 (0.7%)	1 (0.7%)	2 (6.7%)
ABDOMINAL PAIN	2 (1.6%)	1 (0.7%)	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
NEURALGIA	2 (1.6%)	1 (0.7%)	1 (0.7%)	0
FATIGUE	2 (1.6%)	0	2 (1.4%)	2 (6.7%)
LIPOMA	2 (1.6%)	0	1 (0.7%)	0
MYOCARDIAL ISCHEMIA	2 (1.6%)	0	0	1 (3.3%)
NEUROPATHY	2 (1.6%)	0	0	0
URINARY TRACT INFECTION	1 (0.8%)	5 (3.7%)	3 (2.2%)	3 (10.0%)
DEPRESSION	1 (0.8%)	2 (1.5%)	4 (2.9%)	0
RESPIRATORY DISORDER	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
CRAMPS LEGS	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
SGPT INCREASED	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
MICTURITION FREQUENCY	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
PROSTATIC DISORDER	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
ALBUMINURIA	1 (0.8%)	1 (0.7%)	0	2 (6.7%)
BRADYCARDIA	1 (0.8%)	1 (0.7%)	0	0
DYSURIA	1 (0.8%)	1 (0.7%)	0	0
IMPOTENCE	1 (0.8%)	1 (0.7%)	0	0
LEUKOPENIA	1 (0.8%)	1 (0.7%)	0	0
MYALGIA	1 (0.8%)	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
CONSTIPATION	1 (0.8%)	0	3 (2.2%)	1 (3.3%)
BACK PAIN	1 (0.8%)	0	2 (1.4%)	0
HEADACHE	1 (0.8%)	0	1 (0.7%)	2 (6.7%)
APPETITE INCREASED	1 (0.8%)	0	1 (0.7%)	0
DEPRESSION AGGRAVATED	1 (0.8%)	0	1 (0.7%)	0
NERVOUSNESS	1 (0.8%)	0	1 (0.7%)	0
THROMBOCYTOPENIA	1 (0.8%)	0	1 (0.7%)	0
ATRIOVENTRICULAR BLOCK	1 (0.8%)	0	0	0
DEAFNESS	1 (0.8%)	0	0	0
DIVERTICULITIS	1 (0.8%)	0	0	0
DUODENITIS	1 (0.8%)	0	0	0
EDEMA	1 (0.8%)	0	0	0
EXTRASYSTOLES SUPRAVENTRICULAR	1 (0.8%)	0	0	0
FACE EDEMA	1 (0.8%)	0	0	0
GASTRITIS	1 (0.8%)	0	0	0
GASTROESOPHAGEAL REFLUX	1 (0.8%)	0	0	0
HEMORRHAGE RECTUM	1 (0.8%)	0	0	0
HIGH DENSITY LIPOPROTEIN DECREASE	1 (0.8%)	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
HOT FLUSHES	1 (0.8%)	0	0	0
HYPOTHYROIDISM	1 (0.8%)	0	0	0
LYMPHEDEMA	1 (0.8%)	0	0	0
PHARYNGITIS	1 (0.8%)	0	0	0
RASH ERYTHEMATOUS	1 (0.8%)	0	0	0
RENAL FAILURE ACUTE	1 (0.8%)	0	0	0
SKIN HYPERTROPHY	1 (0.8%)	0	0	0
SOMNOLENCE	1 (0.8%)	0	0	0
ANXIETY	0	3 (2.2%)	4 (2.9%)	0
DIABETES MELLITUS AGGRAVATED	0	3 (2.2%)	0	7 (23.3%)
ANGINA PECTORIS	0	2 (1.5%)	1 (0.7%)	0
CARPAL TUNNEL SYNDROME	0	2 (1.5%)	1 (0.7%)	0
GLAUCOMA	0	2 (1.5%)	1 (0.7%)	0
INSOMNIA	0	2 (1.5%)	1 (0.7%)	0
TENDINITIS	0	2 (1.5%)	1 (0.7%)	0
PRURITUS	0	2 (1.5%)	0	1 (3.3%)
BONE DISORDER	0	2 (1.5%)	0	0
ECZEMA	0	2 (1.5%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
GOITRE	0	2 (1.5%)	0	0
HYPOCALCEMIA	0	2 (1.5%)	0	0
BRONCHITIS	0	1 (0.7%)	3 (2.2%)	0
COUGHING	0	1 (0.7%)	2 (1.4%)	2 (6.7%)
ARTHROSIS	0	1 (0.7%)	2 (1.4%)	0
ALOPECIA	0	1 (0.7%)	1 (0.7%)	0
ARTHRITIS AGGRAVATED	0	1 (0.7%)	1 (0.7%)	0
FLATULENCE	0	1 (0.7%)	1 (0.7%)	0
INFECTION FUNGAL	0	1 (0.7%)	1 (0.7%)	0
MOUTH DRY	0	1 (0.7%)	1 (0.7%)	0
RETINAL DISORDER	0	1 (0.7%)	1 (0.7%)	0
TINNITUS	0	1 (0.7%)	1 (0.7%)	0
THIRST	0	1 (0.7%)	0	2 (6.7%)
DYSPEPSIA	0	1 (0.7%)	0	1 (3.3%)
MONILIASIS GENITAL	0	1 (0.7%)	0	1 (3.3%)
NAUSEA	0	1 (0.7%)	0	1 (3.3%)
SKIN DRY	0	1 (0.7%)	0	1 (3.3%)
ALLERGY	0	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
ASTHMA	0	1 (0.7%)	0	0
CARCINOMA	0	1 (0.7%)	0	0
CATARACT	0	1 (0.7%)	0	0
CHEST PAIN	0	1 (0.7%)	0	0
COLITIS	0	1 (0.7%)	0	0
DERMATITIS	0	1 (0.7%)	0	0
DERMATITIS CONTACT	0	1 (0.7%)	0	0
EMOTIONAL LABILITY	0	1 (0.7%)	0	0
GRANULOCYTOPENIA	0	1 (0.7%)	0	0
GYNECOMASTIA	0	1 (0.7%)	0	0
HEPATIC FUNCTION ABNORMAL	0	1 (0.7%)	0	0
HYPERKALEMIA	0	1 (0.7%)	0	0
HYPOCHLOREMIA	0	1 (0.7%)	0	0
HYPONATREMIA	0	1 (0.7%)	0	0
MALAISE	0	1 (0.7%)	0	0
PERIODONTITIS	0	1 (0.7%)	0	0
PSORIASIS	0	1 (0.7%)	0	0
TASTE PERVERSION	0	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
TENOSYNOVITIS	0	1 (0.7%)	0	0
TETANY	0	1 (0.7%)	0	0
THROMBOPHLEBITIS DEEP	0	1 (0.7%)	0	0
THYROIDITIS	0	1 (0.7%)	0	0
VAGINITIS	0	1 (0.7%)	0	0
VASCULAR DISORDER	0	1 (0.7%)	0	0
VISION ABNORMAL	0	1 (0.7%)	0	0
WEIGHT DECREASE	0	1 (0.7%)	0	0
GAMMA-GT INCREASED	0	0	3 (2.2%)	1 (3.3%)
HYPOGLYCEMIA	0	0	3 (2.2%)	0
CLAUDICATION INTERMITTENT	0	0	2 (1.4%)	0
CONJUNCTIVITIS	0	0	2 (1.4%)	0
ECG ABNORMAL SPECIFIC	0	0	2 (1.4%)	0
EXTRASYSTOLES	0	0	2 (1.4%)	0
HEPATOCELLULAR DAMAGE	0	0	2 (1.4%)	0
HYPESTHESIA	0	0	2 (1.4%)	0
PARESTHESIA	0	0	2 (1.4%)	0
SGOT INCREASED	0	0	2 (1.4%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
ALCOHOL INTOLERANCE	0	0	1 (0.7%)	0
ALLERGIC REACTION	0	0	1 (0.7%)	0
ASTHENIA	0	0	1 (0.7%)	0
BLEPHARITIS	0	0	1 (0.7%)	0
CEREBROVASCULAR DISORDER	0	0	1 (0.7%)	0
EJACULATION FAILURE	0	0	1 (0.7%)	0
ESOPHAGITIS	0	0	1 (0.7%)	0
EXOPHTHALMOS	0	0	1 (0.7%)	0
EYE PAIN	0	0	1 (0.7%)	0
GASTROINTESTINAL DISORDER NOS	0	0	1 (0.7%)	0
HEPATIC ENZYMES INCREASED	0	0	1 (0.7%)	0
HEPATITIS	0	0	1 (0.7%)	0
INFECTION VIRAL	0	0	1 (0.7%)	0
LACRIMATION ABNORMAL	0	0	1 (0.7%)	0
LEUKORRHEA	0	0	1 (0.7%)	0
LIVER FATTY	0	0	1 (0.7%)	0
LYMPHOCYTOSIS	0	0	1 (0.7%)	0
MELANOSIS	0	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

- 624 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
MONILIASIS	0	0	1 (0.7%)	0
NEOPLASM NOS	0	0	1 (0.7%)	0
PANCREATITIS	0	0	1 (0.7%)	0
PERIPHERAL ISCHEMIA	0	0	1 (0.7%)	0
PHLEBITIS	0	0	1 (0.7%)	0
SKELETAL PAIN	0	0	1 (0.7%)	0
SKIN DISORDER	0	0	1 (0.7%)	0
TRACHEITIS	0	0	1 (0.7%)	0
TREMOR	0	0	1 (0.7%)	0
UPPER RESP TRACT INFECTION	0	0	1 (0.7%)	0
HYPERGLYCEMIA	0	0	0	4 (13.3%)
POLYURIA	0	0	0	2 (6.7%)
INFLUENZA-LIKE SYMPTOMS	0	0	0	1 (3.3%)
PYURIA	0	0	0	1 (3.3%)
SYNCOPE	0	0	0	1 (3.3%)
APHASIA	0	0	0	0
BONE DEVELOPMENT ABNORMAL	0	0	0	0
CARDIAC FAILURE LEFT	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.1.1c

Summary of Ongoing Adverse Experiences at Open Label Baseline by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	50 (40.3%)	61 (44.9%)	58 (41.7%)	24 (80.0%)
Preferred Term				
DERMATITIS LICHENOID	0	0	0	0
DIARRHEA	0	0	0	0
DYSPHAGIA	0	0	0	0
HERPES SIMPLEX	0	0	0	0
HERPES ZOSTER	0	0	0	0
HYPERCALCEMIA	0	0	0	0
HYPERPARATHYROIDISM	0	0	0	0
INFECTION	0	0	0	0
INFECTION BACTERIAL	0	0	0	0
LEUKOCYTOSIS	0	0	0	0
NEUROPATHY PERIPHERAL	0	0	0	0
OCULAR HEMORRHAGE	0	0	0	0
PALPITATION	0	0	0	0
PHOSPHATASE ALKALINE INCREASED	0	0	0	0
RASH	0	0	0	0
SINUSITIS	0	0	0	0
SPUTUM INCREASED	0	0	0	0
URINE ABNORMAL	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
APPLICATION SITE	1 (0.4%)	0	0	1 (0.4%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
OTITIS EXTERNA	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
AUTONOMIC NERVOUS SYSTEM	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	3 (0.7%)	0	6 (1.4%)
SWEATING INCREASED	0	0	0	0	3 (0.7%)	3 (0.7%)	0	6 (1.4%)
VASOSPASM	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
BODY AS A WHOLE GENERAL	58 (25.3%)	23 (10.0%)	1 (0.4%)	70 (30.6%)	89 (20.7%)	42 (9.8%)	7 (1.6%)	126 (29.3%)
ALCOHOL INTOLERANCE	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
ALLERGIC REACTION	3 (1.3%)	0	0	3 (1.3%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
ALLERGY	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	1 (0.2%)	0	1 (0.2%)
ASTHENIA	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	7 (1.6%)	6 (1.4%)	1 (0.2%)	14 (3.3%)
CHEST PAIN	5 (2.2%)	2 (0.9%)	0	7 (3.1%)	5 (1.2%)	6 (1.4%)	0	11 (2.6%)
CHEST PAIN PRECORDIAL	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
EDEMA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EDEMA DEPENDENT	3 (1.3%)	3 (1.3%)	0	6 (2.6%)	3 (0.7%)	3 (0.7%)	1 (0.2%)	7 (1.6%)
EDEMA GENERALISED	2 (0.9%)	0	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EDEMA LEGS	2 (0.9%)	4 (1.7%)	0	6 (2.6%)	17 (4.0%)	6 (1.4%)	2 (0.5%)	25 (5.8%)
EDEMA PERIORBITAL	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EDEMA PERIPHERAL	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	1 (0.2%)	3 (0.7%)
ESR INCREASED	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
FACE EDEMA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
FATIGUE	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	3 (0.7%)	4 (0.9%)	0	7 (1.6%)
FEVER	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
GRANULOMATOUS LESION	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
HOT FLUSHES	0	0	0	0	2 (0.5%)	0	1 (0.2%)	3 (0.7%)
INFLUENZA-LIKE SYMPTOMS	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
INJURY	35 (15.3%)	1 (0.4%)	0	36 (15.7%)	50 (11.6%)	10 (2.3%)	0	60 (14.0%)
MALAISE	1 (0.4%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	0	0	1 (0.2%)	1 (0.2%)
NECROSIS ISCHEMIC	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
PAIN	8 (3.5%)	5 (2.2%)	0	13 (5.7%)	13 (3.0%)	5 (1.2%)	1 (0.2%)	19 (4.4%)
PALLOR	0	0	0	0	0	1 (0.2%)	1 (0.2%)	2 (0.5%)
RIGORS	0	0	0	0	0	1 (0.2%)	1 (0.2%)	2 (0.5%)
SUDDEN DEATH	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
CARDIOVASCULAR GENERAL	14 (6.1%)	13 (5.7%)	0	26 (11.4%)	32 (7.4%)	10 (2.3%)	1 (0.2%)	43 (10.0%)
CARDIAC FAILURE	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	4 (0.9%)	3 (0.7%)	1 (0.2%)	8 (1.9%)
CARDIAC FAILURE LEFT	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ECG ABNORMAL	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
ECG ABNORMAL SPECIFIC	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
HEART DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HEART VALVE DISORDERS	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
HYPERTENSION	3 (1.3%)	6 (2.6%)	0	9 (3.9%)	12 (2.8%)	1 (0.2%)	0	13 (3.0%)
HYPERTENSION AGGRAVATED	6 (2.6%)	4 (1.7%)	0	10 (4.4%)	7 (1.6%)	2 (0.5%)	0	9 (2.1%)
HYPOTENSION	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
HYPOTENSION POSTURAL	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
SYNCOPE	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	24 (10.5%)	19 (8.3%)	4 (1.7%)	46 (20.1%)	52 (12.1%)	21 (4.9%)	6 (1.4%)	77 (17.9%)
CARPAL TUNNEL SYNDROME	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	0	0	3 (0.7%)
CONVULSIONS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
DIZZINESS	5 (2.2%)	4 (1.7%)	1 (0.4%)	10 (4.4%)	4 (0.9%)	4 (0.9%)	0	8 (1.9%)
EDEMA CEREBRAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HEADACHE	3 (1.3%)	4 (1.7%)	1 (0.4%)	8 (3.5%)	9 (2.1%)	5 (1.2%)	5 (1.2%)	19 (4.4%)
HYPERESTHESIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPERKINESIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPESTHESIA	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
HYPOKINESIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
MIGRAINE	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
MIGRAINE AGGRAVATED	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
NEURALGIA	6 (2.6%)	2 (0.9%)	0	8 (3.5%)	27 (6.3%)	5 (1.2%)	0	32 (7.4%)
NEURITIS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
NEUROPATHY	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
NEUROPATHY PERIPHERAL	1 (0.4%)	3 (1.3%)	1 (0.4%)	5 (2.2%)	1 (0.2%)	0	0	1 (0.2%)
PARESIS	1 (0.4%)	0	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
PARESTHESIA	1 (0.4%)	5 (2.2%)	0	6 (2.6%)	4 (0.9%)	6 (1.4%)	0	10 (2.3%)
PTOSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
SPEECH DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
TETANY	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
TREMOR	0	0	1 (0.4%)	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
TRIGEMINAL NEURALGIA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
VERTIGO	1 (0.4%)	1 (0.4%)	1 (0.4%)	3 (1.3%)	9 (2.1%)	2 (0.5%)	0	11 (2.6%)
COLLAGEN	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ARTHRITIS RHEUMATOID	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ENDOCRINE	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	9 (2.1%)	3 (0.7%)	1 (0.2%)	12 (2.8%)
BREAST PAIN MALE	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GOITRE	2 (0.9%)	0	0	2 (0.9%)	5 (1.2%)	0	0	5 (1.2%)
GYNECOMASTIA	0	0	0	0	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
HYPERPARATHYROIDISM	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
HYPOTHYROIDISM	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
THYROID DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GASTROINTESTINAL SYSTEM	40 (17.5%)	24 (10.5%)	2 (0.9%)	58 (25.3%)	84 (19.5%)	31 (7.2%)	7 (1.6%)	113 (26.3%)
ABDOMINAL PAIN	10 (4.4%)	2 (0.9%)	1 (0.4%)	13 (5.7%)	11 (2.6%)	12 (2.8%)	0	23 (5.3%)
ANUS DISORDER	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
APPETITE INCREASED	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	3 (0.7%)	4 (0.9%)
COLITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	7 (1.6%)	1 (0.2%)	0	8 (1.9%)
CONSTIPATION	7 (3.1%)	3 (1.3%)	0	10 (4.4%)	14 (3.3%)	1 (0.2%)	0	15 (3.5%)
DIARRHEA	4 (1.7%)	3 (1.3%)	1 (0.4%)	8 (3.5%)	11 (2.6%)	2 (0.5%)	0	13 (3.0%)
DIVERTICULITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
DUODENAL ULCER	2 (0.9%)	0	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
DYSPEPSIA	3 (1.3%)	6 (2.6%)	0	9 (3.9%)	6 (1.4%)	6 (1.4%)	0	12 (2.8%)
ENTERITIS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ESOPHAGEAL ULCERATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
ESOPHAGITIS	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
FECAL INCONTINENCE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
FLATULENCE	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
GASTRIC ULCER	0	2 (0.9%)	0	2 (0.9%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GASTRITIS	0	1 (0.4%)	0	1 (0.4%)	5 (1.2%)	1 (0.2%)	0	6 (1.4%)
GASTROENTERITIS	5 (2.2%)	1 (0.4%)	0	6 (2.6%)	12 (2.8%)	0	0	12 (2.8%)
GASTROESOPHAGEAL REFLUX	0	0	0	0	5 (1.2%)	0	0	5 (1.2%)
GASTROINTESTINAL DISORDER NOS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	7 (1.6%)	1 (0.2%)	0	8 (1.9%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
GI HEMORRHAGE	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
GINGIVITIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	0	0	0
HEMORRHAGE RECTUM	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
HEMORRHOIDS	0	0	0	0	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
INTESTINAL ISCHEMIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
INTESTINAL PERFORATION	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
IRRITABLE BOWEL SYNDROME	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
NAUSEA	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	4 (0.9%)	4 (0.9%)	3 (0.7%)	11 (2.6%)
PERIODONTITIS	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	13 (3.0%)	1 (0.2%)	0	14 (3.3%)
SALIVARY GLAND ENLARGEMENT	3 (1.3%)	0	0	3 (1.3%)	0	1 (0.2%)	0	1 (0.2%)
STOMATITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
STOMATITIS ULCERATIVE	0	0	0	0	1 (0.2%)	0	1 (0.2%)	2 (0.5%)
TONGUE EDEMA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
TONGUE ULCERATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
TOOTH ACHE	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	0	0	0	0
TOOTH CARIES	2 (0.9%)	0	0	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
TOOTH DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
VOMITING	3 (1.3%)	0	0	3 (1.3%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
HEARING AND VESTIBULAR	5 (2.2%)	4 (1.7%)	0	9 (3.9%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
DEAFNESS	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EAR DISORDER NOS	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
EARACHE	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
OTOSCLEROSIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
TINNITUS	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
VESTIBULAR DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
HEART RATE AND RHYTHM	3 (1.3%)	9 (3.9%)	2 (0.9%)	14 (6.1%)	17 (4.0%)	14 (3.3%)	4 (0.9%)	33 (7.7%)
ARRHYTHMIA ATRIAL	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
ATRIOVENTRICULAR BLOCK	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
BRADYCARDIA	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
BUNDLE BRANCH BLOCK	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	3 (0.7%)	5 (1.2%)
EXTRASYSTOLES	0	1 (0.4%)	0	1 (0.4%)	4 (0.9%)	1 (0.2%)	1 (0.2%)	6 (1.4%)
FIBRILLATION ATRIAL	1 (0.4%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	5 (1.2%)	5 (1.2%)	0	10 (2.3%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
PALPITATION	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
QT INCREASED	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	0	0	0
TACHYCARDIA	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LIVER AND BILIARY SYSTEM	3 (1.3%)	10 (4.4%)	2 (0.9%)	15 (6.6%)	6 (1.4%)	4 (0.9%)	2 (0.5%)	11 (2.6%)
BILIARY PAIN	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
BILIRUBINEMIA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
CHOLECYSTITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CHOLELITHIASIS	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
GALL BLADDER DISORDER	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
GAMMA-GT INCREASED	1 (0.4%)	5 (2.2%)	0	6 (2.6%)	1 (0.2%)	2 (0.5%)	2 (0.5%)	5 (1.2%)
HEPATIC ENZYMES INCREASED	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	0	0	0
HEPATIC FUNCTION ABNORMAL	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
HEPATITIS CHOLESTATIC	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
HEPATOMEGALY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LIVER FATTY	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
SGPT INCREASED	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	0	0	0
METABOLIC AND NUTRITIONAL	34 (14.8%)	35 (15.3%)	43 (18.8%)	100 (43.7%)	53 (12.3%)	33 (7.7%)	54 (12.6%)	126 (29.3%)
ACIDOSIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
ALKALOSIS RESPIRATORY	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
BLOOD UREA NITROGEN INCREASED	1 (0.4%)	1 (0.4%)	1 (0.4%)	3 (1.3%)	0	0	2 (0.5%)	2 (0.5%)
CALCINOSIS	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
DIABETES MELLITUS AGGRAVATED	4 (1.7%)	4 (1.7%)	15 (6.6%)	23 (10.0%)	0	0	22 (5.1%)	22 (5.1%)
GOUT	0	0	0	0	4 (0.9%)	2 (0.5%)	0	6 (1.4%)
HYPERCHOLESTEROLEMIA	6 (2.6%)	11 (4.8%)	2 (0.9%)	19 (8.3%)	21 (4.9%)	16 (3.7%)	6 (1.4%)	43 (10.0%)
HYPERGLYCEMIA	16 (7.0%)	8 (3.5%)	22 (9.6%)	46 (20.1%)	5 (1.2%)	1 (0.2%)	10 (2.3%)	16 (3.7%)
HYPERKALEMIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
HYPERLIPEMIA	2 (0.9%)	4 (1.7%)	5 (2.2%)	11 (4.8%)	12 (2.8%)	7 (1.6%)	4 (0.9%)	23 (5.3%)
HYPERTRIGLYCERIDEMIA	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
HYPERURICEMIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPOCHOLESTEROLEMIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
HYPOGLYCEMIA	3 (1.3%)	2 (0.9%)	9 (3.9%)	14 (6.1%)	1 (0.2%)	0	5 (1.2%)	6 (1.4%)
HYPOGLYCEMIC REACTION	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
HYPOKALEMIA	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
NPN INCREASED	1 (0.4%)	3 (1.3%)	2 (0.9%)	6 (2.6%)	2 (0.5%)	2 (0.5%)	1 (0.2%)	5 (1.2%)
OBESITY	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
THIRST	2 (0.9%)	0	1 (0.4%)	3 (1.3%)	0	0	1 (0.2%)	1 (0.2%)
WEIGHT DECREASE	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
WEIGHT INCREASE	2 (0.9%)	1 (0.4%)	1 (0.4%)	4 (1.7%)	3 (0.7%)	4 (0.9%)	10 (2.3%)	17 (4.0%)
MUSCULOSKELETAL SYSTEM	48 (21.0%)	18 (7.9%)	0	63 (27.5%)	109 (25.3%)	38 (8.8%)	3 (0.7%)	143 (33.3%)
ARTHRALGIA	12 (5.2%)	8 (3.5%)	0	20 (8.7%)	20 (4.7%)	8 (1.9%)	2 (0.5%)	30 (7.0%)
ARTHRITIS	9 (3.9%)	6 (2.6%)	0	15 (6.6%)	32 (7.4%)	10 (2.3%)	0	42 (9.8%)
ARTHRITIS AGGRAVATED	6 (2.6%)	0	0	6 (2.6%)	0	3 (0.7%)	0	3 (0.7%)
ARTHROPATHY	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ARTHROSIS	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	20 (4.7%)	3 (0.7%)	0	23 (5.3%)
BACK PAIN	16 (7.0%)	2 (0.9%)	0	18 (7.9%)	45 (10.5%)	6 (1.4%)	0	51 (11.9%)
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
BONE DISORDER	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
BURSITIS	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
MUSCLE WEAKNESS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
MYALGIA	3 (1.3%)	4 (1.7%)	0	7 (3.1%)	10 (2.3%)	9 (2.1%)	2 (0.5%)	21 (4.9%)
MYOPATHY	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
MYOSITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
OSTEOMYELITIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
OSTEOPOROSIS	2 (0.9%)	0	0	2 (0.9%)	7 (1.6%)	2 (0.5%)	0	9 (2.1%)
SKELETAL PAIN	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	3 (0.7%)	1 (0.2%)	1 (0.2%)	5 (1.2%)
SYNOVITIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
TENDINITIS	7 (3.1%)	2 (0.9%)	0	9 (3.9%)	8 (1.9%)	3 (0.7%)	0	11 (2.6%)
TORTICOLLIS	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	15 (6.6%)	3 (1.3%)	0	17 (7.4%)	20 (4.7%)	10 (2.3%)	0	30 (7.0%)
ANGINA PECTORIS	9 (3.9%)	0	0	9 (3.9%)	12 (2.8%)	3 (0.7%)	0	15 (3.5%)
ANGINA PECTORIS AGGRAVATED	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
AORTIC STENOSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CARDIOMYOPATHY	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
CORONARY ARTERY DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
MYOCARDIAL INFARCTION	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	5 (1.2%)	5 (1.2%)	0	10 (2.3%)
MYOCARDIAL ISCHEMIA	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
THROMBOSIS CORONARY	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
NEOPLASM	4 (1.7%)	4 (1.7%)	0	8 (3.5%)	16 (3.7%)	9 (2.1%)	0	25 (5.8%)
BASAL CELL CARCINOMA	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	2 (0.5%)	0	0	2 (0.5%)
BLADDER CARCINOMA	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
BRAIN NEOPLASM BENIGN	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
BREAST NEOPLASM FEMALE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CARCINOMA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
GASTRIC CARCINOMA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
LIPOMA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
MELANOMA MALIGNANT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
NEOPLASM MALIGNANT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
NEOPLASM NOS	1 (0.4%)	0	0	1 (0.4%)	5 (1.2%)	4 (0.9%)	0	9 (2.1%)
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PULMONARY CARCINOMA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
THYROID ADENOMA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
UTERINE FIBROID	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
PLATELET BLEEDING AND CLOTTING	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
PURPURA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
THROMBOCYTOPENIA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
PSYCHIATRIC	15 (6.6%)	8 (3.5%)	2 (0.9%)	25 (10.9%)	27 (6.3%)	18 (4.2%)	1 (0.2%)	46 (10.7%)
AMNESIA	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
ANXIETY	6 (2.6%)	2 (0.9%)	0	8 (3.5%)	7 (1.6%)	4 (0.9%)	0	11 (2.6%)
CONFUSION	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
DEMENTIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DEPRESSION	6 (2.6%)	1 (0.4%)	1 (0.4%)	8 (3.5%)	9 (2.1%)	5 (1.2%)	0	14 (3.3%)
EMOTIONAL LABILITY	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
INSOMNIA	2 (0.9%)	0	1 (0.4%)	3 (1.3%)	9 (2.1%)	5 (1.2%)	1 (0.2%)	15 (3.5%)
NERVOUSNESS	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
NEUROSIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
SOMNOLENCE	2 (0.9%)	3 (1.3%)	1 (0.4%)	6 (2.6%)	0	4 (0.9%)	0	4 (0.9%)
SUICIDE ATTEMPT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
RED BLOOD CELL	5 (2.2%)	5 (2.2%)	2 (0.9%)	12 (5.2%)	10 (2.3%)	13 (3.0%)	3 (0.7%)	26 (6.0%)
ANEMIA	3 (1.3%)	4 (1.7%)	2 (0.9%)	9 (3.9%)	6 (1.4%)	11 (2.6%)	3 (0.7%)	20 (4.7%)
ANEMIA B TWELVE DEFICIENCY	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ANEMIA HYPOCHROMIC	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	2 (0.5%)	0	5 (1.2%)
ANEMIA NORMOCHROMIC	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
ERYTHROCYTES ABNORMAL	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
REPRODUCTIVE FEMALE	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	3 (0.7%)	2 (0.5%)	0	5 (1.2%)
MENORRHAGIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
MENSTRUAL DISORDER	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
OVARIAN CYST	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
OVARIAN DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
VAGINITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
REPRODUCTIVE MALE	11 (4.8%)	3 (1.3%)	0	14 (6.1%)	14 (3.3%)	2 (0.5%)	0	16 (3.7%)
EPIDIDYMITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
IMPOTENCE	5 (2.2%)	0	0	5 (2.2%)	5 (1.2%)	1 (0.2%)	0	6 (1.4%)
PENIS DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
PROSTATIC DISORDER	5 (2.2%)	2 (0.9%)	0	7 (3.1%)	7 (1.6%)	1 (0.2%)	0	8 (1.9%)
TESTIS DISORDER	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
RESISTANCE MECHANISM	59 (25.8%)	16 (7.0%)	0	70 (30.6%)	75 (17.4%)	22 (5.1%)	1 (0.2%)	94 (21.9%)
ABSCCESS	2 (0.9%)	0	0	2 (0.9%)	0	1 (0.2%)	0	1 (0.2%)
HERPES SIMPLEX	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	0	0	3 (0.7%)
HERPES ZOSTER	4 (1.7%)	2 (0.9%)	0	6 (2.6%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
INFECTION	7 (3.1%)	3 (1.3%)	0	10 (4.4%)	10 (2.3%)	0	1 (0.2%)	11 (2.6%)
INFECTION BACTERIAL	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
INFECTION FUNGAL	2 (0.9%)	0	0	2 (0.9%)	9 (2.1%)	2 (0.5%)	0	11 (2.6%)
INFECTION VIRAL	23 (10.0%)	5 (2.2%)	0	28 (12.2%)	36 (8.4%)	2 (0.5%)	0	38 (8.8%)
MONILIASIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
MONILIASIS GENITAL	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	1 (0.2%)	0	0	1 (0.2%)
OTITIS MEDIA	2 (0.9%)	0	0	2 (0.9%)	5 (1.2%)	3 (0.7%)	0	8 (1.9%)
SEPSIS	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
UPPER RESP TRACT INFECTION	23 (10.0%)	6 (2.6%)	0	29 (12.7%)	20 (4.7%)	9 (2.1%)	0	29 (6.7%)
RESPIRATORY SYSTEM	49 (21.4%)	19 (8.3%)	0	60 (26.2%)	126 (29.3%)	36 (8.4%)	2 (0.5%)	153 (35.6%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
APNEA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
ASTHMA	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	3 (0.7%)	0	6 (1.4%)
BRONCHITIS	8 (3.5%)	1 (0.4%)	0	9 (3.9%)	60 (14.0%)	8 (1.9%)	1 (0.2%)	69 (16.0%)
CHEST X-RAY ABNORMAL	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
DISEA								
COUGHING	15 (6.6%)	4 (1.7%)	0	19 (8.3%)	10 (2.3%)	5 (1.2%)	0	15 (3.5%)
DYSPNEA	4 (1.7%)	7 (3.1%)	0	11 (4.8%)	9 (2.1%)	4 (0.9%)	0	13 (3.0%)
EPISTAXIS	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	3 (0.7%)	0	4 (0.9%)
HEMOPTYSIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
LARYNGITIS	1 (0.4%)	0	0	1 (0.4%)	4 (0.9%)	0	0	4 (0.9%)
PHARYNGITIS	12 (5.2%)	3 (1.3%)	0	15 (6.6%)	27 (6.3%)	2 (0.5%)	0	29 (6.7%)
PLEURAL EFFUSION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PLEURISY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PNEUMONIA	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
PULMONARY EDEMA	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
RESPIRATORY DISORDER	13 (5.7%)	6 (2.6%)	0	19 (8.3%)	14 (3.3%)	11 (2.6%)	0	25 (5.8%)
RESPIRATORY INSUFFICIENCY	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
RHINITIS	3 (1.3%)	0	0	3 (1.3%)	14 (3.3%)	2 (0.5%)	0	16 (3.7%)
SINUSITIS	4 (1.7%)	0	0	4 (1.7%)	9 (2.1%)	4 (0.9%)	0	13 (3.0%)
TRACHEITIS	0	0	0	0	7 (1.6%)	0	0	7 (1.6%)
SKIN AND APPENDAGES	23 (10.0%)	17 (7.4%)	0	39 (17.0%)	37 (8.6%)	14 (3.3%)	4 (0.9%)	53 (12.3%)
ALOPECIA	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ANGIOEDEMA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
BULLOUS ERUPTION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DERMATITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
DERMATITIS FUNGAL	3 (1.3%)	0	0	3 (1.3%)	2 (0.5%)	0	0	2 (0.5%)
ECZEMA	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	12 (2.8%)	2 (0.5%)	0	14 (3.3%)
FOLLICULITIS	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
FURUNCULOSIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	0	0	1 (0.2%)
HYPERKERATOSIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	0	0	1 (0.2%)
NAIL DISORDER	2 (0.9%)	0	0	2 (0.9%)	4 (0.9%)	0	1 (0.2%)	5 (1.2%)
NEVUS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
PHOTOSENSITIVITY REACTION	0	0	0	0	1 (0.2%)	0	1 (0.2%)	2 (0.5%)

- 635 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
PRURITUS	2 (0.9%)	5 (2.2%)	0	7 (3.1%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
PRURITUS GENITAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PSORIASIS	0	0	0	0	1 (0.2%)	0	1 (0.2%)	2 (0.5%)
PSORIASIS AGGRAVATED	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
RASH	3 (1.3%)	4 (1.7%)	0	7 (3.1%)	2 (0.5%)	5 (1.2%)	0	7 (1.6%)
RASH ERYTHEMATOUS	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	0	1 (0.2%)	0	1 (0.2%)
RASH PUSTULAR	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ROSACEA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
SEBORRHEA	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
SKIN DISORDER	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	0	0	0
SKIN DRY	0	4 (1.7%)	0	4 (1.7%)	1 (0.2%)	0	0	1 (0.2%)
SKIN HYPERTROPHY	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
SKIN ULCERATION	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
URTICARIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
VERRUCA	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
URINARY SYSTEM	32 (14.0%)	8 (3.5%)	1 (0.4%)	38 (16.6%)	48 (11.2%)	22 (5.1%)	4 (0.9%)	71 (16.5%)
ALBUMINURIA	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	2 (0.5%)	5 (1.2%)
CYSTITIS	1 (0.4%)	0	0	1 (0.4%)	7 (1.6%)	2 (0.5%)	0	9 (2.1%)
CYSTITIS HEMORRHAGIC	0	0	0	0	3 (0.7%)	0	0	3 (0.7%)
DYSURIA	2 (0.9%)	0	0	2 (0.9%)	3 (0.7%)	0	0	3 (0.7%)
HEMATURIA	2 (0.9%)	1 (0.4%)	1 (0.4%)	4 (1.7%)	4 (0.9%)	5 (1.2%)	2 (0.5%)	11 (2.6%)
HYDRONEPHROSIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
MICTURITION DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
MICTURITION FREQUENCY	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	3 (0.7%)	0	4 (0.9%)
NOCTURIA	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
POLYURIA	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	0	1 (0.2%)	1 (0.2%)
PYELONEPHRITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PYURIA	4 (1.7%)	1 (0.4%)	0	5 (2.2%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
RENAL CALCULUS	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
RENAL FAILURE ACUTE	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	0	0	0	0
RENAL PAIN	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
STRANGURY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
URETHRAL DISORDER	2 (0.9%)	0	0	2 (0.9%)	0	0	0	0
URINARY INCONTINENCE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
URINARY TRACT INFECTION	21 (9.2%)	3 (1.3%)	0	24 (10.5%)	29 (6.7%)	11 (2.6%)	0	40 (9.3%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
VASCULAR EXTRACARDIAC	14 (6.1%)	10 (4.4%)	0	23 (10.0%)	33 (7.7%)	19 (4.4%)	3 (0.7%)	55 (12.8%)
ARTERITIS	0	0	0	0	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
ATHEROSCLEROSIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
CEREBROVASCULAR DISORDER	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
CLAUDICATION INTERMITTENT	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
CRAMPS LEGS	1 (0.4%)	4 (1.7%)	0	5 (2.2%)	9 (2.1%)	6 (1.4%)	1 (0.2%)	16 (3.7%)
EMBOLISM PULMONARY	0	2 (0.9%)	0	2 (0.9%)	0	1 (0.2%)	0	1 (0.2%)
HEMORRHAGE NOS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
PERIPHERAL ISCHEMIA	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	3 (0.7%)	1 (0.2%)	4 (0.9%)
PHLEBITIS	0	1 (0.4%)	0	1 (0.4%)	5 (1.2%)	0	0	5 (1.2%)
PHLEBITIS SUPERFICIAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
THROMBOPHLEBITIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
VASCULAR DISORDER	4 (1.7%)	1 (0.4%)	0	5 (2.2%)	5 (1.2%)	1 (0.2%)	0	6 (1.4%)
VASCULITIS	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
VEIN DISORDER	6 (2.6%)	0	0	6 (2.6%)	10 (2.3%)	4 (0.9%)	0	14 (3.3%)
VEIN VARICOSE	3 (1.3%)	0	0	3 (1.3%)	4 (0.9%)	0	0	4 (0.9%)
VISION	16 (7.0%)	7 (3.1%)	1 (0.4%)	22 (9.6%)	26 (6.0%)	23 (5.3%)	0	49 (11.4%)
BLEPHARITIS	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
CATARACT	6 (2.6%)	1 (0.4%)	0	7 (3.1%)	6 (1.4%)	4 (0.9%)	0	10 (2.3%)
CONJUNCTIVAL HEMORRHAGE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
CONJUNCTIVITIS	2 (0.9%)	0	0	2 (0.9%)	10 (2.3%)	8 (1.9%)	0	18 (4.2%)
CORNEAL OPACITY	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
DIPLOPIA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
EYE ABNORMALITY	4 (1.7%)	0	0	4 (1.7%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EYE PAIN	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
GLAUCOMA	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
LACRIMATION ABNORMAL	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
MACULA LUTEA DEGENERATION	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
RETINAL DETACHMENT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
RETINAL DISORDER	5 (2.2%)	0	0	5 (2.2%)	5 (1.2%)	2 (0.5%)	0	7 (1.6%)
RETINITIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
VISION ABNORMAL	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	3 (0.7%)	2 (0.5%)	0	5 (1.2%)
VITREOUS DETACHMENT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)

Data Source Table 15.2.1a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	162 (70.7%)	111 (48.5%)	51 (22.3%)	189 (82.5%)	295 (68.6%)	167 (38.8%)	82 (19.1%)	363 (84.4%)
WHO Body System Preferred Term								
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	4 (1.7%)	2 (0.9%)	3 (1.3%)	8 (3.5%)	8 (1.9%)	4 (0.9%)	0	12 (2.8%)
EOSINOPHILIA	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
GRANULOCYTOPENIA	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
LEUKOCYTOSIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
LEUKOPENIA	1 (0.4%)	0	2 (0.9%)	3 (1.3%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
LYMPHADENOPATHY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LYMPHADENOPATHY CERVICAL	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
LYMPHANGITIS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
LYMPHEDEMA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
LYMPHOPENIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)
WHO Body System Preferred Term								
APPLICATION SITE	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
OTITIS EXTERNA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
AUTONOMIC NERVOUS SYSTEM	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
VASOSPASM	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
BODY AS A WHOLE GENERAL	20 (32.8%)	6 (9.8%)	0	23 (37.7%)	17 (21.8%)	7 (9.0%)	1 (1.3%)	20 (25.6%)
ALCOHOL INTOLERANCE	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
ALLERGIC REACTION	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)
ALLERGY	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
ASTHENIA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0
CHEST PAIN	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
EDEMA DEPENDENT	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
EDEMA GENERALISED	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
EDEMA LEGS	0	0	0	0	0	3 (3.8%)	0	3 (3.8%)
EDEMA PERIORBITAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
EDEMA PERIPHERAL	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
FATIGUE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0
FEVER	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
INJURY	12 (19.7%)	0	0	12 (19.7%)	10 (12.8%)	0	0	10 (12.8%)
MALaise	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	1 (1.3%)	2 (2.6%)
PAIN	5 (8.2%)	2 (3.3%)	0	7 (11.5%)	1 (1.3%)	0	0	1 (1.3%)
SUDDEN DEATH	0	0	0	0	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
CARDIOVASCULAR GENERAL	8 (13.1%)	2 (3.3%)	0	10 (16.4%)	2 (2.6%)	3 (3.8%)	0	4 (5.1%)
CARDIAC FAILURE	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	1 (1.3%)	0	0	1 (1.3%)
CARDIAC FAILURE LEFT	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
ECG ABNORMAL	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
HEART VALVE DISORDERS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
HYPERTENSION	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	0	2 (2.6%)	0	2 (2.6%)
HYPERTENSION AGGRAVATED	3 (4.9%)	0	0	3 (4.9%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
HYPOTENSION POSTURAL	0	0	0	0	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_----- 2bd Comb Total ----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
APPLICATION SITE	0	0	0	0
OTITIS EXTERNA	0	0	0	0
AUTONOMIC NERVOUS SYSTEM	0	0	0	0
VASOSPASM	0	0	0	0
BODY AS A WHOLE GENERAL	21 (23.3%)	10 (11.1%)	0	27 (30.0%)
ALCOHOL INTOLERANCE	0	0	0	0
ALLERGIC REACTION	0	0	0	0
ALLERGY	0	0	0	0
ASTHENIA	0	2 (2.2%)	0	2 (2.2%)
CHEST PAIN	3 (3.3%)	1 (1.1%)	0	4 (4.4%)
EDEMA DEPENDENT	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
EDEMA GENERALISED	0	0	0	0
EDEMA LEGS	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
EDEMA PERIORBITAL	0	0	0	0
EDEMA PERIPHERAL	0	0	0	0
FATIGUE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
FEVER	0	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0	0
INJURY	13 (14.4%)	1 (1.1%)	0	14 (15.6%)
MALAISE	0	1 (1.1%)	0	1 (1.1%)
PAIN	2 (2.2%)	3 (3.3%)	0	5 (5.6%)
SUDDEN DEATH	1 (1.1%)	0	0	1 (1.1%)
THERAPEUTIC RESPONSE INCREASED	1 (1.1%)	0	0	1 (1.1%)
CARDIOVASCULAR GENERAL	4 (4.4%)	8 (8.9%)	0	12 (13.3%)
CARDIAC FAILURE	0	1 (1.1%)	0	1 (1.1%)
CARDIAC FAILURE LEFT	0	0	0	0
ECG ABNORMAL	0	0	0	0
HEART VALVE DISORDERS	0	0	0	0
HYPERTENSION	1 (1.1%)	3 (3.3%)	0	4 (4.4%)
HYPERTENSION AGGRAVATED	2 (2.2%)	3 (3.3%)	0	5 (5.6%)
HYPOTENSION POSTURAL	0	1 (1.1%)	0	1 (1.1%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
SYNCOPE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	10 (16.4%)	3 (4.9%)	1 (1.6%)	14 (23.0%)	8 (10.3%)	6 (7.7%)	1 (1.3%)	15 (19.2%)				
CARPAL TUNNEL SYNDROME	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
CONVULSIONS	0	0	0	0	0	0	0	0				
DIZZINESS	3 (4.9%)	0	1 (1.6%)	4 (6.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
HEADACHE	0	1 (1.6%)	0	1 (1.6%)	2 (2.6%)	2 (2.6%)	1 (1.3%)	5 (6.4%)				
HYPESTHESIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
HYPOKINESIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
MIGRAINE	0	0	0	0	0	0	0	0				
MIGRAINE AGGRAVATED	0	0	0	0	0	0	0	0				
NEURALGIA	3 (4.9%)	0	0	3 (4.9%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
NEURITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
NEUROPATHY	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
NEUROPATHY PERIPHERAL	0	0	0	0	0	2 (2.6%)	0	2 (2.6%)				
PARESIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
PARESTHESIA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	2 (2.6%)	0	2 (2.6%)				
TETANY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
TREMOR	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
TRIGEMINAL NEURALGIA	0	0	0	0	0	0	0	0				
VERTIGO	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
COLLAGEN	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ARTHRITIS RHEUMATOID	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ENDOCRINE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
BREAST PAIN MALE	0	0	0	0	0	0	0	0				
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0	0	0	0	0				
GOITRE	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
HYPERPARATHYROIDISM	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
HYPOTHYROIDISM	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
GASTROINTESTINAL SYSTEM	11 (18.0%)	6 (9.8%)	0	16 (26.2%)	15 (19.2%)	11 (14.1%)	1 (1.3%)	23 (29.5%)				

- 641 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd) _-----_---- 2bd Comb Total ----_-----_
015:2bd+S/2bd
(N=90)

Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
SYNCOPE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	6 (6.7%)	10 (11.1%)	2 (2.2%)	17 (18.9%)
CARPAL TUNNEL SYNDROME	0	0	0	0
CONVULSIONS	0	1 (1.1%)	0	1 (1.1%)
DIZZINESS	1 (1.1%)	3 (3.3%)	0	4 (4.4%)
HEADACHE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
HYESTHESIA	0	0	0	0
HYPOKINESIA	0	0	0	0
MIGRAINE	1 (1.1%)	0	0	1 (1.1%)
MIGRAINE AGGRAVATED	1 (1.1%)	0	0	1 (1.1%)
NEURALGIA	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
NEURITIS	0	0	0	0
NEUROPATHY	0	0	0	0
NEUROPATHY PERIPHERAL	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
PARESIS	0	0	0	0
PARESTHESIA	0	2 (2.2%)	0	2 (2.2%)
TETANY	0	0	0	0
TREMOR	0	0	0	0
TRIGEMINAL NEURALGIA	0	1 (1.1%)	0	1 (1.1%)
VERTIGO	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
COLLAGEN	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0
ENDOCRINE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
BREAST PAIN MALE	0	1 (1.1%)	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	1 (1.1%)	0	0	1 (1.1%)
GOITRE	1 (1.1%)	0	0	1 (1.1%)
HYPERPARATHYROIDISM	0	0	0	0
HYPOTHYROIDISM	0	0	0	0
GASTROINTESTINAL SYSTEM	14 (15.6%)	7 (7.8%)	1 (1.1%)	19 (21.1%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
ABDOMINAL PAIN	5 (8.2%)	1 (1.6%)	0	6 (9.8%)	4 (5.1%)	0	0	4 (5.1%)				
ANUS DISORDER	0	0	0	0	0	0	0	0				
APPETITE INCREASED	0	0	0	0	0	0	0	0				
COLITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
CONSTIPATION	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	3 (3.8%)	0	0	3 (3.8%)				
DIARRHEA	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	1 (1.3%)	2 (2.6%)	1 (1.3%)	4 (5.1%)				
DIVERTICULITIS	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
DUODENAL ULCER	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
DYSPEPSIA	0	0	0	0	2 (2.6%)	4 (5.1%)	0	6 (7.7%)				
ENTERITIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ESOPHAGITIS	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
FLATULENCE	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
GASTRIC ULCER	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
GASTRITIS	0	0	0	0	0	0	0	0				
GASTROENTERITIS	2 (3.3%)	0	0	2 (3.3%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
GASTROINTESTINAL DISORDER NOS	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
GI HEMORRHAGE	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
GINGIVITIS	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
HEMORRHAGE RECTUM	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
INTESTINAL PERFORATION	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
NAUSEA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	1 (1.3%)	0	1 (1.3%)				
PERIODONTITIS	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)				
SALIVARY GLAND ENLARGEMENT	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)				
TOOTH ACHE	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
TOOTH CARIES	0	0	0	0	0	0	0	0				
VOMITING	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)				
HEARING AND VESTIBULAR	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	1 (1.3%)	0	0	1 (1.3%)				
DEAFNESS	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
EAR DISORDER NOS	0	0	0	0	0	0	0	0				
OTOSCLEROSIS	0	0	0	0	0	0	0	0				
TINNITUS	0	0	0	0	0	0	0	0				
VESTIBULAR DISORDER	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	2bd Comb Total 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
ABDOMINAL PAIN	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
ANUS DISORDER	1 (1.1%)	0	0	1 (1.1%)
APPETITE INCREASED	1 (1.1%)	0	0	1 (1.1%)
COLITIS	1 (1.1%)	0	0	1 (1.1%)
CONSTIPATION	3 (3.3%)	1 (1.1%)	0	4 (4.4%)
DIARRHEA	1 (1.1%)	0	0	1 (1.1%)
DIVERTICULITIS	0	0	0	0
DUODENAL ULCER	0	0	0	0
DYSPEPSIA	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
ENTERITIS	0	0	0	0
ESOPHAGITIS	0	0	0	0
FLATULENCE	1 (1.1%)	0	0	1 (1.1%)
GASTRIC ULCER	0	1 (1.1%)	0	1 (1.1%)
GASTRITIS	0	1 (1.1%)	0	1 (1.1%)
GASTROENTERITIS	2 (2.2%)	0	0	2 (2.2%)
GASTROINTESTINAL DISORDER NOS	0	0	0	0
GI HEMORRHAGE	0	1 (1.1%)	0	1 (1.1%)
GINGIVITIS	1 (1.1%)	0	0	1 (1.1%)
HEMORRHAGE RECTUM	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0
NAUSEA	2 (2.2%)	0	0	2 (2.2%)
PERIODONTITIS	0	1 (1.1%)	0	1 (1.1%)
SALIVARY GLAND ENLARGEMENT	0	0	0	0
TOOTH ACHE	2 (2.2%)	0	0	2 (2.2%)
TOOTH CARIES	2 (2.2%)	0	0	2 (2.2%)
VOMITING	0	0	0	0
HEARING AND VESTIBULAR	3 (3.3%)	3 (3.3%)	0	6 (6.7%)
DEAFNESS	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
EAR DISORDER NOS	0	1 (1.1%)	0	1 (1.1%)
OTOSCLEROSIS	1 (1.1%)	0	0	1 (1.1%)
TINNITUS	0	1 (1.1%)	0	1 (1.1%)
VESTIBULAR DISORDER	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
HEART RATE AND RHYTHM	1 (1.6%)	0	0	1 (1.6%)	0	5 (6.4%)	1 (1.3%)	6 (7.7%)				
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	0	0				
ATRIOVENTRICULAR BLOCK	0	0	0	0	0	0	0	0				
BRADYCARDIA	0	0	0	0	0	0	0	0				
BUNDLE BRANCH BLOCK	0	0	0	0	0	0	0	0				
EXTRASYSTOLES	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
FIBRILLATION ATRIAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
PALPITATION	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
QT INCREASED	0	0	0	0	0	1 (1.3%)	1 (1.3%)	2 (2.6%)				
TACHYCARDIA	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.6%)	0	2 (2.6%)				
LIVER AND BILIARY SYSTEM	0	2 (3.3%)	0	2 (3.3%)	1 (1.3%)	6 (7.7%)	2 (2.6%)	9 (11.5%)				
BILIRUBINEMIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
GAMMA-GT INCREASED	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	3 (3.8%)	0	4 (5.1%)				
HEPATIC ENZYMES INCREASED	0	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)				
HEPATIC FUNCTION ABNORMAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
HEPATITIS CHOLESTATIC	0	0	0	0	0	0	0	0				
LIVER FATTY	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
SGPT INCREASED	0	0	0	0	0	1 (1.3%)	1 (1.3%)	2 (2.6%)				
METABOLIC AND NUTRITIONAL	12 (19.7%)	8 (13.1%)	12 (19.7%)	29 (47.5%)	11 (14.1%)	8 (10.3%)	15 (19.2%)	30 (38.5%)				
ACIDOSIS	0	0	0	0	0	0	0	0				
ALKALOSIS RESPIRATORY	0	0	0	0	0	0	0	0				
BLOOD UREA NITROGEN INCREASED	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
DIABETES MELLITUS AGGRAVATED	2 (3.3%)	1 (1.6%)	4 (6.6%)	7 (11.5%)	1 (1.3%)	1 (1.3%)	4 (5.1%)	6 (7.7%)				
HYPERCHOLESTEROLEMIA	4 (6.6%)	3 (4.9%)	1 (1.6%)	8 (13.1%)	1 (1.3%)	2 (2.6%)	0	3 (3.8%)				
HYPERGLYCEMIA	5 (8.2%)	2 (3.3%)	6 (9.8%)	13 (21.3%)	4 (5.1%)	3 (3.8%)	5 (6.4%)	12 (15.4%)				
HYPERLIPEMIA	0	1 (1.6%)	3 (4.9%)	4 (6.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
HYPERTRIGLYCERIDEMIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
HYPOGLYCEMIA	0	1 (1.6%)	1 (1.6%)	2 (3.3%)	3 (3.8%)	0	6 (7.7%)	9 (11.5%)				
NPN INCREASED	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	1 (1.3%)	2 (2.6%)				
OBESITY	0	0	0	0	0	0	0	0				
THIRST	1 (1.6%)	0	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)				
WEIGHT INCREASE	0	0	1 (1.6%)	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				

- 645 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	2bd Comb Total 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
HEART RATE AND RHYTHM	2 (2.2%)	4 (4.4%)	1 (1.1%)	7 (7.8%)
ARRHYTHMIA ATRIAL	1 (1.1%)	0	0	1 (1.1%)
ATRIOVENTRICULAR BLOCK	0	1 (1.1%)	0	1 (1.1%)
BRADYCARDIA	0	1 (1.1%)	0	1 (1.1%)
BUNDLE BRANCH BLOCK	0	1 (1.1%)	0	1 (1.1%)
EXTRASYSTOLES	0	0	0	0
FIBRILLATION ATRIAL	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
PALPITATION	0	1 (1.1%)	0	1 (1.1%)
QT INCREASED	0	0	0	0
TACHYCARDIA	0	0	0	0
LIVER AND BILIARY SYSTEM	2 (2.2%)	2 (2.2%)	0	4 (4.4%)
BILIRUBINEMIA	0	0	0	0
GAMMA-GT INCREASED	0	1 (1.1%)	0	1 (1.1%)
HEPATIC ENZYMES INCREASED	0	0	0	0
HEPATIC FUNCTION ABNORMAL	0	1 (1.1%)	0	1 (1.1%)
HEPATITIS CHOLESTATIC	1 (1.1%)	0	0	1 (1.1%)
LIVER FATTY	1 (1.1%)	0	0	1 (1.1%)
SGPT INCREASED	0	0	0	0
METABOLIC AND NUTRITIONAL	11 (12.2%)	19 (21.1%)	16 (17.8%)	41 (45.6%)
ACIDOSIS	0	1 (1.1%)	0	1 (1.1%)
ALKALOSIS RESPIRATORY	0	2 (2.2%)	0	2 (2.2%)
BLOOD UREA NITROGEN INCREASED	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
DIABETES MELLITUS AGGRAVATED	1 (1.1%)	2 (2.2%)	7 (7.8%)	10 (11.1%)
HYPERCHOLESTEROLEMIA	1 (1.1%)	6 (6.7%)	1 (1.1%)	8 (8.9%)
HYPERGLYCEMIA	7 (7.8%)	3 (3.3%)	11 (12.2%)	21 (23.3%)
HYPERLIPEMIA	1 (1.1%)	2 (2.2%)	2 (2.2%)	5 (5.6%)
HYPERTRIGLYCERIDEMIA	0	0	0	0
HYPOGLYCEMIA	0	1 (1.1%)	2 (2.2%)	3 (3.3%)
NPN INCREASED	0	2 (2.2%)	1 (1.1%)	3 (3.3%)
OBESITY	0	1 (1.1%)	0	1 (1.1%)
THIRST	1 (1.1%)	0	0	1 (1.1%)
WEIGHT INCREASE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
MUSCULOSKELETAL SYSTEM	13 (21.3%)	6 (9.8%)	0	18 (29.5%)	15 (19.2%)	5 (6.4%)	0	20 (25.6%)				
ARTHRALGIA	4 (6.6%)	4 (6.6%)	0	8 (13.1%)	5 (6.4%)	1 (1.3%)	0	6 (7.7%)				
ARTHRITIS	3 (4.9%)	1 (1.6%)	0	4 (6.6%)	1 (1.3%)	2 (2.6%)	0	3 (3.8%)				
ARTHRITIS AGGRAVATED	2 (3.3%)	0	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)				
ARTHROPATHY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ARTHROSIS	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
BACK PAIN	5 (8.2%)	1 (1.6%)	0	6 (9.8%)	5 (6.4%)	0	0	5 (6.4%)				
BONE DEVELOPMENT ABNORMAL	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
BONE DISORDER	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
MUSCLE WEAKNESS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
MYALGIA	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	0	1 (1.3%)	0	1 (1.3%)				
MYOSITIS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
OSTEOPOROSIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
SKELETAL PAIN	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
SYNOVITIS	0	0	0	0	0	0	0	0				
TENDINITIS	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	4 (6.6%)	1 (1.6%)	0	4 (6.6%)	7 (9.0%)	0	0	7 (9.0%)				
ANGINA PECTORIS	1 (1.6%)	0	0	1 (1.6%)	6 (7.7%)	0	0	6 (7.7%)				
ANGINA PECTORIS AGGRAVATED	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
CARDIOMYOPATHY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
CORONARY ARTERY DISORDER	0	0	0	0	0	0	0	0				
MYOCARDIAL INFARCTION	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
MYOCARDIAL ISCHEMIA	2 (3.3%)	0	0	2 (3.3%)	0	0	0	0				
THROMBOSIS CORONARY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
NEOPLASM	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	1 (1.3%)	2 (2.6%)	0	3 (3.8%)				
BASAL CELL CARCINOMA	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
GASTRIC CARCINOMA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
LIPOMA	0	0	0	0	0	0	0	0				
NEOPLASM NOS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
PULMONARY CARCINOMA	0	0	0	0	0	0	0	0				
SKIN NEOPLASM MALIGNANT	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_---- 2bd Comb Total -----_----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
MUSCULOSKELETAL SYSTEM	20 (22.2%)	7 (7.8%)	0	25 (27.8%)
ARTHRALGIA	3 (3.3%)	3 (3.3%)	0	6 (6.7%)
ARTHRITIS	5 (5.6%)	3 (3.3%)	0	8 (8.9%)
ARTHRITIS AGGRAVATED	2 (2.2%)	0	0	2 (2.2%)
ARTHROPATHY	0	0	0	0
ARTHROSIS	2 (2.2%)	0	0	2 (2.2%)
BACK PAIN	6 (6.7%)	1 (1.1%)	0	7 (7.8%)
BONE DEVELOPMENT ABNORMAL	0	0	0	0
BONE DISORDER	0	0	0	0
MUSCLE WEAKNESS	0	0	0	0
MYALGIA	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
MYOSITIS	0	0	0	0
OSTEOPOROSIS	1 (1.1%)	0	0	1 (1.1%)
SKELETAL PAIN	1 (1.1%)	0	0	1 (1.1%)
SYNOVITIS	1 (1.1%)	0	0	1 (1.1%)
TENDINITIS	3 (3.3%)	0	0	3 (3.3%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	4 (4.4%)	2 (2.2%)	0	6 (6.7%)
ANGINA PECTORIS	2 (2.2%)	0	0	2 (2.2%)
ANGINA PECTORIS AGGRAVATED	0	0	0	0
CARDIOMYOPATHY	0	0	0	0
CORONARY ARTERY DISORDER	1 (1.1%)	0	0	1 (1.1%)
MYOCARDIAL INFARCTION	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
MYOCARDIAL ISCHEMIA	0	0	0	0
THROMBOSIS CORONARY	0	0	0	0
NEOPLASM	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
BASAL CELL CARCINOMA	0	1 (1.1%)	0	1 (1.1%)
GASTRIC CARCINOMA	0	0	0	0
LIPOMA	1 (1.1%)	0	0	1 (1.1%)
NEOPLASM NOS	0	0	0	0
PULMONARY CARCINOMA	1 (1.1%)	0	0	1 (1.1%)
SKIN NEOPLASM MALIGNANT	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
PLATELET BLEEDING AND CLOTTING THROMBOCYTOPENIA	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
PSYCHIATRIC	4 (6.6%)	4 (6.6%)	1 (1.6%)	9 (14.8%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)
AMNESIA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
ANXIETY	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
CONFUSION	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
DEPRESSION	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
EMOTIONAL LABILITY	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
INSOMNIA	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
NERVOUSNESS	0	0	0	0	0	0	0	0	0	0	0	0
SOMNOLENCE	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.9%)	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
RED BLOOD CELL	3 (4.9%)	0	0	3 (4.9%)	0	3 (3.8%)	0	3 (3.8%)	0	3 (3.8%)	0	3 (3.8%)
ANEMIA	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.6%)	0	2 (2.6%)	0	2 (2.6%)	0	2 (2.6%)
ANEMIA B TWELVE DEFICIENCY	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
ANEMIA HYPOCHROMIC	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
ERYTHROCYTES ABNORMAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
REPRODUCTIVE FEMALE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
MENSTRUAL DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
OVARIAN CYST	0	0	0	0	0	0	0	0	0	0	0	0
VAGINITIS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
REPRODUCTIVE MALE	4 (6.6%)	1 (1.6%)	0	5 (8.2%)	5 (6.4%)	2 (2.6%)	0	7 (9.0%)	5 (6.4%)	2 (2.6%)	0	7 (9.0%)
IMPOTENCE	3 (4.9%)	0	0	3 (4.9%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
PENIS DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
PROSTATIC DISORDER	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)
TESTIS DISORDER	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
RESISTANCE MECHANISM	15 (24.6%)	6 (9.8%)	0	19 (31.1%)	20 (25.6%)	6 (7.7%)	0	24 (30.8%)	20 (25.6%)	6 (7.7%)	0	24 (30.8%)
ABSCESS	0	0	0	0	0	0	0	0	0	0	0	0
HERPES SIMPLEX	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	1 (1.3%)	0	0	1 (1.3%)
HERPES ZOSTER	0	1 (1.6%)	0	1 (1.6%)	3 (3.8%)	1 (1.3%)	0	4 (5.1%)	3 (3.8%)	1 (1.3%)	0	4 (5.1%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_----- 2bd Comb Total -----_----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
PLATELET BLEEDING AND CLOTTING	1 (1.1%)	0	0	1 (1.1%)
THROMBOCYTOPENIA	1 (1.1%)	0	0	1 (1.1%)
PSYCHIATRIC	7 (7.8%)	3 (3.3%)	1 (1.1%)	11 (12.2%)
AMNESIA	0	0	0	0
ANXIETY	4 (4.4%)	2 (2.2%)	0	6 (6.7%)
CONFUSION	0	0	0	0
DEPRESSION	2 (2.2%)	0	1 (1.1%)	3 (3.3%)
EMOTIONAL LABILITY	1 (1.1%)	0	0	1 (1.1%)
INSOMNIA	0	0	1 (1.1%)	1 (1.1%)
NERVOUSNESS	1 (1.1%)	0	0	1 (1.1%)
SOMNOLENCE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
RED BLOOD CELL	2 (2.2%)	2 (2.2%)	2 (2.2%)	6 (6.7%)
ANEMIA	2 (2.2%)	2 (2.2%)	2 (2.2%)	6 (6.7%)
ANEMIA B TWELVE DEFICIENCY	0	0	0	0
ANEMIA HYPOCHROMIC	0	0	0	0
ERYTHROCYTES ABNORMAL	0	0	0	0
REPRODUCTIVE FEMALE	2 (2.2%)	0	0	2 (2.2%)
MENSTRUAL DISORDER	1 (1.1%)	0	0	1 (1.1%)
OVARIAN CYST	1 (1.1%)	0	0	1 (1.1%)
VAGINITIS	0	0	0	0
REPRODUCTIVE MALE	2 (2.2%)	0	0	2 (2.2%)
IMPOTENCE	1 (1.1%)	0	0	1 (1.1%)
PENIS DISORDER	1 (1.1%)	0	0	1 (1.1%)
PROSTATIC DISORDER	0	0	0	0
TESTIS DISORDER	0	0	0	0
RESISTANCE MECHANISM	24 (26.7%)	4 (4.4%)	0	27 (30.0%)
ABSCESS	2 (2.2%)	0	0	2 (2.2%)
HERPES SIMPLEX	0	0	0	0
HERPES ZOSTER	1 (1.1%)	0	0	1 (1.1%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
INFECTION	4 (6.6%)	1 (1.6%)	0	5 (8.2%)	2 (2.6%)	2 (2.6%)	0	4 (5.1%)				
INFECTION BACTERIAL	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)				
INFECTION FUNGAL	0	0	0	0	0	0	0	0				
INFECTION VIRAL	8 (13.1%)	2 (3.3%)	0	10 (16.4%)	8 (10.3%)	1 (1.3%)	0	9 (11.5%)				
MONILIASIS	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)				
MONILIASIS GENITAL	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
OTITIS MEDIA	0	0	0	0	0	0	0	0				
UPPER RESP TRACT INFECTION	5 (8.2%)	1 (1.6%)	0	6 (9.8%)	7 (9.0%)	2 (2.6%)	0	9 (11.5%)				
RESPIRATORY SYSTEM	14 (23.0%)	2 (3.3%)	0	15 (24.6%)	16 (20.5%)	5 (6.4%)	0	19 (24.4%)				
ASTHMA	0	0	0	0	0	0	0	0				
BRONCHITIS	3 (4.9%)	1 (1.6%)	0	4 (6.6%)	2 (2.6%)	0	0	2 (2.6%)				
COUGHING	7 (11.5%)	1 (1.6%)	0	8 (13.1%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)				
DYSPNEA	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	2 (2.6%)	0	4 (5.1%)				
EPISTAXIS	0	0	0	0	0	0	0	0				
LARYNGITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
PHARYNGITIS	4 (6.6%)	0	0	4 (6.6%)	4 (5.1%)	0	0	4 (5.1%)				
PNEUMONIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
PULMONARY EDEMA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
RESPIRATORY DISORDER	3 (4.9%)	0	0	3 (4.9%)	3 (3.8%)	3 (3.8%)	0	6 (7.7%)				
RESPIRATORY INSUFFICIENCY	0	0	0	0	0	0	0	0				
RHINITIS	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
SINUSITIS	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)				
SKIN AND APPENDAGES	7 (11.5%)	7 (11.5%)	0	14 (23.0%)	8 (10.3%)	6 (7.7%)	0	14 (17.9%)				
ALOPECIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
DERMATITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
DERMATITIS FUNGAL	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
ECZEMA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
FURUNCULOSIS	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
HYPERKERATOSIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
NAIL DISORDER	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
NEVUS	0	0	0	0	0	0	0	0				
PRURITUS	1 (1.6%)	3 (4.9%)	0	4 (6.6%)	0	2 (2.6%)	0	2 (2.6%)				

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_----- 2bd Comb Total -----_----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
INFECTION	1 (1.1%)	0	0	1 (1.1%)
INFECTION BACTERIAL	0	0	0	0
INFECTION FUNGAL	2 (2.2%)	0	0	2 (2.2%)
INFECTION VIRAL	7 (7.8%)	2 (2.2%)	0	9 (10.0%)
MONILIASIS	0	1 (1.1%)	0	1 (1.1%)
MONILIASIS GENITAL	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
OTITIS MEDIA	2 (2.2%)	0	0	2 (2.2%)
UPPER RESP TRACT INFECTION	11 (12.2%)	3 (3.3%)	0	14 (15.6%)
RESPIRATORY SYSTEM	19 (21.1%)	12 (13.3%)	0	26 (28.9%)
ASTHMA	0	1 (1.1%)	0	1 (1.1%)
BRONCHITIS	3 (3.3%)	0	0	3 (3.3%)
COUGHING	4 (4.4%)	2 (2.2%)	0	6 (6.7%)
DYSPNEA	1 (1.1%)	5 (5.6%)	0	6 (6.7%)
EPISTAXIS	0	1 (1.1%)	0	1 (1.1%)
LARYNGITIS	0	0	0	0
PHARYNGITIS	4 (4.4%)	3 (3.3%)	0	7 (7.8%)
PNEUMONIA	0	0	0	0
PULMONARY EDEMA	1 (1.1%)	0	0	1 (1.1%)
RESPIRATORY DISORDER	7 (7.8%)	3 (3.3%)	0	10 (11.1%)
RESPIRATORY INSUFFICIENCY	0	1 (1.1%)	0	1 (1.1%)
RHINITIS	1 (1.1%)	0	0	1 (1.1%)
SINUSITIS	2 (2.2%)	0	0	2 (2.2%)
SKIN AND APPENDAGES	8 (8.9%)	4 (4.4%)	0	11 (12.2%)
ALOPECIA	0	0	0	0
DERMATITIS	1 (1.1%)	0	0	1 (1.1%)
DERMATITIS FUNGAL	1 (1.1%)	0	0	1 (1.1%)
ECZEMA	1 (1.1%)	0	0	1 (1.1%)
FURUNCULOSIS	1 (1.1%)	0	0	1 (1.1%)
HYPERKERATOSIS	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
NAIL DISORDER	1 (1.1%)	0	0	1 (1.1%)
NEVUS	0	1 (1.1%)	0	1 (1.1%)
PRURITUS	1 (1.1%)	0	0	1 (1.1%)

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
RASH	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
RASH ERYTHEMATOUS	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)	0	0	0	0
RASH PUSTULAR	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
SEBORRHEA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
SKIN DISORDER	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
SKIN DRY	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
SKIN HYPERTROPHY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
SKIN ULCERATION	0	0	0	0	0	0	0	0	0	0	0	0
URTICARIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
VERRUCA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
URINARY SYSTEM	9 (14.8%)	1 (1.6%)	0	10 (16.4%)	10 (12.8%)	7 (9.0%)	1 (1.3%)	15 (19.2%)				
ALBUMINURIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
CYSTITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
DYSURIA	2 (3.3%)	0	0	2 (3.3%)	0	0	0	0	0	0	0	0
HEMATURIA	0	0	0	0	0	1 (1.3%)	1 (1.3%)	2 (2.6%)	0	0	0	0
HYDRONEPHROSIS	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0	2 (2.6%)	1 (1.3%)	0	3 (3.8%)	0	0	0	0
NOCTURIA	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)	0	0	0	0
POLYURIA	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
PYURIA	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)	0	0	0	0
RENAL CALCULUS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
RENAL FAILURE ACUTE	1 (1.6%)	0	0	1 (1.6%)	0	2 (2.6%)	0	2 (2.6%)	0	0	0	0
URETHRAL DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
URINARY TRACT INFECTION	4 (6.6%)	0	0	4 (6.6%)	6 (7.7%)	3 (3.8%)	0	9 (11.5%)				
VASCULAR EXTRACARDIAC	5 (8.2%)	3 (4.9%)	0	8 (13.1%)	5 (6.4%)	4 (5.1%)	0	8 (10.3%)				
ATHEROSCLEROSIS	0	0	0	0	0	0	0	0	0	0	0	0
CEREBROVASCULAR DISORDER	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
CRAMPS LEGS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	3 (3.8%)	0	3 (3.8%)	0	0	0	0
EMBOLISM PULMONARY	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
HEMORRHAGE NOS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
PERIPHERAL ISCHEMIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
PHLEBITIS	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0

- 653 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_----- 2bd Comb Total -----_----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
RASH	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
RASH ERYTHEMATOUS	0	0	0	0
RASH PUSTULAR	0	0	0	0
SEBORRHEA	0	0	0	0
SKIN DISORDER	1 (1.1%)	0	0	1 (1.1%)
SKIN DRY	0	2 (2.2%)	0	2 (2.2%)
SKIN HYPERTROPHY	0	0	0	0
SKIN ULCERATION	0	1 (1.1%)	0	1 (1.1%)
URTICARIA	0	0	0	0
VERRUCA	0	0	0	0
URINARY SYSTEM	13 (14.4%)	0	0	13 (14.4%)
ALBUMINURIA	0	0	0	0
CYSTITIS	0	0	0	0
DYSURIA	0	0	0	0
HEMATURIA	2 (2.2%)	0	0	2 (2.2%)
HYDRONEPHROSIS	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0
NOCTURIA	0	0	0	0
POLYURIA	1 (1.1%)	0	0	1 (1.1%)
PYURIA	1 (1.1%)	0	0	1 (1.1%)
RENAL CALCULUS	0	0	0	0
RENAL FAILURE ACUTE	0	0	0	0
URETHRAL DISORDER	2 (2.2%)	0	0	2 (2.2%)
URINARY TRACT INFECTION	11 (12.2%)	0	0	11 (12.2%)
VASCULAR EXTRACARDIAC	4 (4.4%)	3 (3.3%)	0	7 (7.8%)
ATHEROSCLEROSIS	1 (1.1%)	0	0	1 (1.1%)
CEREBROVASCULAR DISORDER	0	1 (1.1%)	0	1 (1.1%)
CRAMPS LEGS	0	0	0	0
EMBOLISM PULMONARY	0	1 (1.1%)	0	1 (1.1%)
HEMORRHAGE NOS	0	0	0	0
PERIPHERAL ISCHEMIA	1 (1.1%)	0	0	1 (1.1%)
PHLEBITIS	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	48 (78.7%)	29 (47.5%)	12 (19.7%)	51 (83.6%)	49 (62.8%)	39 (50.0%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
THROMBOPHLEBITIS	0	0	0	0	0	0	0	0	0	0	0	0
VASCULAR DISORDER	1 (1.6%)	0	0	1 (1.6%)	3 (3.8%)	0	0	3 (3.8%)	0	0	0	0
VEIN DISORDER	2 (3.3%)	0	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
VEIN VARICOSE	2 (3.3%)	0	0	2 (3.3%)	0	0	0	0	0	0	0	0
VISION	6 (9.8%)	2 (3.3%)	1 (1.6%)	8 (13.1%)	3 (3.8%)	1 (1.3%)	0	4 (5.1%)	0	0	0	0
BLEPHARITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
CATARACT	4 (6.6%)	0	0	4 (6.6%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
CONJUNCTIVITIS	0	0	0	0	0	0	0	0	0	0	0	0
DIPLOPIA	0	0	0	0	0	0	0	0	0	0	0	0
EYE ABNORMALITY	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
EYE PAIN	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
GLAUCOMA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
MACULA LUTEA DEGENERATION	0	0	0	0	0	0	0	0	0	0	0	0
RETINAL DISORDER	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
RETINITIS	0	0	0	0	0	0	0	0	0	0	0	0
VISION ABNORMAL	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	2 (2.6%)	0	2 (2.6%)	3 (3.8%)	0	0	0	0
EOSINOPHILIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
GRANULOCYTOPENIA	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)	0	0	0	0
LEUKOCYTOSIS	0	0	0	0	0	0	0	0	0	0	0	0
LEUKOPENIA	1 (1.6%)	0	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)	0	0	0	0
LYMPHADENOPATHY CERVICAL	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
LYMPHANGITIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
LYMPHOPENIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0

Data Source Table 15.2.1b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	-----_----- 2bd Comb Total -----_----- 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	65 (72.2%)	43 (47.8%)	19 (21.1%)	76 (84.4%)
WHO Body System Preferred Term				
THROMBOPHLEBITIS	0	1 (1.1%)	0	1 (1.1%)
VASCULAR DISORDER	0	1 (1.1%)	0	1 (1.1%)
VEIN DISORDER	2 (2.2%)	0	0	2 (2.2%)
VEIN VARICOSE	1 (1.1%)	0	0	1 (1.1%)
VISION	7 (7.8%)	4 (4.4%)	0	10 (11.1%)
BLEPHARITIS	0	0	0	0
CATARACT	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
CONJUNCTIVITIS	2 (2.2%)	0	0	2 (2.2%)
DIPLOPIA	0	1 (1.1%)	0	1 (1.1%)
EYE ABNORMALITY	2 (2.2%)	0	0	2 (2.2%)
EYE PAIN	0	0	0	0
GLAUCOMA	1 (1.1%)	0	0	1 (1.1%)
MACULA LUTEA DEGENERATION	1 (1.1%)	0	0	1 (1.1%)
RETINAL DISORDER	3 (3.3%)	0	0	3 (3.3%)
RETINITIS	0	1 (1.1%)	0	1 (1.1%)
VISION ABNORMAL	0	1 (1.1%)	0	1 (1.1%)
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	1 (1.1%)	0	1 (1.1%)	2 (2.2%)
EOSINOPHILIA	0	0	0	0
GRANULOCYTOPENIA	0	0	0	0
LEUKOCYTOSIS	1 (1.1%)	0	0	1 (1.1%)
LEUKOPENIA	0	0	1 (1.1%)	1 (1.1%)
LYMPHADENOPATHY CERVICAL	0	0	0	0
LYMPHANGITIS	0	0	0	0
LYMPHOPENIA	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
APPLICATION SITE	0	0	0	0	2 (1.5%)	1 (0.7%)	0	3 (2.2%)				
OTITIS EXTERNA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
AUTONOMIC NERVOUS SYSTEM	2 (1.6%)	0	0	2 (1.6%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
SWEATING INCREASED	2 (1.6%)	0	0	2 (1.6%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
BODY AS A WHOLE GENERAL	28 (22.6%)	11 (8.9%)	1 (0.8%)	36 (29.0%)	32 (23.5%)	15 (11.0%)	5 (3.7%)	45 (33.1%)				
ALLERGIC REACTION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
ALLERGY	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
ASTHENIA	3 (2.4%)	2 (1.6%)	0	5 (4.0%)	3 (2.2%)	3 (2.2%)	0	6 (4.4%)				
CHEST PAIN	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
CHEST PAIN PRECORDIAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
EDEMA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
EDEMA DEPENDENT	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	0	1 (0.7%)	2 (1.5%)				
EDEMA GENERALISED	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
EDEMA LEGS	10 (8.1%)	2 (1.6%)	1 (0.8%)	13 (10.5%)	2 (1.5%)	3 (2.2%)	1 (0.7%)	6 (4.4%)				
EDEMA PERIORBITAL	0	0	0	0	0	0	0	0				
EDEMA PERIPHERAL	0	0	0	0	1 (0.7%)	0	1 (0.7%)	2 (1.5%)				
ESR INCREASED	0	0	0	0	0	0	0	0				
FACE EDEMA	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
FATIGUE	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	1 (0.7%)	0	0	1 (0.7%)				
FEVER	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
GRANULOMATOUS LESION	0	0	0	0	0	0	0	0				
HOT FLUSHES	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
INJURY	12 (9.7%)	4 (3.2%)	0	16 (12.9%)	24 (17.6%)	2 (1.5%)	0	26 (19.1%)				
MALAISE	0	0	0	0	0	0	0	0				
NECROSIS ISCHEMIC	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
PAIN	5 (4.0%)	1 (0.8%)	0	6 (4.8%)	4 (2.9%)	3 (2.2%)	1 (0.7%)	8 (5.9%)				
PALLOR	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
RIGORS	0	1 (0.8%)	0	1 (0.8%)	0	0	1 (0.7%)	1 (0.7%)				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
APPLICATION SITE	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
OTITIS EXTERNA	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	0	0	0	0
AUTONOMIC NERVOUS SYSTEM	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
SWEATING INCREASED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
BODY AS A WHOLE GENERAL	28 (20.1%)	12 (8.6%)	1 (0.7%)	40 (28.8%)	1 (3.3%)	4 (13.3%)	0	5 (16.7%)
ALLERGIC REACTION	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ALLERGY	0	0	0	0	0	0	0	0
ASTHENIA	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)	0	0	0	0
CHEST PAIN	3 (2.2%)	3 (2.2%)	0	6 (4.3%)	0	2 (6.7%)	0	2 (6.7%)
CHEST PAIN PRECORDIAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EDEMA	0	0	0	0	0	0	0	0
EDEMA DEPENDENT	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	0	0	0
EDEMA GENERALISED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EDEMA LEGS	5 (3.6%)	1 (0.7%)	0	6 (4.3%)	0	0	0	0
EDEMA PERIORBITAL	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
EDEMA PERIPHERAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ESR INCREASED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
FACE EDEMA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
FATIGUE	0	2 (1.4%)	0	2 (1.4%)	1 (3.3%)	0	0	1 (3.3%)
FEVER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GRANULOMATOUS LESION	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
HOT FLUSHES	1 (0.7%)	0	1 (0.7%)	2 (1.4%)	0	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	0	0	0	0
INJURY	14 (10.1%)	3 (2.2%)	0	17 (12.2%)	0	1 (3.3%)	0	1 (3.3%)
MALAISE	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
NECROSIS ISCHEMIC	0	0	0	0	0	0	0	0
PAIN	4 (2.9%)	1 (0.7%)	0	5 (3.6%)	0	0	0	0
PALLOR	0	0	0	0	0	0	0	0
RIGORS	0	0	0	0	0	0	0	0

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
THERAPEUTIC RESPONSE INCREASED	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
CARDIOVASCULAR GENERAL	7 (5.6%)	0	0	7 (5.6%)	12 (8.8%)	3 (2.2%)	0	15 (11.0%)				
CARDIAC FAILURE	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
CARDIAC FAILURE LEFT	0	0	0	0	0	0	0	0				
ECG ABNORMAL	0	0	0	0	0	0	0	0				
ECG ABNORMAL SPECIFIC	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
HEART DISORDER	0	0	0	0	0	0	0	0				
HEART VALVE DISORDERS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
HYPERTENSION	2 (1.6%)	0	0	2 (1.6%)	6 (4.4%)	0	0	6 (4.4%)				
HYPERTENSION AGGRAVATED	2 (1.6%)	0	0	2 (1.6%)	4 (2.9%)	1 (0.7%)	0	5 (3.7%)				
HYPOTENSION	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
HYPOTENSION POSTURAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
SYNCOPE	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	16 (12.9%)	8 (6.5%)	0	23 (18.5%)	20 (14.7%)	5 (3.7%)	2 (1.5%)	26 (19.1%)				
CARPAL TUNNEL SYNDROME	1 (0.8%)	0	0	1 (0.8%)	2 (1.5%)	0	0	2 (1.5%)				
DIZZINESS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
EDEMA CEREBRAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
HEADACHE	2 (1.6%)	3 (2.4%)	0	5 (4.0%)	4 (2.9%)	1 (0.7%)	1 (0.7%)	6 (4.4%)				
HYPERESTHESIA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
HYPERKINESIA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
HYPESTHESIA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
MIGRAINE	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
NEURALGIA	8 (6.5%)	1 (0.8%)	0	9 (7.3%)	11 (8.1%)	1 (0.7%)	0	12 (8.8%)				
NEURITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
NEUROPATHY	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
NEUROPATHY PERIPHERAL	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
PARESIS	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
PARESTHESIA	3 (2.4%)	2 (1.6%)	0	5 (4.0%)	0	3 (2.2%)	0	3 (2.2%)				
PTOSIS	0	0	0	0	0	0	0	0				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
THERAPEUTIC RESPONSE INCREASED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CARDIOVASCULAR GENERAL	12 (8.6%)	6 (4.3%)	0	18 (12.9%)	1 (3.3%)	1 (3.3%)	1 (3.3%)	3 (10.0%)
CARDIAC FAILURE	3 (2.2%)	2 (1.4%)	0	5 (3.6%)	0	0	1 (3.3%)	1 (3.3%)
CARDIAC FAILURE LEFT	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ECG ABNORMAL	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
ECG ABNORMAL SPECIFIC	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEART DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEART VALVE DISORDERS	0	0	0	0	0	0	0	0
HYPERTENSION	4 (2.9%)	1 (0.7%)	0	5 (3.6%)	0	0	0	0
HYPERTENSION AGGRAVATED	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
HYPOTENSION	0	0	0	0	0	0	0	0
HYPOTENSION POSTURAL	0	0	0	0	0	0	0	0
SYNCOPE	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	1 (3.3%)	0	0	1 (3.3%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	14 (10.1%)	5 (3.6%)	3 (2.2%)	22 (15.8%)	1 (3.3%)	3 (10.0%)	1 (3.3%)	5 (16.7%)
CARPAL TUNNEL SYNDROME	0	0	0	0	0	0	0	0
DIZZINESS	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
EDEMA CEREBRAL	0	0	0	0	0	0	0	0
HEADACHE	2 (1.4%)	1 (0.7%)	3 (2.2%)	6 (4.3%)	1 (3.3%)	0	1 (3.3%)	2 (6.7%)
HYPERESTHESIA	0	0	0	0	0	0	0	0
HYPERKINESIA	0	0	0	0	0	0	0	0
HYPESTHESIA	0	1 (0.7%)	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
MIGRAINE	0	0	0	0	0	0	0	0
NEURALGIA	7 (5.0%)	2 (1.4%)	0	9 (6.5%)	0	1 (3.3%)	0	1 (3.3%)
NEURITIS	0	0	0	0	0	0	0	0
NEUROPATHY	0	0	0	0	0	0	0	0
NEUROPATHY PERIPHERAL	0	0	0	0	0	0	0	0
PARESIS	0	0	0	0	0	0	0	0
PARESTHESIA	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
PTOSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
SPEECH DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
TETANY	0	0	0	0	0	0	0	0	0	0	0	0
TREMOR	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
VERTIGO	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	4 (2.9%)	0	0	4 (2.9%)	0	0	0	0
COLLAGEN	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ENDOCRINE	4 (3.2%)	0	1 (0.8%)	5 (4.0%)	5 (3.7%)	3 (2.2%)	0	8 (5.9%)	0	0	0	0
GOITRE	2 (1.6%)	0	0	2 (1.6%)	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
GYNECOMASTIA	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
HYPOTHYROIDISM	1 (0.8%)	0	0	1 (0.8%)	0	2 (1.5%)	0	2 (1.5%)	0	0	0	0
THYROID DISORDER	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GASTROINTESTINAL SYSTEM	26 (21.0%)	9 (7.3%)	1 (0.8%)	33 (26.6%)	32 (23.5%)	8 (5.9%)	2 (1.5%)	39 (28.7%)				
ABDOMINAL PAIN	3 (2.4%)	4 (3.2%)	0	7 (5.6%)	2 (1.5%)	4 (2.9%)	0	6 (4.4%)	0	0	0	0
ANUS DISORDER	1 (0.8%)	0	0	1 (0.8%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
APPETITE INCREASED	0	0	1 (0.8%)	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
COLITIS	3 (2.4%)	0	0	3 (2.4%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	0	0	0	0
CONSTIPATION	7 (5.6%)	0	0	7 (5.6%)	5 (3.7%)	0	0	5 (3.7%)	0	0	0	0
DIARRHEA	1 (0.8%)	0	0	1 (0.8%)	6 (4.4%)	0	0	6 (4.4%)	0	0	0	0
DIVERTICULITIS	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DUODENAL ULCER	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DYSPEPSIA	1 (0.8%)	3 (2.4%)	0	4 (3.2%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	0	0	0	0
ENTERITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ESOPHAGEAL ULCERATION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ESOPHAGITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
FECAL INCONTINENCE	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
FLATULENCE	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GASTRIC ULCER	2 (1.6%)	0	0	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)	0	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GASTRITIS	3 (2.4%)	0	0	3 (2.4%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Relationship to Study Medication								
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
SPEECH DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TETANY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TREMOR	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VERTIGO	4 (2.9%)	0	0	4 (2.9%)	0	0	0	0
COLLAGEN ARTHRITIS RHEUMATOID	0	0	0	0	0	0	0	0
ENDOCRINE	0	0	0	0	0	0	0	0
GOITRE	0	0	0	0	0	0	0	0
GYNECOMASTIA	0	0	0	0	0	0	0	0
HYPOTHYROIDISM	0	0	0	0	0	0	0	0
THYROID DISORDER	0	0	0	0	0	0	0	0
GASTROINTESTINAL SYSTEM	22 (15.8%)	11 (7.9%)	3 (2.2%)	34 (24.5%)	3 (10.0%)	3 (10.0%)	1 (3.3%)	6 (20.0%)
ABDOMINAL PAIN	5 (3.6%)	4 (2.9%)	0	9 (6.5%)	0	0	0	0
ANUS DISORDER	0	0	0	0	0	0	0	0
APPETITE INCREASED	0	0	1 (0.7%)	1 (0.7%)	0	0	1 (3.3%)	1 (3.3%)
COLITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CONSTIPATION	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
DIARRHEA	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	0	1 (3.3%)	0	1 (3.3%)
DIVERTICULITIS	0	0	0	0	0	0	0	0
DUODENAL ULCER	0	0	0	0	0	0	0	0
DYSPEPSIA	2 (1.4%)	0	0	2 (1.4%)	0	2 (6.7%)	0	2 (6.7%)
ENTERITIS	0	0	0	0	0	0	0	0
ESOPHAGEAL ULCERATION	0	0	0	0	0	0	0	0
ESOPHAGITIS	0	0	0	0	0	0	0	0
FECAL INCONTINENCE	0	0	0	0	0	0	0	0
FLATULENCE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GASTRIC ULCER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	0	0	0	0
GASTRITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
GASTROENTERITIS	2 (1.6%)	0	0	2 (1.6%)	7 (5.1%)	0	0	7 (5.1%)				
GASTROESOPHAGEAL REFLUX	1 (0.8%)	0	0	1 (0.8%)	3 (2.2%)	0	0	3 (2.2%)				
GASTROINTESTINAL DISORDER NOS	4 (3.2%)	0	0	4 (3.2%)	3 (2.2%)	0	0	3 (2.2%)				
GI HEMORRHAGE	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
HEMORRHAGE RECTUM	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
HEMORRHOIDS	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
INTESTINAL ISCHEMIA	0	0	0	0	0	0	0	0				
INTESTINAL PERFORATION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
IRRITABLE BOWEL SYNDROME	0	0	0	0	0	0	0	0				
NAUSEA	0	2 (1.6%)	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)				
PERIODONTITIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	3 (2.2%)	0	0	3 (2.2%)				
SALIVARY GLAND ENLARGEMENT	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
STOMATITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
STOMATITIS ULCERATIVE	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
TONGUE EDEMA	0	0	0	0	0	0	0	0				
TONGUE ULCERATION	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
TOOTH CARIES	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
TOOTH DISORDER	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
VOMITING	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
HEARING AND VESTIBULAR	3 (2.4%)	2 (1.6%)	0	5 (4.0%)	1 (0.7%)	0	0	1 (0.7%)				
DEAFNESS	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
EAR DISORDER NOS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
EARACHE	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
TINNITUS	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
HEART RATE AND RHYTHM	6 (4.8%)	3 (2.4%)	2 (1.6%)	9 (7.3%)	5 (3.7%)	5 (3.7%)	2 (1.5%)	12 (8.8%)				
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	0	0				
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	0	0	0				
ATRIOVENTRICULAR BLOCK	2 (1.6%)	0	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
BRADYCARDIA	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	0	0	2 (1.5%)				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
GASTROENTERITIS	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
GASTROESOPHAGEAL REFLUX	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GASTROINTESTINAL DISORDER NOS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GI HEMORRHAGE	0	0	0	0	0	0	0	0
HEMORRHAGE RECTUM	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HEMORRHOIDS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
INTESTINAL ISCHEMIA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0	0	0	0	0
IRRITABLE BOWEL SYNDROME	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
NAUSEA	3 (2.2%)	1 (0.7%)	2 (1.4%)	6 (4.3%)	0	0	0	0
PERIODONTITIS	5 (3.6%)	0	0	5 (3.6%)	3 (10.0%)	0	0	3 (10.0%)
SALIVARY GLAND ENLARGEMENT	0	0	0	0	0	0	0	0
STOMATITIS	0	0	0	0	0	0	0	0
STOMATITIS ULCERATIVE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TONGUE EDEMA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TONGUE ULCERATION	0	0	0	0	0	0	0	0
TOOTH CARIES	0	0	0	0	0	0	0	0
TOOTH DISORDER	0	0	0	0	0	0	0	0
VOMITING	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
HEARING AND VESTIBULAR	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DEAFNESS	0	0	0	0	0	0	0	0
EAR DISORDER NOS	0	0	0	0	0	0	0	0
EARACHE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
TINNITUS	0	0	0	0	0	0	0	0
HEART RATE AND RHYTHM	6 (4.3%)	4 (2.9%)	0	10 (7.2%)	0	2 (6.7%)	0	2 (6.7%)
ARRHYTHMIA ATRIAL	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
ARRHYTHMIA VENTRICULAR	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	0	0	0
BRADYCARDIA	0	0	0	0	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.8%)	2 (1.6%)	0	0	2 (1.5%)	2 (1.5%)				
EXTRASYSTOLES	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)				
FIBRILLATION ATRIAL	1 (0.8%)	0	0	1 (0.8%)	0	3 (2.2%)	0	3 (2.2%)				
PALPITATION	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
TACHYCARDIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)				
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
LIVER AND BILIARY SYSTEM	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	2 (1.5%)	1 (0.7%)	4 (2.9%)				
BILIARY PAIN	0	0	0	0	0	0	0	0				
CHOLECYSTITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
CHOLELITHIASIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
GALL BLADDER DISORDER	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
GAMMA-GT INCREASED	0	0	0	0	0	1 (0.7%)	1 (0.7%)	2 (1.5%)				
HEPATIC FUNCTION ABNORMAL	0	0	0	0	0	0	0	0				
HEPATOMEGALY	0	0	0	0	0	0	0	0				
METABOLIC AND NUTRITIONAL	21 (16.9%)	12 (9.7%)	13 (10.5%)	41 (33.1%)	13 (9.6%)	7 (5.1%)	17 (12.5%)	32 (23.5%)				
BLOOD UREA NITROGEN INCREASED	0	0	0	0	0	0	2 (1.5%)	2 (1.5%)				
CALCINOSIS	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
DIABETES MELLITUS AGGRAVATED	0	0	5 (4.0%)	5 (4.0%)	0	0	3 (2.2%)	3 (2.2%)				
GOUT	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)				
HYPERCHOLESTEROLEMIA	8 (6.5%)	4 (3.2%)	2 (1.6%)	14 (11.3%)	4 (2.9%)	4 (2.9%)	3 (2.2%)	11 (8.1%)				
HYPERGLYCEMIA	1 (0.8%)	1 (0.8%)	2 (1.6%)	4 (3.2%)	2 (1.5%)	0	1 (0.7%)	3 (2.2%)				
HYPERKALEMIA	0	0	0	0	0	0	0	0				
HYPERLIPEMIA	5 (4.0%)	3 (2.4%)	1 (0.8%)	9 (7.3%)	4 (2.9%)	1 (0.7%)	1 (0.7%)	6 (4.4%)				
HYPERTRIGLYCERIDEMIA	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
HYPERURICEMIA	0	0	0	0	0	0	0	0				
HYPOCHOLESTEROLEMIA	0	0	0	0	0	0	0	0				
HYPOGLYCEMIA	0	0	0	0	0	0	5 (3.7%)	5 (3.7%)				
HYPOGLYCEMIC REACTION	0	0	0	0	0	0	0	0				
HYPOKALEMIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
NPN INCREASED	2 (1.6%)	0	0	2 (1.6%)	0	1 (0.7%)	1 (0.7%)	2 (1.5%)				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
BUNDLE BRANCH BLOCK	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EXTRASYSTOLES	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
FIBRILLATION ATRIAL	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
PALPITATION	0	1 (0.7%)	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
TACHYCARDIA	0	0	0	0	0	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	0	0	0	0
LIVER AND BILIARY SYSTEM	4 (2.9%)	2 (1.4%)	1 (0.7%)	6 (4.3%)	0	0	0	0
BILIARY PAIN	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CHOLECYSTITIS	0	0	0	0	0	0	0	0
CHOLELITHIASIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GALL BLADDER DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GAMMA-GT INCREASED	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)	0	0	0	0
HEPATIC FUNCTION ABNORMAL	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
HEPATOMEGALY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
METABOLIC AND NUTRITIONAL	14 (10.1%)	7 (5.0%)	13 (9.4%)	33 (23.7%)	5 (16.7%)	7 (23.3%)	11 (36.7%)	20 (66.7%)
BLOOD UREA NITROGEN INCREASED	0	0	0	0	0	0	0	0
CALCINOSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DIABETES MELLITUS AGGRAVATED	0	0	4 (2.9%)	4 (2.9%)	0	0	10 (33.3%)	10 (33.3%)
GOUT	0	1 (0.7%)	0	1 (0.7%)	1 (3.3%)	0	0	1 (3.3%)
HYPERCHOLESTEROLEMIA	6 (4.3%)	2 (1.4%)	1 (0.7%)	9 (6.5%)	3 (10.0%)	6 (20.0%)	0	9 (30.0%)
HYPERGLYCEMIA	2 (1.4%)	0	7 (5.0%)	9 (6.5%)	0	0	0	0
HYPERKALEMIA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HYPERLIPEMIA	3 (2.2%)	3 (2.2%)	2 (1.4%)	8 (5.8%)	0	0	0	0
HYPERTRIGLYCERIDEMIA	1 (0.7%)	0	0	1 (0.7%)	1 (3.3%)	0	0	1 (3.3%)
HYPERURICEMIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HYPOCHOLESTEROLEMIA	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
HYPOGLYCEMIA	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
HYPOGLYCEMIC REACTION	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
HYPOKALEMIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
NPN INCREASED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0

- 666 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
OBESITY	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
THIRST	0	0	0	0	0	0	0	0				
WEIGHT DECREASE	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
WEIGHT INCREASE	2 (1.6%)	2 (1.6%)	3 (2.4%)	7 (5.6%)	1 (0.7%)	2 (1.5%)	4 (2.9%)	7 (5.1%)				
MUSCULOSKELETAL SYSTEM	35 (28.2%)	14 (11.3%)	1 (0.8%)	47 (37.9%)	44 (32.4%)	12 (8.8%)	1 (0.7%)	55 (40.4%)				
ARTHRALGIA	6 (4.8%)	2 (1.6%)	1 (0.8%)	9 (7.3%)	10 (7.4%)	3 (2.2%)	1 (0.7%)	14 (10.3%)				
ARTHRITIS	9 (7.3%)	3 (2.4%)	0	12 (9.7%)	14 (10.3%)	3 (2.2%)	0	17 (12.5%)				
ARTHRITIS AGGRAVATED	0	2 (1.6%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)				
ARTHROPATHY	0	0	0	0	0	0	0	0				
ARTHRITIS	6 (4.8%)	0	0	6 (4.8%)	8 (5.9%)	1 (0.7%)	0	9 (6.6%)				
BACK PAIN	13 (10.5%)	2 (1.6%)	0	15 (12.1%)	19 (14.0%)	1 (0.7%)	0	20 (14.7%)				
BONE DISORDER	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
BURSITIS	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
MYALGIA	3 (2.4%)	3 (2.4%)	0	6 (4.8%)	2 (1.5%)	2 (1.5%)	1 (0.7%)	5 (3.7%)				
MYOPATHY	1 (0.8%)	0	0	1 (0.8%)	2 (1.5%)	0	0	2 (1.5%)				
OSTEOMYELITIS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
OSTEOPOROSIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	4 (2.9%)	1 (0.7%)	0	5 (3.7%)				
SKELETAL PAIN	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	1 (0.7%)	0	0	1 (0.7%)				
TENDINITIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	4 (2.9%)	2 (1.5%)	0	6 (4.4%)				
TORTICOLLIS	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	9 (6.6%)	2 (1.5%)	0	11 (8.1%)				
ANGINA PECTORIS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	7 (5.1%)	0	0	7 (5.1%)				
AORTIC STENOSIS	0	0	0	0	0	0	0	0				
MYOCARDIAL INFARCTION	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
MYOCARDIAL ISCHEMIA	0	0	0	0	0	0	0	0				
THROMBOSIS CORONARY	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
NEOPLASM	4 (3.2%)	2 (1.6%)	0	6 (4.8%)	5 (3.7%)	3 (2.2%)	0	8 (5.9%)				
BASAL CELL CARCINOMA	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
OBESITY	0	0	0	0	0	0	0	0
THIRST	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
WEIGHT DECREASE	0	0	0	0	0	0	0	0
WEIGHT INCREASE	0	0	1 (0.7%)	1 (0.7%)	0	0	2 (6.7%)	2 (6.7%)
MUSCULOSKELETAL SYSTEM	28 (20.1%)	10 (7.2%)	1 (0.7%)	37 (26.6%)	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
ARTHRALGIA	4 (2.9%)	3 (2.2%)	0	7 (5.0%)	0	0	0	0
ARTHTRITIS	8 (5.8%)	4 (2.9%)	0	12 (8.6%)	1 (3.3%)	0	0	1 (3.3%)
ARTHTRITIS AGGRAVATED	0	0	0	0	0	0	0	0
ARTHROPATHY	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ARTHROSIS	6 (4.3%)	1 (0.7%)	0	7 (5.0%)	0	1 (3.3%)	0	1 (3.3%)
BACK PAIN	12 (8.6%)	3 (2.2%)	0	15 (10.8%)	0	0	0	0
BONE DISORDER	0	0	0	0	0	0	0	0
BURSITIS	0	0	0	0	0	0	0	0
MYALGIA	5 (3.6%)	3 (2.2%)	1 (0.7%)	9 (6.5%)	0	1 (3.3%)	0	1 (3.3%)
MYOPATHY	0	0	0	0	0	0	0	0
OSTEOMYELITIS	0	0	0	0	0	0	0	0
OSTEOPOROSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SKELETAL PAIN	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
TENDINITIS	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
TORTICOLLIS	0	0	0	0	0	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	10 (7.2%)	5 (3.6%)	0	15 (10.8%)	0	1 (3.3%)	0	1 (3.3%)
ANGINA PECTORIS	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
AORTIC STENOSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MYOCARDIAL INFARCTION	3 (2.2%)	2 (1.4%)	0	5 (3.6%)	0	0	0	0
MYOCARDIAL ISCHEMIA	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	1 (3.3%)	0	1 (3.3%)
THROMBOSIS CORONARY	0	0	0	0	0	0	0	0
NEOPLASM	7 (5.0%)	4 (2.9%)	0	11 (7.9%)	0	0	0	0
BASAL CELL CARCINOMA	0	0	0	0	0	0	0	0

- 669 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
BLADDER CARCINOMA	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
BRAIN NEOPLASM BENIGN	0	0	0	0	0	0	0	0				
BREAST NEOPLASM FEMALE	0	0	0	0	0	0	0	0				
CARCINOMA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
HEPATIC NEOPLASM MALIGNANT	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
LIPOMA	0	0	0	0	0	0	0	0				
MELANOMA MALIGNANT	0	0	0	0	0	0	0	0				
NEOPLASM MALIGNANT	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
NEOPLASM NOS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0				
THYROID ADENOMA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
UTERINE FIBROID	0	0	0	0	0	0	0	0				
PLATELET BLEEDING AND CLOTTING	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
PURPURA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
THROMBOCYTOPENIA	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
PSYCHIATRIC	6 (4.8%)	7 (5.6%)	0	13 (10.5%)	11 (8.1%)	3 (2.2%)	0	14 (10.3%)				
AMNESIA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
ANXIETY	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	1 (0.7%)	0	0	1 (0.7%)				
DEMENTIA	0	0	0	0	0	0	0	0				
DEPRESSION	4 (3.2%)	2 (1.6%)	0	6 (4.8%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
INSOMNIA	0	2 (1.6%)	0	2 (1.6%)	6 (4.4%)	0	0	6 (4.4%)				
NERVOUSNESS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
NEUROSIS	0	0	0	0	0	0	0	0				
SOMNOLENCE	0	2 (1.6%)	0	2 (1.6%)	0	2 (1.5%)	0	2 (1.5%)				
SUICIDE ATTEMPT	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
RED BLOOD CELL	2 (1.6%)	7 (5.6%)	0	9 (7.3%)	1 (0.7%)	2 (1.5%)	1 (0.7%)	4 (2.9%)				
ANEMIA	1 (0.8%)	6 (4.8%)	0	7 (5.6%)	1 (0.7%)	2 (1.5%)	1 (0.7%)	4 (2.9%)				
ANEMIA HYPOCHROMIC	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	0	0	1 (0.7%)				
ANEMIA NORMOCHROMIC	0	0	0	0	0	0	0	0				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
BLADDER CARCINOMA	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
BRAIN NEOPLASM BENIGN	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
BREAST NEOPLASM FEMALE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CARCINOMA	0	0	0	0	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
LIPOMA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MELANOMA MALIGNANT	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0
NEOPLASM NOS	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
PHARYNX NEOPLASM MALIGNANT	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
THYROID ADENOMA	0	0	0	0	0	0	0	0
UTERINE FIBROID	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PLATELET BLEEDING AND CLOTTING	0	0	0	0	0	0	0	0
PURPURA	0	0	0	0	0	0	0	0
THROMBOCYTOPENIA	0	0	0	0	0	0	0	0
PSYCHIATRIC	10 (7.2%)	7 (5.0%)	1 (0.7%)	18 (12.9%)	0	1 (3.3%)	0	1 (3.3%)
AMNESIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ANXIETY	4 (2.9%)	3 (2.2%)	0	7 (5.0%)	0	0	0	0
DEMENTIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DEPRESSION	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	0	0	0
INSOMNIA	3 (2.2%)	2 (1.4%)	1 (0.7%)	6 (4.3%)	0	1 (3.3%)	0	1 (3.3%)
NERVOUSNESS	2 (1.4%)	0	1 (0.7%)	3 (2.2%)	0	0	0	0
NEUROSIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
SOMNOLENCE	0	0	0	0	0	0	0	0
SUICIDE ATTEMPT	0	0	0	0	0	0	0	0
RED BLOOD CELL	3 (2.2%)	2 (1.4%)	1 (0.7%)	6 (4.3%)	4 (13.3%)	2 (6.7%)	1 (3.3%)	7 (23.3%)
ANEMIA	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)	3 (10.0%)	2 (6.7%)	1 (3.3%)	6 (20.0%)
ANEMIA HYPOCHROMIC	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ANEMIA NORMOCHROMIC	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
ERYTHROCYTES ABNORMAL	0	0	0	0	0	0	0	0	0	0	0	0
REPRODUCTIVE FEMALE	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MENORRHAGIA	0	0	0	0	0	0	0	0	0	0	0	0
MENSTRUAL DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
OVARIAN DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
VAGINITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
REPRODUCTIVE MALE	6 (4.8%)	1 (0.8%)	0	7 (5.6%)	6 (4.4%)	1 (0.7%)	0	7 (5.1%)	0	0	0	0
EPIDIDYMITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
IMPOTENCE	4 (3.2%)	1 (0.8%)	0	5 (4.0%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PROSTATIC DISORDER	2 (1.6%)	0	0	2 (1.6%)	4 (2.9%)	1 (0.7%)	0	5 (3.7%)	0	0	0	0
TESTIS DISORDER	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RESISTANCE MECHANISM	17 (13.7%)	9 (7.3%)	0	24 (19.4%)	22 (16.2%)	8 (5.9%)	1 (0.7%)	29 (21.3%)	0	0	0	0
ABSCESS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
HERPES SIMPLEX	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HERPES ZOSTER	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
INFECTION	4 (3.2%)	0	0	4 (3.2%)	3 (2.2%)	0	1 (0.7%)	4 (2.9%)	0	0	0	0
INFECTION BACTERIAL	1 (0.8%)	0	0	1 (0.8%)	0	2 (1.5%)	0	2 (1.5%)	0	0	0	0
INFECTION FUNGAL	4 (3.2%)	0	0	4 (3.2%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)	0	0	0	0
INFECTION VIRAL	11 (8.9%)	2 (1.6%)	0	13 (10.5%)	10 (7.4%)	0	0	10 (7.4%)	0	0	0	0
MONILIASIS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0	0	0	0	0
MONILIASIS GENITAL	0	0	0	0	0	0	0	0	0	0	0	0
OTITIS MEDIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)	0	0	0	0
SEPSIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
UPPER RESP TRACT INFECTION	2 (1.6%)	3 (2.4%)	0	5 (4.0%)	7 (5.1%)	3 (2.2%)	0	10 (7.4%)	0	0	0	0
RESPIRATORY SYSTEM	37 (29.8%)	12 (9.7%)	0	45 (36.3%)	43 (31.6%)	9 (6.6%)	0	49 (36.0%)	0	0	0	0
APNEA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ASTHMA	0	2 (1.6%)	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
BRONCHITIS	16 (12.9%)	2 (1.6%)	0	18 (14.5%)	20 (14.7%)	3 (2.2%)	0	23 (16.9%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
ERYTHROCYTES ABNORMAL	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
REPRODUCTIVE FEMALE	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
MENORRHAGIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MENSTRUAL DISORDER	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	1 (3.3%)	0	1 (3.3%)
OVARIAN DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VAGINITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
REPRODUCTIVE MALE	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
EPIDIDYMITIS	0	0	0	0	0	0	0	0
IMPOTENCE	0	0	0	0	0	0	0	0
PROSTATIC DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TESTIS DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RESISTANCE MECHANISM	28 (20.1%)	4 (2.9%)	0	32 (23.0%)	8 (26.7%)	1 (3.3%)	0	9 (30.0%)
ABSCESS	0	0	0	0	0	0	0	0
HERPES SIMPLEX	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
HERPES ZOSTER	0	0	0	0	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
INFECTION	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
INFECTION BACTERIAL	0	0	0	0	0	0	0	0
INFECTION FUNGAL	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
INFECTION VIRAL	12 (8.6%)	0	0	12 (8.6%)	3 (10.0%)	0	0	3 (10.0%)
MONILIASIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
MONILIASIS GENITAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
OTITIS MEDIA	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
SEPSIS	0	0	0	0	2 (6.7%)	0	0	2 (6.7%)
UPPER RESP TRACT INFECTION	8 (5.8%)	3 (2.2%)	0	11 (7.9%)	3 (10.0%)	0	0	3 (10.0%)
RESPIRATORY SYSTEM	42 (30.2%)	13 (9.4%)	1 (0.7%)	52 (37.4%)	3 (10.0%)	2 (6.7%)	1 (3.3%)	6 (20.0%)
APNEA	0	0	0	0	0	0	0	0
ASTHMA	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
BRONCHITIS	23 (16.5%)	3 (2.2%)	1 (0.7%)	27 (19.4%)	1 (3.3%)	0	0	1 (3.3%)

- 672 -

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
CHEST X-RAY ABNORMAL	0	0	0	0	0	0	0	0	0	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0	0	0	0	0
DISEA												
COUGHING	0	2 (1.6%)	0	2 (1.6%)	6 (4.4%)	1 (0.7%)	0	7 (5.1%)	0	0	0	0
DYSPNEA	4 (3.2%)	2 (1.6%)	0	6 (4.8%)	4 (2.9%)	2 (1.5%)	0	6 (4.4%)	0	0	0	0
EPISTAXIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEMOPTYSIS	0	0	0	0	0	0	0	0	0	0	0	0
LARYNGITIS	2 (1.6%)	0	0	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)	0	0	0	0
PHARYNGITIS	10 (8.1%)	0	0	10 (8.1%)	6 (4.4%)	2 (1.5%)	0	8 (5.9%)	0	0	0	0
PLEURAL EFFUSION	0	0	0	0	0	0	0	0	0	0	0	0
PLEURISY	0	0	0	0	0	0	0	0	0	0	0	0
PNEUMONIA	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PULMONARY EDEMA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
RESPIRATORY DISORDER	7 (5.6%)	3 (2.4%)	0	10 (8.1%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
RHINITIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	5 (3.7%)	1 (0.7%)	0	6 (4.4%)	0	0	0	0
SINUSITIS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	4 (2.9%)	0	0	4 (2.9%)	0	0	0	0
TRACHEITIS	1 (0.8%)	0	0	1 (0.8%)	5 (3.7%)	0	0	5 (3.7%)	0	0	0	0
SKIN AND APPENDAGES	9 (7.3%)	6 (4.8%)	1 (0.8%)	15 (12.1%)	13 (9.6%)	4 (2.9%)	0	16 (11.8%)	0	0	0	0
ALOPECIA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ANGIOEDEMA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
BULLOUS ERUPTION	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
DERMATITIS	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
DERMATITIS FUNGAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ECZEMA	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
FOLLICULITIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
FURUNCULOSIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HYPERKERATOSIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
NAIL DISORDER	2 (1.6%)	0	1 (0.8%)	3 (2.4%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PHOTOSENSITIVITY REACTION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PRURITUS	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
CHEST X-RAY ABNORMAL	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DISEA								
COUGHING	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
DYSPNEA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EPISTAXIS	0	2 (1.4%)	0	2 (1.4%)	0	1 (3.3%)	0	1 (3.3%)
HEMOPTYSIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
LARYNGITIS	0	0	0	0	0	0	0	0
PHARYNGITIS	10 (7.2%)	0	0	10 (7.2%)	0	0	0	0
PLEURAL EFFUSION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PLEURISY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PNEUMONIA	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
PULMONARY EDEMA	1 (0.7%)	0	0	1 (0.7%)	0	0	1 (3.3%)	1 (3.3%)
RESPIRATORY DISORDER	5 (3.6%)	6 (4.3%)	0	11 (7.9%)	0	1 (3.3%)	0	1 (3.3%)
RHINITIS	6 (4.3%)	0	0	6 (4.3%)	1 (3.3%)	0	0	1 (3.3%)
SINUSITIS	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
TRACHEITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SKIN AND APPENDAGES	14 (10.1%)	2 (1.4%)	3 (2.2%)	19 (13.7%)	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
ALOPECIA	0	0	0	0	0	0	0	0
ANGIOEDEMA	0	0	0	0	0	0	0	0
BULLOUS ERUPTION	0	0	0	0	0	0	0	0
DERMATITIS	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
DERMATITIS FUNGAL	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
ECZEMA	7 (5.0%)	0	0	7 (5.0%)	0	0	0	0
FOLLICULITIS	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
FURUNCULOSIS	0	0	0	0	0	0	0	0
HYPERKERATOSIS	0	0	0	0	0	0	0	0
NAIL DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	0	0	0	0
PHOTOSENSITIVITY REACTION	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
PRURITUS	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0

- 674 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
PRURITUS GENITAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
PSORIASIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
PSORIASIS AGGRAVATED	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
RASH	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
RASH ERYTHEMATOUS	0	0	0	0	0	0	0	0				
RASH PUSTULAR	0	0	0	0	0	0	0	0				
ROSACEA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
SEBORRHEA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
SKIN DRY	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
SKIN HYPERTROPHY	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
SKIN ULCERATION	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	0	0	0	0				
VERRUCA	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
URINARY SYSTEM	12 (9.7%)	5 (4.0%)	1 (0.8%)	17 (13.7%)	12 (8.8%)	5 (3.7%)	1 (0.7%)	17 (12.5%)				
ALBUMINURIA	0	0	1 (0.8%)	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
CYSTITIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	2 (1.5%)	0	0	2 (1.5%)				
CYSTITIS HEMORRHAGIC	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
DYSURIA	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)				
HEMATURIA	1 (0.8%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	1 (0.7%)	0	1 (0.7%)	2 (1.5%)				
MICTURITION DISORDER	0	0	0	0	0	0	0	0				
MICTURITION FREQUENCY	1 (0.8%)	0	0	1 (0.8%)	0	3 (2.2%)	0	3 (2.2%)				
POLYURIA	0	0	0	0	0	0	0	0				
PYELONEPHRITIS	0	0	0	0	0	0	0	0				
PYURIA	0	0	0	0	0	0	0	0				
RENAL CALCULUS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
RENAL PAIN	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
STRANGURY	0	0	0	0	0	0	0	0				
URINARY INCONTINENCE	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
URINARY TRACT INFECTION	6 (4.8%)	4 (3.2%)	0	10 (8.1%)	8 (5.9%)	2 (1.5%)	0	10 (7.4%)				
VASCULAR EXTRACARDIAC	8 (6.5%)	6 (4.8%)	1 (0.8%)	15 (12.1%)	12 (8.8%)	5 (3.7%)	2 (1.5%)	19 (14.0%)				
ARTERITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Relationship to Study Medication								
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
PRURITUS GENITAL	0	0	0	0	0	0	0	0
PSORIASIS	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
PSORIASIS AGGRAVATED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
RASH	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
RASH ERYTHEMATOUS	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
RASH PUSTULAR	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ROSACEA	0	0	0	0	0	0	0	0
SEBORRHEA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SKIN DRY	0	0	0	0	0	0	0	0
SKIN HYPERTROPHY	0	0	0	0	0	0	0	0
SKIN ULCERATION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VERRUCA	0	0	0	0	0	0	0	0
URINARY SYSTEM	19 (13.7%)	7 (5.0%)	2 (1.4%)	28 (20.1%)	5 (16.7%)	5 (16.7%)	0	9 (30.0%)
ALBUMINURIA	0	0	1 (0.7%)	1 (0.7%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
CYSTITIS	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	0	0	0	0
CYSTITIS HEMORRHAGIC	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
DYSURIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEMATURIA	0	3 (2.2%)	0	3 (2.2%)	2 (6.7%)	1 (3.3%)	0	3 (10.0%)
MICTURITION DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0	0	0	0	0
POLYURIA	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
PYELONEPHRITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PYURIA	0	0	0	0	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
RENAL CALCULUS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RENAL PAIN	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
STRANGURY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
URINARY INCONTINENCE	0	0	0	0	0	0	0	0
URINARY TRACT INFECTION	13 (9.4%)	3 (2.2%)	0	16 (11.5%)	2 (6.7%)	2 (6.7%)	0	4 (13.3%)
VASCULAR EXTRACARDIAC	12 (8.6%)	7 (5.0%)	0	19 (13.7%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
ARTERITIS	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)				
WHO Body System Preferred Term												
CEREBROVASCULAR DISORDER	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
CLAUDICATION INTERMITTENT	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
CRAMPS LEGS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	4 (2.9%)	2 (1.5%)	1 (0.7%)	7 (5.1%)				
EMBOLISM PULMONARY	0	0	0	0	0	0	0	0				
PERIPHERAL ISCHEMIA	0	2 (1.6%)	1 (0.8%)	3 (2.4%)	0	0	0	0				
PHLEBITIS	3 (2.4%)	0	0	3 (2.4%)	1 (0.7%)	0	0	1 (0.7%)				
PHLEBITIS SUPERFICIAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
THROMBOPHLEBITIS DEEP	0	0	0	0	0	0	0	0				
VASCULAR DISORDER	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
VASCULITIS	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
VEIN DISORDER	3 (2.4%)	1 (0.8%)	0	4 (3.2%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
VEIN VARICOSE	0	0	0	0	3 (2.2%)	0	0	3 (2.2%)				
VISION	8 (6.5%)	8 (6.5%)	0	16 (12.9%)	7 (5.1%)	4 (2.9%)	0	11 (8.1%)				
BLEPHARITIS	0	0	0	0	0	0	0	0				
CATARACT	2 (1.6%)	0	0	2 (1.6%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
CONJUNCTIVAL HEMORRHAGE	0	0	0	0	0	0	0	0				
CONJUNCTIVITIS	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)				
CORNEAL OPACITY	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
EYE ABNORMALITY	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
GLAUCOMA	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	0	0	0	0				
LACRIMATION ABNORMAL	0	0	0	0	0	0	0	0				
RETINAL DETACHMENT	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
RETINAL DISORDER	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	2 (1.5%)	0	0	2 (1.5%)				
VISION ABNORMAL	0	2 (1.6%)	0	2 (1.6%)	1 (0.7%)	0	0	1 (0.7%)				
VITREOUS DETACHMENT	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
EOSINOPHILIA	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
LEUKOPENIA	0	1 (0.8%)	0	1 (0.8%)	0	2 (1.5%)	0	2 (1.5%)				
LYMPHADENOPATHY	0	0	0	0	0	0	0	0				

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Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Relationship to Study Medication								
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
CEREBROVASCULAR DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CLAUDICATION INTERMITTENT	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
CRAMPS LEGS	3 (2.2%)	3 (2.2%)	0	6 (4.3%)	1 (3.3%)	0	0	1 (3.3%)
EMBOLISM PULMONARY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PERIPHERAL ISCHEMIA	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
PHLEBITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PHLEBITIS SUPERFICIAL	0	0	0	0	0	0	0	0
THROMBOPHLEBITIS DEEP	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
VASCULAR DISORDER	3 (2.2%)	0	0	3 (2.2%)	0	0	0	0
VASCULITIS	0	0	0	0	0	0	0	0
VEIN DISORDER	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
VEIN VARICOSE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VISION	11 (7.9%)	8 (5.8%)	0	19 (13.7%)	0	3 (10.0%)	0	3 (10.0%)
BLEPHARITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CATARACT	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
CONJUNCTIVAL HEMORRHAGE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CONJUNCTIVITIS	6 (4.3%)	4 (2.9%)	0	10 (7.2%)	0	1 (3.3%)	0	1 (3.3%)
CORNEAL OPACITY	0	0	0	0	0	0	0	0
EYE ABNORMALITY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GLAUCOMA	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
LACRIMATION ABNORMAL	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
RETINAL DETACHMENT	0	0	0	0	0	0	0	0
RETINAL DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VISION ABNORMAL	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
VITREOUS DETACHMENT	0	0	0	0	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTEM	1 (0.7%)	0	0	1 (0.7%)	4 (13.3%)	0	0	4 (13.3%)
EOSINOPHILIA	0	0	0	0	0	0	0	0
LEUKOPENIA	0	0	0	0	4 (13.3%)	0	0	4 (13.3%)
LYMPHADENOPATHY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total 020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (71.0%)	50 (40.3%)	20 (16.1%)	105 (84.7%)	102 (75.0%)	49 (36.0%)	24 (17.6%)	114 (83.8%)
WHO Body System Preferred Term								
LYMPHANGITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0
LYMPHEDEMA	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)

Data Source Table 15.2.1c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	88 (63.3%)	51 (36.7%)	23 (16.5%)	115 (82.7%)	16 (53.3%)	17 (56.7%)	15 (50.0%)	28 (93.3%)
WHO Body System Preferred Term								
LYMPHANGITIS	0	0	0	0	0	0	0	0
LYMPHEDEMA	0	0	0	0	0	0	0	0

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Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
APPLICATION SITE	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	4 (0.9%)	0	5 (1.2%)
OTITIS EXTERNA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	3 (0.7%)	0	4 (0.9%)
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
AUTONOMIC NERVOUS SYSTEM	0	1 (0.4%)	0	1 (0.4%)	4 (0.9%)	2 (0.5%)	0	6 (1.4%)
SWEATING INCREASED	0	0	0	0	4 (0.9%)	2 (0.5%)	0	6 (1.4%)
VASOSPASM	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
BODY AS A WHOLE GENERAL	32 (14.0%)	38 (16.6%)	11 (4.8%)	70 (30.6%)	56 (13.0%)	69 (16.0%)	20 (4.7%)	126 (29.3%)
ALCOHOL INTOLERANCE	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ALLERGIC REACTION	1 (0.4%)	1 (0.4%)	1 (0.4%)	3 (1.3%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
ALLERGY	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
ASTHENIA	0	4 (1.7%)	0	4 (1.7%)	5 (1.2%)	9 (2.1%)	0	14 (3.3%)
CHEST PAIN	3 (1.3%)	3 (1.3%)	1 (0.4%)	7 (3.1%)	6 (1.4%)	5 (1.2%)	0	11 (2.6%)
CHEST PAIN PRECORDIAL	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EDEMA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
EDEMA DEPENDENT	3 (1.3%)	2 (0.9%)	1 (0.4%)	6 (2.6%)	3 (0.7%)	4 (0.9%)	0	7 (1.6%)
EDEMA GENERALISED	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	0	1 (0.2%)	2 (0.5%)
EDEMA LEGS	2 (0.9%)	2 (0.9%)	2 (0.9%)	6 (2.6%)	12 (2.8%)	10 (2.3%)	3 (0.7%)	25 (5.8%)
EDEMA PERIORBITAL	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EDEMA PERIPHERAL	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	0	0	3 (0.7%)
ESR INCREASED	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
FACE EDEMA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
FATIGUE	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
FEVER	0	2 (0.9%)	0	2 (0.9%)	0	2 (0.5%)	0	2 (0.5%)
GRANULOMATOUS LESION	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
HOT FLUSHES	0	0	0	0	0	1 (0.2%)	2 (0.5%)	3 (0.7%)
INFLUENZA-LIKE SYMPTOMS	0	0	1 (0.4%)	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
INJURY	13 (5.7%)	18 (7.9%)	5 (2.2%)	36 (15.7%)	11 (2.6%)	36 (8.4%)	13 (3.0%)	60 (14.0%)
MALAISE	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	0	1 (0.2%)	0	1 (0.2%)
NECROSIS ISCHEMIC	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
PAIN	5 (2.2%)	8 (3.5%)	0	13 (5.7%)	7 (1.6%)	11 (2.6%)	1 (0.2%)	19 (4.4%)
PALLOR	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
RIGORS	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
SUDDEN DEATH	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	0	0	2 (0.9%)	0	2 (0.5%)	0	2 (0.5%)
CARDIOVASCULAR GENERAL	5 (2.2%)	18 (7.9%)	6 (2.6%)	26 (11.4%)	17 (4.0%)	21 (4.9%)	7 (1.6%)	43 (10.0%)
CARDIAC FAILURE	0	1 (0.4%)	4 (1.7%)	5 (2.2%)	0	6 (1.4%)	2 (0.5%)	8 (1.9%)
CARDIAC FAILURE LEFT	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
ECG ABNORMAL	0	0	1 (0.4%)	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
ECG ABNORMAL SPECIFIC	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
HEART DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HEART VALVE DISORDERS	0	0	1 (0.4%)	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
HYPERTENSION	2 (0.9%)	7 (3.1%)	0	9 (3.9%)	6 (1.4%)	6 (1.4%)	1 (0.2%)	13 (3.0%)
HYPERTENSION AGGRAVATED	2 (0.9%)	6 (2.6%)	2 (0.9%)	10 (4.4%)	3 (0.7%)	5 (1.2%)	1 (0.2%)	9 (2.1%)
HYPOTENSION	0	0	0	0	1 (0.2%)	1 (0.2%)	1 (0.2%)	3 (0.7%)
HYPOTENSION POSTURAL	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
SYNCOPE	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	1 (0.2%)	2 (0.5%)	2 (0.5%)	5 (1.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	23 (10.0%)	22 (9.6%)	2 (0.9%)	46 (20.1%)	27 (6.3%)	52 (12.1%)	7 (1.6%)	77 (17.9%)
CARPAL TUNNEL SYNDROME	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
CONVULSIONS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
DIZZINESS	6 (2.6%)	3 (1.3%)	1 (0.4%)	10 (4.4%)	5 (1.2%)	3 (0.7%)	0	8 (1.9%)
EDEMA CEREBRAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HEADACHE	5 (2.2%)	3 (1.3%)	0	8 (3.5%)	10 (2.3%)	8 (1.9%)	1 (0.2%)	19 (4.4%)
HYPERESTHESIA	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
HYPERKINESIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
HYPESTHESIA	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
HYPOKINESIA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
MIGRAINE	0	1 (0.4%)	0	1 (0.4%)	0	2 (0.5%)	0	2 (0.5%)
MIGRAINE AGGRAVATED	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
NEURALGIA	2 (0.9%)	6 (2.6%)	0	8 (3.5%)	1 (0.2%)	27 (6.3%)	4 (0.9%)	32 (7.4%)
NEURITIS	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
NEUROPATHY	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	2 (0.5%)	0	2 (0.5%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
NEUROPATHY PERIPHERAL	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	0	1 (0.2%)	0	1 (0.2%)
PARESIS	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
PARESTHESIA	4 (1.7%)	2 (0.9%)	0	6 (2.6%)	5 (1.2%)	5 (1.2%)	0	10 (2.3%)
PTOSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
SPEECH DISORDER	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
TETANY	1 (0.4%)	0	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
TREMOR	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
TRIGEMINAL NEURALGIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
VERTIGO	0	3 (1.3%)	0	3 (1.3%)	4 (0.9%)	6 (1.4%)	1 (0.2%)	11 (2.6%)
COLLAGEN	0	1 (0.4%)	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
ARTHRITIS RHEUMATOID	0	1 (0.4%)	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
ENDOCRINE	2 (0.9%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	7 (1.6%)	5 (1.2%)	1 (0.2%)	12 (2.8%)
BREAST PAIN MALE	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GOITRE	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
GYNECOMASTIA	0	0	0	0	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
HYPERPARATHYROIDISM	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
HYPOTHYROIDISM	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
THYROID DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GASTROINTESTINAL SYSTEM	37 (16.2%)	24 (10.5%)	12 (5.2%)	58 (25.3%)	58 (13.5%)	65 (15.1%)	11 (2.6%)	113 (26.3%)
ABDOMINAL PAIN	6 (2.6%)	7 (3.1%)	0	13 (5.7%)	13 (3.0%)	9 (2.1%)	1 (0.2%)	23 (5.3%)
ANUS DISORDER	0	0	1 (0.4%)	1 (0.4%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
APPETITE INCREASED	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
COLITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	2 (0.5%)	6 (1.4%)	0	8 (1.9%)
CONSTIPATION	9 (3.9%)	1 (0.4%)	0	10 (4.4%)	8 (1.9%)	7 (1.6%)	0	15 (3.5%)
DIARRHEA	3 (1.3%)	4 (1.7%)	1 (0.4%)	8 (3.5%)	3 (0.7%)	9 (2.1%)	1 (0.2%)	13 (3.0%)
DIVERTICULITIS	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
DUODENAL ULCER	1 (0.4%)	0	1 (0.4%)	2 (0.9%)	0	1 (0.2%)	1 (0.2%)	2 (0.5%)
DYSPEPSIA	4 (1.7%)	4 (1.7%)	1 (0.4%)	9 (3.9%)	7 (1.6%)	5 (1.2%)	0	12 (2.8%)
ENTERITIS	0	0	1 (0.4%)	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
ESOPHAGEAL ULCERATION	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
ESOPHAGITIS	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
FECAL INCONTINENCE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
FLATULENCE	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	1 (0.2%)	3 (0.7%)
GASTRIC ULCER	0	0	2 (0.9%)	2 (0.9%)	0	5 (1.2%)	0	5 (1.2%)
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
GASTRITIS	0	0	1 (0.4%)	1 (0.4%)	5 (1.2%)	1 (0.2%)	0	6 (1.4%)
GASTROENTERITIS	5 (2.2%)	1 (0.4%)	0	6 (2.6%)	2 (0.5%)	10 (2.3%)	0	12 (2.8%)
GASTROESOPHAGEAL REFLUX	0	0	0	0	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
GASTROINTESTINAL DISORDER NOS	1 (0.4%)	0	1 (0.4%)	2 (0.9%)	2 (0.5%)	4 (0.9%)	2 (0.5%)	8 (1.9%)
GI HEMORRHAGE	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	1 (0.2%)	0	1 (0.2%)
GINGIVITIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	0	0	0
HEMORRHAGE RECTUM	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	1 (0.2%)	2 (0.5%)
HEMORRHOIDS	0	0	0	0	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
INTESTINAL ISCHEMIA	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
INTESTINAL PERFORATION	0	0	1 (0.4%)	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
IRRITABLE BOWEL SYNDROME	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
NAUSEA	2 (0.9%)	3 (1.3%)	0	5 (2.2%)	7 (1.6%)	4 (0.9%)	0	11 (2.6%)
PERIODONTITIS	1 (0.4%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	3 (0.7%)	9 (2.1%)	2 (0.5%)	14 (3.3%)
SALIVARY GLAND ENLARGEMENT	3 (1.3%)	0	0	3 (1.3%)	1 (0.2%)	0	0	1 (0.2%)
STOMATITIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
STOMATITIS ULCERATIVE	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
TONGUE EDEMA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
TONGUE ULCERATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
TOOTH ACHE	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	0	0	0	0
TOOTH CARIES	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
TOOTH DISORDER	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
VOMITING	2 (0.9%)	0	1 (0.4%)	3 (1.3%)	0	3 (0.7%)	0	3 (0.7%)
HEARING AND VESTIBULAR	3 (1.3%)	3 (1.3%)	3 (1.3%)	9 (3.9%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
DEAFNESS	1 (0.4%)	2 (0.9%)	2 (0.9%)	5 (2.2%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EAR DISORDER NOS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
EARACHE	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
OTOSCLEROSIS	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
TINNITUS	1 (0.4%)	0	0	1 (0.4%)	0	2 (0.5%)	0	2 (0.5%)
VESTIBULAR DISORDER	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
HEART RATE AND RHYTHM	8 (3.5%)	7 (3.1%)	0	14 (6.1%)	19 (4.4%)	9 (2.1%)	5 (1.2%)	33 (7.7%)
ARRHYTHMIA ATRIAL	0	1 (0.4%)	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
ATRIOVENTRICULAR BLOCK	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	2 (0.5%)	4 (0.9%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
BRADYCARDIA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	2 (0.5%)	3 (0.7%)
BUNDLE BRANCH BLOCK	0	1 (0.4%)	0	1 (0.4%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
EXTRASYSTOLES	1 (0.4%)	0	0	1 (0.4%)	5 (1.2%)	1 (0.2%)	0	6 (1.4%)
FIBRILLATION ATRIAL	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	4 (0.9%)	5 (1.2%)	1 (0.2%)	10 (2.3%)
PALPITATION	0	2 (0.9%)	0	2 (0.9%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
QT INCREASED	2 (0.9%)	0	0	2 (0.9%)	0	0	0	0
TACHYCARDIA	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LIVER AND BILIARY SYSTEM	11 (4.8%)	4 (1.7%)	1 (0.4%)	15 (6.6%)	4 (0.9%)	6 (1.4%)	3 (0.7%)	11 (2.6%)
BILIARY PAIN	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
BILIRUBINEMIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
CHOLECYSTITIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
CHOLELITHIASIS	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
GALL BLADDER DISORDER	0	0	0	0	0	1 (0.2%)	1 (0.2%)	2 (0.5%)
GAMMA-GT INCREASED	5 (2.2%)	1 (0.4%)	0	6 (2.6%)	1 (0.2%)	2 (0.5%)	2 (0.5%)	5 (1.2%)
HEPATIC ENZYMES INCREASED	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
HEPATIC FUNCTION ABNORMAL	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
HEPATITIS CHOLESTATIC	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
HEPATOMEGALY	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
LIVER FATTY	2 (0.9%)	0	0	2 (0.9%)	0	0	0	0
SGPT INCREASED	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
METABOLIC AND NUTRITIONAL	47 (20.5%)	62 (27.1%)	4 (1.7%)	100 (43.7%)	41 (9.5%)	83 (19.3%)	15 (3.5%)	126 (29.3%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
ACIDOSIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ALKALOSIS RESPIRATORY	2 (0.9%)	0	0	2 (0.9%)	0	0	0	0
BLOOD UREA NITROGEN INCREASED	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	2 (0.5%)	0	0	2 (0.5%)
CALCINOSIS	0	0	0	0	1 (0.2%)	1 (0.2%)	1 (0.2%)	3 (0.7%)
DIABETES MELLITUS AGGRAVATED	5 (2.2%)	16 (7.0%)	2 (0.9%)	23 (10.0%)	2 (0.5%)	17 (4.0%)	3 (0.7%)	22 (5.1%)
GOUT	0	0	0	0	1 (0.2%)	4 (0.9%)	1 (0.2%)	6 (1.4%)
HYPERCHOLESTEROLEMIA	13 (5.7%)	6 (2.6%)	0	19 (8.3%)	17 (4.0%)	24 (5.6%)	2 (0.5%)	43 (10.0%)
HYPERGLYCEMIA	17 (7.4%)	28 (12.2%)	1 (0.4%)	46 (20.1%)	4 (0.9%)	9 (2.1%)	3 (0.7%)	16 (3.7%)
HYPERKALEMIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPERLIPEMIA	4 (1.7%)	7 (3.1%)	0	11 (4.8%)	7 (1.6%)	14 (3.3%)	2 (0.5%)	23 (5.3%)
HYPERTRIGLYCERIDEMIA	1 (0.4%)	0	0	1 (0.4%)	0	4 (0.9%)	0	4 (0.9%)
HYPERURICEMIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPOCHOLESTEROLEMIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPOGLYCEMIA	6 (2.6%)	7 (3.1%)	1 (0.4%)	14 (6.1%)	2 (0.5%)	2 (0.5%)	2 (0.5%)	6 (1.4%)
HYPOGLYCEMIC REACTION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
HYPOKALEMIA	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
NPN INCREASED	4 (1.7%)	2 (0.9%)	0	6 (2.6%)	1 (0.2%)	4 (0.9%)	0	5 (1.2%)
OBESITY	0	1 (0.4%)	0	1 (0.4%)	0	2 (0.5%)	0	2 (0.5%)
THIRST	0	3 (1.3%)	0	3 (1.3%)	0	0	1 (0.2%)	1 (0.2%)
WEIGHT DECREASE	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
WEIGHT INCREASE	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	3 (0.7%)	12 (2.8%)	2 (0.5%)	17 (4.0%)
MUSCULOSKELETAL SYSTEM	25 (10.9%)	41 (17.9%)	4 (1.7%)	63 (27.5%)	47 (10.9%)	98 (22.8%)	19 (4.4%)	143 (33.3%)
ARTHRALGIA	9 (3.9%)	9 (3.9%)	2 (0.9%)	20 (8.7%)	12 (2.8%)	15 (3.5%)	3 (0.7%)	30 (7.0%)
ARTHRITIS	6 (2.6%)	8 (3.5%)	1 (0.4%)	15 (6.6%)	9 (2.1%)	25 (5.8%)	8 (1.9%)	42 (9.8%)
ARTHRITIS AGGRAVATED	1 (0.4%)	5 (2.2%)	0	6 (2.6%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
ARTHROPATHY	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ARTHROSIS	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	7 (1.6%)	14 (3.3%)	2 (0.5%)	23 (5.3%)
BACK PAIN	4 (1.7%)	14 (6.1%)	0	18 (7.9%)	8 (1.9%)	38 (8.8%)	5 (1.2%)	51 (11.9%)
BONE DEVELOPMENT ABNORMAL	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
BONE DISORDER	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
BURSITIS	0	0	0	0	1 (0.2%)	0	1 (0.2%)	2 (0.5%)
MUSCLE WEAKNESS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
MYALGIA	3 (1.3%)	4 (1.7%)	0	7 (3.1%)	7 (1.6%)	14 (3.3%)	0	21 (4.9%)
MYOPATHY	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
MYOSITIS	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
OSTEOMYELITIS	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
OSTEOPOROSIS	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	7 (1.6%)	1 (0.2%)	9 (2.1%)
SKELETAL PAIN	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	5 (1.2%)	0	5 (1.2%)
SYNOVITIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
TENDINITIS	3 (1.3%)	6 (2.6%)	0	9 (3.9%)	5 (1.2%)	5 (1.2%)	1 (0.2%)	11 (2.6%)
TORTICOLLIS	0	0	0	0	0	3 (0.7%)	0	3 (0.7%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	8 (3.5%)	7 (3.1%)	2 (0.9%)	17 (7.4%)	11 (2.6%)	10 (2.3%)	10 (2.3%)	30 (7.0%)
ANGINA PECTORIS	5 (2.2%)	3 (1.3%)	1 (0.4%)	9 (3.9%)	5 (1.2%)	7 (1.6%)	3 (0.7%)	15 (3.5%)
ANGINA PECTORIS AGGRAVATED	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
AORTIC STENOSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CARDIOMYOPATHY	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
CORONARY ARTERY DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
MYOCARDIAL INFARCTION	1 (0.4%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	0	2 (0.5%)	8 (1.9%)	10 (2.3%)
MYOCARDIAL ISCHEMIA	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	5 (1.2%)	0	0	5 (1.2%)
THROMBOSIS CORONARY	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
NEOPLASM	2 (0.9%)	3 (1.3%)	3 (1.3%)	8 (3.5%)	8 (1.9%)	7 (1.6%)	10 (2.3%)	25 (5.8%)
BASAL CELL CARCINOMA	0	3 (1.3%)	0	3 (1.3%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
BLADDER CARCINOMA	0	0	0	0	0	1 (0.2%)	2 (0.5%)	3 (0.7%)
BRAIN NEOPLASM BENIGN	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
BREAST NEOPLASM FEMALE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CARCINOMA	0	0	0	0	0	0	2 (0.5%)	2 (0.5%)
GASTRIC CARCINOMA	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	0	0	0	0	0	0	2 (0.5%)	2 (0.5%)
LIPOMA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
MELANOMA MALIGNANT	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
NEOPLASM MALIGNANT	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
NEOPLASM NOS	1 (0.4%)	0	0	1 (0.4%)	5 (1.2%)	3 (0.7%)	1 (0.2%)	9 (2.1%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
PULMONARY CARCINOMA	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
THYROID ADENOMA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
UTERINE FIBROID	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
PLATELET BLEEDING AND CLOTTING	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	2 (0.5%)	0	5 (1.2%)
PURPURA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
THROMBOCYTOPENIA	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
PSYCHIATRIC	9 (3.9%)	16 (7.0%)	2 (0.9%)	25 (10.9%)	23 (5.3%)	23 (5.3%)	1 (0.2%)	46 (10.7%)
AMNESIA	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
ANXIETY	3 (1.3%)	5 (2.2%)	0	8 (3.5%)	5 (1.2%)	6 (1.4%)	0	11 (2.6%)
CONFUSION	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
DEMENTIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
DEPRESSION	5 (2.2%)	2 (0.9%)	1 (0.4%)	8 (3.5%)	8 (1.9%)	5 (1.2%)	1 (0.2%)	14 (3.3%)
EMOTIONAL LABILITY	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
INSOMNIA	0	3 (1.3%)	0	3 (1.3%)	8 (1.9%)	7 (1.6%)	0	15 (3.5%)
NERVOUSNESS	1 (0.4%)	0	0	1 (0.4%)	0	4 (0.9%)	0	4 (0.9%)
NEUROSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
SOMNOLENCE	1 (0.4%)	4 (1.7%)	1 (0.4%)	6 (2.6%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
SUICIDE ATTEMPT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
RED BLOOD CELL	9 (3.9%)	0	3 (1.3%)	12 (5.2%)	15 (3.5%)	10 (2.3%)	1 (0.2%)	26 (6.0%)
ANEMIA	6 (2.6%)	0	3 (1.3%)	9 (3.9%)	12 (2.8%)	7 (1.6%)	1 (0.2%)	20 (4.7%)
ANEMIA B TWELVE DEFICIENCY	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ANEMIA HYPOCHROMIC	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
ANEMIA NORMOCHROMIC	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
ERYTHROCYTES ABNORMAL	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
REPRODUCTIVE FEMALE	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	2 (0.5%)	4 (0.9%)	0	5 (1.2%)
MENORRHAGIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
MENSTRUAL DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	3 (0.7%)	0	3 (0.7%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
OVARIAN CYST	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
OVARIAN DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
VAGINITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
REPRODUCTIVE MALE	7 (3.1%)	5 (2.2%)	2 (0.9%)	14 (6.1%)	5 (1.2%)	10 (2.3%)	2 (0.5%)	16 (3.7%)
EPIDIDYMITIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
IMPOTENCE	0	5 (2.2%)	0	5 (2.2%)	1 (0.2%)	4 (0.9%)	1 (0.2%)	6 (1.4%)
PENIS DISORDER	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
PROSTATIC DISORDER	6 (2.6%)	0	1 (0.4%)	7 (3.1%)	3 (0.7%)	4 (0.9%)	1 (0.2%)	8 (1.9%)
TESTIS DISORDER	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
RESISTANCE MECHANISM	31 (13.5%)	41 (17.9%)	5 (2.2%)	70 (30.6%)	47 (10.9%)	51 (11.9%)	4 (0.9%)	94 (21.9%)
ABSCESS	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	1 (0.2%)	0	0	1 (0.2%)
HERPES SIMPLEX	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
HERPES ZOSTER	0	4 (1.7%)	2 (0.9%)	6 (2.6%)	2 (0.5%)	0	1 (0.2%)	3 (0.7%)
INFECTION	4 (1.7%)	4 (1.7%)	2 (0.9%)	10 (4.4%)	2 (0.5%)	8 (1.9%)	1 (0.2%)	11 (2.6%)
INFECTION BACTERIAL	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
INFECTION FUNGAL	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	6 (1.4%)	5 (1.2%)	0	11 (2.6%)
INFECTION VIRAL	7 (3.1%)	21 (9.2%)	0	28 (12.2%)	13 (3.0%)	25 (5.8%)	0	38 (8.8%)
MONILIASIS	3 (1.3%)	0	0	3 (1.3%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
MONILIASIS GENITAL	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	1 (0.2%)	0	0	1 (0.2%)
OTITIS MEDIA	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	4 (0.9%)	4 (0.9%)	0	8 (1.9%)
SEPSIS	0	0	0	0	0	3 (0.7%)	0	3 (0.7%)
UPPER RESP TRACT INFECTION	19 (8.3%)	10 (4.4%)	0	29 (12.7%)	17 (4.0%)	10 (2.3%)	2 (0.5%)	29 (6.7%)
RESPIRATORY SYSTEM	31 (13.5%)	36 (15.7%)	4 (1.7%)	60 (26.2%)	66 (15.3%)	107 (24.9%)	10 (2.3%)	153 (35.6%)
APNEA	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
ASTHMA	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	3 (0.7%)	0	6 (1.4%)
BRONCHITIS	5 (2.2%)	4 (1.7%)	0	9 (3.9%)	14 (3.3%)	52 (12.1%)	3 (0.7%)	69 (16.0%)
CHEST X-RAY ABNORMAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEA	0	0	0	0	1 (0.2%)	1 (0.2%)	1 (0.2%)	3 (0.7%)
COUGHING	14 (6.1%)	5 (2.2%)	0	19 (8.3%)	12 (2.8%)	2 (0.5%)	1 (0.2%)	15 (3.5%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
DYSPNEA	3 (1.3%)	6 (2.6%)	2 (0.9%)	11 (4.8%)	5 (1.2%)	7 (1.6%)	1 (0.2%)	13 (3.0%)
EPISTAXIS	0	0	1 (0.4%)	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
HEMOPTYSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LARYNGITIS	1 (0.4%)	0	0	1 (0.4%)	3 (0.7%)	1 (0.2%)	0	4 (0.9%)
PHARYNGITIS	6 (2.6%)	9 (3.9%)	0	15 (6.6%)	11 (2.6%)	17 (4.0%)	1 (0.2%)	29 (6.7%)
PLEURAL EFFUSION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PLEURISY	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
PNEUMONIA	0	1 (0.4%)	0	1 (0.4%)	0	4 (0.9%)	0	4 (0.9%)
PULMONARY EDEMA	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
RESPIRATORY DISORDER	4 (1.7%)	15 (6.6%)	0	19 (8.3%)	13 (3.0%)	11 (2.6%)	1 (0.2%)	25 (5.8%)
RESPIRATORY INSUFFICIENCY	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
RHINITIS	3 (1.3%)	0	0	3 (1.3%)	6 (1.4%)	10 (2.3%)	0	16 (3.7%)
SINUSITIS	1 (0.4%)	2 (0.9%)	1 (0.4%)	4 (1.7%)	5 (1.2%)	8 (1.9%)	0	13 (3.0%)
TRACHEITIS	0	0	0	0	1 (0.2%)	6 (1.4%)	0	7 (1.6%)
SKIN AND APPENDAGES	25 (10.9%)	17 (7.4%)	3 (1.3%)	39 (17.0%)	32 (7.4%)	20 (4.7%)	3 (0.7%)	53 (12.3%)
ALOPECIA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ANGIOEDEMA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
BULLOUS ERUPTION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DERMATITIS	0	2 (0.9%)	0	2 (0.9%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
DERMATITIS FUNGAL	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	2 (0.5%)	0	2 (0.5%)
ECZEMA	2 (0.9%)	2 (0.9%)	1 (0.4%)	5 (2.2%)	9 (2.1%)	5 (1.2%)	0	14 (3.3%)
FOLLICULITIS	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
FURUNCULOSIS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	1 (0.2%)	0	1 (0.2%)
HYPERKERATOSIS	3 (1.3%)	0	0	3 (1.3%)	0	1 (0.2%)	0	1 (0.2%)
NAIL DISORDER	2 (0.9%)	0	0	2 (0.9%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
NEVUS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PHOTOSENSITIVITY REACTION	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
PRURITUS	5 (2.2%)	1 (0.4%)	1 (0.4%)	7 (3.1%)	2 (0.5%)	2 (0.5%)	0	4 (0.9%)
PRURITUS GENITAL	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PSORIASIS	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
PSORIASIS AGGRAVATED	0	0	0	0	1 (0.2%)	1 (0.2%)	1 (0.2%)	3 (0.7%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
RASH	6 (2.6%)	1 (0.4%)	0	7 (3.1%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
RASH ERYTHEMATOUS	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	0	0	1 (0.2%)
RASH PUSTULAR	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
ROSACEA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
SEBORRHEA	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
SKIN DISORDER	0	3 (1.3%)	0	3 (1.3%)	0	0	0	0
SKIN DRY	0	4 (1.7%)	0	4 (1.7%)	1 (0.2%)	0	0	1 (0.2%)
SKIN HYPERTROPHY	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
SKIN ULCERATION	0	0	1 (0.4%)	1 (0.4%)	1 (0.2%)	1 (0.2%)	2 (0.5%)	4 (0.9%)
URTICARIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
VERRUCA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
URINARY SYSTEM	27 (11.8%)	12 (5.2%)	4 (1.7%)	38 (16.6%)	40 (9.3%)	31 (7.2%)	10 (2.3%)	71 (16.5%)
ALBUMINURIA	0	1 (0.4%)	0	1 (0.4%)	3 (0.7%)	2 (0.5%)	0	5 (1.2%)
CYSTITIS	0	0	1 (0.4%)	1 (0.4%)	4 (0.9%)	4 (0.9%)	1 (0.2%)	9 (2.1%)
CYSTITIS HEMORRHAGIC	0	0	0	0	0	3 (0.7%)	0	3 (0.7%)
DYSURIA	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	0	1 (0.2%)	3 (0.7%)
HEMATURIA	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	6 (1.4%)	2 (0.5%)	3 (0.7%)	11 (2.6%)
HYDRONEPHROSIS	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
MICTURITION DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
MICTURITION FREQUENCY	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	3 (0.7%)	0	1 (0.2%)	4 (0.9%)
NOCTURIA	0	0	1 (0.4%)	1 (0.4%)	0	0	0	0
POLYURIA	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	0	0	1 (0.2%)	1 (0.2%)
PYELONEPHRITIS	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
PYURIA	3 (1.3%)	1 (0.4%)	1 (0.4%)	5 (2.2%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
RENAL CALCULUS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
RENAL FAILURE ACUTE	2 (0.9%)	0	1 (0.4%)	3 (1.3%)	0	0	0	0
RENAL PAIN	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
STRANGURY	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
URETHRAL DISORDER	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
URINARY INCONTINENCE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
URINARY TRACT INFECTION	14 (6.1%)	8 (3.5%)	2 (0.9%)	24 (10.5%)	23 (5.3%)	15 (3.5%)	2 (0.5%)	40 (9.3%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
VASCULAR EXTRACARDIAC	10 (4.4%)	10 (4.4%)	6 (2.6%)	23 (10.0%)	21 (4.9%)	32 (7.4%)	6 (1.4%)	55 (12.8%)
ARTERITIS	0	0	0	0	2 (0.5%)	1 (0.2%)	1 (0.2%)	4 (0.9%)
ATHEROSCLEROSIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
CEREBROVASCULAR DISORDER	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	2 (0.5%)	1 (0.2%)	3 (0.7%)
CLAUDICATION INTERMITTENT	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
CRAMPS LEGS	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	8 (1.9%)	8 (1.9%)	0	16 (3.7%)
EMBOLISM PULMONARY	0	1 (0.4%)	1 (0.4%)	2 (0.9%)	0	0	1 (0.2%)	1 (0.2%)
HEMORRHAGE NOS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
PERIPHERAL ISCHEMIA	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	1 (0.2%)	2 (0.5%)	1 (0.2%)	4 (0.9%)
PHLEBITIS	0	0	1 (0.4%)	1 (0.4%)	1 (0.2%)	3 (0.7%)	1 (0.2%)	5 (1.2%)
PHLEBITIS SUPERFICIAL	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
THROMBOPHLEBITIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
VASCULAR DISORDER	2 (0.9%)	0	3 (1.3%)	5 (2.2%)	2 (0.5%)	2 (0.5%)	2 (0.5%)	6 (1.4%)
VASCULITIS	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
VEIN DISORDER	3 (1.3%)	3 (1.3%)	0	6 (2.6%)	5 (1.2%)	9 (2.1%)	0	14 (3.3%)
VEIN VARICOSE	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	1 (0.2%)	3 (0.7%)	0	4 (0.9%)
VISION	10 (4.4%)	11 (4.8%)	3 (1.3%)	22 (9.6%)	26 (6.0%)	20 (4.7%)	4 (0.9%)	49 (11.4%)
BLEPHARITIS	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
CATARACT	2 (0.9%)	3 (1.3%)	2 (0.9%)	7 (3.1%)	4 (0.9%)	3 (0.7%)	3 (0.7%)	10 (2.3%)
CONJUNCTIVAL HEMORRHAGE	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
CONJUNCTIVITIS	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	10 (2.3%)	8 (1.9%)	0	18 (4.2%)
CORNEAL OPACITY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DIPLOPIA	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
EYE ABNORMALITY	3 (1.3%)	0	1 (0.4%)	4 (1.7%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
EYE PAIN	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
GLAUCOMA	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	4 (0.9%)	1 (0.2%)	0	5 (1.2%)
LACRIMATION ABNORMAL	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
MACULA LUTEA DEGENERATION	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
RETINAL DETACHMENT	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
RETINAL DISORDER	2 (0.9%)	3 (1.3%)	0	5 (2.2%)	4 (0.9%)	3 (0.7%)	0	7 (1.6%)
RETINITIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Entered Study 009

Intensity of Adverse Experience	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	149 (65.1%)	147 (64.2%)	52 (22.7%)	189 (82.5%)	251 (58.4%)	300 (69.8%)	101 (23.5%)	363 (84.4%)
WHO Body System Preferred Term								
VISION ABNORMAL	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	4 (0.9%)	0	5 (1.2%)
VITREOUS DETACHMENT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	4 (1.7%)	4 (1.7%)	0	8 (3.5%)	4 (0.9%)	8 (1.9%)	0	12 (2.8%)
EOSINOPHILIA	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
GRANULOCYTOPENIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
LEUKOCYTOSIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
LEUKOPENIA	3 (1.3%)	0	0	3 (1.3%)	3 (0.7%)	4 (0.9%)	0	7 (1.6%)
LYMPHADENOPATHY	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
LYMPHADENOPATHY CERVICAL	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
LYMPHANGITIS	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
LYMPHEDEMA	0	0	0	0	0	2 (0.5%)	0	2 (0.5%)
LYMPHOPENIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)
WHO Body System Preferred Term								
APPLICATION SITE	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
OTITIS EXTERNA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
AUTONOMIC NERVOUS SYSTEM	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
VASOSPASM	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
BODY AS A WHOLE GENERAL	11 (18.0%)	13 (21.3%)	2 (3.3%)	23 (37.7%)	10 (12.8%)	10 (12.8%)	3 (3.8%)	20 (25.6%)
ALCOHOL INTOLERANCE	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
ALLERGIC REACTION	0	0	1 (1.6%)	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
ALLERGY	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
ASTHENIA	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0
CHEST PAIN	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
EDEMA DEPENDENT	0	1 (1.6%)	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)
EDEMA GENERALISED	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
EDEMA LEGS	0	0	0	0	1 (1.3%)	1 (1.3%)	1 (1.3%)	3 (3.8%)
EDEMA PERIORBITAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
EDEMA PERIPHERAL	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
FATIGUE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0
FEVER	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)
INJURY	6 (9.8%)	5 (8.2%)	1 (1.6%)	12 (19.7%)	3 (3.8%)	6 (7.7%)	1 (1.3%)	10 (12.8%)
MALAISE	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
PAIN	3 (4.9%)	4 (6.6%)	0	7 (11.5%)	0	1 (1.3%)	0	1 (1.3%)
SUDDEN DEATH	0	0	0	0	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
CARDIOVASCULAR GENERAL	1 (1.6%)	8 (13.1%)	3 (4.9%)	10 (16.4%)	1 (1.3%)	3 (3.8%)	1 (1.3%)	4 (5.1%)
CARDIAC FAILURE	0	0	3 (4.9%)	3 (4.9%)	0	0	1 (1.3%)	1 (1.3%)
CARDIAC FAILURE LEFT	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
ECG ABNORMAL	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0
HEART VALVE DISORDERS	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0
HYPERTENSION	0	3 (4.9%)	0	3 (4.9%)	0	2 (2.6%)	0	2 (2.6%)
HYPERTENSION AGGRAVATED	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
APPLICATION SITE	0	0	0	0
OTITIS EXTERNA	0	0	0	0
AUTONOMIC NERVOUS SYSTEM	0	0	0	0
VASOSPASM	0	0	0	0
BODY AS A WHOLE GENERAL	11 (12.2%)	15 (16.7%)	6 (6.7%)	27 (30.0%)
ALCOHOL INTOLERANCE	0	0	0	0
ALLERGIC REACTION	0	0	0	0
ALLERGY	0	0	0	0
ASTHENIA	0	2 (2.2%)	0	2 (2.2%)
CHEST PAIN	2 (2.2%)	1 (1.1%)	1 (1.1%)	4 (4.4%)
EDEMA DEPENDENT	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
EDEMA GENERALISED	0	0	0	0
EDEMA LEGS	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
EDEMA PERIORBITAL	0	0	0	0
EDEMA PERIPHERAL	0	0	0	0
FATIGUE	2 (2.2%)	0	0	2 (2.2%)
FEVER	0	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0	0
INJURY	4 (4.4%)	7 (7.8%)	3 (3.3%)	14 (15.6%)
MALAISE	0	1 (1.1%)	0	1 (1.1%)
PAIN	2 (2.2%)	3 (3.3%)	0	5 (5.6%)
SUDDEN DEATH	0	0	1 (1.1%)	1 (1.1%)
THERAPEUTIC RESPONSE INCREASED	1 (1.1%)	0	0	1 (1.1%)
CARDIOVASCULAR GENERAL	3 (3.3%)	7 (7.8%)	2 (2.2%)	12 (13.3%)
CARDIAC FAILURE	0	1 (1.1%)	0	1 (1.1%)
CARDIAC FAILURE LEFT	0	0	0	0
ECG ABNORMAL	0	0	0	0
HEART VALVE DISORDERS	0	0	0	0
HYPERTENSION	2 (2.2%)	2 (2.2%)	0	4 (4.4%)
HYPERTENSION AGGRAVATED	0	3 (3.3%)	2 (2.2%)	5 (5.6%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

- 695 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total 015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)
WHO Body System Preferred Term								
HYPOTENSION POSTURAL	0	0	0	0	0	0	0	0
SYNCOPE	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	6 (9.8%)	8 (13.1%)	0	14 (23.0%)	9 (11.5%)	6 (7.7%)	0	15 (19.2%)
CARPAL TUNNEL SYNDROME	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
CONVULSIONS	0	0	0	0	0	0	0	0
DIZZINESS	2 (3.3%)	2 (3.3%)	0	4 (6.6%)	2 (2.6%)	0	0	2 (2.6%)
HEADACHE	1 (1.6%)	0	0	1 (1.6%)	3 (3.8%)	2 (2.6%)	0	5 (6.4%)
HYPESTHESIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
HYPOKINESIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
MIGRAINE	0	0	0	0	0	0	0	0
MIGRAINE AGGRAVATED	0	0	0	0	0	0	0	0
NEURALGIA	0	3 (4.9%)	0	3 (4.9%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
NEURITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
NEUROPATHY	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)
NEUROPATHY PERIPHERAL	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)
PARESIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
PARESTHESIA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)
TETANY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
TREMOR	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
TRIGEMINAL NEURALGIA	0	0	0	0	0	0	0	0
VERTIGO	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
COLLAGEN	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
ARTHRITIS RHEUMATOID	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
ENDOCRINE	1 (1.6%)	1 (1.6%)	1 (1.6%)	2 (3.3%)	0	0	0	0
BREAST PAIN MALE	0	0	0	0	0	0	0	0
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0	0	0	0	0
GOITRE	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
HYPERPARATHYROIDISM	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0
HYPOTHYROIDISM	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
HYPOTENSION POSTURAL SYNCOPE	1 (1.1%) 1 (1.1%)	0 1 (1.1%)	0 0	1 (1.1%) 2 (2.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	8 (8.9%)	8 (8.9%)	2 (2.2%)	17 (18.9%)
CARPAL TUNNEL SYNDROME	0	0	0	0
CONVULSIONS	1 (1.1%)	0	0	1 (1.1%)
DIZZINESS	2 (2.2%)	1 (1.1%)	1 (1.1%)	4 (4.4%)
HEADACHE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
HYPESTHESIA	0	0	0	0
HYPOKINESIA	0	0	0	0
MIGRAINE	0	1 (1.1%)	0	1 (1.1%)
MIGRAINE AGGRAVATED	0	0	1 (1.1%)	1 (1.1%)
NEURALGIA	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
NEURITIS	0	0	0	0
NEUROPATHY	0	0	0	0
NEUROPATHY PERIPHERAL	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
PARESIS	0	0	0	0
PARESTHESIA	2 (2.2%)	0	0	2 (2.2%)
TETANY	0	0	0	0
TREMOR	0	0	0	0
TRIGEMINAL NEURALGIA	1 (1.1%)	0	0	1 (1.1%)
VERTIGO	0	2 (2.2%)	0	2 (2.2%)
COLLAGEN	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0
ENDOCRINE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
BREAST PAIN MALE	0	1 (1.1%)	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	1 (1.1%)	0	0	1 (1.1%)
GOITRE	1 (1.1%)	0	0	1 (1.1%)
HYPERPARATHYROIDISM	0	0	0	0
HYPOTHYROIDISM	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

- 697 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
GASTROINTESTINAL SYSTEM	11 (18.0%)	8 (13.1%)	2 (3.3%)	16 (26.2%)	12 (15.4%)	10 (12.8%)	7 (9.0%)	23 (29.5%)				
ABDOMINAL PAIN	2 (3.3%)	4 (6.6%)	0	6 (9.8%)	2 (2.6%)	2 (2.6%)	0	4 (5.1%)				
ANUS DISORDER	0	0	0	0	0	0	0	0				
APPETITE INCREASED	0	0	0	0	0	0	0	0				
COLITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
CONSTIPATION	3 (4.9%)	0	0	3 (4.9%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
DIARRHEA	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	0	3 (3.8%)	1 (1.3%)	4 (5.1%)				
DIVERTICULITIS	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
DUODENAL ULCER	0	0	1 (1.6%)	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
DYSPEPSIA	0	0	0	0	2 (2.6%)	4 (5.1%)	0	6 (7.7%)				
ENTERITIS	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
ESOPHAGITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)				
FLATULENCE	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
GASTRIC ULCER	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
GASTRITIS	0	0	0	0	0	0	0	0				
GASTROENTERITIS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)				
GASTROINTESTINAL DISORDER NOS	1 (1.6%)	0	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)				
GI HEMORRHAGE	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
GINGIVITIS	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
HEMORRHAGE RECTUM	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
INTESTINAL PERFORATION	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
NAUSEA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	1 (1.3%)	0	1 (1.3%)				
PERIODONTITIS	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	1 (1.3%)	2 (2.6%)				
SALIVARY GLAND ENLARGEMENT	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)				
TOOTH ACHE	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)				
TOOTH CARIES	0	0	0	0	0	0	0	0				
VOMITING	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	1 (1.3%)	2 (2.6%)				
HEARING AND VESTIBULAR	0	1 (1.6%)	1 (1.6%)	2 (3.3%)	0	1 (1.3%)	0	1 (1.3%)				
DEAFNESS	0	0	1 (1.6%)	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
EAR DISORDER NOS	0	0	0	0	0	0	0	0				
OTOSCLEROSIS	0	0	0	0	0	0	0	0				
TINNITUS	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
GASTROINTESTINAL SYSTEM	14 (15.6%)	6 (6.7%)	3 (3.3%)	19 (21.1%)
ABDOMINAL PAIN	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
ANUS DISORDER	0	0	1 (1.1%)	1 (1.1%)
APPETITE INCREASED	1 (1.1%)	0	0	1 (1.1%)
COLITIS	1 (1.1%)	0	0	1 (1.1%)
CONSTIPATION	4 (4.4%)	0	0	4 (4.4%)
DIARRHEA	1 (1.1%)	0	0	1 (1.1%)
DIVERTICULITIS	0	0	0	0
DUODENAL ULCER	0	0	0	0
DYSPEPSIA	2 (2.2%)	0	1 (1.1%)	3 (3.3%)
ENTERITIS	0	0	0	0
ESOPHAGITIS	0	0	0	0
FLATULENCE	1 (1.1%)	0	0	1 (1.1%)
GASTRIC ULCER	0	0	1 (1.1%)	1 (1.1%)
GASTRITIS	0	0	1 (1.1%)	1 (1.1%)
GASTROENTERITIS	2 (2.2%)	0	0	2 (2.2%)
GASTROINTESTINAL DISORDER NOS	0	0	0	0
GI HEMORRHAGE	0	1 (1.1%)	0	1 (1.1%)
GINGIVITIS	1 (1.1%)	0	0	1 (1.1%)
HEMORRHAGE RECTUM	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0
NAUSEA	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
PERIODONTITIS	1 (1.1%)	0	0	1 (1.1%)
SALIVARY GLAND ENLARGEMENT	0	0	0	0
TOOTH ACHE	0	2 (2.2%)	0	2 (2.2%)
TOOTH CARIES	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
VOMITING	0	0	0	0
HEARING AND VESTIBULAR	3 (3.3%)	1 (1.1%)	2 (2.2%)	6 (6.7%)
DEAFNESS	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
EAR DISORDER NOS	1 (1.1%)	0	0	1 (1.1%)
OTOSCLEROSIS	0	0	1 (1.1%)	1 (1.1%)
TINNITUS	1 (1.1%)	0	0	1 (1.1%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
VESTIBULAR DISORDER	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
HEART RATE AND RHYTHM	0	1 (1.6%)	0	1 (1.6%)	4 (5.1%)	2 (2.6%)	0	6 (7.7%)				
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	0	0				
ATRIOVENTRICULAR BLOCK	0	0	0	0	0	0	0	0				
BRADYCARDIA	0	0	0	0	0	0	0	0				
BUNDLE BRANCH BLOCK	0	0	0	0	0	0	0	0				
EXTRASYSTOLES	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
FIBRILLATION ATRIAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
PALPITATION	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
QT INCREASED	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)				
TACHYCARDIA	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
LIVER AND BILIARY SYSTEM	1 (1.6%)	2 (3.3%)	0	2 (3.3%)	7 (9.0%)	2 (2.6%)	0	9 (11.5%)				
BILIRUBINEMIA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
GAMMA-GT INCREASED	0	1 (1.6%)	0	1 (1.6%)	4 (5.1%)	0	0	4 (5.1%)				
HEPATIC ENZYMES INCREASED	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
HEPATIC FUNCTION ABNORMAL	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
HEPATITIS CHOLESTATIC	0	0	0	0	0	0	0	0				
LIVER FATTY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
SGPT INCREASED	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
METABOLIC AND NUTRITIONAL	12 (19.7%)	21 (34.4%)	0	29 (47.5%)	13 (16.7%)	16 (20.5%)	2 (2.6%)	30 (38.5%)				
ACIDOSIS	0	0	0	0	0	0	0	0				
ALKALOSIS RESPIRATORY	0	0	0	0	0	0	0	0				
BLOOD UREA NITROGEN INCREASED	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
DIABETES MELLITUS AGGRAVATED	2 (3.3%)	5 (8.2%)	0	7 (11.5%)	1 (1.3%)	4 (5.1%)	1 (1.3%)	6 (7.7%)				
HYPERCHOLESTEROLEMIA	6 (9.8%)	2 (3.3%)	0	8 (13.1%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
HYPERGLYCEMIA	5 (8.2%)	8 (13.1%)	0	13 (21.3%)	4 (5.1%)	8 (10.3%)	0	12 (15.4%)				
HYPERLIPEMIA	0	4 (6.6%)	0	4 (6.6%)	0	2 (2.6%)	0	2 (2.6%)				
HYPERTRIGLYCERIDEMIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
HYPOGLYCEMIA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	5 (6.4%)	3 (3.8%)	1 (1.3%)	9 (11.5%)				
NPN INCREASED	0	1 (1.6%)	0	1 (1.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
VESTIBULAR DISORDER	0	0	0	0
HEART RATE AND RHYTHM	4 (4.4%)	4 (4.4%)	0	7 (7.8%)
ARRHYTHMIA ATRIAL	0	1 (1.1%)	0	1 (1.1%)
ATRIOVENTRICULAR BLOCK	1 (1.1%)	0	0	1 (1.1%)
BRADYCARDIA	1 (1.1%)	0	0	1 (1.1%)
BUNDLE BRANCH BLOCK	0	1 (1.1%)	0	1 (1.1%)
EXTRASYSTOLES	0	0	0	0
FIBRILLATION ATRIAL	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
PALPITATION	0	1 (1.1%)	0	1 (1.1%)
QT INCREASED	0	0	0	0
TACHYCARDIA	0	0	0	0
LIVER AND BILIARY SYSTEM	3 (3.3%)	0	1 (1.1%)	4 (4.4%)
BILIRUBINEMIA	0	0	0	0
GAMMA-GT INCREASED	1 (1.1%)	0	0	1 (1.1%)
HEPATIC ENZYMES INCREASED	0	0	0	0
HEPATIC FUNCTION ABNORMAL	1 (1.1%)	0	0	1 (1.1%)
HEPATITIS CHOLESTATIC	0	0	1 (1.1%)	1 (1.1%)
LIVER FATTY	1 (1.1%)	0	0	1 (1.1%)
SGPT INCREASED	0	0	0	0
METABOLIC AND NUTRITIONAL	22 (24.4%)	25 (27.8%)	2 (2.2%)	41 (45.6%)
ACIDOSIS	1 (1.1%)	0	0	1 (1.1%)
ALKALOSIS RESPIRATORY	2 (2.2%)	0	0	2 (2.2%)
BLOOD UREA NITROGEN INCREASED	2 (2.2%)	0	0	2 (2.2%)
DIABETES MELLITUS AGGRAVATED	2 (2.2%)	7 (7.8%)	1 (1.1%)	10 (11.1%)
HYPERCHOLESTEROLEMIA	5 (5.6%)	3 (3.3%)	0	8 (8.9%)
HYPERGLYCEMIA	8 (8.9%)	12 (13.3%)	1 (1.1%)	21 (23.3%)
HYPERLIPEMIA	4 (4.4%)	1 (1.1%)	0	5 (5.6%)
HYPERTRIGLYCERIDEMIA	0	0	0	0
HYPOGLYCEMIA	0	3 (3.3%)	0	3 (3.3%)
NPN INCREASED	3 (3.3%)	0	0	3 (3.3%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

- 701 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
OBESITY	0	0	0	0	0	0	0	0	0	0	0	0
THIRST	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)	0	1 (1.3%)	0	1 (1.3%)
WEIGHT INCREASE	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)	0	1 (1.3%)	0	1 (1.3%)
MUSCULOSKELETAL SYSTEM	7 (11.5%)	12 (19.7%)	2 (3.3%)	18 (29.5%)	7 (9.0%)	12 (15.4%)	2 (2.6%)	20 (25.6%)				
ARTHRALGIA	2 (3.3%)	5 (8.2%)	1 (1.6%)	8 (13.1%)	3 (3.8%)	2 (2.6%)	1 (1.3%)	6 (7.7%)				
ARTHRITIS	1 (1.6%)	2 (3.3%)	1 (1.6%)	4 (6.6%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
ARTHRITIS AGGRAVATED	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	2 (2.6%)	0	2 (2.6%)				
ARTHROPATHY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ARTHROSIS	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
BACK PAIN	3 (4.9%)	3 (4.9%)	0	6 (9.8%)	0	5 (6.4%)	0	5 (6.4%)				
BONE DEVELOPMENT ABNORMAL	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
BONE DISORDER	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
MUSCLE WEAKNESS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
MYALGIA	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	0	1 (1.3%)	0	1 (1.3%)				
MYOSITIS	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0				
OSTEOPOROSIS	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
SKELETAL PAIN	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
SYNOVITIS	0	0	0	0	0	0	0	0				
TENDINITIS	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	0	3 (3.8%)	0	3 (3.8%)				
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	2 (3.3%)	2 (3.3%)	0	4 (6.6%)	2 (2.6%)	4 (5.1%)	1 (1.3%)	7 (9.0%)				
ANGINA PECTORIS	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	3 (3.8%)	1 (1.3%)	6 (7.7%)				
ANGINA PECTORIS AGGRAVATED	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
CARDIOMYOPATHY	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
CORONARY ARTERY DISORDER	0	0	0	0	0	0	0	0				
MYOCARDIAL INFARCTION	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
MYOCARDIAL ISCHEMIA	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
THROMBOSIS CORONARY	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
NEOPLASM	0	1 (1.6%)	1 (1.6%)	2 (3.3%)	1 (1.3%)	1 (1.3%)	1 (1.3%)	3 (3.8%)				
BASAL CELL CARCINOMA	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
OBESITY	0	1 (1.1%)	0	1 (1.1%)
THIRST	0	1 (1.1%)	0	1 (1.1%)
WEIGHT INCREASE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
MUSCULOSKELETAL SYSTEM	11 (12.2%)	17 (18.9%)	0	25 (27.8%)
ARTHRALGIA	4 (4.4%)	2 (2.2%)	0	6 (6.7%)
ARTHRITIS	3 (3.3%)	5 (5.6%)	0	8 (8.9%)
ARTHRITIS AGGRAVATED	0	2 (2.2%)	0	2 (2.2%)
ARTHROPATHY	0	0	0	0
ARTHROSIS	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
BACK PAIN	1 (1.1%)	6 (6.7%)	0	7 (7.8%)
BONE DEVELOPMENT ABNORMAL	0	0	0	0
BONE DISORDER	0	0	0	0
MUSCLE WEAKNESS	0	0	0	0
MYALGIA	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
MYOSITIS	0	0	0	0
OSTEOPOROSIS	0	1 (1.1%)	0	1 (1.1%)
SKELETAL PAIN	1 (1.1%)	0	0	1 (1.1%)
SYNOVITIS	1 (1.1%)	0	0	1 (1.1%)
TENDINITIS	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	4 (4.4%)	1 (1.1%)	1 (1.1%)	6 (6.7%)
ANGINA PECTORIS	2 (2.2%)	0	0	2 (2.2%)
ANGINA PECTORIS AGGRAVATED	0	0	0	0
CARDIOMYOPATHY	0	0	0	0
CORONARY ARTERY DISORDER	1 (1.1%)	0	0	1 (1.1%)
MYOCARDIAL INFARCTION	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
MYOCARDIAL ISCHEMIA	0	0	0	0
THROMBOSIS CORONARY	0	0	0	0
NEOPLASM	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
BASAL CELL CARCINOMA	0	1 (1.1%)	0	1 (1.1%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

- 703 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
GASTRIC CARCINOMA	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
LIPOMA	0	0	0	0	0	0	0	0				
NEOPLASM NOS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
PULMONARY CARCINOMA	0	0	0	0	0	0	0	0				
SKIN NEOPLASM MALIGNANT	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
PLATELET BLEEDING AND CLOTTING	0	0	0	0	0	0	0	0				
THROMBOCYTOPENIA	0	0	0	0	0	0	0	0				
PSYCHIATRIC	4 (6.6%)	4 (6.6%)	1 (1.6%)	9 (14.8%)	2 (2.6%)	4 (5.1%)	0	5 (6.4%)				
AMNESIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
ANXIETY	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
CONFUSION	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
DEPRESSION	3 (4.9%)	0	0	3 (4.9%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
EMOTIONAL LABILITY	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
INSOMNIA	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
NERVOUSNESS	0	0	0	0	0	0	0	0				
SOMNOLENCE	1 (1.6%)	1 (1.6%)	1 (1.6%)	3 (4.9%)	0	1 (1.3%)	0	1 (1.3%)				
RED BLOOD CELL	2 (3.3%)	0	1 (1.6%)	3 (4.9%)	3 (3.8%)	0	0	3 (3.8%)				
ANEMIA	0	0	1 (1.6%)	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)				
ANEMIA B TWELVE DEFICIENCY	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
ANEMIA HYPOCHROMIC	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
ERYTHROCYTES ABNORMAL	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
REPRODUCTIVE FEMALE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
MENSTRUAL DISORDER	0	0	0	0	0	0	0	0				
OVARIAN CYST	0	0	0	0	0	0	0	0				
VAGINITIS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
REPRODUCTIVE MALE	2 (3.3%)	3 (4.9%)	0	5 (8.2%)	5 (6.4%)	1 (1.3%)	1 (1.3%)	7 (9.0%)				
IMPOTENCE	0	3 (4.9%)	0	3 (4.9%)	0	1 (1.3%)	0	1 (1.3%)				
PENIS DISORDER	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd) _-----_---- 2bd Comb Total ----_-----_
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
GASTRIC CARCINOMA	0	0	0	0
LIPOMA	1 (1.1%)	0	0	1 (1.1%)
NEOPLASM NOS	0	0	0	0
PULMONARY CARCINOMA	0	0	1 (1.1%)	1 (1.1%)
SKIN NEOPLASM MALIGNANT	0	0	0	0
PLATELET BLEEDING AND CLOTTING	0	1 (1.1%)	0	1 (1.1%)
THROMBOCYTOPENIA	0	1 (1.1%)	0	1 (1.1%)
PSYCHIATRIC	3 (3.3%)	8 (8.9%)	1 (1.1%)	11 (12.2%)
AMNESIA	0	0	0	0
ANXIETY	2 (2.2%)	4 (4.4%)	0	6 (6.7%)
CONFUSION	0	0	0	0
DEPRESSION	1 (1.1%)	1 (1.1%)	1 (1.1%)	3 (3.3%)
EMOTIONAL LABILITY	0	1 (1.1%)	0	1 (1.1%)
INSOMNIA	0	1 (1.1%)	0	1 (1.1%)
NERVOUSNESS	1 (1.1%)	0	0	1 (1.1%)
SOMNOLENCE	0	2 (2.2%)	0	2 (2.2%)
RED BLOOD CELL	4 (4.4%)	0	2 (2.2%)	6 (6.7%)
ANEMIA	4 (4.4%)	0	2 (2.2%)	6 (6.7%)
ANEMIA B TWELVE DEFICIENCY	0	0	0	0
ANEMIA HYPOCHROMIC	0	0	0	0
ERYTHROCYTES ABNORMAL	0	0	0	0
REPRODUCTIVE FEMALE	2 (2.2%)	0	0	2 (2.2%)
MENSTRUAL DISORDER	1 (1.1%)	0	0	1 (1.1%)
OVARIAN CYST	1 (1.1%)	0	0	1 (1.1%)
VAGINITIS	0	0	0	0
REPRODUCTIVE MALE	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
IMPOTENCE	0	1 (1.1%)	0	1 (1.1%)
PENIS DISORDER	0	0	1 (1.1%)	1 (1.1%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
PROSTATIC DISORDER	2 (3.3%)	0	0	2 (3.3%)	4 (5.1%)	0	1 (1.3%)	5 (6.4%)				
TESTIS DISORDER	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
RESISTANCE MECHANISM	5 (8.2%)	15 (24.6%)	1 (1.6%)	19 (31.1%)	11 (14.1%)	13 (16.7%)	2 (2.6%)	24 (30.8%)				
ABSCCESS	0	0	0	0	0	0	0	0				
HERPES SIMPLEX	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
HERPES ZOSTER	0	1 (1.6%)	0	1 (1.6%)	0	2 (2.6%)	2 (2.6%)	4 (5.1%)				
INFECTION	2 (3.3%)	2 (3.3%)	1 (1.6%)	5 (8.2%)	2 (2.6%)	1 (1.3%)	1 (1.3%)	4 (5.1%)				
INFECTION BACTERIAL	0	2 (3.3%)	0	2 (3.3%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
INFECTION FUNGAL	0	0	0	0	0	0	0	0				
INFECTION VIRAL	2 (3.3%)	8 (13.1%)	0	10 (16.4%)	2 (2.6%)	7 (9.0%)	0	9 (11.5%)				
MONILIASIS	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)				
MONILIASIS GENITAL	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
OTITIS MEDIA	0	0	0	0	0	0	0	0				
UPPER RESP TRACT INFECTION	1 (1.6%)	5 (8.2%)	0	6 (9.8%)	7 (9.0%)	2 (2.6%)	0	9 (11.5%)				
RESPIRATORY SYSTEM	12 (19.7%)	4 (6.6%)	1 (1.6%)	15 (24.6%)	7 (9.0%)	14 (17.9%)	0	19 (24.4%)				
ASTHMA	0	0	0	0	0	0	0	0				
BRONCHITIS	3 (4.9%)	1 (1.6%)	0	4 (6.6%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
COUGHING	6 (9.8%)	2 (3.3%)	0	8 (13.1%)	4 (5.1%)	1 (1.3%)	0	5 (6.4%)				
DYSPNEA	0	0	1 (1.6%)	1 (1.6%)	0	4 (5.1%)	0	4 (5.1%)				
EPISTAXIS	0	0	0	0	0	0	0	0				
LARYNGITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
PHARYNGITIS	2 (3.3%)	2 (3.3%)	0	4 (6.6%)	1 (1.3%)	3 (3.8%)	0	4 (5.1%)				
PNEUMONIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
PULMONARY EDEMA	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
RESPIRATORY DISORDER	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	0	6 (7.7%)	0	6 (7.7%)				
RESPIRATORY INSUFFICIENCY	0	0	0	0	0	0	0	0				
RHINITIS	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
SINUSITIS	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
SKIN AND APPENDAGES	8 (13.1%)	7 (11.5%)	2 (3.3%)	14 (23.0%)	11 (14.1%)	4 (5.1%)	0	14 (17.9%)				
ALOPECIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
PROSTATIC DISORDER	0	0	0	0
TESTIS DISORDER	0	0	0	0
RESISTANCE MECHANISM	15 (16.7%)	13 (14.4%)	2 (2.2%)	27 (30.0%)
ABSCCESS	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
HERPES SIMPLEX	0	0	0	0
HERPES ZOSTER	0	1 (1.1%)	0	1 (1.1%)
INFECTION	0	1 (1.1%)	0	1 (1.1%)
INFECTION BACTERIAL	0	0	0	0
INFECTION FUNGAL	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
INFECTION VIRAL	3 (3.3%)	6 (6.7%)	0	9 (10.0%)
MONILIASIS	1 (1.1%)	0	0	1 (1.1%)
MONILIASIS GENITAL	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
OTITIS MEDIA	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
UPPER RESP TRACT INFECTION	11 (12.2%)	3 (3.3%)	0	14 (15.6%)
RESPIRATORY SYSTEM	12 (13.3%)	18 (20.0%)	3 (3.3%)	26 (28.9%)
ASTHMA	0	1 (1.1%)	0	1 (1.1%)
BRONCHITIS	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
COUGHING	4 (4.4%)	2 (2.2%)	0	6 (6.7%)
DYSPNEA	3 (3.3%)	2 (2.2%)	1 (1.1%)	6 (6.7%)
EPISTAXIS	0	0	1 (1.1%)	1 (1.1%)
LARYNGITIS	0	0	0	0
PHARYNGITIS	3 (3.3%)	4 (4.4%)	0	7 (7.8%)
PNEUMONIA	0	0	0	0
PULMONARY EDEMA	0	1 (1.1%)	0	1 (1.1%)
RESPIRATORY DISORDER	3 (3.3%)	7 (7.8%)	0	10 (11.1%)
RESPIRATORY INSUFFICIENCY	0	0	1 (1.1%)	1 (1.1%)
RHINITIS	1 (1.1%)	0	0	1 (1.1%)
SINUSITIS	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
SKIN AND APPENDAGES	6 (6.7%)	6 (6.7%)	1 (1.1%)	11 (12.2%)
ALOPECIA	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

- 707 -

CONFIDENTIAL
BRL-049653/RSD-
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Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
DERMATITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
DERMATITIS FUNGAL	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
ECZEMA	0	1 (1.6%)	1 (1.6%)	2 (3.3%)	1 (1.3%)	1 (1.3%)	0	2 (2.6%)	0	0	0	0
FURUNCULOSIS	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)	0	0	0	0
HYPERKERATOSIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
NAIL DISORDER	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
NEVUS	0	0	0	0	0	0	0	0	0	0	0	0
PRURITUS	2 (3.3%)	1 (1.6%)	1 (1.6%)	4 (6.6%)	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
RASH	3 (4.9%)	0	0	3 (4.9%)	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
RASH ERYTHEMATOUS	0	1 (1.6%)	0	1 (1.6%)	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
RASH PUSTULAR	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
SEBORRHEA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
SKIN DISORDER	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
SKIN DRY	0	2 (3.3%)	0	2 (3.3%)	0	0	0	0	0	0	0	0
SKIN HYPERTROPHY	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
SKIN ULCERATION	0	0	0	0	0	0	0	0	0	0	0	0
URTICARIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
VERRUCA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0	0	0	0	0
URINARY SYSTEM	6 (9.8%)	2 (3.3%)	2 (3.3%)	10 (16.4%)	12 (15.4%)	6 (7.7%)	1 (1.3%)	15 (19.2%)				
ALBUMINURIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0	0	0	0	0
CYSTITIS	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0	0	0	0	0
DYSURIA	2 (3.3%)	0	0	2 (3.3%)	0	0	0	0	0	0	0	0
HEMATURIA	0	0	0	0	2 (2.6%)	0	0	2 (2.6%)	0	0	0	0
HYDRONEPHROSIS	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0	2 (2.6%)	1 (1.3%)	0	3 (3.8%)	0	0	0	0
NOCTURIA	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)	0	0	0	0
POLYURIA	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)	0	0	0	0
PYURIA	1 (1.6%)	0	0	1 (1.6%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)	0	0	0	0
RENAL CALCULUS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)	0	0	0	0
RENAL FAILURE ACUTE	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	1 (1.3%)	2 (2.6%)	0	0	0	0
URETHRAL DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
URINARY TRACT INFECTION	2 (3.3%)	1 (1.6%)	1 (1.6%)	4 (6.6%)	4 (5.1%)	5 (6.4%)	0	9 (11.5%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
DERMATITIS	0	1 (1.1%)	0	1 (1.1%)
DERMATITIS FUNGAL	0	1 (1.1%)	0	1 (1.1%)
ECZEMA	1 (1.1%)	0	0	1 (1.1%)
FURUNCULOSIS	1 (1.1%)	0	0	1 (1.1%)
HYPERKERATOSIS	2 (2.2%)	0	0	2 (2.2%)
NAIL DISORDER	1 (1.1%)	0	0	1 (1.1%)
NEVUS	0	1 (1.1%)	0	1 (1.1%)
PRURITUS	1 (1.1%)	0	0	1 (1.1%)
RASH	2 (2.2%)	1 (1.1%)	0	3 (3.3%)
RASH ERYTHEMATOUS	0	0	0	0
RASH PUSTULAR	0	0	0	0
SEBORRHEA	0	0	0	0
SKIN DISORDER	0	1 (1.1%)	0	1 (1.1%)
SKIN DRY	0	2 (2.2%)	0	2 (2.2%)
SKIN HYPERTROPHY	0	0	0	0
SKIN ULCERATION	0	0	1 (1.1%)	1 (1.1%)
URTICARIA	0	0	0	0
VERRUCA	0	0	0	0
URINARY SYSTEM	9 (10.0%)	4 (4.4%)	1 (1.1%)	13 (14.4%)
ALBUMINURIA	0	0	0	0
CYSTITIS	0	0	0	0
DYSURIA	0	0	0	0
HEMATURIA	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
HYDRONEPHROSIS	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0
NOCTURIA	0	0	0	0
POLYURIA	0	1 (1.1%)	0	1 (1.1%)
PYURIA	0	0	1 (1.1%)	1 (1.1%)
RENAL CALCULUS	0	0	0	0
RENAL FAILURE ACUTE	0	0	0	0
URETHRAL DISORDER	0	2 (2.2%)	0	2 (2.2%)
URINARY TRACT INFECTION	8 (8.9%)	2 (2.2%)	1 (1.1%)	11 (12.2%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)	48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)				
WHO Body System Preferred Term												
VASCULAR EXTRACARDIAC	2 (3.3%)	4 (6.6%)	3 (4.9%)	8 (13.1%)	5 (6.4%)	2 (2.6%)	2 (2.6%)	8 (10.3%)				
ATHEROSCLEROSIS	0	0	0	0	0	0	0	0				
CEREBROVASCULAR DISORDER	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
CRAMPS LEGS	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
EMBOLISM PULMONARY	0	0	1 (1.6%)	1 (1.6%)	0	0	0	0				
HEMORRHAGE NOS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
PERIPHERAL ISCHEMIA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
PHLEBITIS	0	0	0	0	0	0	1 (1.3%)	1 (1.3%)				
THROMBOPHLEBITIS	0	0	0	0	0	0	0	0				
VASCULAR DISORDER	0	0	1 (1.6%)	1 (1.6%)	2 (2.6%)	0	1 (1.3%)	3 (3.8%)				
VEIN DISORDER	0	2 (3.3%)	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)				
VEIN VARICOSE	1 (1.6%)	1 (1.6%)	0	2 (3.3%)	0	0	0	0				
VISION	3 (4.9%)	5 (8.2%)	1 (1.6%)	8 (13.1%)	1 (1.3%)	2 (2.6%)	1 (1.3%)	4 (5.1%)				
BLEPHARITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
CATARACT	1 (1.6%)	2 (3.3%)	1 (1.6%)	4 (6.6%)	1 (1.3%)	0	0	1 (1.3%)				
CONJUNCTIVITIS	0	0	0	0	0	0	0	0				
DIPLOPIA	0	0	0	0	0	0	0	0				
EYE ABNORMALITY	1 (1.6%)	0	0	1 (1.6%)	0	0	1 (1.3%)	1 (1.3%)				
EYE PAIN	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)				
GLAUCOMA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
MACULA LUTEA DEGENERATION	0	0	0	0	0	0	0	0				
RETINAL DISORDER	0	0	0	0	1 (1.3%)	1 (1.3%)	0	2 (2.6%)				
RETINITIS	0	0	0	0	0	0	0	0				
VISION ABNORMAL	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	2 (2.6%)	1 (1.3%)	0	3 (3.8%)				
EOSINOPHILIA	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
GRANULOCYTOPENIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
LEUKOCYTOSIS	0	0	0	0	0	0	0	0				
LEUKOPENIA	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)				
LYMPHADENOPATHY CERVICAL	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
VASCULAR EXTRACARDIAC	3 (3.3%)	4 (4.4%)	1 (1.1%)	7 (7.8%)
ATHEROSCLEROSIS	0	1 (1.1%)	0	1 (1.1%)
CEREBROVASCULAR DISORDER	0	1 (1.1%)	0	1 (1.1%)
CRAMPS LEGS	0	0	0	0
EMBOLISM PULMONARY	0	1 (1.1%)	0	1 (1.1%)
HEMORRHAGE NOS	0	0	0	0
PERIPHERAL ISCHEMIA	1 (1.1%)	0	0	1 (1.1%)
PHLEBITIS	0	0	0	0
THROMBOPHLEBITIS	0	1 (1.1%)	0	1 (1.1%)
VASCULAR DISORDER	0	0	1 (1.1%)	1 (1.1%)
VEIN DISORDER	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
VEIN VARICOSE	1 (1.1%)	0	0	1 (1.1%)
VISION	6 (6.7%)	4 (4.4%)	1 (1.1%)	10 (11.1%)
BLEPHARITIS	0	0	0	0
CATARACT	0	1 (1.1%)	1 (1.1%)	2 (2.2%)
CONJUNCTIVITIS	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
DIPLOPIA	0	1 (1.1%)	0	1 (1.1%)
EYE ABNORMALITY	2 (2.2%)	0	0	2 (2.2%)
EYE PAIN	0	0	0	0
GLAUCOMA	1 (1.1%)	0	0	1 (1.1%)
MACULA LUTEA DEGENERATION	1 (1.1%)	0	0	1 (1.1%)
RETINAL DISORDER	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
RETINITIS	1 (1.1%)	0	0	1 (1.1%)
VISION ABNORMAL	0	1 (1.1%)	0	1 (1.1%)
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
EOSINOPHILIA	0	0	0	0
GRANULOCYTOPENIA	0	0	0	0
LEUKOCYTOSIS	0	1 (1.1%)	0	1 (1.1%)
LEUKOPENIA	1 (1.1%)	0	0	1 (1.1%)
LYMPHADENOPATHY CERVICAL	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total	015:1bd+S/2bd (N=78)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total		Mild	Moderate	Severe	Total
Patients with Adverse Experiences	45 (73.8%)	41 (67.2%)	16 (26.2%)	51 (83.6%)		48 (61.5%)	50 (64.1%)	20 (25.6%)	62 (79.5%)
WHO Body System Preferred Term									
LYMPHANGITIS	0	0	0	0		0	1 (1.3%)	0	1 (1.3%)
LYMPHOPENIA	0	0	0	0		1 (1.3%)	0	0	1 (1.3%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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100TV9/1/CPMS-009

Data Source Table 15.2.2b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)

-----_----- 2bd Comb Total -----
015:2bd+S/2bd
(N=90)

Intensity of Adverse Experience	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	56 (62.2%)	56 (62.2%)	16 (17.8%)	76 (84.4%)
WHO Body System Preferred Term				
LYMPHANGITIS	0	0	0	0
LYMPHOPENIA	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)
WHO Body System Preferred Term								
APPLICATION SITE	0	0	0	0	1 (0.7%)	2 (1.5%)	0	3 (2.2%)
OTITIS EXTERNA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
AUTONOMIC NERVOUS SYSTEM	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)
SWEATING INCREASED	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)
BODY AS A WHOLE GENERAL	14 (11.3%)	19 (15.3%)	10 (8.1%)	36 (29.0%)	19 (14.0%)	25 (18.4%)	8 (5.9%)	45 (33.1%)
ALLERGIC REACTION	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
ALLERGY	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
ASTHENIA	2 (1.6%)	3 (2.4%)	0	5 (4.0%)	3 (2.2%)	3 (2.2%)	0	6 (4.4%)
CHEST PAIN	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	0	0	2 (1.5%)
CHEST PAIN PRECORDIAL	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
EDEMA	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)
EDEMA DEPENDENT	0	2 (1.6%)	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)
EDEMA GENERALISED	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0
EDEMA LEGS	7 (5.6%)	4 (3.2%)	2 (1.6%)	13 (10.5%)	1 (0.7%)	4 (2.9%)	1 (0.7%)	6 (4.4%)
EDEMA PERIORBITAL	0	0	0	0	0	0	0	0
EDEMA PERIPHERAL	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)
ESR INCREASED	0	0	0	0	0	0	0	0
FACE EDEMA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
FATIGUE	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	0	1 (0.7%)	0	1 (0.7%)
FEVER	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
GRANULOMATOUS LESION	0	0	0	0	0	0	0	0
HOT FLUSHES	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
INJURY	3 (2.4%)	8 (6.5%)	5 (4.0%)	16 (12.9%)	4 (2.9%)	15 (11.0%)	7 (5.1%)	26 (19.1%)
MALAISE	0	0	0	0	0	0	0	0
NECROSIS ISCHEMIC	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0
PAIN	2 (1.6%)	3 (2.4%)	1 (0.8%)	6 (4.8%)	3 (2.2%)	5 (3.7%)	0	8 (5.9%)
PALLOR	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
APPLICATION SITE	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
OTITIS EXTERNA	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
TYMPANIC MEMBRANE PERFORATION	0	0	0	0	0	0	0	0
AUTONOMIC NERVOUS SYSTEM	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SWEATING INCREASED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
BODY AS A WHOLE GENERAL	21 (15.1%)	22 (15.8%)	2 (1.4%)	40 (28.8%)	2 (6.7%)	3 (10.0%)	0	5 (16.7%)
ALLERGIC REACTION	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
ALLERGY	0	0	0	0	0	0	0	0
ASTHENIA	0	3 (2.2%)	0	3 (2.2%)	0	0	0	0
CHEST PAIN	3 (2.2%)	3 (2.2%)	0	6 (4.3%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
CHEST PAIN PRECORDIAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EDEMA	0	0	0	0	0	0	0	0
EDEMA DEPENDENT	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
EDEMA GENERALISED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EDEMA LEGS	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
EDEMA PERIORBITAL	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
EDEMA PERIPHERAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ESR INCREASED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
FACE EDEMA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
FATIGUE	2 (1.4%)	0	0	2 (1.4%)	1 (3.3%)	0	0	1 (3.3%)
FEVER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GRANULOMATOUS LESION	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
HOT FLUSHES	0	1 (0.7%)	1 (0.7%)	2 (1.4%)	0	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	0	0	0	0	0	0	0
INJURY	4 (2.9%)	12 (8.6%)	1 (0.7%)	17 (12.2%)	0	1 (3.3%)	0	1 (3.3%)
MALAISE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NECROSIS ISCHEMIC	0	0	0	0	0	0	0	0
PAIN	2 (1.4%)	3 (2.2%)	0	5 (3.6%)	0	0	0	0
PALLOR	0	0	0	0	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
RIGORS	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
CARDIOVASCULAR GENERAL	3 (2.4%)	1 (0.8%)	4 (3.2%)	7 (5.6%)	7 (5.1%)	8 (5.9%)	1 (0.7%)	15 (11.0%)	1 (0.7%)	0	0	1 (0.7%)
CARDIAC FAILURE	0	0	1 (0.8%)	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CARDIAC FAILURE LEFT	0	0	0	0	0	0	0	0	0	0	0	0
ECG ABNORMAL	0	0	0	0	0	0	0	0	0	0	0	0
ECG ABNORMAL SPECIFIC	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEART DISORDER	0	0	0	0	0	0	0	0	0	0	0	0
HEART VALVE DISORDERS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HYPERTENSION	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	3 (2.2%)	1 (0.7%)	6 (4.4%)	1 (0.7%)	0	0	1 (0.7%)
HYPERTENSION AGGRAVATED	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	2 (1.5%)	3 (2.2%)	0	5 (3.7%)	0	0	0	0
HYPOTENSION	0	0	1 (0.8%)	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
HYPOTENSION POSTURAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SYNCOPE	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	0	0	0	0	0	0	0	0
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	6 (4.8%)	18 (14.5%)	2 (1.6%)	23 (18.5%)	9 (6.6%)	16 (11.8%)	3 (2.2%)	26 (19.1%)				
CARPAL TUNNEL SYNDROME	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
DIZZINESS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	2 (1.5%)	0	0	2 (1.5%)	0	0	0	0
EDEMA CEREBRAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEADACHE	2 (1.6%)	3 (2.4%)	0	5 (4.0%)	3 (2.2%)	2 (1.5%)	1 (0.7%)	6 (4.4%)	0	0	0	0
HYPERESTHESIA	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	0
HYPERKINESIA	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
HYPESTHESIA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
MIGRAINE	0	2 (1.6%)	0	2 (1.6%)	0	0	0	0	0	0	0	0
NEURALGIA	0	9 (7.3%)	0	9 (7.3%)	1 (0.7%)	9 (6.6%)	2 (1.5%)	12 (8.8%)	0	0	0	0
NEURITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NEUROPATHY	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NEUROPATHY PERIPHERAL	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
PARESIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
RIGORS	0	0	0	0	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CARDIOVASCULAR GENERAL	7 (5.0%)	10 (7.2%)	1 (0.7%)	18 (12.9%)	0	2 (6.7%)	1 (3.3%)	3 (10.0%)
CARDIAC FAILURE	0	4 (2.9%)	1 (0.7%)	5 (3.6%)	0	1 (3.3%)	0	1 (3.3%)
CARDIAC FAILURE LEFT	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
ECG ABNORMAL	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
ECG ABNORMAL SPECIFIC	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEART DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEART VALVE DISORDERS	0	0	0	0	0	0	0	0
HYPERTENSION	3 (2.2%)	2 (1.4%)	0	5 (3.6%)	0	0	0	0
HYPERTENSION AGGRAVATED	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
HYPOTENSION	0	0	0	0	0	0	0	0
HYPOTENSION POSTURAL	0	0	0	0	0	0	0	0
SYNCOPE	0	2 (1.4%)	0	2 (1.4%)	0	0	1 (3.3%)	1 (3.3%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	11 (7.9%)	14 (10.1%)	1 (0.7%)	22 (15.8%)	1 (3.3%)	3 (10.0%)	1 (3.3%)	5 (16.7%)
CARPAL TUNNEL SYNDROME	0	0	0	0	0	0	0	0
DIZZINESS	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
EDEMA CEREBRAL	0	0	0	0	0	0	0	0
HEADACHE	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
HYPERESTHESIA	0	0	0	0	0	0	0	0
HYPERKINESIA	0	0	0	0	0	0	0	0
HYPESTHESIA	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
MIGRAINE	0	0	0	0	0	0	0	0
NEURALGIA	0	8 (5.8%)	1 (0.7%)	9 (6.5%)	0	0	1 (3.3%)	1 (3.3%)
NEURITIS	0	0	0	0	0	0	0	0
NEUROPATHY	0	0	0	0	0	0	0	0
NEUROPATHY PERIPHERAL	0	0	0	0	0	0	0	0
PARESIS	0	0	0	0	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
PARESTHESIA	2 (1.6%)	3 (2.4%)	0	5 (4.0%)	3 (2.2%)	0	0	3 (2.2%)				
PTOSIS	0	0	0	0	0	0	0	0				
SPEECH DISORDER	0	0	0	0	0	0	0	0				
TETANY	0	0	0	0	0	0	0	0				
TREMOR	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
VERTIGO	1 (0.8%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	0	4 (2.9%)	0	4 (2.9%)				
COLLAGEN	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
ARTHRITIS RHEUMATOID	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
ENDOCRINE	3 (2.4%)	1 (0.8%)	1 (0.8%)	5 (4.0%)	4 (2.9%)	4 (2.9%)	0	7 (5.1%)				
GOITRE	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
GYNECOMASTIA	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
HYPOTHYROIDISM	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
THYROID DISORDER	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
GASTROINTESTINAL SYSTEM	19 (15.3%)	17 (13.7%)	3 (2.4%)	33 (26.6%)	17 (12.5%)	27 (19.9%)	4 (2.9%)	39 (28.7%)				
ABDOMINAL PAIN	3 (2.4%)	3 (2.4%)	1 (0.8%)	7 (5.6%)	3 (2.2%)	3 (2.2%)	0	6 (4.4%)				
ANUS DISORDER	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
APPETITE INCREASED	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
COLITIS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	1 (0.7%)	3 (2.2%)	0	4 (2.9%)				
CONSTIPATION	3 (2.4%)	4 (3.2%)	0	7 (5.6%)	3 (2.2%)	2 (1.5%)	0	5 (3.7%)				
DIARRHEA	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	5 (3.7%)	0	6 (4.4%)				
DIVERTICULITIS	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
DUODENAL ULCER	0	0	1 (0.8%)	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
DYSPEPSIA	3 (2.4%)	1 (0.8%)	0	4 (3.2%)	1 (0.7%)	3 (2.2%)	0	4 (2.9%)				
ENTERITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
ESOPHAGEAL ULCERATION	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
ESOPHAGITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
FECAL INCONTINENCE	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
FLATULENCE	0	1 (0.8%)	0	1 (0.8%)	0	0	1 (0.7%)	1 (0.7%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
PARESTHESIA	0	1 (0.7%)	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
PTOSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SPEECH DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
TETANY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
TREMOR	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VERTIGO	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	0	0	0	0
COLLAGEN	0	0	0	0	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0	0	0	0	0
ENDOCRINE	0	0	0	0	0	0	0	0
GOITRE	0	0	0	0	0	0	0	0
GYNECOMASTIA	0	0	0	0	0	0	0	0
HYPOTHYROIDISM	0	0	0	0	0	0	0	0
THYROID DISORDER	0	0	0	0	0	0	0	0
GASTROINTESTINAL SYSTEM	19 (13.7%)	18 (12.9%)	1 (0.7%)	34 (24.5%)	2 (6.7%)	2 (6.7%)	3 (10.0%)	6 (20.0%)
ABDOMINAL PAIN	6 (4.3%)	3 (2.2%)	0	9 (6.5%)	0	0	0	0
ANUS DISORDER	0	0	0	0	0	0	0	0
APETITE INCREASED	1 (0.7%)	0	0	1 (0.7%)	1 (3.3%)	0	0	1 (3.3%)
COLITIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CONSTIPATION	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
DIARRHEA	1 (0.7%)	3 (2.2%)	0	4 (2.9%)	0	0	1 (3.3%)	1 (3.3%)
DIVERTICULITIS	0	0	0	0	0	0	0	0
DUODENAL ULCER	0	0	0	0	0	0	0	0
DYSPEPSIA	2 (1.4%)	0	0	2 (1.4%)	1 (3.3%)	1 (3.3%)	0	2 (6.7%)
ENTERITIS	0	0	0	0	0	0	0	0
ESOPHAGEAL ULCERATION	0	0	0	0	0	0	0	0
ESOPHAGITIS	0	0	0	0	0	0	0	0
FECAL INCONTINENCE	0	0	0	0	0	0	0	0
FLATULENCE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
GASTRIC ULCER	0	2 (1.6%)	0	2 (1.6%)	0	2 (1.5%)	0	2 (1.5%)	0	2 (1.5%)	0	2 (1.5%)
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)	0	0	1 (0.7%)	1 (0.7%)
GASTRITIS	3 (2.4%)	0	0	3 (2.4%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
GASTROENTERITIS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	6 (4.4%)	0	7 (5.1%)	0	0	0	0
GASTROESOPHAGEAL REFLUX	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
GASTROINTESTINAL DISORDER NOS	1 (0.8%)	3 (2.4%)	0	4 (3.2%)	0	1 (0.7%)	2 (1.5%)	3 (2.2%)	0	0	0	0
GI HEMORRHAGE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HEMORRHAGE RECTUM	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	0
HEMORRHOIDS	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
INTESTINAL ISCHEMIA	0	0	0	0	0	0	0	0	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
IRRITABLE BOWEL SYNDROME	0	0	0	0	0	0	0	0	0	0	0	0
NAUSEA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
PERIODONTITIS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)	0	0	0	0
SALIVARY GLAND ENLARGEMENT	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
STOMATITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
STOMATITIS ULCERATIVE	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TONGUE EDEMA	0	0	0	0	0	0	0	0	0	0	0	0
TONGUE ULCERATION	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
TOOTH CARIES	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TOOTH DISORDER	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
VOMITING	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
HEARING AND VESTIBULAR	3 (2.4%)	2 (1.6%)	0	5 (4.0%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DEAFNESS	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
EAR DISORDER NOS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
EARACHE	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
TINNITUS	0	2 (1.6%)	0	2 (1.6%)	0	0	0	0	0	0	0	0
HEART RATE AND RHYTHM	5 (4.0%)	3 (2.4%)	1 (0.8%)	9 (7.3%)	6 (4.4%)	4 (2.9%)	2 (1.5%)	12 (8.8%)	0	0	0	0
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	0	0	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
GASTRIC ULCER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	0	0	0	0
GASTRITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GASTROENTERITIS	0	3 (2.2%)	0	3 (2.2%)	0	0	0	0
GASTROESOPHAGEAL REFLUX	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GASTROINTESTINAL DISORDER NOS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GI HEMORRHAGE	0	0	0	0	0	0	0	0
HEMORRHAGE RECTUM	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HEMORRHOIDS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
INTESTINAL ISCHEMIA	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0	0	0	0	0
IRRITABLE BOWEL SYNDROME	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NAUSEA	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	0	0	0
PERIODONTITIS	1 (0.7%)	4 (2.9%)	0	5 (3.6%)	0	1 (3.3%)	2 (6.7%)	3 (10.0%)
SALIVARY GLAND ENLARGEMENT	0	0	0	0	0	0	0	0
STOMATITIS	0	0	0	0	0	0	0	0
STOMATITIS ULCERATIVE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TONGUE EDEMA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
TONGUE ULCERATION	0	0	0	0	0	0	0	0
TOOTH CARIES	0	0	0	0	0	0	0	0
TOOTH DISORDER	0	0	0	0	0	0	0	0
VOMITING	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
HEARING AND VESTIBULAR	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DEAFNESS	0	0	0	0	0	0	0	0
EAR DISORDER NOS	0	0	0	0	0	0	0	0
EARACHE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TINNITUS	0	0	0	0	0	0	0	0
HEART RATE AND RHYTHM	7 (5.0%)	2 (1.4%)	1 (0.7%)	10 (7.2%)	1 (3.3%)	0	1 (3.3%)	2 (6.7%)
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	1 (3.3%)	1 (3.3%)

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	0	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	0	1 (0.7%)	1 (0.7%)	2 (1.5%)	0	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
BRADYCARDIA	1 (0.8%)	0	0	1 (0.8%)	0	0	2 (1.5%)	2 (1.5%)	0	0	0	0
BUNDLE BRANCH BLOCK	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)	0	0	0	0
EXTRASYSTOLES	2 (1.6%)	0	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
FIBRILLATION ATRIAL	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)	0	0	0	0
PALPITATION	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
TACHYCARDIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
LIVER AND BILIARY SYSTEM	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)	0	0	0	0
BILIARY PAIN	0	0	0	0	0	0	0	0	0	0	0	0
CHOLECYSTITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CHOLELITHIASIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GALL BLADDER DISORDER	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
GAMMA-GT INCREASED	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
HEPATIC FUNCTION ABNORMAL	0	0	0	0	0	0	0	0	0	0	0	0
HEPATOMEGALY	0	0	0	0	0	0	0	0	0	0	0	0
METABOLIC AND NUTRITIONAL	18 (14.5%)	23 (18.5%)	4 (3.2%)	41 (33.1%)	13 (9.6%)	19 (14.0%)	5 (3.7%)	32 (23.5%)				
BLOOD UREA NITROGEN INCREASED	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)	0	0	0	0
CALCINOSIS	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	0	0	0	0	0	0	0	0
DIABETES MELLITUS AGGRAVATED	1 (0.8%)	4 (3.2%)	0	5 (4.0%)	0	3 (2.2%)	0	3 (2.2%)	0	0	0	0
GOUT	0	1 (0.8%)	1 (0.8%)	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)	0	0	0	0
HYPERCHOLESTEROLEMIA	10 (8.1%)	4 (3.2%)	0	14 (11.3%)	3 (2.2%)	7 (5.1%)	1 (0.7%)	11 (8.1%)	0	0	0	0
HYPERGLYCEMIA	3 (2.4%)	1 (0.8%)	0	4 (3.2%)	0	2 (1.5%)	1 (0.7%)	3 (2.2%)	0	0	0	0
HYPERKALEMIA	0	0	0	0	0	0	0	0	0	0	0	0
HYPERLIPEMIA	3 (2.4%)	5 (4.0%)	1 (0.8%)	9 (7.3%)	2 (1.5%)	3 (2.2%)	1 (0.7%)	6 (4.4%)	0	0	0	0
HYPERTRIGLYCERIDEMIA	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HYPERURICEMIA	0	0	0	0	0	0	0	0	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
ARRHYTHMIA VENTRICULAR	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	0	0	0
BRADYCARDIA	0	0	0	0	0	0	0	0
BUNDLE BRANCH BLOCK	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EXTRASYSTOLES	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
FIBRILLATION ATRIAL	3 (2.2%)	2 (1.4%)	1 (0.7%)	6 (4.3%)	0	0	0	0
PALPITATION	1 (0.7%)	0	0	1 (0.7%)	1 (3.3%)	0	0	1 (3.3%)
TACHYCARDIA	0	0	0	0	0	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	0	0	0	0
LIVER AND BILIARY SYSTEM	2 (1.4%)	3 (2.2%)	3 (2.2%)	6 (4.3%)	0	0	0	0
BILIARY PAIN	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
CHOLECYSTITIS	0	0	0	0	0	0	0	0
CHOLELITHIASIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
GALL BLADDER DISORDER	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
GAMMA-GT INCREASED	0	1 (0.7%)	2 (1.4%)	3 (2.2%)	0	0	0	0
HEPATIC FUNCTION ABNORMAL	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
HEPATOMEGALY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
METABOLIC AND NUTRITIONAL	6 (4.3%)	26 (18.7%)	2 (1.4%)	33 (23.7%)	4 (13.3%)	15 (50.0%)	4 (13.3%)	20 (66.7%)
BLOOD UREA NITROGEN INCREASED	0	0	0	0	0	0	0	0
CALCINOSIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DIABETES MELLITUS AGGRAVATED	0	3 (2.2%)	1 (0.7%)	4 (2.9%)	1 (3.3%)	7 (23.3%)	2 (6.7%)	10 (33.3%)
GOUT	0	1 (0.7%)	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
HYPERCHOLESTEROLEMIA	2 (1.4%)	7 (5.0%)	0	9 (6.5%)	2 (6.7%)	6 (20.0%)	1 (3.3%)	9 (30.0%)
HYPERGLYCEMIA	1 (0.7%)	6 (4.3%)	2 (1.4%)	9 (6.5%)	0	0	0	0
HYPERKALEMIA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
HYPERLIPEMIA	2 (1.4%)	6 (4.3%)	0	8 (5.8%)	0	0	0	0
HYPERTRIGLYCERIDEMIA	0	1 (0.7%)	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
HYPERURICEMIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
HYPOCHOLESTEROLEMIA	0	0	0	0	0	0	0	0	0	0	0	0
HYPOGLYCEMIA	0	0	0	0	2 (1.5%)	2 (1.5%)	1 (0.7%)	5 (3.7%)				
HYPOGLYCEMIC REACTION	0	0	0	0	0	0	0	0				
HYPOKALEMIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
NPN INCREASED	0	2 (1.6%)	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
OBESITY	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
THIRST	0	0	0	0	0	0	0	0				
WEIGHT DECREASE	0	2 (1.6%)	0	2 (1.6%)	0	0	0	0				
WEIGHT INCREASE	0	6 (4.8%)	1 (0.8%)	7 (5.6%)	3 (2.2%)	3 (2.2%)	1 (0.7%)	7 (5.1%)				
MUSCULOSKELETAL SYSTEM	14 (11.3%)	35 (28.2%)	6 (4.8%)	47 (37.9%)	15 (11.0%)	38 (27.9%)	10 (7.4%)	55 (40.4%)				
ARTHRALGIA	3 (2.4%)	5 (4.0%)	1 (0.8%)	9 (7.3%)	7 (5.1%)	6 (4.4%)	1 (0.7%)	14 (10.3%)				
ARTHRITIS	3 (2.4%)	6 (4.8%)	3 (2.4%)	12 (9.7%)	1 (0.7%)	12 (8.8%)	4 (2.9%)	17 (12.5%)				
ARTHRITIS AGGRAVATED	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)				
ARTHROPATHY	0	0	0	0	0	0	0	0				
ARTHROSIS	0	5 (4.0%)	1 (0.8%)	6 (4.8%)	3 (2.2%)	5 (3.7%)	1 (0.7%)	9 (6.6%)				
BACK PAIN	4 (3.2%)	11 (8.9%)	0	15 (12.1%)	1 (0.7%)	15 (11.0%)	4 (2.9%)	20 (14.7%)				
BONE DISORDER	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
BURSITIS	0	0	1 (0.8%)	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
MYALGIA	2 (1.6%)	4 (3.2%)	0	6 (4.8%)	0	5 (3.7%)	0	5 (3.7%)				
MYOPATHY	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
OSTEOMYELITIS	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0				
OSTEOPOROSIS	0	3 (2.4%)	0	3 (2.4%)	1 (0.7%)	3 (2.2%)	1 (0.7%)	5 (3.7%)				
SKELETAL PAIN	0	2 (1.6%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)				
TENDINITIS	3 (2.4%)	0	0	3 (2.4%)	0	5 (3.7%)	1 (0.7%)	6 (4.4%)				
TORTICOLLIS	0	2 (1.6%)	0	2 (1.6%)	0	0	0	0				
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	0	2 (1.6%)	1 (0.8%)	3 (2.4%)	3 (2.2%)	6 (4.4%)	2 (1.5%)	11 (8.1%)				
ANGINA PECTORIS	0	2 (1.6%)	0	2 (1.6%)	3 (2.2%)	3 (2.2%)	1 (0.7%)	7 (5.1%)				
AORTIC STENOSIS	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
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Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
HYPOCHOLESTEROLEMIA	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
HYPOGLYCEMIA	0	0	0	0	0	0	1 (3.3%)	1 (3.3%)
HYPOGLYCEMIC REACTION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
HYPOKALEMIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
NPN INCREASED	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
OBESITY	0	0	0	0	0	0	0	0
THIRST	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
WEIGHT DECREASE	0	0	0	0	0	0	0	0
WEIGHT INCREASE	0	1 (0.7%)	0	1 (0.7%)	0	2 (6.7%)	0	2 (6.7%)
MUSCULOSKELETAL SYSTEM	17 (12.2%)	22 (15.8%)	3 (2.2%)	37 (26.6%)	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
ARTHRALGIA	2 (1.4%)	4 (2.9%)	1 (0.7%)	7 (5.0%)	0	0	0	0
ARTHRITIS	5 (3.6%)	6 (4.3%)	1 (0.7%)	12 (8.6%)	0	1 (3.3%)	0	1 (3.3%)
ARTHRITIS AGGRAVATED	0	0	0	0	0	0	0	0
ARTHROPATHY	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ARTHROSIS	4 (2.9%)	3 (2.2%)	0	7 (5.0%)	0	1 (3.3%)	0	1 (3.3%)
BACK PAIN	3 (2.2%)	11 (7.9%)	1 (0.7%)	15 (10.8%)	0	0	0	0
BONE DISORDER	0	0	0	0	0	0	0	0
BURSITIS	0	0	0	0	0	0	0	0
MYALGIA	4 (2.9%)	5 (3.6%)	0	9 (6.5%)	1 (3.3%)	0	0	1 (3.3%)
MYOPATHY	0	0	0	0	0	0	0	0
OSTEOMYELITIS	0	0	0	0	0	0	0	0
OSTEOPOROSIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
SKELETAL PAIN	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
TENDINITIS	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
TORTICOLLIS	0	0	0	0	0	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	7 (5.0%)	2 (1.4%)	7 (5.0%)	15 (10.8%)	1 (3.3%)	0	0	1 (3.3%)
ANGINA PECTORIS	2 (1.4%)	2 (1.4%)	2 (1.4%)	6 (4.3%)	0	0	0	0
AORTIC STENOSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
MYOCARDIAL INFARCTION	0	0	1 (0.8%)	1 (0.8%)	0	2 (1.5%)	2 (1.5%)	4 (2.9%)				
MYOCARDIAL ISCHEMIA	0	0	0	0	0	0	0	0				
THROMBOSIS CORONARY	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
NEOPLASM	3 (2.4%)	0	3 (2.4%)	6 (4.8%)	2 (1.5%)	5 (3.7%)	1 (0.7%)	8 (5.9%)				
BASAL CELL CARCINOMA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
BLADDER CARCINOMA	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
BRAIN NEOPLASM BENIGN	0	0	0	0	0	0	0	0				
BREAST NEOPLASM FEMALE	0	0	0	0	0	0	0	0				
CARCINOMA	0	0	2 (1.6%)	2 (1.6%)	0	0	0	0				
HEPATIC NEOPLASM MALIGNANT	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0				
LIPOMA	0	0	0	0	0	0	0	0				
MELANOMA MALIGNANT	0	0	0	0	0	0	0	0				
NEOPLASM MALIGNANT	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
NEOPLASM NOS	3 (2.4%)	0	0	3 (2.4%)	1 (0.7%)	2 (1.5%)	1 (0.7%)	4 (2.9%)				
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0				
THYROID ADENOMA	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
UTERINE FIBROID	0	0	0	0	0	0	0	0				
PLATELET BLEEDING AND CLOTTING	1 (0.8%)	0	0	1 (0.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
PURPURA	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
THROMBOCYTOPENIA	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
PSYCHIATRIC	7 (5.6%)	5 (4.0%)	1 (0.8%)	13 (10.5%)	6 (4.4%)	8 (5.9%)	0	14 (10.3%)				
AMNESIA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
ANXIETY	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	0	1 (0.7%)	0	1 (0.7%)				
DEMENTIA	0	0	0	0	0	0	0	0				
DEPRESSION	4 (3.2%)	1 (0.8%)	1 (0.8%)	6 (4.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
INSOMNIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	3 (2.2%)	3 (2.2%)	0	6 (4.4%)				
NERVOUSNESS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
NEUROSIS	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
MYOCARDIAL INFARCTION	0	0	5 (3.6%)	5 (3.6%)	0	0	0	0
MYOCARDIAL ISCHEMIA	4 (2.9%)	0	0	4 (2.9%)	1 (3.3%)	0	0	1 (3.3%)
THROMBOSIS CORONARY	0	0	0	0	0	0	0	0
NEOPLASM	3 (2.2%)	2 (1.4%)	6 (4.3%)	11 (7.9%)	0	0	0	0
BASAL CELL CARCINOMA	0	0	0	0	0	0	0	0
BLADDER CARCINOMA	0	0	2 (1.4%)	2 (1.4%)	0	0	0	0
BRAIN NEOPLASM BENIGN	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
BREAST NEOPLASM FEMALE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CARCINOMA	0	0	0	0	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
LIPOMA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MELANOMA MALIGNANT	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0
NEOPLASM NOS	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
PHARYNX NEOPLASM MALIGNANT	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
THYROID ADENOMA	0	0	0	0	0	0	0	0
UTERINE FIBROID	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PLATELET BLEEDING AND CLOTTING	0	0	0	0	0	0	0	0
PURPURA	0	0	0	0	0	0	0	0
THROMBOCYTOPENIA	0	0	0	0	0	0	0	0
PSYCHIATRIC	10 (7.2%)	9 (6.5%)	0	18 (12.9%)	0	1 (3.3%)	0	1 (3.3%)
AMNESIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ANXIETY	4 (2.9%)	3 (2.2%)	0	7 (5.0%)	0	0	0	0
DEMENTIA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DEPRESSION	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	0	0	0
INSOMNIA	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	0	1 (3.3%)	0	1 (3.3%)
NERVOUSNESS	0	3 (2.2%)	0	3 (2.2%)	0	0	0	0
NEUROSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
SOMNOLENCE	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
SUICIDE ATTEMPT	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
RED BLOOD CELL	5 (4.0%)	3 (2.4%)	1 (0.8%)	9 (7.3%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
ANEMIA	4 (3.2%)	2 (1.6%)	1 (0.8%)	7 (5.6%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
ANEMIA HYPOCHROMIC	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)				
ANEMIA NORMOCHROMIC	0	0	0	0	0	0	0	0				
ERYTHROCYTES ABNORMAL	0	0	0	0	0	0	0	0				
REPRODUCTIVE FEMALE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
MENORRHAGIA	0	0	0	0	0	0	0	0				
MENSTRUAL DISORDER	0	0	0	0	0	0	0	0				
OVARIAN DISORDER	0	0	0	0	0	0	0	0				
VAGINITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
REPRODUCTIVE MALE	2 (1.6%)	5 (4.0%)	1 (0.8%)	7 (5.6%)	3 (2.2%)	3 (2.2%)	1 (0.7%)	7 (5.1%)				
EPIDIDYMITIS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
IMPOTENCE	1 (0.8%)	3 (2.4%)	1 (0.8%)	5 (4.0%)	0	1 (0.7%)	0	1 (0.7%)				
PROSTATIC DISORDER	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	2 (1.5%)	1 (0.7%)	5 (3.7%)				
TESTIS DISORDER	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
RESISTANCE MECHANISM	11 (8.9%)	13 (10.5%)	2 (1.6%)	24 (19.4%)	15 (11.0%)	18 (13.2%)	0	29 (21.3%)				
ABSCCESS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
HERPES SIMPLEX	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
HERPES ZOSTER	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0				
INFECTION	0	3 (2.4%)	1 (0.8%)	4 (3.2%)	1 (0.7%)	3 (2.2%)	0	4 (2.9%)				
INFECTION BACTERIAL	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
INFECTION FUNGAL	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
INFECTION VIRAL	4 (3.2%)	9 (7.3%)	0	13 (10.5%)	3 (2.2%)	7 (5.1%)	0	10 (7.4%)				
MONILIASIS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	0	0	0				
MONILIASIS GENITAL	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
SOMNOLENCE	0	0	0	0	0	0	0	0
SUICIDE ATTEMPT	0	0	0	0	0	0	0	0
RED BLOOD CELL	4 (2.9%)	2 (1.4%)	0	6 (4.3%)	3 (10.0%)	4 (13.3%)	0	7 (23.3%)
ANEMIA	3 (2.2%)	0	0	3 (2.2%)	2 (6.7%)	4 (13.3%)	0	6 (20.0%)
ANEMIA HYPOCHROMIC	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
ANEMIA NORMOCHROMIC	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
ERYTHROCYTES ABNORMAL	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
REPRODUCTIVE FEMALE	2 (1.4%)	2 (1.4%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
MENORRHAGIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MENSTRUAL DISORDER	0	2 (1.4%)	0	2 (1.4%)	0	1 (3.3%)	0	1 (3.3%)
OVARIAN DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VAGINITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
REPRODUCTIVE MALE	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
EPIDIDYMITIS	0	0	0	0	0	0	0	0
IMPOTENCE	0	0	0	0	0	0	0	0
PROSTATIC DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
TESTIS DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
RESISTANCE MECHANISM	19 (13.7%)	14 (10.1%)	1 (0.7%)	32 (23.0%)	2 (6.7%)	6 (20.0%)	1 (3.3%)	9 (30.0%)
ABSCCESS	0	0	0	0	0	0	0	0
HERPES SIMPLEX	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
HERPES ZOSTER	0	0	0	0	2 (6.7%)	0	0	2 (6.7%)
INFECTION	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	0	0	0
INFECTION BACTERIAL	0	0	0	0	0	0	0	0
INFECTION FUNGAL	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
INFECTION VIRAL	6 (4.3%)	6 (4.3%)	0	12 (8.6%)	0	3 (10.0%)	0	3 (10.0%)
MONILIASIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MONILIASIS GENITAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
OTITIS MEDIA	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
SEPSIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
UPPER RESP TRACT INFECTION	4 (3.2%)	1 (0.8%)	0	5 (4.0%)	7 (5.1%)	3 (2.2%)	0	10 (7.4%)				
RESPIRATORY SYSTEM	18 (14.5%)	31 (25.0%)	3 (2.4%)	45 (36.3%)	20 (14.7%)	35 (25.7%)	4 (2.9%)	49 (36.0%)				
APNEA	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)				
ASTHMA	2 (1.6%)	0	0	2 (1.6%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
BRONCHITIS	3 (2.4%)	15 (12.1%)	0	18 (14.5%)	3 (2.2%)	19 (14.0%)	1 (0.7%)	23 (16.9%)				
CHEST X-RAY ABNORMAL	0	0	0	0	0	0	0	0				
CHRONIC OBSTRUCTIVE AIRWAYS	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	0	0	0	0				
DISEA												
COUGHING	2 (1.6%)	0	0	2 (1.6%)	5 (3.7%)	1 (0.7%)	1 (0.7%)	7 (5.1%)				
DYSPNEA	1 (0.8%)	4 (3.2%)	1 (0.8%)	6 (4.8%)	3 (2.2%)	3 (2.2%)	0	6 (4.4%)				
EPISTAXIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
HEMOPTYSIS	0	0	0	0	0	0	0	0				
LARYNGITIS	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	2 (1.5%)	0	0	2 (1.5%)				
PHARYNGITIS	4 (3.2%)	5 (4.0%)	1 (0.8%)	10 (8.1%)	4 (2.9%)	4 (2.9%)	0	8 (5.9%)				
PLEURAL EFFUSION	0	0	0	0	0	0	0	0				
PLEURISY	0	0	0	0	0	0	0	0				
PNEUMONIA	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
PULMONARY EDEMA	0	0	0	0	1 (0.7%)	0	1 (0.7%)	2 (1.5%)				
RESPIRATORY DISORDER	6 (4.8%)	4 (3.2%)	0	10 (8.1%)	0	3 (2.2%)	0	3 (2.2%)				
RHINITIS	1 (0.8%)	2 (1.6%)	0	3 (2.4%)	2 (1.5%)	4 (2.9%)	0	6 (4.4%)				
SINUSITIS	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)				
TRACHEITIS	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	4 (2.9%)	0	5 (3.7%)				
SKIN AND APPENDAGES	10 (8.1%)	5 (4.0%)	2 (1.6%)	15 (12.1%)	8 (5.9%)	7 (5.1%)	1 (0.7%)	16 (11.8%)				
ALOPECIA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
ANGIOEDEMA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
BULLOUS ERUPTION	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
DERMATITIS	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
OTITIS MEDIA	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
SEPSIS	0	0	0	0	0	2 (6.7%)	0	2 (6.7%)
UPPER RESP TRACT INFECTION	6 (4.3%)	4 (2.9%)	1 (0.7%)	11 (7.9%)	0	2 (6.7%)	1 (3.3%)	3 (10.0%)
RESPIRATORY SYSTEM	26 (18.7%)	35 (25.2%)	3 (2.2%)	52 (37.4%)	2 (6.7%)	5 (16.7%)	0	6 (20.0%)
APNEA	0	0	0	0	0	0	0	0
ASTHMA	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
BRONCHITIS	8 (5.8%)	17 (12.2%)	2 (1.4%)	27 (19.4%)	0	1 (3.3%)	0	1 (3.3%)
CHEST X-RAY ABNORMAL	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
DISEA								
COUGHING	3 (2.2%)	1 (0.7%)	0	4 (2.9%)	2 (6.7%)	0	0	2 (6.7%)
DYSPNEA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
EPISTAXIS	2 (1.4%)	0	0	2 (1.4%)	0	1 (3.3%)	0	1 (3.3%)
HEMOPTYSIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
LARYNGITIS	0	0	0	0	0	0	0	0
PHARYNGITIS	3 (2.2%)	7 (5.0%)	0	10 (7.2%)	0	0	0	0
PLEURAL EFFUSION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PLEURISY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PNEUMONIA	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
PULMONARY EDEMA	1 (0.7%)	0	0	1 (0.7%)	0	1 (3.3%)	0	1 (3.3%)
RESPIRATORY DISORDER	7 (5.0%)	3 (2.2%)	1 (0.7%)	11 (7.9%)	0	1 (3.3%)	0	1 (3.3%)
RHINITIS	3 (2.2%)	3 (2.2%)	0	6 (4.3%)	0	1 (3.3%)	0	1 (3.3%)
SINUSITIS	1 (0.7%)	5 (3.6%)	0	6 (4.3%)	0	0	0	0
TRACHEITIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
SKIN AND APPENDAGES	13 (9.4%)	6 (4.3%)	0	19 (13.7%)	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
ALOPECIA	0	0	0	0	0	0	0	0
ANGIOEDEMA	0	0	0	0	0	0	0	0
BULLOUS ERUPTION	0	0	0	0	0	0	0	0
DERMATITIS	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
DERMATITIS FUNGAL	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
ECZEMA	4 (3.2%)	0	0	4 (3.2%)	0	3 (2.2%)	0	3 (2.2%)				
FOLLICULITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
FURUNCULOSIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
HYPERKERATOSIS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
NAIL DISORDER	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	1 (0.7%)	0	0	1 (0.7%)				
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
PHOTOSENSITIVITY REACTION	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
PRURITUS	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
PRURITUS GENITAL	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
PSORIASIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
PSORIASIS AGGRAVATED	0	1 (0.8%)	0	1 (0.8%)	0	0	1 (0.7%)	1 (0.7%)				
RASH	1 (0.8%)	0	0	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
RASH ERYTHEMATOUS	0	0	0	0	0	0	0	0				
RASH PUSTULAR	0	0	0	0	0	0	0	0				
ROSACEA	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
SEBORRHEA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
SKIN DRY	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
SKIN HYPERTROPHY	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
SKIN ULCERATION	0	1 (0.8%)	2 (1.6%)	3 (2.4%)	0	0	0	0				
VERRUCA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
URINARY SYSTEM	10 (8.1%)	8 (6.5%)	2 (1.6%)	17 (13.7%)	8 (5.9%)	10 (7.4%)	2 (1.5%)	17 (12.5%)				
ALBUMINURIA	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
CYSTITIS	1 (0.8%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
CYSTITIS HEMORRHAGIC	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
DYSURIA	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)				
HEMATURIA	3 (2.4%)	0	0	3 (2.4%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
MICTURITION DISORDER	0	0	0	0	0	0	0	0				
MICTURITION FREQUENCY	0	0	1 (0.8%)	1 (0.8%)	3 (2.2%)	0	0	3 (2.2%)				
POLYURIA	0	0	0	0	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
DERMATITIS FUNGAL	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
ECZEMA	5 (3.6%)	2 (1.4%)	0	7 (5.0%)	0	0	0	0
FOLLICULITIS	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
FURUNCULOSIS	0	0	0	0	0	0	0	0
HYPERKERATOSIS	0	0	0	0	0	0	0	0
NAIL DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0	0	0	0	0	0
PHOTOSENSITIVITY REACTION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PRURITUS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PRURITUS GENITAL	0	0	0	0	0	0	0	0
PSORIASIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PSORIASIS AGGRAVATED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RASH	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
RASH ERYTHEMATOUS	0	0	0	0	1 (3.3%)	0	0	1 (3.3%)
RASH PUSTULAR	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ROSACEA	0	0	0	0	0	0	0	0
SEBORRHEA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SKIN DRY	0	0	0	0	0	0	0	0
SKIN HYPERTROPHY	0	0	0	0	0	0	0	0
SKIN ULCERATION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VERRUCA	0	0	0	0	0	0	0	0
URINARY SYSTEM	17 (12.2%)	9 (6.5%)	4 (2.9%)	28 (20.1%)	5 (16.7%)	4 (13.3%)	2 (6.7%)	9 (30.0%)
ALBUMINURIA	1 (0.7%)	0	0	1 (0.7%)	2 (6.7%)	0	0	2 (6.7%)
CYSTITIS	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	0	0	0
CYSTITIS HEMORRHAGIC	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
DYSURIA	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
HEMATURIA	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)	1 (3.3%)	0	2 (6.7%)	3 (10.0%)
MICTURITION DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MICTURITION FREQUENCY	0	0	0	0	0	0	0	0
POLYURIA	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
PYELONEPHRITIS	0	0	0	0	0	0	0	0	0	0	0	0
PYURIA	0	0	0	0	0	0	0	0	0	0	0	0
RENAL CALCULUS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
RENAL PAIN	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
STRANGURY	0	0	0	0	0	0	0	0	0	0	0	0
URINARY INCONTINENCE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
URINARY TRACT INFECTION	6 (4.8%)	4 (3.2%)	0	10 (8.1%)	1 (0.7%)	7 (5.1%)	2 (1.5%)	10 (7.4%)				
VASCULAR EXTRACARDIAC	7 (5.6%)	6 (4.8%)	3 (2.4%)	15 (12.1%)	6 (4.4%)	13 (9.6%)	0	19 (14.0%)				
ARTERITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
CEREBROVASCULAR DISORDER	0	2 (1.6%)	0	2 (1.6%)	0	0	0	0				
CLAUDICATION INTERMITTENT	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
CRAMPS LEGS	2 (1.6%)	0	0	2 (1.6%)	3 (2.2%)	4 (2.9%)	0	7 (5.1%)				
EMBOLISM PULMONARY	0	0	0	0	0	0	0	0				
PERIPHERAL ISCHEMIA	1 (0.8%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	0	0	0	0				
PHLEBITIS	1 (0.8%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	0	1 (0.7%)	0	1 (0.7%)				
PHLEBITIS SUPERFICIAL	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
THROMBOPHLEBITIS DEEP	0	0	0	0	0	0	0	0				
VASCULAR DISORDER	0	0	1 (0.8%)	1 (0.8%)	1 (0.7%)	1 (0.7%)	0	2 (1.5%)				
VASCULITIS	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
VEIN DISORDER	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	1 (0.7%)	3 (2.2%)	0	4 (2.9%)				
VEIN VARICOSE	0	0	0	0	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
VISION	9 (7.3%)	5 (4.0%)	2 (1.6%)	16 (12.9%)	4 (2.9%)	5 (3.7%)	2 (1.5%)	11 (8.1%)				
BLEPHARITIS	0	0	0	0	0	0	0	0				
CATARACT	1 (0.8%)	0	1 (0.8%)	2 (1.6%)	1 (0.7%)	1 (0.7%)	2 (1.5%)	4 (2.9%)				
CONJUNCTIVAL HEMORRHAGE	0	0	0	0	0	0	0	0				
CONJUNCTIVITIS	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	1 (0.7%)	2 (1.5%)	0	3 (2.2%)				
CORNEAL OPACITY	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
EYE ABNORMALITY	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)				
GLAUCOMA	3 (2.4%)	0	0	3 (2.4%)	0	0	0	0				

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
PYELONEPHRITIS	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
PYURIA	0	0	0	0	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
RENAL CALCULUS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
RENAL PAIN	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
STRANGURY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
URINARY INCONTINENCE	0	0	0	0	0	0	0	0
URINARY TRACT INFECTION	14 (10.1%)	2 (1.4%)	0	16 (11.5%)	2 (6.7%)	2 (6.7%)	0	4 (13.3%)
VASCULAR EXTRACARDIAC	8 (5.8%)	11 (7.9%)	3 (2.2%)	19 (13.7%)	0	2 (6.7%)	0	2 (6.7%)
ARTERITIS	2 (1.4%)	0	1 (0.7%)	3 (2.2%)	0	0	0	0
CEREBROVASCULAR DISORDER	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
CLAUDICATION INTERMITTENT	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
CRAMPS LEGS	3 (2.2%)	3 (2.2%)	0	6 (4.3%)	0	1 (3.3%)	0	1 (3.3%)
EMBOLISM PULMONARY	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
PERIPHERAL ISCHEMIA	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
PHLEBITIS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PHLEBITIS SUPERFICIAL	0	0	0	0	0	0	0	0
THROMBOPHLEBITIS DEEP	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
VASCULAR DISORDER	1 (0.7%)	1 (0.7%)	1 (0.7%)	3 (2.2%)	0	0	0	0
VASCULITIS	0	0	0	0	0	0	0	0
VEIN DISORDER	2 (1.4%)	4 (2.9%)	0	6 (4.3%)	0	0	0	0
VEIN VARICOSE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
VISION	12 (8.6%)	8 (5.8%)	0	19 (13.7%)	1 (3.3%)	2 (6.7%)	0	3 (10.0%)
BLEPHARITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CATARACT	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	1 (3.3%)	0	1 (3.3%)
CONJUNCTIVAL HEMORRHAGE	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CONJUNCTIVITIS	7 (5.0%)	3 (2.2%)	0	10 (7.2%)	0	1 (3.3%)	0	1 (3.3%)
CORNEAL OPACITY	0	0	0	0	0	0	0	0
EYE ABNORMALITY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GLAUCOMA	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	76 (61.3%)	83 (66.9%)	30 (24.2%)	105 (84.7%)	75 (55.1%)	97 (71.3%)	34 (25.0%)	114 (83.8%)				
WHO Body System Preferred Term												
LACRIMATION ABNORMAL	0	0	0	0	0	0	0	0	0	0	0	0
RETINAL DETACHMENT	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0	0	0	0	0
RETINAL DISORDER	2 (1.6%)	2 (1.6%)	0	4 (3.2%)	2 (1.5%)	0	0	2 (1.5%)	1 (0.7%)	0	0	1 (0.7%)
VISION ABNORMAL	1 (0.8%)	1 (0.8%)	0	2 (1.6%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
VITREOUS DETACHMENT	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	1 (0.8%)	3 (2.4%)	0	4 (3.2%)	0	3 (2.2%)	0	3 (2.2%)	0	0	0	0
EOSINOPHILIA	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0	0	0	0	0
LEUKOPENIA	0	1 (0.8%)	0	1 (0.8%)	0	2 (1.5%)	0	2 (1.5%)	0	0	0	0
LYMPHADENOPATHY	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHANGITIS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0	0	0	0	0
LYMPHEDEMA	0	1 (0.8%)	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.2c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Intensity
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)

	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Intensity of Adverse Experience	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Patients with Adverse Experiences	79 (56.8%)	94 (67.6%)	28 (20.1%)	115 (82.7%)	20 (66.7%)	25 (83.3%)	9 (30.0%)	28 (93.3%)
WHO Body System Preferred Term								
LACRIMATION ABNORMAL	1 (0.7%)	0	0	1 (0.7%)	1 (3.3%)	0	0	1 (3.3%)
RETINAL DETACHMENT	0	0	0	0	0	0	0	0
RETINAL DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
VISION ABNORMAL	0	2 (1.4%)	0	2 (1.4%)	0	0	0	0
VITREOUS DETACHMENT	0	0	0	0	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	0	1 (0.7%)	0	1 (0.7%)	3 (10.0%)	1 (3.3%)	0	4 (13.3%)
EOSINOPHILIA	0	0	0	0	0	0	0	0
LEUKOPENIA	0	0	0	0	3 (10.0%)	1 (3.3%)	0	4 (13.3%)
LYMPHADENOPATHY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
LYMPHANGITIS	0	0	0	0	0	0	0	0
LYMPHEDEMA	0	0	0	0	0	0	0	0

Note: Any missing or unknown intensity is assumed, for the purpose of analyses, to be severe.

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	32 (14.0%)	20 (8.7%)	0	49 (21.4%)	62 (14.4%)	27 (6.3%)	4 (0.9%)	87 (20.2%)
WHO Body System Preferred Term								
BODY AS A WHOLE GENERAL	6 (2.6%)	1 (0.4%)	0	7 (3.1%)	14 (3.3%)	4 (0.9%)	0	18 (4.2%)
CHEST PAIN	0	1 (0.4%)	0	1 (0.4%)	0	3 (0.7%)	0	3 (0.7%)
INJURY	4 (1.7%)	0	0	4 (1.7%)	12 (2.8%)	1 (0.2%)	0	13 (3.0%)
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	0	0	2 (0.9%)	2 (0.5%)	0	0	2 (0.5%)
CARDIOVASCULAR GENERAL	7 (3.1%)	1 (0.4%)	0	8 (3.5%)	3 (0.7%)	3 (0.7%)	1 (0.2%)	7 (1.6%)
CARDIAC FAILURE	3 (1.3%)	1 (0.4%)	0	4 (1.7%)	2 (0.5%)	2 (0.5%)	1 (0.2%)	5 (1.2%)
CARDIAC FAILURE LEFT	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
HYPERTENSION AGGRAVATED	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
SYNCOPE	2 (0.9%)	0	0	2 (0.9%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
DIZZINESS	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
HYPESTHESIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
NEURALGIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PARESTHESIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
COLLAGEN	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ARTHRITIS RHEUMATOID	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ENDOCRINE	2 (0.9%)	0	0	2 (0.9%)	0	0	1 (0.2%)	1 (0.2%)
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GOITRE	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GYNECOMASTIA	0	0	0	0	0	0	1 (0.2%)	1 (0.2%)
HYPERPARATHYROIDISM	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GASTROINTESTINAL SYSTEM	4 (1.7%)	6 (2.6%)	0	10 (4.4%)	8 (1.9%)	2 (0.5%)	0	10 (2.3%)
ABDOMINAL PAIN	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ANUS DISORDER	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
COLITIS	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
CONSTIPATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DUODENAL ULCER	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ENTERITIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
GASTRIC ULCER	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0

Data Source Table 15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	32 (14.0%)	20 (8.7%)	0	49 (21.4%)	62 (14.4%)	27 (6.3%)	4 (0.9%)	87 (20.2%)
WHO Body System Preferred Term								
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GASTRITIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
GASTROINTESTINAL DISORDER NOS	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
GI HEMORRHAGE	0	2 (0.9%)	0	2 (0.9%)	0	0	0	0
HEMORRHAGE RECTUM	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
INTESTINAL PERFORATION	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
VOMITING	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
HEARING AND VESTIBULAR	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	0	0
DEAFNESS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
OTOSCLEROSIS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
HEART RATE AND RHYTHM	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	5 (1.2%)	4 (0.9%)	0	9 (2.1%)
ARRHYTHMIA ATRIAL	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
ATRIOVENTRICULAR BLOCK	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
BRADYCARDIA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
FIBRILLATION ATRIAL	0	1 (0.4%)	0	1 (0.4%)	2 (0.5%)	3 (0.7%)	0	5 (1.2%)
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
LIVER AND BILIARY SYSTEM	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	1 (0.2%)	0	1 (0.2%)
BILIARY PAIN	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
CHOLELITHIASIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GALL BLADDER DISORDER	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
HEPATITIS CHOLESTATIC	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
METABOLIC AND NUTRITIONAL	1 (0.4%)	1 (0.4%)	0	2 (0.9%)	0	0	1 (0.2%)	1 (0.2%)
DIABETES MELLITUS AGGRAVATED	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
HYPERGLYCEMIA	1 (0.4%)	0	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
MUSCULOSKELETAL SYSTEM	4 (1.7%)	0	0	4 (1.7%)	6 (1.4%)	1 (0.2%)	1 (0.2%)	8 (1.9%)
ARTHRALGIA	1 (0.4%)	0	0	1 (0.4%)	0	0	1 (0.2%)	1 (0.2%)
ARTHRITIS	1 (0.4%)	0	0	1 (0.4%)	4 (0.9%)	0	0	4 (0.9%)
ARTHROPATHY	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0

Data Source Table 15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	32 (14.0%)	20 (8.7%)	0	49 (21.4%)	62 (14.4%)	27 (6.3%)	4 (0.9%)	87 (20.2%)
WHO Body System Preferred Term								
ARTHROSIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
BURSITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
MYALGIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	5 (1.2%)	6 (1.4%)	0	11 (2.6%)
ANGINA PECTORIS	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
MYOCARDIAL INFARCTION	2 (0.9%)	2 (0.9%)	0	4 (1.7%)	3 (0.7%)	4 (0.9%)	0	7 (1.6%)
MYOCARDIAL ISCHEMIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
THROMBOSIS CORONARY	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
NEOPLASM	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	8 (1.9%)	5 (1.2%)	0	13 (3.0%)
BASAL CELL CARCINOMA	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
BLADDER CARCINOMA	0	0	0	0	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
BRAIN NEOPLASM BENIGN CARCINOMA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
GASTRIC CARCINOMA	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
HEPATIC NEOPLASM MALIGNANT	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
MELANOMA MALIGNANT	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
NEOPLASM MALIGNANT	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
NEOPLASM NOS	0	0	0	0	1 (0.2%)	1 (0.2%)	0	2 (0.5%)
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PULMONARY CARCINOMA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
PSYCHIATRIC	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
DEMENTIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
SUICIDE ATTEMPT	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
RED BLOOD CELL ANEMIA	2 (0.9%)	1 (0.4%)	0	3 (1.3%)	0	1 (0.2%)	0	1 (0.2%)
REPRODUCTIVE MALE PROSTATIC DISORDER	0	1 (0.4%)	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)

Data Source Table 15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	32 (14.0%)	20 (8.7%)	0	49 (21.4%)	62 (14.4%)	27 (6.3%)	4 (0.9%)	87 (20.2%)
WHO Body System Preferred Term								
RESISTANCE MECHANISM	4 (1.7%)	0	0	4 (1.7%)	3 (0.7%)	0	0	3 (0.7%)
ABSCESS	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
INFECTION	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	0	0	2 (0.5%)
INFECTION BACTERIAL	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
OTITIS MEDIA	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
UPPER RESP TRACT INFECTION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
RESPIRATORY SYSTEM	3 (1.3%)	2 (0.9%)	0	5 (2.2%)	2 (0.5%)	4 (0.9%)	1 (0.2%)	7 (1.6%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
DYSPNEA	1 (0.4%)	2 (0.9%)	0	3 (1.3%)	0	0	0	0
EPISTAXIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
PNEUMONIA	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
PULMONARY EDEMA	2 (0.9%)	0	0	2 (0.9%)	0	1 (0.2%)	1 (0.2%)	2 (0.5%)
RESPIRATORY DISORDER	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
RESPIRATORY INSUFFICIENCY	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
SKIN AND APPENDAGES	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
PSORIASIS AGGRAVATED	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
SKIN ULCERATION	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
URINARY SYSTEM	0	1 (0.4%)	0	1 (0.4%)	4 (0.9%)	0	0	4 (0.9%)
HEMATURIA	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
HYDRONEPHROSIS	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
PYELONEPHRITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
RENAL FAILURE ACUTE	0	1 (0.4%)	0	1 (0.4%)	0	0	0	0
RENAL PAIN	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
VASCULAR EXTRACARDIAC	1 (0.4%)	3 (1.3%)	0	4 (1.7%)	6 (1.4%)	3 (0.7%)	0	9 (2.1%)
ARTERITIS	0	0	0	0	2 (0.5%)	0	0	2 (0.5%)
CEREBROVASCULAR DISORDER	0	2 (0.9%)	0	2 (0.9%)	1 (0.2%)	2 (0.5%)	0	3 (0.7%)
EMBOLISM PULMONARY	0	1 (0.4%)	0	1 (0.4%)	0	1 (0.2%)	0	1 (0.2%)
PERIPHERAL ISCHEMIA	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
PHLEBITIS	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
THROMBOPHLEBITIS DEEP	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)

Data Source Table 15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Entered Study 009

Relationship to Study Medication	2bd Comb Total (N=229)				4bd Mono Total (N=430)			
	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	32 (14.0%)	20 (8.7%)	0	49 (21.4%)	62 (14.4%)	27 (6.3%)	4 (0.9%)	87 (20.2%)
WHO Body System Preferred Term								
VASCULAR DISORDER	1 (0.4%)	0	0	1 (0.4%)	1 (0.2%)	0	0	1 (0.2%)
VEIN DISORDER	0	0	0	0	1 (0.2%)	0	0	1 (0.2%)
VISION	1 (0.4%)	0	0	1 (0.4%)	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
CATARACT	0	0	0	0	2 (0.5%)	1 (0.2%)	0	3 (0.7%)
EYE ABNORMALITY	1 (0.4%)	0	0	1 (0.4%)	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)
LEUKOPENIA	0	0	0	0	0	1 (0.2%)	0	1 (0.2%)

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				2bd Comb Total				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	11 (18.0%)	6 (9.8%)	0	17 (27.9%)	9 (11.5%)	6 (7.7%)	0	13 (16.7%)				
WHO Body System Preferred Term												
BODY AS A WHOLE GENERAL	2 (3.3%)	0	0	2 (3.3%)	0	1 (1.3%)	0	1 (1.3%)				
CHEST PAIN	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
INJURY	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
CARDIOVASCULAR GENERAL	5 (8.2%)	1 (1.6%)	0	6 (9.8%)	1 (1.3%)	0	0	1 (1.3%)				
CARDIAC FAILURE	2 (3.3%)	1 (1.6%)	0	3 (4.9%)	1 (1.3%)	0	0	1 (1.3%)				
CARDIAC FAILURE LEFT	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
HYPERTENSION AGGRAVATED	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
SYNCOPE	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	0	0	0	0	0	0	0				
DIZZINESS	0	0	0	0	0	0	0	0				
COLLAGEN	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ARTHRITIS RHEUMATOID	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
ENDOCRINE	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0	0	0	0	0				
GOITRE	0	0	0	0	0	0	0	0				
HYPERPARATHYROIDISM	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
GASTROINTESTINAL SYSTEM	1 (1.6%)	2 (3.3%)	0	3 (4.9%)	2 (2.6%)	2 (2.6%)	0	4 (5.1%)				
ANUS DISORDER	0	0	0	0	0	0	0	0				
COLITIS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
DUODENAL ULCER	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0				
ENTERITIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				
GASTRIC ULCER	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
GASTRITIS	0	0	0	0	0	0	0	0				
GASTROINTESTINAL DISORDER NOS	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)				
GI HEMORRHAGE	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0				
INTESTINAL PERFORATION	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)				

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	2bd Comb Total 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	12 (13.3%)	8 (8.9%)	0	19 (21.1%)
WHO Body System Preferred Term				
BODY AS A WHOLE GENERAL	4 (4.4%)	0	0	4 (4.4%)
CHEST PAIN	0	0	0	0
INJURY	3 (3.3%)	0	0	3 (3.3%)
THERAPEUTIC RESPONSE INCREASED	1 (1.1%)	0	0	1 (1.1%)
CARDIOVASCULAR GENERAL	1 (1.1%)	0	0	1 (1.1%)
CARDIAC FAILURE	0	0	0	0
CARDIAC FAILURE LEFT	0	0	0	0
HYPERTENSION AGGRAVATED	0	0	0	0
SYNCOPE	1 (1.1%)	0	0	1 (1.1%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	1 (1.1%)	0	1 (1.1%)
DIZZINESS	0	1 (1.1%)	0	1 (1.1%)
COLLAGEN	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0
ENDOCRINE	1 (1.1%)	0	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	1 (1.1%)	0	0	1 (1.1%)
GOITRE	1 (1.1%)	0	0	1 (1.1%)
HYPERPARATHYROIDISM	0	0	0	0
GASTROINTESTINAL SYSTEM	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
ANUS DISORDER	1 (1.1%)	0	0	1 (1.1%)
COLITIS	0	0	0	0
DUODENAL ULCER	0	0	0	0
ENTERITIS	0	0	0	0
GASTRIC ULCER	0	0	0	0
GASTRITIS	0	1 (1.1%)	0	1 (1.1%)
GASTROINTESTINAL DISORDER NOS	0	0	0	0
GI HEMORRHAGE	0	1 (1.1%)	0	1 (1.1%)
INTESTINAL PERFORATION	0	0	0	0

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	11 (18.0%)	6 (9.8%)	0	17 (27.9%)	9 (11.5%)	6 (7.7%)	0	13 (16.7%)
WHO Body System Preferred Term								
VOMITING	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
HEARING AND VESTIBULAR	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
DEAFNESS	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
OTOSCLEROSIS	0	0	0	0	0	0	0	0
HEART RATE AND RHYTHM	0	0	0	0	0	0	0	0
ARRHYTHMIA ATRIAL	0	0	0	0	0	0	0	0
FIBRILLATION ATRIAL	0	0	0	0	0	0	0	0
LIVER AND BILIARY SYSTEM	0	0	0	0	0	0	0	0
HEPATITIS CHOLESTATIC	0	0	0	0	0	0	0	0
METABOLIC AND NUTRITIONAL	1 (1.6%)	0	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)
DIABETES MELLITUS AGGRAVATED	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
HYPERGLYCEMIA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
MUSCULOSKELETAL SYSTEM	2 (3.3%)	0	0	2 (3.3%)	2 (2.6%)	0	0	2 (2.6%)
ARTHRALGIA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
ARTHRITIS	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
ARTHROPATHY	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
BONE DEVELOPMENT ABNORMAL	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	1 (1.6%)	0	0	1 (1.6%)	1 (1.3%)	0	0	1 (1.3%)
ANGINA PECTORIS	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
MYOCARDIAL INFARCTION	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
NEOPLASM	0	1 (1.6%)	0	1 (1.6%)	0	1 (1.3%)	0	1 (1.3%)
BASAL CELL CARCINOMA	0	0	0	0	0	0	0	0
GASTRIC CARCINOMA	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
PULMONARY CARCINOMA	0	0	0	0	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0

- 745 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	2bd Comb Total 015:2bd+S/2bd (N=90)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	12 (13.3%)	8 (8.9%)	0	19 (21.1%)
WHO Body System Preferred Term				
VOMITING	0	0	0	0
HEARING AND VESTIBULAR	1 (1.1%)	0	0	1 (1.1%)
DEAFNESS	0	0	0	0
OTOSCLEROSIS	1 (1.1%)	0	0	1 (1.1%)
HEART RATE AND RHYTHM	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
ARRHYTHMIA ATRIAL	1 (1.1%)	0	0	1 (1.1%)
FIBRILLATION ATRIAL	0	1 (1.1%)	0	1 (1.1%)
LIVER AND BILIARY SYSTEM	1 (1.1%)	0	0	1 (1.1%)
HEPATITIS CHOLESTATIC	1 (1.1%)	0	0	1 (1.1%)
METABOLIC AND NUTRITIONAL	0	0	0	0
DIABETES MELLITUS AGGRAVATED	0	0	0	0
HYPERGLYCEMIA	0	0	0	0
MUSCULOSKELETAL SYSTEM	0	0	0	0
ARTHRALGIA	0	0	0	0
ARTHRITIS	0	0	0	0
ARTHROPATHY	0	0	0	0
BONE DEVELOPMENT ABNORMAL	0	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
VALVE				
ANGINA PECTORIS	0	0	0	0
MYOCARDIAL INFARCTION	1 (1.1%)	2 (2.2%)	0	3 (3.3%)
NEOPLASM	1 (1.1%)	1 (1.1%)	0	2 (2.2%)
BASAL CELL CARCINOMA	0	1 (1.1%)	0	1 (1.1%)
GASTRIC CARCINOMA	0	0	0	0
PULMONARY CARCINOMA	1 (1.1%)	0	0	1 (1.1%)
SKIN NEOPLASM MALIGNANT	0	0	0	0

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)				015:1bd+S/2bd (N=78)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	11 (18.0%)	6 (9.8%)	0	17 (27.9%)	9 (11.5%)	6 (7.7%)	0	13 (16.7%)
WHO Body System Preferred Term								
RED BLOOD CELL ANEMIA	1 (1.6%) 1 (1.6%)	0 0	0 0	1 (1.6%) 1 (1.6%)	0 0	0 0	0 0	0 0
REPRODUCTIVE MALE PROSTATIC DISORDER	0 0	0 0	0 0	0 0	0 0	1 (1.3%) 1 (1.3%)	0 0	1 (1.3%) 1 (1.3%)
RESISTANCE MECHANISM ABSCESS	1 (1.6%) 0	0 0	0 0	1 (1.6%) 0	1 (1.3%) 0	0 0	0 0	1 (1.3%) 0
INFECTION INFECTION BACTERIAL	1 (1.6%) 0	0 0	0 0	1 (1.6%) 0	0 1 (1.3%)	0 0	0 0	0 1 (1.3%)
OTITIS MEDIA	0	0	0	0	0	0	0	0
RESPIRATORY SYSTEM DYSPNEA	1 (1.6%) 1 (1.6%)	0 0	0 0	1 (1.6%) 1 (1.6%)	1 (1.3%) 0	0 0	0 0	1 (1.3%) 0
EPISTAXIS	0	0	0	0	0	0	0	0
PNEUMONIA	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
PULMONARY EDEMA	1 (1.6%)	0	0	1 (1.6%)	0	0	0	0
RESPIRATORY INSUFFICIENCY	0	0	0	0	0	0	0	0
URINARY SYSTEM HYDRONEPHROSIS	0 0	0 0	0 0	0 0	0 0	1 (1.3%) 1 (1.3%)	0 0	1 (1.3%) 1 (1.3%)
RENAL FAILURE ACUTE	0	0	0	0	0	1 (1.3%)	0	1 (1.3%)
VASCULAR EXTRACARDIAC CEREBROVASCULAR DISORDER	0 0	2 (3.3%) 1 (1.6%)	0 0	2 (3.3%) 1 (1.6%)	1 (1.3%) 0	0 0	0 0	1 (1.3%) 0
EMBOLISM PULMONARY	0	1 (1.6%)	0	1 (1.6%)	0	0	0	0
VASCULAR DISORDER	0	0	0	0	1 (1.3%)	0	0	1 (1.3%)
VISION EYE ABNORMALITY	0 0	0 0	0 0	0 0	1 (1.3%) 1 (1.3%)	0 0	0 0	1 (1.3%) 1 (1.3%)

- 747 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

(Cont'd)	2bd Comb Total 015:2bd+S/2bd (N=90)			
	Not Rel.	Unlikely	Susp/Prob	Total
Relationship to Study Medication				
Patients with Adverse Experiences	12 (13.3%)	8 (8.9%)	0	19 (21.1%)
WHO Body System Preferred Term				
RED BLOOD CELL ANEMIA	1 (1.1%) 1 (1.1%)	1 (1.1%) 1 (1.1%)	0 0	2 (2.2%) 2 (2.2%)
REPRODUCTIVE MALE PROSTATIC DISORDER	0 0	0 0	0 0	0 0
RESISTANCE MECHANISM ABSCESS INFECTION INFECTION BACTERIAL OTITIS MEDIA	2 (2.2%) 1 (1.1%) 0 0 1 (1.1%)	0 0 0 0 0	0 0 0 0 0	2 (2.2%) 1 (1.1%) 0 0 1 (1.1%)
RESPIRATORY SYSTEM DYSPNEA EPISTAXIS PNEUMONIA PULMONARY EDEMA RESPIRATORY INSUFFICIENCY	1 (1.1%) 0 0 0 1 (1.1%) 0	2 (2.2%) 2 (2.2%) 1 (1.1%) 0 0 1 (1.1%)	0 0 0 0 0 0	3 (3.3%) 2 (2.2%) 1 (1.1%) 0 1 (1.1%) 1 (1.1%)
URINARY SYSTEM HYDRONEPHROSIS RENAL FAILURE ACUTE	0 0 0	0 0 0	0 0 0	0 0 0
VASCULAR EXTRACARDIAC CEREBROVASCULAR DISORDER EMBOLISM PULMONARY VASCULAR DISORDER	0 0 0 0	1 (1.1%) 1 (1.1%) 0 0	0 0 0 0	1 (1.1%) 1 (1.1%) 0 0
VISION EYE ABNORMALITY	0 0	0 0	0 0	0 0

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				4bd Mono Total				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	21 (16.9%)	5 (4.0%)	1 (0.8%)	27 (21.8%)	24 (17.6%)	9 (6.6%)	1 (0.7%)	31 (22.8%)				
WHO Body System Preferred Term												
BODY AS A WHOLE GENERAL	5 (4.0%)	1 (0.8%)	0	6 (4.8%)	7 (5.1%)	0	0	7 (5.1%)				
CHEST PAIN	0	0	0	0	0	0	0	0				
INJURY	4 (3.2%)	1 (0.8%)	0	5 (4.0%)	7 (5.1%)	0	0	7 (5.1%)				
THERAPEUTIC RESPONSE INCREASED	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
CARDIOVASCULAR GENERAL	2 (1.6%)	0	0	2 (1.6%)	0	0	0	0				
CARDIAC FAILURE	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
SYNCOPE	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	1 (0.8%)	0	1 (0.8%)	1 (0.7%)	0	0	1 (0.7%)				
DIZZINESS	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
HYPESTHESIA	0	0	0	0	0	0	0	0				
NEURALGIA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
PARESTHESIA	0	1 (0.8%)	0	1 (0.8%)	0	0	0	0				
ENDOCRINE	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0				
GYNECOMASTIA	0	0	1 (0.8%)	1 (0.8%)	0	0	0	0				
GASTROINTESTINAL SYSTEM	5 (4.0%)	0	0	5 (4.0%)	3 (2.2%)	1 (0.7%)	0	4 (2.9%)				
ABDOMINAL PAIN	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
COLITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
CONSTIPATION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
DUODENAL ULCER	1 (0.8%)	0	0	1 (0.8%)	0	1 (0.7%)	0	1 (0.7%)				
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
GASTROINTESTINAL DISORDER NOS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
HEMORRHAGE RECTUM	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
INTESTINAL PERFORATION	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)				
VOMITING	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0				
HEART RATE AND RHYTHM	0	0	0	0	3 (2.2%)	3 (2.2%)	0	6 (4.4%)				

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	17 (12.2%)	12 (8.6%)	1 (0.7%)	27 (19.4%)	0	1 (3.3%)	1 (3.3%)	2 (6.7%)
WHO Body System Preferred Term								
BODY AS A WHOLE GENERAL	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	1 (3.3%)	0	1 (3.3%)
CHEST PAIN	0	2 (1.4%)	0	2 (1.4%)	0	1 (3.3%)	0	1 (3.3%)
INJURY	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
THERAPEUTIC RESPONSE INCREASED	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
CARDIOVASCULAR GENERAL	1 (0.7%)	3 (2.2%)	0	4 (2.9%)	0	0	1 (3.3%)	1 (3.3%)
CARDIAC FAILURE	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	0	1 (3.3%)	1 (3.3%)
SYNCOPE	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
DIZZINESS	0	0	0	0	0	0	0	0
HYPESTHESIA	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
NEURALGIA	0	0	0	0	0	0	0	0
PARESTHESIA	0	0	0	0	0	0	0	0
ENDOCRINE	0	0	0	0	0	0	0	0
GYNECOMASTIA	0	0	0	0	0	0	0	0
GASTROINTESTINAL SYSTEM	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
ABDOMINAL PAIN	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
COLITIS	0	0	0	0	0	0	0	0
CONSTIPATION	0	0	0	0	0	0	0	0
DUODENAL ULCER	0	0	0	0	0	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0	0	0	0	0	0
GASTROINTESTINAL DISORDER NOS	0	0	0	0	0	0	0	0
HEMORRHAGE RECTUM	0	0	0	0	0	0	0	0
INTESTINAL PERFORATION	0	0	0	0	0	0	0	0
VOMITING	0	0	0	0	0	0	0	0
HEART RATE AND RHYTHM	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	21 (16.9%)	5 (4.0%)	1 (0.8%)	27 (21.8%)	24 (17.6%)	9 (6.6%)	1 (0.7%)	31 (22.8%)
WHO Body System Preferred Term								
ARRHYTHMIA VENTRICULAR	0	0	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	0	0	1 (0.7%)	1 (0.7%)	0	2 (1.5%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
BRADYCARDIA	0	0	0	0	2 (1.5%)	0	0	2 (1.5%)
FIBRILLATION ATRIAL	0	0	0	0	0	2 (1.5%)	0	2 (1.5%)
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
LIVER AND BILIARY SYSTEM	0	0	0	0	0	0	0	0
BILIARY PAIN	0	0	0	0	0	0	0	0
CHOLELITHIASIS	0	0	0	0	0	0	0	0
GALL BLADDER DISORDER	0	0	0	0	0	0	0	0
METABOLIC AND NUTRITIONAL	0	0	0	0	0	0	0	0
HYPERGLYCEMIA	0	0	0	0	0	0	0	0
MUSCULOSKELETAL SYSTEM	5 (4.0%)	0	0	5 (4.0%)	0	1 (0.7%)	1 (0.7%)	2 (1.5%)
ARTHRALGIA	0	0	0	0	0	0	1 (0.7%)	1 (0.7%)
ARTHRITIS	3 (2.4%)	0	0	3 (2.4%)	0	0	0	0
ARTHROSIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0
BURSITIS	1 (0.8%)	0	0	1 (0.8%)	0	0	0	0
MYALGIA	0	0	0	0	0	1 (0.7%)	0	1 (0.7%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	0	1 (0.8%)	0	1 (0.8%)	3 (2.2%)	2 (1.5%)	0	5 (3.7%)
ANGINA PECTORIS	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
MYOCARDIAL INFARCTION	0	1 (0.8%)	0	1 (0.8%)	2 (1.5%)	2 (1.5%)	0	4 (2.9%)
MYOCARDIAL ISCHEMIA	0	0	0	0	0	0	0	0
THROMBOSIS CORONARY	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)
NEOPLASM	2 (1.6%)	1 (0.8%)	0	3 (2.4%)	2 (1.5%)	1 (0.7%)	0	3 (2.2%)
BASAL CELL CARCINOMA	0	0	0	0	1 (0.7%)	0	0	1 (0.7%)

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	17 (12.2%)	12 (8.6%)	1 (0.7%)	27 (19.4%)	0	1 (3.3%)	1 (3.3%)	2 (6.7%)
WHO Body System Preferred Term								
ARRHYTHMIA VENTRICULAR	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0	0	0	0	0	0
BRADYCARDIA	0	0	0	0	0	0	0	0
FIBRILLATION ATRIAL	2 (1.4%)	1 (0.7%)	0	3 (2.2%)	0	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0	0	0	0	0	0
LIVER AND BILIARY SYSTEM	1 (0.7%)	1 (0.7%)	0	1 (0.7%)	0	0	0	0
BILIARY PAIN	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CHOLELITHIASIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
GALL BLADDER DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
METABOLIC AND NUTRITIONAL	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
HYPERGLYCEMIA	0	0	1 (0.7%)	1 (0.7%)	0	0	0	0
MUSCULOSKELETAL SYSTEM	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ARTHRALGIA	0	0	0	0	0	0	0	0
ARTHRITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
ARTHROSIS	0	0	0	0	0	0	0	0
BURSITIS	0	0	0	0	0	0	0	0
MYALGIA	0	0	0	0	0	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	1 (3.3%)	0	1 (3.3%)
ANGINA PECTORIS	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
MYOCARDIAL INFARCTION	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
MYOCARDIAL ISCHEMIA	0	0	0	0	0	1 (3.3%)	0	1 (3.3%)
THROMBOSIS CORONARY	0	0	0	0	0	0	0	0
NEOPLASM	4 (2.9%)	3 (2.2%)	0	7 (5.0%)	0	0	0	0
BASAL CELL CARCINOMA	0	0	0	0	0	0	0	0

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	21(16.9%)	5(4.0%)	1(0.8%)	27(21.8%)	24(17.6%)	9(6.6%)	1(0.7%)	31(22.8%)
WHO Body System Preferred Term								
BLADDER CARCINOMA	0	0	0	0	0	1(0.7%)	0	1(0.7%)
BRAIN NEOPLASM BENIGN CARCINOMA	0	0	0	0	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	1(0.8%)	1(0.8%)	0	2(1.6%)	0	0	0	0
MELANOMA MALIGNANT	1(0.8%)	0	0	1(0.8%)	0	0	0	0
NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0
NEOPLASM NOS	0	0	0	0	1(0.7%)	0	0	1(0.7%)
PHARYNX NEOPLASM MALIGNANT	0	0	0	0	1(0.7%)	0	0	1(0.7%)
PSYCHIATRIC	0	0	0	0	1(0.7%)	0	0	1(0.7%)
DEMENTIA	0	0	0	0	0	0	0	0
SUICIDE ATTEMPT	0	0	0	0	1(0.7%)	0	0	1(0.7%)
RED BLOOD CELL ANEMIA	0	1(0.8%)	0	1(0.8%)	0	0	0	0
	0	1(0.8%)	0	1(0.8%)	0	0	0	0
REPRODUCTIVE MALE PROSTATIC DISORDER	0	0	0	0	1(0.7%)	0	0	1(0.7%)
	0	0	0	0	1(0.7%)	0	0	1(0.7%)
RESISTANCE MECHANISM	1(0.8%)	0	0	1(0.8%)	1(0.7%)	0	0	1(0.7%)
INFECTION	1(0.8%)	0	0	1(0.8%)	1(0.7%)	0	0	1(0.7%)
UPPER RESP TRACT INFECTION	0	0	0	0	0	0	0	0
RESPIRATORY SYSTEM	1(0.8%)	0	0	1(0.8%)	0	2(1.5%)	0	2(1.5%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEA	1(0.8%)	0	0	1(0.8%)	0	0	0	0
PNEUMONIA	0	0	0	0	1(0.7%)	0	0	1(0.7%)
PULMONARY EDEMA	0	0	0	0	1(0.7%)	0	0	1(0.7%)
RESPIRATORY DISORDER	0	0	0	0	0	0	0	0
SKIN AND APPENDAGES	1(0.8%)	0	0	1(0.8%)	1(0.7%)	0	0	1(0.7%)

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	17 (12.2%)	12 (8.6%)	1 (0.7%)	27 (19.4%)	0	1 (3.3%)	1 (3.3%)	2 (6.7%)
WHO Body System Preferred Term								
BLADDER CARCINOMA	1 (0.7%)	1 (0.7%)	0	2 (1.4%)	0	0	0	0
BRAIN NEOPLASM BENIGN CARCINOMA	1 (0.7%) 0	0 0	0 0	1 (0.7%) 0	0 0	0 0	0 0	0 0
HEPATIC NEOPLASM MALIGNANT	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
MELANOMA MALIGNANT	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
NEOPLASM MALIGNANT	0	0	0	0	0	0	0	0
NEOPLASM NOS	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PHARYNX NEOPLASM MALIGNANT	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PSYCHIATRIC	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
DEMENTIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
SUICIDE ATTEMPT	0	0	0	0	0	0	0	0
RED BLOOD CELL ANEMIA	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
REPRODUCTIVE MALE PROSTATIC DISORDER	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
RESISTANCE MECHANISM	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
INFECTION	0	0	0	0	0	0	0	0
UPPER RESP TRACT INFECTION	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RESPIRATORY SYSTEM	1 (0.7%)	2 (1.4%)	0	3 (2.2%)	0	0	1 (3.3%)	1 (3.3%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEA	0 1 (0.7%)	0 1 (0.7%)	0 0	0 2 (1.4%)	0 0	0 0	0 1 (3.3%)	0 1 (3.3%)
PNEUMONIA	0	0	0	0	0	0	0	0
PULMONARY EDEMA	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
RESPIRATORY DISORDER	0	0	0	0	0	0	0	0
SKIN AND APPENDAGES	0	0	0	0	0	0	0	0

- 754 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)				020:2bd/4bd (N=136)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	21(16.9%)	5(4.0%)	1(0.8%)	27(21.8%)	24(17.6%)	9(6.6%)	1(0.7%)	31(22.8%)
WHO Body System Preferred Term								
PSORIASIS AGGRAVATED	0	0	0	0	1(0.7%)	0	0	1(0.7%)
SKIN ULCERATION	1(0.8%)	0	0	1(0.8%)	0	0	0	0
URINARY SYSTEM	1(0.8%)	0	0	1(0.8%)	1(0.7%)	0	0	1(0.7%)
HEMATURIA	0	0	0	0	1(0.7%)	0	0	1(0.7%)
PYELONEPHRITIS	0	0	0	0	0	0	0	0
RENAL PAIN	1(0.8%)	0	0	1(0.8%)	0	0	0	0
VASCULAR EXTRACARDIAC	3(2.4%)	1(0.8%)	0	4(3.2%)	1(0.7%)	0	0	1(0.7%)
ARTERITIS	0	0	0	0	0	0	0	0
CEREBROVASCULAR DISORDER	1(0.8%)	1(0.8%)	0	2(1.6%)	0	0	0	0
EMBOLISM PULMONARY	0	0	0	0	0	0	0	0
PERIPHERAL ISCHEMIA	1(0.8%)	0	0	1(0.8%)	0	0	0	0
PHLEBITIS	1(0.8%)	0	0	1(0.8%)	0	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0	0	0	0	0	0
VASCULAR DISORDER	0	0	0	0	0	0	0	0
VEIN DISORDER	0	0	0	0	1(0.7%)	0	0	1(0.7%)
VISION	0	0	0	0	2(1.5%)	0	0	2(1.5%)
CATARACT	0	0	0	0	2(1.5%)	0	0	2(1.5%)
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	0	0	0	0	0	1(0.7%)	0	1(0.7%)
LEUKOPENIA	0	0	0	0	0	1(0.7%)	0	1(0.7%)

- 755 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences
by Relationship to Study Medication
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

(Cont'd)	4bd Mono Total 020:G/4bd (N=139)				025:Total (N=30)			
Relationship to Study Medication	Not Rel.	Unlikely	Susp/Prob	Total	Not Rel.	Unlikely	Susp/Prob	Total
Patients with Adverse Experiences	17 (12.2%)	12 (8.6%)	1 (0.7%)	27 (19.4%)	0	1 (3.3%)	1 (3.3%)	2 (6.7%)
WHO Body System Preferred Term								
PSORIASIS AGGRAVATED	0	0	0	0	0	0	0	0
SKIN ULCERATION	0	0	0	0	0	0	0	0
URINARY SYSTEM	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
HEMATURIA	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
PYELONEPHRITIS	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
RENAL PAIN	0	0	0	0	0	0	0	0
VASCULAR EXTRACARDIAC	2 (1.4%)	2 (1.4%)	0	4 (2.9%)	0	0	0	0
ARTERITIS	2 (1.4%)	0	0	2 (1.4%)	0	0	0	0
CEREBROVASCULAR DISORDER	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
EMBOLISM PULMONARY	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
PERIPHERAL ISCHEMIA	0	0	0	0	0	0	0	0
PHLEBITIS	0	0	0	0	0	0	0	0
THROMBOPHLEBITIS DEEP	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
VASCULAR DISORDER	1 (0.7%)	0	0	1 (0.7%)	0	0	0	0
VEIN DISORDER	0	0	0	0	0	0	0	0
VISION	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
CATARACT	0	1 (0.7%)	0	1 (0.7%)	0	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	0	0	0	0	0	0	0	0
LEUKOPENIA	0	0	0	0	0	0	0	0

*This section contained patient narratives which are textual descriptions of medical history, treatment and outcome for individual patients who experienced a clinically important adverse event including serious adverse events during the trial. They have been excluded to protect patient privacy. This data may be made available subject to an approved research proposal and a determination of the ability to provide information from the specific narratives whilst protecting the patient's privacy. For further information please see the Patient Level Data section of the **GSK Clinical Study Register**.*

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
INJURY	4 (1.7%)	13 (3.0%)
MYOCARDIAL INFARCTION	4 (1.7%)	7 (1.6%)
CARDIAC FAILURE	4 (1.7%)	5 (1.2%)
FIBRILLATION ATRIAL	1 (0.4%)	5 (1.2%)
ARTHRITIS	1 (0.4%)	4 (0.9%)
CEREBROVASCULAR DISORDER	2 (0.9%)	3 (0.7%)
ANGINA PECTORIS	1 (0.4%)	3 (0.7%)
CHEST PAIN	1 (0.4%)	3 (0.7%)
PNEUMONIA	1 (0.4%)	3 (0.7%)
BLADDER CARCINOMA	0	3 (0.7%)
CATARACT	0	3 (0.7%)
PULMONARY EDEMA	2 (0.9%)	2 (0.5%)
SYNCOPE	2 (0.9%)	2 (0.5%)
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	2 (0.5%)
DUODENAL ULCER	1 (0.4%)	2 (0.5%)
INFECTION	1 (0.4%)	2 (0.5%)
ABDOMINAL PAIN	0	2 (0.5%)
ARTERITIS	0	2 (0.5%)
ATRIOVENTRICULAR BLOCK	0	2 (0.5%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
BRADYCARDIA	0	2 (0.5%)
CARCINOMA	0	2 (0.5%)
HEMATURIA	0	2 (0.5%)
HEPATIC NEOPLASM MALIGNANT	0	2 (0.5%)
NEOPLASM NOS	0	2 (0.5%)
ANEMIA	3 (1.3%)	1 (0.2%)
ARTHRALGIA	1 (0.4%)	1 (0.2%)
BASAL CELL CARCINOMA	1 (0.4%)	1 (0.2%)
COLITIS	1 (0.4%)	1 (0.2%)
DIZZINESS	1 (0.4%)	1 (0.2%)
EMBOLISM PULMONARY	1 (0.4%)	1 (0.2%)
GASTROINTESTINAL DISORDER NOS	1 (0.4%)	1 (0.2%)
HYPERGLYCEMIA	1 (0.4%)	1 (0.2%)
INTESTINAL PERFORATION	1 (0.4%)	1 (0.2%)
PROSTATIC DISORDER	1 (0.4%)	1 (0.2%)
VASCULAR DISORDER	1 (0.4%)	1 (0.2%)
VOMITING	1 (0.4%)	1 (0.2%)
ARRHYTHMIA VENTRICULAR	0	1 (0.2%)
ARTHROSIS	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.2%)
BILIARY PAIN	0	1 (0.2%)
BRAIN NEOPLASM BENIGN	0	1 (0.2%)
BURSITIS	0	1 (0.2%)
CHOLELITHIASIS	0	1 (0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	1 (0.2%)
CONSTIPATION	0	1 (0.2%)
DEMENTIA	0	1 (0.2%)
GALL BLADDER DISORDER	0	1 (0.2%)
GASTRIC ULCER HEMORRHAGIC	0	1 (0.2%)
GYNECOMASTIA	0	1 (0.2%)
HEMORRHAGE RECTUM	0	1 (0.2%)
HYPESTHESIA	0	1 (0.2%)
LEUKOPENIA	0	1 (0.2%)
MELANOMA MALIGNANT	0	1 (0.2%)
MYALGIA	0	1 (0.2%)
MYOCARDIAL ISCHEMIA	0	1 (0.2%)
NEOPLASM MALIGNANT	0	1 (0.2%)
NEURALGIA	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
PARESTHESIA	0	1 (0.2%)
PERIPHERAL ISCHEMIA	0	1 (0.2%)
PHARYNX NEOPLASM MALIGNANT	0	1 (0.2%)
PHLEBITIS	0	1 (0.2%)
PSORIASIS AGGRAVATED	0	1 (0.2%)
PYELONEPHRITIS	0	1 (0.2%)
RENAL PAIN	0	1 (0.2%)
RESPIRATORY DISORDER	0	1 (0.2%)
SKIN ULCERATION	0	1 (0.2%)
SUICIDE ATTEMPT	0	1 (0.2%)
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.2%)
THROMBOPHLEBITIS DEEP	0	1 (0.2%)
THROMBOSIS CORONARY	0	1 (0.2%)
UPPER RESP TRACT INFECTION	0	1 (0.2%)
VEIN DISORDER	0	1 (0.2%)
DYSPNEA	3 (1.3%)	0
GI HEMORRHAGE	2 (0.9%)	0
ABSCESS	1 (0.4%)	0
ANUS DISORDER	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
ARRHYTHMIA ATRIAL	1 (0.4%)	0
ARTHRITIS RHEUMATOID	1 (0.4%)	0
ARTHROPATHY	1 (0.4%)	0
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0
CARDIAC FAILURE LEFT	1 (0.4%)	0
DEAFNESS	1 (0.4%)	0
DIABETES MELLITUS AGGRAVATED	1 (0.4%)	0
ENTERITIS	1 (0.4%)	0
EPISTAXIS	1 (0.4%)	0
EYE ABNORMALITY	1 (0.4%)	0
GASTRIC CARCINOMA	1 (0.4%)	0
GASTRIC ULCER	1 (0.4%)	0
GASTRITIS	1 (0.4%)	0
GOITRE	1 (0.4%)	0
HEPATITIS CHOLESTATIC	1 (0.4%)	0
HYDRONEPHROSIS	1 (0.4%)	0
HYPERPARATHYROIDISM	1 (0.4%)	0
HYPERTENSION AGGRAVATED	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3a

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Serious Non-Fatal Adverse Experiences	49 (21.4%)	87 (20.2%)
Preferred Term		
INFECTION BACTERIAL	1 (0.4%)	0
OTITIS MEDIA	1 (0.4%)	0
OTOSCLEROSIS	1 (0.4%)	0
PULMONARY CARCINOMA	1 (0.4%)	0
RENAL FAILURE ACUTE	1 (0.4%)	0
RESPIRATORY INSUFFICIENCY	1 (0.4%)	0
SKIN NEOPLASM MALIGNANT	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
INJURY	1 (1.6%)	0	3 (3.3%)
MYOCARDIAL INFARCTION	1 (1.6%)	0	3 (3.3%)
ANEMIA	1 (1.6%)	0	2 (2.2%)
DYSPNEA	1 (1.6%)	0	2 (2.2%)
CEREBROVASCULAR DISORDER	1 (1.6%)	0	1 (1.1%)
GI HEMORRHAGE	1 (1.6%)	0	1 (1.1%)
PULMONARY EDEMA	1 (1.6%)	0	1 (1.1%)
SYNCOPE	1 (1.6%)	0	1 (1.1%)
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	1 (1.1%)
ABSCESS	0	0	1 (1.1%)
ANUS DISORDER	0	0	1 (1.1%)
ARRHYTHMIA ATRIAL	0	0	1 (1.1%)
BASAL CELL CARCINOMA	0	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	0	0	1 (1.1%)
DIZZINESS	0	0	1 (1.1%)
EPISTAXIS	0	0	1 (1.1%)
FIBRILLATION ATRIAL	0	0	1 (1.1%)
GASTRITIS	0	0	1 (1.1%)
GOITRE	0	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
HEPATITIS CHOLESTATIC	0	0	1 (1.1%)
OTITIS MEDIA	0	0	1 (1.1%)
OTOSCLEROSIS	0	0	1 (1.1%)
PULMONARY CARCINOMA	0	0	1 (1.1%)
RESPIRATORY INSUFFICIENCY	0	0	1 (1.1%)
CARDIAC FAILURE	3 (4.9%)	1 (1.3%)	0
ANGINA PECTORIS	0	1 (1.3%)	0
ARTHRITIS RHEUMATOID	0	1 (1.3%)	0
ARTHROPATHY	0	1 (1.3%)	0
BONE DEVELOPMENT ABNORMAL	0	1 (1.3%)	0
CHEST PAIN	0	1 (1.3%)	0
DIABETES MELLITUS AGGRAVATED	0	1 (1.3%)	0
ENTERITIS	0	1 (1.3%)	0
EYE ABNORMALITY	0	1 (1.3%)	0
GASTRIC CARCINOMA	0	1 (1.3%)	0
GASTRIC ULCER	0	1 (1.3%)	0
GASTROINTESTINAL DISORDER NOS	0	1 (1.3%)	0
HYDRONEPHROSIS	0	1 (1.3%)	0
INFECTION BACTERIAL	0	1 (1.3%)	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
INTESTINAL PERFORATION	0	1 (1.3%)	0
PNEUMONIA	0	1 (1.3%)	0
PROSTATIC DISORDER	0	1 (1.3%)	0
RENAL FAILURE ACUTE	0	1 (1.3%)	0
VASCULAR DISORDER	0	1 (1.3%)	0
VOMITING	0	1 (1.3%)	0
ARTHRALGIA	1 (1.6%)	0	0
ARTHRITIS	1 (1.6%)	0	0
CARDIAC FAILURE LEFT	1 (1.6%)	0	0
COLITIS	1 (1.6%)	0	0
DEAFNESS	1 (1.6%)	0	0
DUODENAL ULCER	1 (1.6%)	0	0
EMBOLISM PULMONARY	1 (1.6%)	0	0
HYPERGLYCEMIA	1 (1.6%)	0	0
HYPERPARATHYROIDISM	1 (1.6%)	0	0
HYPERTENSION AGGRAVATED	1 (1.6%)	0	0
INFECTION	1 (1.6%)	0	0
SKIN NEOPLASM MALIGNANT	1 (1.6%)	0	0
ABDOMINAL PAIN	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
ARRHYTHMIA VENTRICULAR	0	0	0
ARTERITIS	0	0	0
ARTHROSIS	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0
BILIARY PAIN	0	0	0
BLADDER CARCINOMA	0	0	0
BRADYCARDIA	0	0	0
BRAIN NEOPLASM BENIGN	0	0	0
BURSITIS	0	0	0
CARCINOMA	0	0	0
CATARACT	0	0	0
CHOLELITHIASIS	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	0	0
CONSTIPATION	0	0	0
DEMENTIA	0	0	0
GALL BLADDER DISORDER	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0
GYNECOMASTIA	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
HEMATURIA	0	0	0
HEMORRHAGE RECTUM	0	0	0
HEPATIC NEOPLASM MALIGNANT	0	0	0
HYPESTHESIA	0	0	0
LEUKOPENIA	0	0	0
MELANOMA MALIGNANT	0	0	0
MYALGIA	0	0	0
MYOCARDIAL ISCHEMIA	0	0	0
NEOPLASM MALIGNANT	0	0	0
NEOPLASM NOS	0	0	0
NEURALGIA	0	0	0
PARESTHESIA	0	0	0
PERIPHERAL ISCHEMIA	0	0	0
PHARYNX NEOPLASM MALIGNANT	0	0	0
PHLEBITIS	0	0	0
PSORIASIS AGGRAVATED	0	0	0
PYELONEPHRITIS	0	0	0
RENAL PAIN	0	0	0
RESPIRATORY DISORDER	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3b

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Serious Non-Fatal Adverse Experiences	17 (27.9%)	13 (16.7%)	19 (21.1%)
Preferred Term			
SKIN ULCERATION	0	0	0
SUICIDE ATTEMPT	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0
THROMBOSIS CORONARY	0	0	0
UPPER RESP TRACT INFECTION	0	0	0
VEIN DISORDER	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
INJURY	5 (4.0%)	7 (5.1%)	1 (0.7%)	0
ARTHRITIS	3 (2.4%)	0	1 (0.7%)	0
CEREBROVASCULAR DISORDER	2 (1.6%)	0	1 (0.7%)	0
CARCINOMA	2 (1.6%)	0	0	0
MYOCARDIAL INFARCTION	1 (0.8%)	4 (2.9%)	2 (1.4%)	0
DUODENAL ULCER	1 (0.8%)	1 (0.7%)	0	0
INFECTION	1 (0.8%)	1 (0.7%)	0	0
CARDIAC FAILURE	1 (0.8%)	0	3 (2.2%)	1 (3.3%)
ABDOMINAL PAIN	1 (0.8%)	0	1 (0.7%)	0
HEPATIC NEOPLASM MALIGNANT	1 (0.8%)	0	1 (0.7%)	0
SYNCOPE	1 (0.8%)	0	1 (0.7%)	0
THERAPEUTIC RESPONSE INCREASED	1 (0.8%)	0	1 (0.7%)	0
ANEMIA	1 (0.8%)	0	0	0
ARTHROSIS	1 (0.8%)	0	0	0
BURSITIS	1 (0.8%)	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	1 (0.8%)	0	0	0
COLITIS	1 (0.8%)	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
DIZZINESS	1 (0.8%)	0	0	0
GYNECOMASTIA	1 (0.8%)	0	0	0
HEMORRHAGE RECTUM	1 (0.8%)	0	0	0
PARESTHESIA	1 (0.8%)	0	0	0
PERIPHERAL ISCHEMIA	1 (0.8%)	0	0	0
PHLEBITIS	1 (0.8%)	0	0	0
RENAL PAIN	1 (0.8%)	0	0	0
SKIN ULCERATION	1 (0.8%)	0	0	0
VOMITING	1 (0.8%)	0	0	0
FIBRILLATION ATRIAL	0	2 (1.5%)	3 (2.2%)	0
CATARACT	0	2 (1.5%)	1 (0.7%)	0
ATRIOVENTRICULAR BLOCK	0	2 (1.5%)	0	0
BRADYCARDIA	0	2 (1.5%)	0	0
ANGINA PECTORIS	0	1 (0.7%)	2 (1.4%)	0
BLADDER CARCINOMA	0	1 (0.7%)	2 (1.4%)	0
PNEUMONIA	0	1 (0.7%)	2 (1.4%)	0
HEMATURIA	0	1 (0.7%)	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
NEOPLASM NOS	0	1 (0.7%)	1 (0.7%)	0
PULMONARY EDEMA	0	1 (0.7%)	0	1 (3.3%)
ARTHRALGIA	0	1 (0.7%)	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.7%)	0	0
BASAL CELL CARCINOMA	0	1 (0.7%)	0	0
CONSTIPATION	0	1 (0.7%)	0	0
GASTRIC ULCER HEMORRHAGIC	0	1 (0.7%)	0	0
GASTROINTESTINAL DISORDER NOS	0	1 (0.7%)	0	0
INTESTINAL PERFORATION	0	1 (0.7%)	0	0
LEUKOPENIA	0	1 (0.7%)	0	0
MYALGIA	0	1 (0.7%)	0	0
NEOPLASM MALIGNANT	0	1 (0.7%)	0	0
NEURALGIA	0	1 (0.7%)	0	0
PROSTATIC DISORDER	0	1 (0.7%)	0	0
PSORIASIS AGGRAVATED	0	1 (0.7%)	0	0
SUICIDE ATTEMPT	0	1 (0.7%)	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
THROMBOSIS CORONARY	0	1 (0.7%)	0	0
VEIN DISORDER	0	1 (0.7%)	0	0
CHEST PAIN	0	0	2 (1.4%)	1 (3.3%)
ARTERITIS	0	0	2 (1.4%)	0
ARRHYTHMIA VENTRICULAR	0	0	1 (0.7%)	0
BILIARY PAIN	0	0	1 (0.7%)	0
BRAIN NEOPLASM BENIGN	0	0	1 (0.7%)	0
CHOLELITHIASIS	0	0	1 (0.7%)	0
DEMENTIA	0	0	1 (0.7%)	0
EMBOLISM PULMONARY	0	0	1 (0.7%)	0
GALL BLADDER DISORDER	0	0	1 (0.7%)	0
HYPERGLYCEMIA	0	0	1 (0.7%)	0
MELANOMA MALIGNANT	0	0	1 (0.7%)	0
PHARYNX NEOPLASM MALIGNANT	0	0	1 (0.7%)	0
PYELONEPHRITIS	0	0	1 (0.7%)	0
RESPIRATORY DISORDER	0	0	1 (0.7%)	0
THROMBOPHLEBITIS DEEP	0	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
UPPER RESP TRACT INFECTION	0	0	1 (0.7%)	0
VASCULAR DISORDER	0	0	1 (0.7%)	0
HYPESTHESIA	0	0	0	1 (3.3%)
MYOCARDIAL ISCHEMIA	0	0	0	1 (3.3%)
ABSCESS	0	0	0	0
ANUS DISORDER	0	0	0	0
ARRHYTHMIA ATRIAL	0	0	0	0
ARTHRITIS RHEUMATOID	0	0	0	0
ARTHROPATHY	0	0	0	0
BONE DEVELOPMENT ABNORMAL	0	0	0	0
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0
CARDIAC FAILURE LEFT	0	0	0	0
DEAFNESS	0	0	0	0
DIABETES MELLITUS AGGRAVATED	0	0	0	0
DYSPNEA	0	0	0	0
ENTERITIS	0	0	0	0
EPISTAXIS	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.3c

Summary of Serious Non-Fatal On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Serious Non-Fatal Adverse Experiences	27 (21.8%)	31 (22.8%)	27 (19.4%)	2 (6.7%)
Preferred Term				
EYE ABNORMALITY	0	0	0	0
GASTRIC CARCINOMA	0	0	0	0
GASTRIC ULCER	0	0	0	0
GASTRITIS	0	0	0	0
GI HEMORRHAGE	0	0	0	0
GOITRE	0	0	0	0
HEPATITIS CHOLESTATIC	0	0	0	0
HYDRONEPHROSIS	0	0	0	0
HYPERPARATHYROIDISM	0	0	0	0
HYPERTENSION AGGRAVATED	0	0	0	0
INFECTION BACTERIAL	0	0	0	0
OTITIS MEDIA	0	0	0	0
OTOSCLEROSIS	0	0	0	0
PULMONARY CARCINOMA	0	0	0	0
RENAL FAILURE ACUTE	0	0	0	0
RESPIRATORY INSUFFICIENCY	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
APPLICATION SITE	1 (0.4%)	5 (1.2%)
OTITIS EXTERNA	1 (0.4%)	4 (0.9%)
TYMPANIC MEMBRANE PERFORATION	0	1 (0.2%)
AUTONOMIC NERVOUS SYSTEM	1 (0.4%)	6 (1.4%)
SWEATING INCREASED	0	6 (1.4%)
VASOSPASM	1 (0.4%)	0
BODY AS A WHOLE GENERAL	70 (30.6%)	126 (29.3%)
ALCOHOL INTOLERANCE	1 (0.4%)	0
ALLERGIC REACTION	3 (1.3%)	3 (0.7%)
ALLERGY	2 (0.9%)	1 (0.2%)
ASTHENIA	4 (1.7%)	14 (3.3%)
CHEST PAIN	7 (3.1%)	11 (2.6%)
CHEST PAIN PRECORDIAL	0	2 (0.5%)
EDEMA	0	2 (0.5%)
EDEMA DEPENDENT	6 (2.6%)	7 (1.6%)
EDEMA GENERALISED	2 (0.9%)	2 (0.5%)
EDEMA LEGS	6 (2.6%)	25 (5.8%)
EDEMA PERIORBITAL	1 (0.4%)	2 (0.5%)
EDEMA PERIPHERAL	1 (0.4%)	3 (0.7%)
ESR INCREASED	0	1 (0.2%)
FACE EDEMA	0	2 (0.5%)
FATIGUE	4 (1.7%)	7 (1.6%)
FEVER	2 (0.9%)	2 (0.5%)
GRANULOMATOUS LESION	0	2 (0.5%)
HOT FLUSHES	0	3 (0.7%)
INFLUENZA-LIKE SYMPTOMS	1 (0.4%)	1 (0.2%)
INJURY	36 (15.7%)	60 (14.0%)
MALaise	4 (1.7%)	1 (0.2%)
NECROSIS ISCHEMIC	0	1 (0.2%)
PAIN	13 (5.7%)	19 (4.4%)
PALLOR	0	1 (0.2%)
RIGORS	0	2 (0.5%)
SUDDEN DEATH	1 (0.4%)	0
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	2 (0.5%)
CARDIOVASCULAR GENERAL	26 (11.4%)	43 (10.0%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
CARDIAC FAILURE	5 (2.2%)	8 (1.9%)
CARDIAC FAILURE LEFT	1 (0.4%)	2 (0.5%)
ECG ABNORMAL	1 (0.4%)	1 (0.2%)
ECG ABNORMAL SPECIFIC	0	2 (0.5%)
HEART DISORDER	0	1 (0.2%)
HEART VALVE DISORDERS	1 (0.4%)	1 (0.2%)
HYPERTENSION	9 (3.9%)	13 (3.0%)
HYPERTENSION AGGRAVATED	10 (4.4%)	9 (2.1%)
HYPOTENSION	0	3 (0.7%)
HYPOTENSION POSTURAL	1 (0.4%)	1 (0.2%)
SYNCOPE	4 (1.7%)	5 (1.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	46 (20.1%)	77 (17.9%)
CARPAL TUNNEL SYNDROME	1 (0.4%)	3 (0.7%)
CONVULSIONS	1 (0.4%)	0
DIZZINESS	10 (4.4%)	8 (1.9%)
EDEMA CEREBRAL	0	1 (0.2%)
HEADACHE	8 (3.5%)	19 (4.4%)
HYPERESTHESIA	0	1 (0.2%)
HYPERKINESIA	0	1 (0.2%)
HYPESTHESIA	1 (0.4%)	3 (0.7%)
HYPOKINESIA	1 (0.4%)	0
MIGRAINE	1 (0.4%)	2 (0.5%)
MIGRAINE AGGRAVATED	1 (0.4%)	0
NEURALGIA	8 (3.5%)	32 (7.4%)
NEURITIS	1 (0.4%)	1 (0.2%)
NEUROPATHY	2 (0.9%)	2 (0.5%)
NEUROPATHY PERIPHERAL	5 (2.2%)	1 (0.2%)
PARESIS	1 (0.4%)	1 (0.2%)
PARESTHESIA	6 (2.6%)	10 (2.3%)
PTOSIS	0	1 (0.2%)
SPEECH DISORDER	0	1 (0.2%)
TETANY	1 (0.4%)	1 (0.2%)
TREMOR	1 (0.4%)	2 (0.5%)
TRIGEMINAL NEURALGIA	1 (0.4%)	0
VERTIGO	3 (1.3%)	11 (2.6%)
COLLAGEN	1 (0.4%)	1 (0.2%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
ARTHRITIS RHEUMATOID	1 (0.4%)	1 (0.2%)
ENDOCRINE	4 (1.7%)	12 (2.8%)
BREAST PAIN MALE	1 (0.4%)	0
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0
GOITRE	2 (0.9%)	5 (1.2%)
GYNECOMASTIA	0	4 (0.9%)
HYPERPARATHYROIDISM	1 (0.4%)	0
HYPOTHYROIDISM	1 (0.4%)	3 (0.7%)
THYROID DISORDER	0	1 (0.2%)
GASTROINTESTINAL SYSTEM	58 (25.3%)	113 (26.3%)
ABDOMINAL PAIN	13 (5.7%)	23 (5.3%)
ANUS DISORDER	1 (0.4%)	4 (0.9%)
APPETITE INCREASED	1 (0.4%)	4 (0.9%)
COLITIS	2 (0.9%)	8 (1.9%)
CONSTIPATION	10 (4.4%)	15 (3.5%)
DIARRHEA	8 (3.5%)	13 (3.0%)
DIVERTICULITIS	2 (0.9%)	2 (0.5%)
DUODENAL ULCER	2 (0.9%)	2 (0.5%)
DYSPEPSIA	9 (3.9%)	12 (2.8%)
ENTERITIS	1 (0.4%)	1 (0.2%)
ESOPHAGEAL ULCERATION	0	1 (0.2%)
ESOPHAGITIS	2 (0.9%)	1 (0.2%)
FECAL INCONTINENCE	0	1 (0.2%)
FLATULENCE	2 (0.9%)	3 (0.7%)
GASTRIC ULCER	2 (0.9%)	5 (1.2%)
GASTRIC ULCER HEMORRHAGIC	0	1 (0.2%)
GASTRITIS	1 (0.4%)	6 (1.4%)
GASTROENTERITIS	6 (2.6%)	12 (2.8%)
GASTROESOPHAGEAL REFLUX	0	5 (1.2%)
GASTROINTESTINAL DISORDER NOS	2 (0.9%)	8 (1.9%)
GI HEMORRHAGE	2 (0.9%)	1 (0.2%)
GINGIVITIS	3 (1.3%)	0
HEMORRHAGE RECTUM	1 (0.4%)	2 (0.5%)
HEMORRHOIDS	0	4 (0.9%)
INTESTINAL ISCHEMIA	0	1 (0.2%)
INTESTINAL PERFORATION	1 (0.4%)	1 (0.2%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
IRRITABLE BOWEL SYNDROME	0	1 (0.2%)
NAUSEA	5 (2.2%)	11 (2.6%)
PERIODONTITIS	4 (1.7%)	14 (3.3%)
SALIVARY GLAND ENLARGEMENT	3 (1.3%)	1 (0.2%)
STOMATITIS	0	1 (0.2%)
STOMATITIS ULCERATIVE	0	2 (0.5%)
TONGUE EDEMA	0	1 (0.2%)
TONGUE ULCERATION	0	1 (0.2%)
TOOTH ACHE	4 (1.7%)	0
TOOTH CARIES	2 (0.9%)	1 (0.2%)
TOOTH DISORDER	0	1 (0.2%)
VOMITING	3 (1.3%)	3 (0.7%)
HEARING AND VESTIBULAR	9 (3.9%)	7 (1.6%)
DEAFNESS	5 (2.2%)	2 (0.5%)
EAR DISORDER NOS	1 (0.4%)	1 (0.2%)
EARACHE	0	2 (0.5%)
OTOSCLEROSIS	1 (0.4%)	0
TINNITUS	1 (0.4%)	2 (0.5%)
VESTIBULAR DISORDER	1 (0.4%)	0
HEART RATE AND RHYTHM	14 (6.1%)	33 (7.7%)
ARRHYTHMIA ATRIAL	1 (0.4%)	1 (0.2%)
ARRHYTHMIA VENTRICULAR	0	1 (0.2%)
ATRIOVENTRICULAR BLOCK	1 (0.4%)	4 (0.9%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.2%)
BRADYCARDIA	1 (0.4%)	3 (0.7%)
BUNDLE BRANCH BLOCK	1 (0.4%)	5 (1.2%)
EXTRASYSTOLES	1 (0.4%)	6 (1.4%)
FIBRILLATION ATRIAL	4 (1.7%)	10 (2.3%)
PALPITATION	2 (0.9%)	3 (0.7%)
QT INCREASED	2 (0.9%)	0
TACHYCARDIA	3 (1.3%)	3 (0.7%)
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.2%)
LIVER AND BILIARY SYSTEM	15 (6.6%)	11 (2.6%)
BILIARY PAIN	0	1 (0.2%)
BILIRUBINEMIA	1 (0.4%)	0

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
CHOLECYSTITIS	0	1 (0.2%)
CHOLELITHIASIS	0	2 (0.5%)
GALL BLADDER DISORDER	0	2 (0.5%)
GAMMA-GT INCREASED	6 (2.6%)	5 (1.2%)
HEPATIC ENZYMES INCREASED	2 (0.9%)	0
HEPATIC FUNCTION ABNORMAL	2 (0.9%)	2 (0.5%)
HEPATITIS CHOLESTATIC	1 (0.4%)	0
HEPATOMEGALY	0	1 (0.2%)
LIVER FATTY	2 (0.9%)	0
SGPT INCREASED	2 (0.9%)	0
METABOLIC AND NUTRITIONAL	100 (43.7%)	126 (29.3%)
ACIDOSIS	1 (0.4%)	0
ALKALOSIS RESPIRATORY	2 (0.9%)	0
BLOOD UREA NITROGEN INCREASED	3 (1.3%)	2 (0.5%)
CALCINOSIS	0	3 (0.7%)
DIABETES MELLITUS AGGRAVATED	23 (10.0%)	22 (5.1%)
GOUT	0	6 (1.4%)
HYPERCHOLESTEROLEMIA	19 (8.3%)	43 (10.0%)
HYPERGLYCEMIA	46 (20.1%)	16 (3.7%)
HYPERKALEMIA	0	1 (0.2%)
HYPERLIPEMIA	11 (4.8%)	23 (5.3%)
HYPERTRIGLYCERIDEMIA	1 (0.4%)	4 (0.9%)
HYPERURICEMIA	0	1 (0.2%)
HYPOCHOLESTEROLEMIA	0	1 (0.2%)
HYPOGLYCEMIA	14 (6.1%)	6 (1.4%)
HYPOGLYCEMIC REACTION	0	1 (0.2%)
HYPOKALEMIA	0	3 (0.7%)
NPN INCREASED	6 (2.6%)	5 (1.2%)
OBESITY	1 (0.4%)	2 (0.5%)
THIRST	3 (1.3%)	1 (0.2%)
WEIGHT DECREASE	0	2 (0.5%)
WEIGHT INCREASE	4 (1.7%)	17 (4.0%)
MUSCULOSKELETAL SYSTEM	63 (27.5%)	143 (33.3%)
ARTHRALGIA	20 (8.7%)	30 (7.0%)
ARTHRITIS	15 (6.6%)	42 (9.8%)
ARTHRITIS AGGRAVATED	6 (2.6%)	3 (0.7%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
ARTHROPATHY	1 (0.4%)	2 (0.5%)
ARTHROSIS	4 (1.7%)	23 (5.3%)
BACK PAIN	18 (7.9%)	51 (11.9%)
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0
BONE DISORDER	1 (0.4%)	1 (0.2%)
BURSITIS	0	2 (0.5%)
MUSCLE WEAKNESS	1 (0.4%)	0
MYALGIA	7 (3.1%)	21 (4.9%)
MYOPATHY	0	3 (0.7%)
MYOSITIS	2 (0.9%)	0
OSTEOMYELITIS	0	1 (0.2%)
OSTEOPOROSIS	2 (0.9%)	9 (2.1%)
SKELETAL PAIN	3 (1.3%)	5 (1.2%)
SYNOVITIS	1 (0.4%)	0
TENDINITIS	9 (3.9%)	11 (2.6%)
TORTICOLLIS	0	3 (0.7%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	17 (7.4%)	30 (7.0%)
ANGINA PECTORIS	9 (3.9%)	15 (3.5%)
ANGINA PECTORIS AGGRAVATED	1 (0.4%)	0
AORTIC STENOSIS	0	1 (0.2%)
CARDIOMYOPATHY	1 (0.4%)	0
CORONARY ARTERY DISORDER	1 (0.4%)	0
MYOCARDIAL INFARCTION	4 (1.7%)	10 (2.3%)
MYOCARDIAL ISCHEMIA	2 (0.9%)	5 (1.2%)
THROMBOSIS CORONARY	1 (0.4%)	1 (0.2%)
NEOPLASM	8 (3.5%)	25 (5.8%)
BASAL CELL CARCINOMA	3 (1.3%)	2 (0.5%)
BLADDER CARCINOMA	0	3 (0.7%)
BRAIN NEOPLASM BENIGN	0	1 (0.2%)
BREAST NEOPLASM FEMALE	0	1 (0.2%)
CARCINOMA	0	2 (0.5%)
GASTRIC CARCINOMA	1 (0.4%)	0
HEPATIC NEOPLASM MALIGNANT	0	2 (0.5%)
LIPOMA	1 (0.4%)	1 (0.2%)
MELANOMA MALIGNANT	0	1 (0.2%)
NEOPLASM MALIGNANT	0	1 (0.2%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
NEOPLASM NOS	1 (0.4%)	9 (2.1%)
PHARYNX NEOPLASM MALIGNANT	0	1 (0.2%)
PULMONARY CARCINOMA	1 (0.4%)	0
SKIN NEOPLASM MALIGNANT	1 (0.4%)	0
THYROID ADENOMA	0	1 (0.2%)
UTERINE FIBROID	0	1 (0.2%)
PLATELET BLEEDING AND CLOTTING	1 (0.4%)	5 (1.2%)
PURPURA	0	2 (0.5%)
THROMBOCYTOPENIA	1 (0.4%)	3 (0.7%)
PSYCHIATRIC	25 (10.9%)	46 (10.7%)
AMNESIA	1 (0.4%)	2 (0.5%)
ANXIETY	8 (3.5%)	11 (2.6%)
CONFUSION	1 (0.4%)	0
DEMENTIA	0	1 (0.2%)
DEPRESSION	8 (3.5%)	14 (3.3%)
EMOTIONAL LABILITY	2 (0.9%)	0
INSOMNIA	3 (1.3%)	15 (3.5%)
NERVOUSNESS	1 (0.4%)	4 (0.9%)
NEUROSIS	0	1 (0.2%)
SOMNOLENCE	6 (2.6%)	4 (0.9%)
SUICIDE ATTEMPT	0	1 (0.2%)
RED BLOOD CELL	12 (5.2%)	26 (6.0%)
ANEMIA	9 (3.9%)	20 (4.7%)
ANEMIA B TWELVE DEFICIENCY	1 (0.4%)	0
ANEMIA HYPOCHROMIC	1 (0.4%)	5 (1.2%)
ANEMIA NORMOCHROMIC	0	1 (0.2%)
ERYTHROCYTES ABNORMAL	1 (0.4%)	1 (0.2%)
REPRODUCTIVE FEMALE	4 (1.7%)	5 (1.2%)
MENORRHAGIA	0	1 (0.2%)
MENSTRUAL DISORDER	1 (0.4%)	3 (0.7%)
OVARIAN CYST	1 (0.4%)	0
OVARIAN DISORDER	0	1 (0.2%)
VAGINITIS	2 (0.9%)	2 (0.5%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
REPRODUCTIVE MALE	14 (6.1%)	16 (3.7%)
EPIDIDYMITIS	0	1 (0.2%)
IMPOTENCE	5 (2.2%)	6 (1.4%)
PENIS DISORDER	1 (0.4%)	0
PROSTATIC DISORDER	7 (3.1%)	8 (1.9%)
TESTIS DISORDER	1 (0.4%)	2 (0.5%)
RESISTANCE MECHANISM	70 (30.6%)	94 (21.9%)
ABSCCESS	2 (0.9%)	1 (0.2%)
HERPES SIMPLEX	1 (0.4%)	3 (0.7%)
HERPES ZOSTER	6 (2.6%)	3 (0.7%)
INFECTION	10 (4.4%)	11 (2.6%)
INFECTION BACTERIAL	4 (1.7%)	3 (0.7%)
INFECTION FUNGAL	2 (0.9%)	11 (2.6%)
INFECTION VIRAL	28 (12.2%)	38 (8.8%)
MONILIASIS	3 (1.3%)	3 (0.7%)
MONILIASIS GENITAL	4 (1.7%)	1 (0.2%)
OTITIS MEDIA	2 (0.9%)	8 (1.9%)
SEPSIS	0	3 (0.7%)
UPPER RESP TRACT INFECTION	29 (12.7%)	29 (6.7%)
RESPIRATORY SYSTEM	60 (26.2%)	153 (35.6%)
APNEA	0	1 (0.2%)
ASTHMA	1 (0.4%)	6 (1.4%)
BRONCHITIS	9 (3.9%)	69 (16.0%)
CHEST X-RAY ABNORMAL	0	1 (0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	3 (0.7%)
COUGHING	19 (8.3%)	15 (3.5%)
DYSPNEA	11 (4.8%)	13 (3.0%)
EPISTAXIS	1 (0.4%)	4 (0.9%)
HEMOPTYSIS	0	1 (0.2%)
LARYNGITIS	1 (0.4%)	4 (0.9%)
PHARYNGITIS	15 (6.6%)	29 (6.7%)
PLEURAL EFFUSION	0	1 (0.2%)
PLEURISY	0	1 (0.2%)
PNEUMONIA	1 (0.4%)	4 (0.9%)
PULMONARY EDEMA	2 (0.9%)	4 (0.9%)
RESPIRATORY DISORDER	19 (8.3%)	25 (5.8%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
RESPIRATORY INSUFFICIENCY	1 (0.4%)	0
RHINITIS	3 (1.3%)	16 (3.7%)
SINUSITIS	4 (1.7%)	13 (3.0%)
TRACHEITIS	0	7 (1.6%)
SKIN AND APPENDAGES	39 (17.0%)	53 (12.3%)
ALOPECIA	1 (0.4%)	1 (0.2%)
ANGIOEDEMA	0	1 (0.2%)
BULLOUS ERUPTION	0	1 (0.2%)
DERMATITIS	2 (0.9%)	4 (0.9%)
DERMATITIS FUNGAL	3 (1.3%)	2 (0.5%)
ECZEMA	5 (2.2%)	14 (3.3%)
FOLLICULITIS	0	3 (0.7%)
FURUNCULOSIS	3 (1.3%)	1 (0.2%)
HYPERKERATOSIS	3 (1.3%)	1 (0.2%)
NAIL DISORDER	2 (0.9%)	5 (1.2%)
NEVUS	1 (0.4%)	0
PHOTOSENSITIVITY ALLERGIC REACT	0	1 (0.2%)
PHOTOSENSITIVITY REACTION	0	2 (0.5%)
PRURITUS	7 (3.1%)	4 (0.9%)
PRURITUS GENITAL	0	1 (0.2%)
PSORIASIS	0	2 (0.5%)
PSORIASIS AGGRAVATED	0	3 (0.7%)
RASH	7 (3.1%)	7 (1.6%)
RASH ERYTHEMATOUS	3 (1.3%)	1 (0.2%)
RASH PUSTULAR	1 (0.4%)	1 (0.2%)
ROSACEA	0	2 (0.5%)
SEBORRHEA	1 (0.4%)	2 (0.5%)
SKIN DISORDER	3 (1.3%)	0
SKIN DRY	4 (1.7%)	1 (0.2%)
SKIN HYPERTROPHY	1 (0.4%)	2 (0.5%)
SKIN ULCERATION	1 (0.4%)	4 (0.9%)
URTICARIA	1 (0.4%)	0
VERRUCA	1 (0.4%)	1 (0.2%)
URINARY SYSTEM	38 (16.6%)	71 (16.5%)
ALBUMINURIA	1 (0.4%)	5 (1.2%)
CYSTITIS	1 (0.4%)	9 (2.1%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
CYSTITIS HEMORRHAGIC	0	3 (0.7%)
DYSURIA	2 (0.9%)	3 (0.7%)
HEMATURIA	4 (1.7%)	11 (2.6%)
HYDRONEPHROSIS	1 (0.4%)	0
MICTURITION DISORDER	0	1 (0.2%)
MICTURITION FREQUENCY	3 (1.3%)	4 (0.9%)
NOCTURIA	1 (0.4%)	0
POLYURIA	3 (1.3%)	1 (0.2%)
PYELONEPHRITIS	0	1 (0.2%)
PYURIA	5 (2.2%)	3 (0.7%)
RENAL CALCULUS	1 (0.4%)	2 (0.5%)
RENAL FAILURE ACUTE	3 (1.3%)	0
RENAL PAIN	0	2 (0.5%)
STRANGURY	0	1 (0.2%)
URETHRAL DISORDER	2 (0.9%)	0
URINARY INCONTINENCE	0	1 (0.2%)
URINARY TRACT INFECTION	24 (10.5%)	40 (9.3%)
VASCULAR EXTRACARDIAC	23 (10.0%)	55 (12.8%)
ARTERITIS	0	4 (0.9%)
ATHEROSCLEROSIS	1 (0.4%)	0
CEREBROVASCULAR DISORDER	2 (0.9%)	3 (0.7%)
CLAUDICATION INTERMITTENT	0	3 (0.7%)
CRAMPS LEGS	5 (2.2%)	16 (3.7%)
EMBOLISM PULMONARY	2 (0.9%)	1 (0.2%)
HEMORRHAGE NOS	1 (0.4%)	0
PERIPHERAL ISCHEMIA	2 (0.9%)	4 (0.9%)
PHLEBITIS	1 (0.4%)	5 (1.2%)
PHLEBITIS SUPERFICIAL	0	1 (0.2%)
THROMBOPHLEBITIS	1 (0.4%)	0
THROMBOPHLEBITIS DEEP	0	2 (0.5%)
VASCULAR DISORDER	5 (2.2%)	6 (1.4%)
VASCULITIS	0	1 (0.2%)
VEIN DISORDER	6 (2.6%)	14 (3.3%)
VEIN VARICOSE	3 (1.3%)	4 (0.9%)
VISION	22 (9.6%)	49 (11.4%)
BLEPHARITIS	1 (0.4%)	1 (0.2%)

Data Source Table 15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
WHO Body System Preferred Term		
CATARACT	7 (3.1%)	10 (2.3%)
CONJUNCTIVAL HEMORRHAGE	0	1 (0.2%)
CONJUNCTIVITIS	2 (0.9%)	18 (4.2%)
CORNEAL OPACITY	0	1 (0.2%)
DIPLOPIA	1 (0.4%)	0
EYE ABNORMALITY	4 (1.7%)	2 (0.5%)
EYE PAIN	2 (0.9%)	0
GLAUCOMA	2 (0.9%)	5 (1.2%)
LACRIMATION ABNORMAL	0	2 (0.5%)
MACULA LUTEA DEGENERATION	1 (0.4%)	0
RETINAL DETACHMENT	0	1 (0.2%)
RETINAL DISORDER	5 (2.2%)	7 (1.6%)
RETINITIS	1 (0.4%)	0
VISION ABNORMAL	2 (0.9%)	5 (1.2%)
VITREOUS DETACHMENT	0	1 (0.2%)
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	8 (3.5%)	12 (2.8%)
EOSINOPHILIA	1 (0.4%)	1 (0.2%)
GRANULOCYTOPENIA	1 (0.4%)	0
LEUKOCYTOSIS	1 (0.4%)	0
LEUKOPENIA	3 (1.3%)	7 (1.6%)
LYMPHADENOPATHY	0	1 (0.2%)
LYMPHADENOPATHY CERVICAL	1 (0.4%)	0
LYMPHANGITIS	1 (0.4%)	1 (0.2%)
LYMPHEDEMA	0	2 (0.5%)
LYMPHOPENIA	1 (0.4%)	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
APPLICATION SITE	0	1 (1.3%)	0
OTITIS EXTERNA	0	1 (1.3%)	0
TYMPANIC MEMBRANE PERFORATION	0	0	0
AUTONOMIC NERVOUS SYSTEM	0	1 (1.3%)	0
SWEATING INCREASED	0	0	0
VASOSPASM	0	1 (1.3%)	0
BODY AS A WHOLE GENERAL	23 (37.7%)	20 (25.6%)	27 (30.0%)
ALCOHOL INTOLERANCE	0	1 (1.3%)	0
ALLERGIC REACTION	1 (1.6%)	2 (2.6%)	0
ALLERGY	1 (1.6%)	1 (1.3%)	0
ASTHENIA	2 (3.3%)	0	2 (2.2%)
CHEST PAIN	1 (1.6%)	2 (2.6%)	4 (4.4%)
CHEST PAIN PRECORDIAL	0	0	0
EDEMA	0	0	0
EDEMA DEPENDENT	1 (1.6%)	2 (2.6%)	3 (3.3%)
EDEMA GENERALISED	1 (1.6%)	1 (1.3%)	0
EDEMA LEGS	0	3 (3.8%)	3 (3.3%)
EDEMA PERIORBITAL	0	1 (1.3%)	0
EDEMA PERIPHERAL	1 (1.6%)	0	0
ESR INCREASED	0	0	0
FACE EDEMA	0	0	0
FATIGUE	2 (3.3%)	0	2 (2.2%)
FEVER	1 (1.6%)	1 (1.3%)	0
GRANULOMATOUS LESION	0	0	0
HOT FLUSHES	0	0	0
INFLUENZA-LIKE SYMPTOMS	0	1 (1.3%)	0
INJURY	12 (19.7%)	10 (12.8%)	14 (15.6%)
MALAISE	1 (1.6%)	2 (2.6%)	1 (1.1%)
NECROSIS ISCHEMIC	0	0	0
PAIN	7 (11.5%)	1 (1.3%)	5 (5.6%)
PALLOR	0	0	0
RIGORS	0	0	0
SUDDEN DEATH	0	0	1 (1.1%)
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	1 (1.1%)
CARDIOVASCULAR GENERAL	10 (16.4%)	4 (5.1%)	12 (13.3%)
CARDIAC FAILURE	3 (4.9%)	1 (1.3%)	1 (1.1%)

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
CARDIAC FAILURE LEFT	1 (1.6%)	0	0
ECG ABNORMAL	1 (1.6%)	0	0
ECG ABNORMAL SPECIFIC	0	0	0
HEART DISORDER	0	0	0
HEART VALVE DISORDERS	1 (1.6%)	0	0
HYPERTENSION	3 (4.9%)	2 (2.6%)	4 (4.4%)
HYPERTENSION AGGRAVATED	3 (4.9%)	2 (2.6%)	5 (5.6%)
HYPOTENSION	0	0	0
HYPOTENSION POSTURAL	0	0	1 (1.1%)
SYNCOPE	2 (3.3%)	0	2 (2.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	14 (23.0%)	15 (19.2%)	17 (18.9%)
CARPAL TUNNEL SYNDROME	1 (1.6%)	0	0
CONVULSIONS	0	0	1 (1.1%)
DIZZINESS	4 (6.6%)	2 (2.6%)	4 (4.4%)
EDEMA CEREBRAL	0	0	0
HEADACHE	1 (1.6%)	5 (6.4%)	2 (2.2%)
HYPERESTHESIA	0	0	0
HYPERKINESIA	0	0	0
HYPESTHESIA	1 (1.6%)	0	0
HYPOKINESIA	0	1 (1.3%)	0
MIGRAINE	0	0	1 (1.1%)
MIGRAINE AGGRAVATED	0	0	1 (1.1%)
NEURALGIA	3 (4.9%)	2 (2.6%)	3 (3.3%)
NEURITIS	1 (1.6%)	0	0
NEUROPATHY	1 (1.6%)	1 (1.3%)	0
NEUROPATHY PERIPHERAL	0	2 (2.6%)	3 (3.3%)
PARESIS	0	1 (1.3%)	0
PARESTHESIA	2 (3.3%)	2 (2.6%)	2 (2.2%)
PTOSIS	0	0	0
SPEECH DISORDER	0	0	0
TETANY	0	1 (1.3%)	0
TREMOR	1 (1.6%)	0	0
TRIGEMINAL NEURALGIA	0	0	1 (1.1%)
VERTIGO	0	1 (1.3%)	2 (2.2%)
COLLAGEN	0	1 (1.3%)	0
ARTHRITIS RHEUMATOID	0	1 (1.3%)	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
ENDOCRINE	2 (3.3%)	0	2 (2.2%)
BREAST PAIN MALE	0	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	0	0	1 (1.1%)
GOITRE	1 (1.6%)	0	1 (1.1%)
GYNECOMASTIA	0	0	0
HYPERPARATHYROIDISM	1 (1.6%)	0	0
HYPOTHYROIDISM	1 (1.6%)	0	0
THYROID DISORDER	0	0	0
GASTROINTESTINAL SYSTEM	16 (26.2%)	23 (29.5%)	19 (21.1%)
ABDOMINAL PAIN	6 (9.8%)	4 (5.1%)	3 (3.3%)
ANUS DISORDER	0	0	1 (1.1%)
APPETITE INCREASED	0	0	1 (1.1%)
COLITIS	1 (1.6%)	0	1 (1.1%)
CONSTIPATION	3 (4.9%)	3 (3.8%)	4 (4.4%)
DIARRHEA	3 (4.9%)	4 (5.1%)	1 (1.1%)
DIVERTICULITIS	1 (1.6%)	1 (1.3%)	0
DUODENAL ULCER	1 (1.6%)	1 (1.3%)	0
DYSPEPSIA	0	6 (7.7%)	3 (3.3%)
ENTERITIS	0	1 (1.3%)	0
ESOPHAGEAL ULCERATION	0	0	0
ESOPHAGITIS	1 (1.6%)	1 (1.3%)	0
FECAL INCONTINENCE	0	0	0
FLATULENCE	0	1 (1.3%)	1 (1.1%)
GASTRIC ULCER	0	1 (1.3%)	1 (1.1%)
GASTRIC ULCER HEMORRHAGIC	0	0	0
GASTRITIS	0	0	1 (1.1%)
GASTROENTERITIS	2 (3.3%)	2 (2.6%)	2 (2.2%)
GASTROESOPHAGEAL REFLUX	0	0	0
GASTROINTESTINAL DISORDER NOS	1 (1.6%)	1 (1.3%)	0
GI HEMORRHAGE	1 (1.6%)	0	1 (1.1%)
GINGIVITIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
HEMORRHAGE RECTUM	1 (1.6%)	0	0
HEMORRHOIDS	0	0	0
INTESTINAL ISCHEMIA	0	0	0
INTESTINAL PERFORATION	0	1 (1.3%)	0
IRRITABLE BOWEL SYNDROME	0	0	0
NAUSEA	2 (3.3%)	1 (1.3%)	2 (2.2%)
PERIODONTITIS	1 (1.6%)	2 (2.6%)	1 (1.1%)

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
SALIVARY GLAND ENLARGEMENT	1 (1.6%)	2 (2.6%)	0
STOMATITIS	0	0	0
STOMATITIS ULCERATIVE	0	0	0
TONGUE EDEMA	0	0	0
TONGUE ULCERATION	0	0	0
TOOTH ACHE	0	2 (2.6%)	2 (2.2%)
TOOTH CARIES	0	0	2 (2.2%)
TOOTH DISORDER	0	0	0
VOMITING	1 (1.6%)	2 (2.6%)	0
HEARING AND VESTIBULAR	2 (3.3%)	1 (1.3%)	6 (6.7%)
DEAFNESS	1 (1.6%)	1 (1.3%)	3 (3.3%)
EAR DISORDER NOS	0	0	1 (1.1%)
EARACHE	0	0	0
OTOSCLEROSIS	0	0	1 (1.1%)
TINNITUS	0	0	1 (1.1%)
VESTIBULAR DISORDER	1 (1.6%)	0	0
HEART RATE AND RHYTHM	1 (1.6%)	6 (7.7%)	7 (7.8%)
ARRHYTHMIA ATRIAL	0	0	1 (1.1%)
ARRHYTHMIA VENTRICULAR	0	0	0
ATRIOVENTRICULAR BLOCK	0	0	1 (1.1%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0
BRADYCARDIA	0	0	1 (1.1%)
BUNDLE BRANCH BLOCK	0	0	1 (1.1%)
EXTRASYSTOLES	0	1 (1.3%)	0
FIBRILLATION ATRIAL	0	1 (1.3%)	3 (3.3%)
PALPITATION	0	1 (1.3%)	1 (1.1%)
QT INCREASED	0	2 (2.6%)	0
TACHYCARDIA	1 (1.6%)	2 (2.6%)	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0
LIVER AND BILIARY SYSTEM	2 (3.3%)	9 (11.5%)	4 (4.4%)
BILIARY PAIN	0	0	0
BILIRUBINEMIA	1 (1.6%)	0	0
CHOLECYSTITIS	0	0	0
CHOLELITHIASIS	0	0	0
GALL BLADDER DISORDER	0	0	0
GAMMA-GT INCREASED	1 (1.6%)	4 (5.1%)	1 (1.1%)

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
HEPATIC ENZYMES INCREASED	1 (1.6%)	1 (1.3%)	0
HEPATIC FUNCTION ABNORMAL	0	1 (1.3%)	1 (1.1%)
HEPATITIS CHOLESTATIC	0	0	1 (1.1%)
HEPATOMEGALY	0	0	0
LIVER FATTY	0	1 (1.3%)	1 (1.1%)
SGPT INCREASED	0	2 (2.6%)	0
METABOLIC AND NUTRITIONAL	29 (47.5%)	30 (38.5%)	41 (45.6%)
ACIDOSIS	0	0	1 (1.1%)
ALKALOSIS RESPIRATORY	0	0	2 (2.2%)
BLOOD UREA NITROGEN INCREASED	1 (1.6%)	0	2 (2.2%)
CALCINOSIS	0	0	0
DIABETES MELLITUS AGGRAVATED	7 (11.5%)	6 (7.7%)	10 (11.1%)
GOUT	0	0	0
HYPERCHOLESTEROLEMIA	8 (13.1%)	3 (3.8%)	8 (8.9%)
HYPERGLYCEMIA	13 (21.3%)	12 (15.4%)	21 (23.3%)
HYPERKALEMIA	0	0	0
HYPERLIPEMIA	4 (6.6%)	2 (2.6%)	5 (5.6%)
HYPERTRIGLYCERIDEMIA	0	1 (1.3%)	0
HYPERURICEMIA	0	0	0
HYPOCHOLESTEROLEMIA	0	0	0
HYPOGLYCEMIA	2 (3.3%)	9 (11.5%)	3 (3.3%)
HYPOGLYCEMIC REACTION	0	0	0
HYPOKALEMIA	0	0	0
NPN INCREASED	1 (1.6%)	2 (2.6%)	3 (3.3%)
OBESITY	0	0	1 (1.1%)
THIRST	1 (1.6%)	1 (1.3%)	1 (1.1%)
WEIGHT DECREASE	0	0	0
WEIGHT INCREASE	1 (1.6%)	1 (1.3%)	2 (2.2%)
MUSCULOSKELETAL SYSTEM	18 (29.5%)	20 (25.6%)	25 (27.8%)
ARTHRALGIA	8 (13.1%)	6 (7.7%)	6 (6.7%)
ARTHRITIS	4 (6.6%)	3 (3.8%)	8 (8.9%)
ARTHRITIS AGGRAVATED	2 (3.3%)	2 (2.6%)	2 (2.2%)
ARTHROPATHY	0	1 (1.3%)	0
ARTHROSIS	1 (1.6%)	1 (1.3%)	2 (2.2%)
BACK PAIN	6 (9.8%)	5 (6.4%)	7 (7.8%)
BONE DEVELOPMENT ABNORMAL	0	1 (1.3%)	0
BONE DISORDER	0	1 (1.3%)	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
BURSITIS	0	0	0
MUSCLE WEAKNESS	0	1 (1.3%)	0
MYALGIA	3 (4.9%)	1 (1.3%)	3 (3.3%)
MYOPATHY	0	0	0
MYOSITIS	2 (3.3%)	0	0
OSTEOMYELITIS	0	0	0
OSTEOPOROSIS	0	1 (1.3%)	1 (1.1%)
SKELETAL PAIN	2 (3.3%)	0	1 (1.1%)
SYNOVITIS	0	0	1 (1.1%)
TENDINITIS	3 (4.9%)	3 (3.8%)	3 (3.3%)
TORTICOLLIS	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	4 (6.6%)	7 (9.0%)	6 (6.7%)
ANGINA PECTORIS	1 (1.6%)	6 (7.7%)	2 (2.2%)
ANGINA PECTORIS AGGRAVATED	1 (1.6%)	0	0
AORTIC STENOSIS	0	0	0
CARDIOMYOPATHY	0	1 (1.3%)	0
CORONARY ARTERY DISORDER	0	0	1 (1.1%)
MYOCARDIAL INFARCTION	1 (1.6%)	0	3 (3.3%)
MYOCARDIAL ISCHEMIA	2 (3.3%)	0	0
THROMBOSIS CORONARY	0	1 (1.3%)	0
NEOPLASM	2 (3.3%)	3 (3.8%)	3 (3.3%)
BASAL CELL CARCINOMA	1 (1.6%)	1 (1.3%)	1 (1.1%)
BLADDER CARCINOMA	0	0	0
BRAIN NEOPLASM BENIGN	0	0	0
BREAST NEOPLASM FEMALE	0	0	0
CARCINOMA	0	0	0
GASTRIC CARCINOMA	0	1 (1.3%)	0
HEPATIC NEOPLASM MALIGNANT	0	0	0
LIPOMA	0	0	1 (1.1%)
MELANOMA MALIGNANT	0	0	0
NEOPLASM MALIGNANT	0	0	0
NEOPLASM NOS	0	1 (1.3%)	0
PHARYNX NEOPLASM MALIGNANT	0	0	0
PULMONARY CARCINOMA	0	0	1 (1.1%)
SKIN NEOPLASM MALIGNANT	1 (1.6%)	0	0
THYROID ADENOMA	0	0	0
UTERINE FIBROID	0	0	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
PLATELET BLEEDING AND CLOTTING	0	0	1 (1.1%)
PURPURA	0	0	0
THROMBOCYTOPENIA	0	0	1 (1.1%)
PSYCHIATRIC	9 (14.8%)	5 (6.4%)	11 (12.2%)
AMNESIA	1 (1.6%)	0	0
ANXIETY	0	2 (2.6%)	6 (6.7%)
CONFUSION	1 (1.6%)	0	0
DEMENTIA	0	0	0
DEPRESSION	3 (4.9%)	2 (2.6%)	3 (3.3%)
EMOTIONAL LABILITY	1 (1.6%)	0	1 (1.1%)
INSOMNIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
NERVOUSNESS	0	0	1 (1.1%)
NEUROSIS	0	0	0
SOMNOLENCE	3 (4.9%)	1 (1.3%)	2 (2.2%)
SUICIDE ATTEMPT	0	0	0
RED BLOOD CELL	3 (4.9%)	3 (3.8%)	6 (6.7%)
ANEMIA	1 (1.6%)	2 (2.6%)	6 (6.7%)
ANEMIA B TWELVE DEFICIENCY	1 (1.6%)	0	0
ANEMIA HYPOCHROMIC	1 (1.6%)	0	0
ANEMIA NORMOCHROMIC	0	0	0
ERYTHROCYTES ABNORMAL	0	1 (1.3%)	0
REPRODUCTIVE FEMALE	2 (3.3%)	0	2 (2.2%)
MENORRHAGIA	0	0	0
MENSTRUAL DISORDER	0	0	1 (1.1%)
OVARIAN CYST	0	0	1 (1.1%)
OVARIAN DISORDER	0	0	0
VAGINITIS	2 (3.3%)	0	0
REPRODUCTIVE MALE	5 (8.2%)	7 (9.0%)	2 (2.2%)
EPIDIDYMITIS	0	0	0
IMPOTENCE	3 (4.9%)	1 (1.3%)	1 (1.1%)
PENIS DISORDER	0	0	1 (1.1%)
PROSTATIC DISORDER	2 (3.3%)	5 (6.4%)	0
TESTIS DISORDER	0	1 (1.3%)	0
RESISTANCE MECHANISM	19 (31.1%)	24 (30.8%)	27 (30.0%)

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
ABSCCESS	0	0	2 (2.2%)
HERPES SIMPLEX	0	1 (1.3%)	0
HERPES ZOSTER	1 (1.6%)	4 (5.1%)	1 (1.1%)
INFECTION	5 (8.2%)	4 (5.1%)	1 (1.1%)
INFECTION BACTERIAL	2 (3.3%)	2 (2.6%)	0
INFECTION FUNGAL	0	0	2 (2.2%)
INFECTION VIRAL	10 (16.4%)	9 (11.5%)	9 (10.0%)
MONILIASIS	0	2 (2.6%)	1 (1.1%)
MONILIASIS GENITAL	0	1 (1.3%)	3 (3.3%)
OTITIS MEDIA	0	0	2 (2.2%)
SEPSIS	0	0	0
UPPER RESP TRACT INFECTION	6 (9.8%)	9 (11.5%)	14 (15.6%)
RESPIRATORY SYSTEM	15 (24.6%)	19 (24.4%)	26 (28.9%)
APNEA	0	0	0
ASTHMA	0	0	1 (1.1%)
BRONCHITIS	4 (6.6%)	2 (2.6%)	3 (3.3%)
CHEST X-RAY ABNORMAL	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	0	0
COUGHING	8 (13.1%)	5 (6.4%)	6 (6.7%)
DYSPNEA	1 (1.6%)	4 (5.1%)	6 (6.7%)
EPISTAXIS	0	0	1 (1.1%)
HEMOPTYSIS	0	0	0
LARYNGITIS	1 (1.6%)	0	0
PHARYNGITIS	4 (6.6%)	4 (5.1%)	7 (7.8%)
PLEURAL EFFUSION	0	0	0
PLEURISY	0	0	0
PNEUMONIA	0	1 (1.3%)	0
PULMONARY EDEMA	1 (1.6%)	0	1 (1.1%)
RESPIRATORY DISORDER	3 (4.9%)	6 (7.7%)	10 (11.1%)
RESPIRATORY INSUFFICIENCY	0	0	1 (1.1%)
RHINITIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
SINUSITIS	0	2 (2.6%)	2 (2.2%)
TRACHEITIS	0	0	0
SKIN AND APPENDAGES	14 (23.0%)	14 (17.9%)	11 (12.2%)
ALOPECIA	0	1 (1.3%)	0
ANGIOEDEMA	0	0	0
BULLOUS ERUPTION	0	0	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
DERMATITIS	1 (1.6%)	0	1 (1.1%)
DERMATITIS FUNGAL	1 (1.6%)	1 (1.3%)	1 (1.1%)
ECZEMA	2 (3.3%)	2 (2.6%)	1 (1.1%)
FOLLICULITIS	0	0	0
FURUNCULOSIS	0	2 (2.6%)	1 (1.1%)
HYPERKERATOSIS	1 (1.6%)	0	2 (2.2%)
NAIL DISORDER	1 (1.6%)	0	1 (1.1%)
NEVUS	0	0	1 (1.1%)
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0
PHOTOSENSITIVITY REACTION	0	0	0
PRURITUS	4 (6.6%)	2 (2.6%)	1 (1.1%)
PRURITUS GENITAL	0	0	0
PSORIASIS	0	0	0
PSORIASIS AGGRAVATED	0	0	0
RASH	3 (4.9%)	1 (1.3%)	3 (3.3%)
RASH ERYTHEMATOUS	1 (1.6%)	2 (2.6%)	0
RASH PUSTULAR	0	1 (1.3%)	0
ROSACEA	0	0	0
SEBORRHEA	0	1 (1.3%)	0
SKIN DISORDER	2 (3.3%)	0	1 (1.1%)
SKIN DRY	2 (3.3%)	0	2 (2.2%)
SKIN HYPERTROPHY	0	1 (1.3%)	0
SKIN ULCERATION	0	0	1 (1.1%)
URTICARIA	0	1 (1.3%)	0
VERRUCA	1 (1.6%)	0	0
URINARY SYSTEM	10 (16.4%)	15 (19.2%)	13 (14.4%)
ALBUMINURIA	1 (1.6%)	0	0
CYSTITIS	1 (1.6%)	0	0
CYSTITIS HEMORRHAGIC	0	0	0
DYSURIA	2 (3.3%)	0	0
HEMATURIA	0	2 (2.6%)	2 (2.2%)
HYDRONEPHROSIS	0	1 (1.3%)	0
MICTURITION DISORDER	0	0	0
MICTURITION FREQUENCY	0	3 (3.8%)	0
NOCTURIA	0	1 (1.3%)	0
POLYURIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
PELONEPHRITIS	0	0	0
PYURIA	1 (1.6%)	3 (3.8%)	1 (1.1%)

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
RENAL CALCULUS	0	1 (1.3%)	0
RENAL FAILURE ACUTE	1 (1.6%)	2 (2.6%)	0
RENAL PAIN	0	0	0
STRANGURY	0	0	0
URETHRAL DISORDER	0	0	2 (2.2%)
URINARY INCONTINENCE	0	0	0
URINARY TRACT INFECTION	4 (6.6%)	9 (11.5%)	11 (12.2%)
VASCULAR EXTRACARDIAC	8 (13.1%)	8 (10.3%)	7 (7.8%)
ARTERITIS	0	0	0
ATHEROSCLEROSIS	0	0	1 (1.1%)
CEREBROVASCULAR DISORDER	1 (1.6%)	0	1 (1.1%)
CLAUDICATION INTERMITTENT	0	0	0
CRAMPS LEGS	2 (3.3%)	3 (3.8%)	0
EMBOLISM PULMONARY	1 (1.6%)	0	1 (1.1%)
HEMORRHAGE NOS	0	1 (1.3%)	0
PERIPHERAL ISCHEMIA	0	1 (1.3%)	1 (1.1%)
PHLEBITIS	0	1 (1.3%)	0
PHLEBITIS SUPERFICIAL	0	0	0
THROMBOPHLEBITIS	0	0	1 (1.1%)
THROMBOPHLEBITIS DEEP	0	0	0
VASCULAR DISORDER	1 (1.6%)	3 (3.8%)	1 (1.1%)
VASCULITIS	0	0	0
VEIN DISORDER	2 (3.3%)	2 (2.6%)	2 (2.2%)
VEIN VARICOSE	2 (3.3%)	0	1 (1.1%)
VISION	8 (13.1%)	4 (5.1%)	10 (11.1%)
BLEPHARITIS	1 (1.6%)	0	0
CATARACT	4 (6.6%)	1 (1.3%)	2 (2.2%)
CONJUNCTIVAL HEMORRHAGE	0	0	0
CONJUNCTIVITIS	0	0	2 (2.2%)
CORNEAL OPACITY	0	0	0
DIPLOPIA	0	0	1 (1.1%)
EYE ABNORMALITY	1 (1.6%)	1 (1.3%)	2 (2.2%)
EYE PAIN	1 (1.6%)	1 (1.3%)	0
GLAUCOMA	1 (1.6%)	0	1 (1.1%)
LACRIMATION ABNORMAL	0	0	0
MACULA LUTEA DEGENERATION	0	0	1 (1.1%)
RETINAL DETACHMENT	0	0	0

Data Source Table 15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
WHO Body System Preferred Term			
RETINAL DISORDER	0	2 (2.6%)	3 (3.3%)
RETINITIS	0	0	1 (1.1%)
VISION ABNORMAL	1 (1.6%)	0	1 (1.1%)
VITREOUS DETACHMENT	0	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	3 (4.9%)	3 (3.8%)	2 (2.2%)
EOSINOPHILIA	1 (1.6%)	0	0
GRANULOCYTOPENIA	0	1 (1.3%)	0
LEUKOCYTOSIS	0	0	1 (1.1%)
LEUKOPENIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
LYMPHADENOPATHY	0	0	0
LYMPHADENOPATHY CERVICAL	1 (1.6%)	0	0
LYMPHANGITIS	0	1 (1.3%)	0
LYMPHEDEMA	0	0	0
LYMPHOPENIA	0	1 (1.3%)	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
APPLICATION SITE	0	3 (2.2%)	2 (1.4%)	0
OTITIS EXTERNA	0	2 (1.5%)	2 (1.4%)	0
TYMPANIC MEMBRANE PERFORATION	0	1 (0.7%)	0	0
AUTONOMIC NERVOUS SYSTEM	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
SWEATING INCREASED	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
VASOSPASM	0	0	0	0
BODY AS A WHOLE GENERAL	36 (29.0%)	45 (33.1%)	40 (28.8%)	5 (16.7%)
ALCOHOL INTOLERANCE	0	0	0	0
ALLERGIC REACTION	0	1 (0.7%)	2 (1.4%)	0
ALLERGY	0	1 (0.7%)	0	0
ASTHENIA	5 (4.0%)	6 (4.4%)	3 (2.2%)	0
CHEST PAIN	1 (0.8%)	2 (1.5%)	6 (4.3%)	2 (6.7%)
CHEST PAIN PRECORDIAL	0	1 (0.7%)	1 (0.7%)	0
EDEMA	0	2 (1.5%)	0	0
EDEMA DEPENDENT	2 (1.6%)	2 (1.5%)	3 (2.2%)	0
EDEMA GENERALISED	1 (0.8%)	0	1 (0.7%)	0
EDEMA LEGS	13 (10.5%)	6 (4.4%)	6 (4.3%)	0
EDEMA PERIORBITAL	0	0	1 (0.7%)	1 (3.3%)
EDEMA PERIPHERAL	0	2 (1.5%)	1 (0.7%)	0
ESR INCREASED	0	0	1 (0.7%)	0
FACE EDEMA	0	1 (0.7%)	1 (0.7%)	0
FATIGUE	3 (2.4%)	1 (0.7%)	2 (1.4%)	1 (3.3%)
FEVER	0	1 (0.7%)	1 (0.7%)	0
GRANULOMATOUS LESION	0	0	2 (1.4%)	0
HOT FLUSHES	1 (0.8%)	0	2 (1.4%)	0
INFLUENZA-LIKE SYMPTOMS	0	1 (0.7%)	0	0
INJURY	16 (12.9%)	26 (19.1%)	17 (12.2%)	1 (3.3%)
MALAISE	0	0	1 (0.7%)	0
NECROSIS ISCHEMIC	1 (0.8%)	0	0	0
PAIN	6 (4.8%)	8 (5.9%)	5 (3.6%)	0
PALLOR	0	1 (0.7%)	0	0
RIGORS	1 (0.8%)	1 (0.7%)	0	0
SUDDEN DEATH	0	0	0	0

- 972 -

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Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
THERAPEUTIC RESPONSE INCREASED	1 (0.8%)	0	1 (0.7%)	0
CARDIOVASCULAR GENERAL	7 (5.6%)	15 (11.0%)	18 (12.9%)	3 (10.0%)
CARDIAC FAILURE	1 (0.8%)	1 (0.7%)	5 (3.6%)	1 (3.3%)
CARDIAC FAILURE LEFT	0	0	2 (1.4%)	0
ECG ABNORMAL	0	0	0	1 (3.3%)
ECG ABNORMAL SPECIFIC	0	1 (0.7%)	1 (0.7%)	0
HEART DISORDER	0	0	1 (0.7%)	0
HEART VALVE DISORDERS	0	1 (0.7%)	0	0
HYPERTENSION	2 (1.6%)	6 (4.4%)	5 (3.6%)	0
HYPERTENSION AGGRAVATED	2 (1.6%)	5 (3.7%)	2 (1.4%)	0
HYPOTENSION	1 (0.8%)	2 (1.5%)	0	0
HYPOTENSION POSTURAL	0	1 (0.7%)	0	0
SYNCOPE	2 (1.6%)	0	2 (1.4%)	1 (3.3%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	23 (18.5%)	26 (19.1%)	22 (15.8%)	5 (16.7%)
CARPAL TUNNEL SYNDROME	1 (0.8%)	2 (1.5%)	0	0
CONVULSIONS	0	0	0	0
DIZZINESS	3 (2.4%)	2 (1.5%)	3 (2.2%)	0
EDEMA CEREBRAL	0	1 (0.7%)	0	0
HEADACHE	5 (4.0%)	6 (4.4%)	6 (4.3%)	2 (6.7%)
HYPERESTHESIA	1 (0.8%)	0	0	0
HYPERKINESIA	1 (0.8%)	0	0	0
HYPESTHESIA	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
HYPOKINESIA	0	0	0	0
MIGRAINE	2 (1.6%)	0	0	0
MIGRAINE AGGRAVATED	0	0	0	0
NEURALGIA	9 (7.3%)	12 (8.8%)	9 (6.5%)	1 (3.3%)
NEURITIS	0	1 (0.7%)	0	0
NEUROPATHY	1 (0.8%)	1 (0.7%)	0	0
NEUROPATHY PERIPHERAL	1 (0.8%)	0	0	0
PARESIS	0	1 (0.7%)	0	0
PARESTHESIA	5 (4.0%)	3 (2.2%)	1 (0.7%)	1 (3.3%)
PTOSIS	0	0	1 (0.7%)	0
SPEECH DISORDER	0	0	1 (0.7%)	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
TETANY	0	0	1 (0.7%)	0
TREMOR	0	1 (0.7%)	1 (0.7%)	0
TRIGEMINAL NEURALGIA	0	0	0	0
VERTIGO	3 (2.4%)	4 (2.9%)	4 (2.9%)	0
COLLAGEN	0	1 (0.7%)	0	0
ARTHRITIS RHEUMATOID	0	1 (0.7%)	0	0
ENDOCRINE	5 (4.0%)	7 (5.1%)	0	0
BREAST PAIN MALE	0	0	0	0
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0
GOITRE	2 (1.6%)	3 (2.2%)	0	0
GYNECOMASTIA	2 (1.6%)	2 (1.5%)	0	0
HYPERPARATHYROIDISM	0	0	0	0
HYPOTHYROIDISM	1 (0.8%)	2 (1.5%)	0	0
THYROID DISORDER	0	1 (0.7%)	0	0
GASTROINTESTINAL SYSTEM	33 (26.6%)	39 (28.7%)	34 (24.5%)	6 (20.0%)
ABDOMINAL PAIN	7 (5.6%)	6 (4.4%)	9 (6.5%)	0
ANUS DISORDER	1 (0.8%)	3 (2.2%)	0	0
APPETITE INCREASED	1 (0.8%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
COLITIS	3 (2.4%)	4 (2.9%)	1 (0.7%)	0
CONSTIPATION	7 (5.6%)	5 (3.7%)	3 (2.2%)	0
DIARRHEA	1 (0.8%)	6 (4.4%)	4 (2.9%)	1 (3.3%)
DIVERTICULITIS	1 (0.8%)	1 (0.7%)	0	0
DUODENAL ULCER	1 (0.8%)	1 (0.7%)	0	0
DYSPEPSIA	4 (3.2%)	4 (2.9%)	2 (1.4%)	2 (6.7%)
ENTERITIS	0	1 (0.7%)	0	0
ESOPHAGEAL ULCERATION	0	1 (0.7%)	0	0
ESOPHAGITIS	1 (0.8%)	0	0	0
FECAL INCONTINENCE	1 (0.8%)	0	0	0
FLATULENCE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
GASTRIC ULCER	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
GASTRIC ULCER HEMORRHAGIC	0	1 (0.7%)	0	0
GASTRITIS	3 (2.4%)	2 (1.5%)	1 (0.7%)	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
GASTROENTERITIS	2 (1.6%)	7 (5.1%)	3 (2.2%)	0
GASTROESOPHAGEAL REFLUX	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
GASTROINTESTINAL DISORDER NOS	4 (3.2%)	3 (2.2%)	1 (0.7%)	0
GI HEMORRHAGE	0	1 (0.7%)	0	0
GINGIVITIS	0	0	0	0
HEMORRHAGE RECTUM	1 (0.8%)	0	1 (0.7%)	0
HEMORRHOIDS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
INTESTINAL ISCHEMIA	0	0	1 (0.7%)	0
INTESTINAL PERFORATION	0	1 (0.7%)	0	0
IRRITABLE BOWEL SYNDROME	0	0	1 (0.7%)	0
NAUSEA	2 (1.6%)	3 (2.2%)	6 (4.3%)	0
PERIODONTITIS	3 (2.4%)	3 (2.2%)	5 (3.6%)	3 (10.0%)
SALIVARY GLAND ENLARGEMENT	1 (0.8%)	0	0	0
STOMATITIS	0	1 (0.7%)	0	0
STOMATITIS ULCERATIVE	0	1 (0.7%)	1 (0.7%)	0
TONGUE EDEMA	0	0	1 (0.7%)	0
TONGUE ULCERATION	1 (0.8%)	0	0	0
TOOTH ACHE	0	0	0	0
TOOTH CARIES	0	1 (0.7%)	0	0
TOOTH DISORDER	1 (0.8%)	0	0	0
VOMITING	1 (0.8%)	0	2 (1.4%)	0
HEARING AND VESTIBULAR	5 (4.0%)	1 (0.7%)	1 (0.7%)	0
DEAFNESS	1 (0.8%)	1 (0.7%)	0	0
EAR DISORDER NOS	1 (0.8%)	0	0	0
EARACHE	1 (0.8%)	0	1 (0.7%)	0
OTOSCLEROSIS	0	0	0	0
TINNITUS	2 (1.6%)	0	0	0
VESTIBULAR DISORDER	0	0	0	0
HEART RATE AND RHYTHM	9 (7.3%)	12 (8.8%)	10 (7.2%)	2 (6.7%)
ARRHYTHMIA ATRIAL	0	0	0	1 (3.3%)
ARRHYTHMIA VENTRICULAR	0	0	1 (0.7%)	0
ATRIOVENTRICULAR BLOCK	2 (1.6%)	2 (1.5%)	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.7%)	0	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
BRADYCARDIA	1 (0.8%)	2 (1.5%)	0	0
BUNDLE BRANCH BLOCK	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
EXTRASYSTOLES	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
FIBRILLATION ATRIAL	1 (0.8%)	3 (2.2%)	6 (4.3%)	0
PALPITATION	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
QT INCREASED	0	0	0	0
TACHYCARDIA	2 (1.6%)	1 (0.7%)	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.7%)	0	0
LIVER AND BILIARY SYSTEM	1 (0.8%)	4 (2.9%)	6 (4.3%)	0
BILIARY PAIN	0	0	1 (0.7%)	0
BILIRUBINEMIA	0	0	0	0
CHOLECYSTITIS	0	1 (0.7%)	0	0
CHOLELITHIASIS	0	1 (0.7%)	1 (0.7%)	0
GALL BLADDER DISORDER	1 (0.8%)	0	1 (0.7%)	0
GAMMA-GT INCREASED	0	2 (1.5%)	3 (2.2%)	0
HEPATIC ENZYMES INCREASED	0	0	0	0
HEPATIC FUNCTION ABNORMAL	0	0	2 (1.4%)	0
HEPATITIS CHOLESTATIC	0	0	0	0
HEPATOMEGALY	0	0	1 (0.7%)	0
LIVER FATTY	0	0	0	0
SGPT INCREASED	0	0	0	0
METABOLIC AND NUTRITIONAL	41 (33.1%)	32 (23.5%)	33 (23.7%)	20 (66.7%)
ACIDOSIS	0	0	0	0
ALKALOSIS RESPIRATORY	0	0	0	0
BLOOD UREA NITROGEN INCREASED	0	2 (1.5%)	0	0
CALCINOSIS	2 (1.6%)	0	1 (0.7%)	0
DIABETES MELLITUS AGGRAVATED	5 (4.0%)	3 (2.2%)	4 (2.9%)	10 (33.3%)
GOUT	2 (1.6%)	2 (1.5%)	1 (0.7%)	1 (3.3%)
HYPERCHOLESTEROLEMIA	14 (11.3%)	11 (8.1%)	9 (6.5%)	9 (30.0%)
HYPERGLYCEMIA	4 (3.2%)	3 (2.2%)	9 (6.5%)	0
HYPERKALEMIA	0	0	1 (0.7%)	0
HYPERLIPEMIA	9 (7.3%)	6 (4.4%)	8 (5.8%)	0
HYPERTRIGLYCERIDEMIA	1 (0.8%)	1 (0.7%)	1 (0.7%)	1 (3.3%)

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
HYPERURICEMIA	0	0	1 (0.7%)	0
HYPOCHOLESTEROLEMIA	0	0	0	1 (3.3%)
HYPOGLYCEMIA	0	5 (3.7%)	0	1 (3.3%)
HYPOGLYCEMIC REACTION	0	0	1 (0.7%)	0
HYPOKALEMIA	2 (1.6%)	0	1 (0.7%)	0
NPN INCREASED	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
OBESITY	1 (0.8%)	1 (0.7%)	0	0
THIRST	0	0	1 (0.7%)	0
WEIGHT DECREASE	2 (1.6%)	0	0	0
WEIGHT INCREASE	7 (5.6%)	7 (5.1%)	1 (0.7%)	2 (6.7%)
MUSCULOSKELETAL SYSTEM	47 (37.9%)	55 (40.4%)	37 (26.6%)	3 (10.0%)
ARTHRALGIA	9 (7.3%)	14 (10.3%)	7 (5.0%)	0
ARTHRITIS	12 (9.7%)	17 (12.5%)	12 (8.6%)	1 (3.3%)
ARTHRITIS AGGRAVATED	2 (1.6%)	1 (0.7%)	0	0
ARTHROPATHY	0	0	2 (1.4%)	0
ARTHROSIS	6 (4.8%)	9 (6.6%)	7 (5.0%)	1 (3.3%)
BACK PAIN	15 (12.1%)	20 (14.7%)	15 (10.8%)	0
BONE DEVELOPMENT ABNORMAL	0	0	0	0
BONE DISORDER	1 (0.8%)	0	0	0
BURSITIS	1 (0.8%)	1 (0.7%)	0	0
MUSCLE WEAKNESS	0	0	0	0
MYALGIA	6 (4.8%)	5 (3.7%)	9 (6.5%)	1 (3.3%)
MYOPATHY	1 (0.8%)	2 (1.5%)	0	0
MYOSITIS	0	0	0	0
OSTEOMYELITIS	1 (0.8%)	0	0	0
OSTEOPOROSIS	3 (2.4%)	5 (3.7%)	1 (0.7%)	0
SKELETAL PAIN	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
SYNOVITIS	0	0	0	0
TENDINITIS	3 (2.4%)	6 (4.4%)	2 (1.4%)	0
TORTICOLLIS	2 (1.6%)	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	3 (2.4%)	11 (8.1%)	15 (10.8%)	1 (3.3%)
ANGINA PECTORIS	2 (1.6%)	7 (5.1%)	6 (4.3%)	0
ANGINA PECTORIS AGGRAVATED	0	0	0	0

- 977 -

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
AORTIC STENOSIS	0	0	1 (0.7%)	0
CARDIOMYOPATHY	0	0	0	0
CORONARY ARTERY DISORDER	0	0	0	0
MYOCARDIAL INFARCTION	1 (0.8%)	4 (2.9%)	5 (3.6%)	0
MYOCARDIAL ISCHEMIA	0	0	4 (2.9%)	1 (3.3%)
THROMBOSIS CORONARY	0	1 (0.7%)	0	0
NEOPLASM	6 (4.8%)	8 (5.9%)	11 (7.9%)	0
BASAL CELL CARCINOMA	0	2 (1.5%)	0	0
BLADDER CARCINOMA	0	1 (0.7%)	2 (1.4%)	0
BRAIN NEOPLASM BENIGN	0	0	1 (0.7%)	0
BREAST NEOPLASM FEMALE	0	0	1 (0.7%)	0
CARCINOMA	2 (1.6%)	0	0	0
GASTRIC CARCINOMA	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	1 (0.8%)	0	1 (0.7%)	0
LIPOMA	0	0	1 (0.7%)	0
MELANOMA MALIGNANT	0	0	1 (0.7%)	0
NEOPLASM MALIGNANT	0	1 (0.7%)	0	0
NEOPLASM NOS	3 (2.4%)	4 (2.9%)	2 (1.4%)	0
PHARYNX NEOPLASM MALIGNANT	0	0	1 (0.7%)	0
PULMONARY CARCINOMA	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	0	0	0
THYROID ADENOMA	0	1 (0.7%)	0	0
UTERINE FIBROID	0	0	1 (0.7%)	0
PLATELET BLEEDING AND CLOTTING	1 (0.8%)	4 (2.9%)	0	0
PURPURA	0	2 (1.5%)	0	0
THROMBOCYTOPENIA	1 (0.8%)	2 (1.5%)	0	0
PSYCHIATRIC	13 (10.5%)	14 (10.3%)	18 (12.9%)	1 (3.3%)
AMNESIA	0	1 (0.7%)	1 (0.7%)	0
ANXIETY	3 (2.4%)	1 (0.7%)	7 (5.0%)	0
CONFUSION	0	0	0	0
DEMENTIA	0	0	1 (0.7%)	0
DEPRESSION	6 (4.8%)	4 (2.9%)	4 (2.9%)	0

- 978 -

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Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
EMOTIONAL LABILITY	0	0	0	0
INSOMNIA	2 (1.6%)	6 (4.4%)	6 (4.3%)	1 (3.3%)
NERVOUSNESS	1 (0.8%)	0	3 (2.2%)	0
NEUROSIS	0	0	1 (0.7%)	0
SOMNOLENCE	2 (1.6%)	2 (1.5%)	0	0
SUICIDE ATTEMPT	0	1 (0.7%)	0	0
RED BLOOD CELL	9 (7.3%)	4 (2.9%)	6 (4.3%)	7 (23.3%)
ANEMIA	7 (5.6%)	4 (2.9%)	3 (2.2%)	6 (20.0%)
ANEMIA B TWELVE DEFICIENCY	0	0	0	0
ANEMIA HYPOCHROMIC	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
ANEMIA NORMOCHROMIC	0	0	1 (0.7%)	0
ERYTHROCYTES ABNORMAL	0	0	0	1 (3.3%)
REPRODUCTIVE FEMALE	0	1 (0.7%)	3 (2.2%)	1 (3.3%)
MENORRHAGIA	0	0	1 (0.7%)	0
MENSTRUAL DISORDER	0	0	2 (1.4%)	1 (3.3%)
OVARIAN CYST	0	0	0	0
OVARIAN DISORDER	0	0	1 (0.7%)	0
VAGINITIS	0	1 (0.7%)	1 (0.7%)	0
REPRODUCTIVE MALE	7 (5.6%)	7 (5.1%)	2 (1.4%)	0
EPIDIDYMITIS	1 (0.8%)	0	0	0
IMPOTENCE	5 (4.0%)	1 (0.7%)	0	0
PENIS DISORDER	0	0	0	0
PROSTATIC DISORDER	2 (1.6%)	5 (3.7%)	1 (0.7%)	0
TESTIS DISORDER	0	1 (0.7%)	1 (0.7%)	0
RESISTANCE MECHANISM	24 (19.4%)	29 (21.3%)	32 (23.0%)	9 (30.0%)
ABSCESS	1 (0.8%)	0	0	0
HERPES SIMPLEX	0	1 (0.7%)	2 (1.4%)	0
HERPES ZOSTER	1 (0.8%)	0	0	2 (6.7%)
INFECTION	4 (3.2%)	4 (2.9%)	3 (2.2%)	0
INFECTION BACTERIAL	1 (0.8%)	2 (1.5%)	0	0
INFECTION FUNGAL	4 (3.2%)	4 (2.9%)	3 (2.2%)	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
INFECTION VIRAL	13 (10.5%)	10 (7.4%)	12 (8.6%)	3 (10.0%)
MONILIASIS	2 (1.6%)	0	1 (0.7%)	0
MONILIASIS GENITAL	0	0	1 (0.7%)	0
OTITIS MEDIA	2 (1.6%)	3 (2.2%)	3 (2.2%)	0
SEPSIS	0	1 (0.7%)	0	2 (6.7%)
UPPER RESP TRACT INFECTION	5 (4.0%)	10 (7.4%)	11 (7.9%)	3 (10.0%)
RESPIRATORY SYSTEM	45 (36.3%)	49 (36.0%)	52 (37.4%)	6 (20.0%)
APNEA	0	1 (0.7%)	0	0
ASTHMA	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
BRONCHITIS	18 (14.5%)	23 (16.9%)	27 (19.4%)	1 (3.3%)
CHEST X-RAY ABNORMAL	0	0	1 (0.7%)	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	2 (1.6%)	0	1 (0.7%)	0
COUGHING	2 (1.6%)	7 (5.1%)	4 (2.9%)	2 (6.7%)
DYSPNEA	6 (4.8%)	6 (4.4%)	1 (0.7%)	0
EPISTAXIS	0	1 (0.7%)	2 (1.4%)	1 (3.3%)
HEMOPTYSIS	0	0	1 (0.7%)	0
LARYNGITIS	2 (1.6%)	2 (1.5%)	0	0
PHARYNGITIS	10 (8.1%)	8 (5.9%)	10 (7.2%)	0
PLEURAL EFFUSION	0	0	1 (0.7%)	0
PLEURISY	0	0	1 (0.7%)	0
PNEUMONIA	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
PULMONARY EDEMA	0	2 (1.5%)	1 (0.7%)	1 (3.3%)
RESPIRATORY DISORDER	10 (8.1%)	3 (2.2%)	11 (7.9%)	1 (3.3%)
RESPIRATORY INSUFFICIENCY	0	0	0	0
RHINITIS	3 (2.4%)	6 (4.4%)	6 (4.3%)	1 (3.3%)
SINUSITIS	3 (2.4%)	4 (2.9%)	6 (4.3%)	0
TRACHEITIS	1 (0.8%)	5 (3.7%)	1 (0.7%)	0
SKIN AND APPENDAGES	15 (12.1%)	16 (11.8%)	19 (13.7%)	3 (10.0%)
ALOPECIA	0	1 (0.7%)	0	0
ANGIOEDEMA	0	1 (0.7%)	0	0
BULLOUS ERUPTION	1 (0.8%)	0	0	0
DERMATITIS	0	2 (1.5%)	2 (1.4%)	0
DERMATITIS FUNGAL	0	1 (0.7%)	0	1 (3.3%)

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
ECZEMA	4 (3.2%)	3 (2.2%)	7 (5.0%)	0
FOLLICULITIS	0	1 (0.7%)	2 (1.4%)	0
FURUNCULOSIS	0	1 (0.7%)	0	0
HYPERKERATOSIS	1 (0.8%)	0	0	0
NAIL DISORDER	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
NEVUS	0	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	1 (0.7%)	0	0
PHOTOSENSITIVITY REACTION	0	1 (0.7%)	1 (0.7%)	0
PRURITUS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
PRURITUS GENITAL	0	1 (0.7%)	0	0
PSORIASIS	0	1 (0.7%)	1 (0.7%)	0
PSORIASIS AGGRAVATED	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
RASH	1 (0.8%)	2 (1.5%)	3 (2.2%)	1 (3.3%)
RASH ERYTHEMATOUS	0	0	0	1 (3.3%)
RASH PUSTULAR	0	0	1 (0.7%)	0
ROSACEA	2 (1.6%)	0	0	0
SEBORRHEA	0	1 (0.7%)	1 (0.7%)	0
SKIN DISORDER	0	0	0	0
SKIN DRY	1 (0.8%)	0	0	0
SKIN HYPERTROPHY	1 (0.8%)	1 (0.7%)	0	0
SKIN ULCERATION	3 (2.4%)	0	1 (0.7%)	0
URTICARIA	0	0	0	0
VERRUCA	1 (0.8%)	0	0	0
URINARY SYSTEM	17 (13.7%)	17 (12.5%)	28 (20.1%)	9 (30.0%)
ALBUMINURIA	1 (0.8%)	1 (0.7%)	1 (0.7%)	2 (6.7%)
CYSTITIS	3 (2.4%)	2 (1.5%)	4 (2.9%)	0
CYSTITIS HEMORRHAGIC	1 (0.8%)	0	2 (1.4%)	0
DYSURIA	0	2 (1.5%)	1 (0.7%)	0
HEMATURIA	3 (2.4%)	2 (1.5%)	3 (2.2%)	3 (10.0%)
HYDRONEPHROSIS	0	0	0	0
MICTURITION DISORDER	0	0	1 (0.7%)	0
MICTURITION FREQUENCY	1 (0.8%)	3 (2.2%)	0	0
NOCTURIA	0	0	0	0
POLYURIA	0	0	1 (0.7%)	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
PYELONEPHRITIS	0	0	1 (0.7%)	0
PYURIA	0	0	0	3 (10.0%)
RENAL CALCULUS	1 (0.8%)	0	1 (0.7%)	0
RENAL FAILURE ACUTE	0	0	0	0
RENAL PAIN	1 (0.8%)	0	1 (0.7%)	0
STRANGURY	0	0	1 (0.7%)	0
URETHRAL DISORDER	0	0	0	0
URINARY INCONTINENCE	0	1 (0.7%)	0	0
URINARY TRACT INFECTION	10 (8.1%)	10 (7.4%)	16 (11.5%)	4 (13.3%)
VASCULAR EXTRACARDIAC	15 (12.1%)	19 (14.0%)	19 (13.7%)	2 (6.7%)
ARTERITIS	0	1 (0.7%)	3 (2.2%)	0
ATHEROSCLEROSIS	0	0	0	0
CEREBROVASCULAR DISORDER	2 (1.6%)	0	1 (0.7%)	0
CLAUDICATION INTERMITTENT	1 (0.8%)	0	2 (1.4%)	0
CRAMPS LEGS	2 (1.6%)	7 (5.1%)	6 (4.3%)	1 (3.3%)
EMBOLISM PULMONARY	0	0	1 (0.7%)	0
HEMORRHAGE NOS	0	0	0	0
PERIPHERAL ISCHEMIA	3 (2.4%)	0	0	1 (3.3%)
PHLEBITIS	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
PHLEBITIS SUPERFICIAL	0	1 (0.7%)	0	0
THROMBOPHLEBITIS	0	0	0	0
THROMBOPHLEBITIS DEEP	0	0	2 (1.4%)	0
VASCULAR DISORDER	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
VASCULITIS	0	1 (0.7%)	0	0
VEIN DISORDER	4 (3.2%)	4 (2.9%)	6 (4.3%)	0
VEIN VARICOSE	0	3 (2.2%)	1 (0.7%)	0
VISION	16 (12.9%)	11 (8.1%)	19 (13.7%)	3 (10.0%)
BLEPHARITIS	0	0	1 (0.7%)	0
CATARACT	2 (1.6%)	4 (2.9%)	3 (2.2%)	1 (3.3%)
CONJUNCTIVAL HEMORRHAGE	0	0	1 (0.7%)	0
CONJUNCTIVITIS	4 (3.2%)	3 (2.2%)	10 (7.2%)	1 (3.3%)
CORNEAL OPACITY	0	1 (0.7%)	0	0
DIPLOPIA	0	0	0	0

Data Source Table 15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Body System and Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
WHO Body System Preferred Term				
EYE ABNORMALITY	0	1 (0.7%)	1 (0.7%)	0
EYE PAIN	0	0	0	0
GLAUCOMA	3 (2.4%)	0	2 (1.4%)	0
LACRIMATION ABNORMAL	0	0	1 (0.7%)	1 (3.3%)
MACULA LUTEA DEGENERATION	0	0	0	0
RETINAL DETACHMENT	1 (0.8%)	0	0	0
RETINAL DISORDER	4 (3.2%)	2 (1.5%)	1 (0.7%)	0
RETINITIS	0	0	0	0
VISION ABNORMAL	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
VITREOUS DETACHMENT	0	1 (0.7%)	0	0
WHITE CELL AND RETICULOENDOTHELIAL SYSTE	4 (3.2%)	3 (2.2%)	1 (0.7%)	4 (13.3%)
EOSINOPHILIA	1 (0.8%)	0	0	0
GRANULOCYTOPENIA	0	0	0	0
LEUKOCYTOSIS	0	0	0	0
LEUKOPENIA	1 (0.8%)	2 (1.5%)	0	4 (13.3%)
LYMPHADENOPATHY	0	0	1 (0.7%)	0
LYMPHADENOPATHY CERVICAL	0	0	0	0
LYMPHANGITIS	1 (0.8%)	0	0	0
LYMPHEDEMA	1 (0.8%)	1 (0.7%)	0	0
LYMPHOPENIA	0	0	0	0

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
BRONCHITIS	9 (3.9%)	69 (16.0%)
INJURY	36 (15.7%)	60 (14.0%)
BACK PAIN	18 (7.9%)	51 (11.9%)
HYPERCHOLESTEROLEMIA	19 (8.3%)	43 (10.0%)
ARTHRITIS	15 (6.6%)	42 (9.8%)
URINARY TRACT INFECTION	24 (10.5%)	40 (9.3%)
INFECTION VIRAL	28 (12.2%)	38 (8.8%)
NEURALGIA	8 (3.5%)	32 (7.4%)
ARTHRALGIA	20 (8.7%)	30 (7.0%)
UPPER RESP TRACT INFECTION	29 (12.7%)	29 (6.7%)
PHARYNGITIS	15 (6.6%)	29 (6.7%)
RESPIRATORY DISORDER	19 (8.3%)	25 (5.8%)
EDEMA LEGS	6 (2.6%)	25 (5.8%)
ABDOMINAL PAIN	13 (5.7%)	23 (5.3%)
HYPERLIPEMIA	11 (4.8%)	23 (5.3%)
ARTHROSIS	4 (1.7%)	23 (5.3%)
DIABETES MELLITUS AGGRAVATED	23 (10.0%)	22 (5.1%)
MYALGIA	7 (3.1%)	21 (4.9%)
ANEMIA	9 (3.9%)	20 (4.7%)
PAIN	13 (5.7%)	19 (4.4%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
HEADACHE	8 (3.5%)	19 (4.4%)
CONJUNCTIVITIS	2 (0.9%)	18 (4.2%)
WEIGHT INCREASE	4 (1.7%)	17 (4.0%)
HYPERGLYCEMIA	46 (20.1%)	16 (3.7%)
CRAMPS LEGS	5 (2.2%)	16 (3.7%)
RHINITIS	3 (1.3%)	16 (3.7%)
COUGHING	19 (8.3%)	15 (3.5%)
CONSTIPATION	10 (4.4%)	15 (3.5%)
ANGINA PECTORIS	9 (3.9%)	15 (3.5%)
INSOMNIA	3 (1.3%)	15 (3.5%)
DEPRESSION	8 (3.5%)	14 (3.3%)
VEIN DISORDER	6 (2.6%)	14 (3.3%)
ECZEMA	5 (2.2%)	14 (3.3%)
ASTHENIA	4 (1.7%)	14 (3.3%)
PERIODONTITIS	4 (1.7%)	14 (3.3%)
DYSPNEA	11 (4.8%)	13 (3.0%)
HYPERTENSION	9 (3.9%)	13 (3.0%)
DIARRHEA	8 (3.5%)	13 (3.0%)
SINUSITIS	4 (1.7%)	13 (3.0%)
DYSPEPSIA	9 (3.9%)	12 (2.8%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
GASTROENTERITIS	6 (2.6%)	12 (2.8%)
INFECTION	10 (4.4%)	11 (2.6%)
TENDINITIS	9 (3.9%)	11 (2.6%)
ANXIETY	8 (3.5%)	11 (2.6%)
CHEST PAIN	7 (3.1%)	11 (2.6%)
NAUSEA	5 (2.2%)	11 (2.6%)
HEMATURIA	4 (1.7%)	11 (2.6%)
VERTIGO	3 (1.3%)	11 (2.6%)
INFECTION FUNGAL	2 (0.9%)	11 (2.6%)
CATARACT	7 (3.1%)	10 (2.3%)
PARESTHESIA	6 (2.6%)	10 (2.3%)
FIBRILLATION ATRIAL	4 (1.7%)	10 (2.3%)
MYOCARDIAL INFARCTION	4 (1.7%)	10 (2.3%)
HYPERTENSION AGGRAVATED	10 (4.4%)	9 (2.1%)
OSTEOPOROSIS	2 (0.9%)	9 (2.1%)
CYSTITIS	1 (0.4%)	9 (2.1%)
NEOPLASM NOS	1 (0.4%)	9 (2.1%)
DIZZINESS	10 (4.4%)	8 (1.9%)
PROSTATIC DISORDER	7 (3.1%)	8 (1.9%)
CARDIAC FAILURE	5 (2.2%)	8 (1.9%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
COLITIS	2 (0.9%)	8 (1.9%)
GASTROINTESTINAL DISORDER NOS	2 (0.9%)	8 (1.9%)
OTITIS MEDIA	2 (0.9%)	8 (1.9%)
RASH	7 (3.1%)	7 (1.6%)
EDEMA DEPENDENT	6 (2.6%)	7 (1.6%)
RETINAL DISORDER	5 (2.2%)	7 (1.6%)
FATIGUE	4 (1.7%)	7 (1.6%)
LEUKOPENIA	3 (1.3%)	7 (1.6%)
TRACHEITIS	0	7 (1.6%)
HYPOGLYCEMIA	14 (6.1%)	6 (1.4%)
IMPOTENCE	5 (2.2%)	6 (1.4%)
VASCULAR DISORDER	5 (2.2%)	6 (1.4%)
ASTHMA	1 (0.4%)	6 (1.4%)
EXTRASYSTOLES	1 (0.4%)	6 (1.4%)
GASTRITIS	1 (0.4%)	6 (1.4%)
GOUT	0	6 (1.4%)
SWEATING INCREASED	0	6 (1.4%)
GAMMA-GT INCREASED	6 (2.6%)	5 (1.2%)
NPN INCREASED	6 (2.6%)	5 (1.2%)
SYNCOPE	4 (1.7%)	5 (1.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
SKELETAL PAIN	3 (1.3%)	5 (1.2%)
GASTRIC ULCER	2 (0.9%)	5 (1.2%)
GLAUCOMA	2 (0.9%)	5 (1.2%)
GOITRE	2 (0.9%)	5 (1.2%)
MYOCARDIAL ISCHEMIA	2 (0.9%)	5 (1.2%)
NAIL DISORDER	2 (0.9%)	5 (1.2%)
VISION ABNORMAL	2 (0.9%)	5 (1.2%)
ALBUMINURIA	1 (0.4%)	5 (1.2%)
ANEMIA HYPOCHROMIC	1 (0.4%)	5 (1.2%)
BUNDLE BRANCH BLOCK	1 (0.4%)	5 (1.2%)
PHLEBITIS	1 (0.4%)	5 (1.2%)
GASTROESOPHAGEAL REFLUX	0	5 (1.2%)
PRURITUS	7 (3.1%)	4 (0.9%)
SOMNOLENCE	6 (2.6%)	4 (0.9%)
MICTURITION FREQUENCY	3 (1.3%)	4 (0.9%)
VEIN VARICOSE	3 (1.3%)	4 (0.9%)
DERMATITIS	2 (0.9%)	4 (0.9%)
PERIPHERAL ISCHEMIA	2 (0.9%)	4 (0.9%)
PULMONARY EDEMA	2 (0.9%)	4 (0.9%)
ANUS DISORDER	1 (0.4%)	4 (0.9%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
APPETITE INCREASED	1 (0.4%)	4 (0.9%)
ATRIOVENTRICULAR BLOCK	1 (0.4%)	4 (0.9%)
EPISTAXIS	1 (0.4%)	4 (0.9%)
HYPERTRIGLYCERIDEMIA	1 (0.4%)	4 (0.9%)
LARYNGITIS	1 (0.4%)	4 (0.9%)
NERVOUSNESS	1 (0.4%)	4 (0.9%)
OTITIS EXTERNA	1 (0.4%)	4 (0.9%)
PNEUMONIA	1 (0.4%)	4 (0.9%)
SKIN ULCERATION	1 (0.4%)	4 (0.9%)
ARTERITIS	0	4 (0.9%)
GYNECOMASTIA	0	4 (0.9%)
HEMORRHOIDS	0	4 (0.9%)
ARTHRITIS AGGRAVATED	6 (2.6%)	3 (0.7%)
HERPES ZOSTER	6 (2.6%)	3 (0.7%)
PYURIA	5 (2.2%)	3 (0.7%)
INFECTION BACTERIAL	4 (1.7%)	3 (0.7%)
ALLERGIC REACTION	3 (1.3%)	3 (0.7%)
MONILIASIS	3 (1.3%)	3 (0.7%)
TACHYCARDIA	3 (1.3%)	3 (0.7%)
VOMITING	3 (1.3%)	3 (0.7%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
CEREBROVASCULAR DISORDER	2 (0.9%)	3 (0.7%)
DYSURIA	2 (0.9%)	3 (0.7%)
FLATULENCE	2 (0.9%)	3 (0.7%)
PALPITATION	2 (0.9%)	3 (0.7%)
BRADYCARDIA	1 (0.4%)	3 (0.7%)
CARPAL TUNNEL SYNDROME	1 (0.4%)	3 (0.7%)
EDEMA PERIPHERAL	1 (0.4%)	3 (0.7%)
HERPES SIMPLEX	1 (0.4%)	3 (0.7%)
HYPESTHESIA	1 (0.4%)	3 (0.7%)
HYPOTHYROIDISM	1 (0.4%)	3 (0.7%)
MENSTRUAL DISORDER	1 (0.4%)	3 (0.7%)
THROMBOCYTOPENIA	1 (0.4%)	3 (0.7%)
BLADDER CARCINOMA	0	3 (0.7%)
CALCINOSIS	0	3 (0.7%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	3 (0.7%)
CLAUDICATION INTERMITTENT	0	3 (0.7%)
CYSTITIS HEMORRHAGIC	0	3 (0.7%)
FOLLICULITIS	0	3 (0.7%)
HOT FLUSHES	0	3 (0.7%)
HYPOKALEMIA	0	3 (0.7%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
HYPOTENSION	0	3 (0.7%)
MYOPATHY	0	3 (0.7%)
PSORIASIS AGGRAVATED	0	3 (0.7%)
SEPSIS	0	3 (0.7%)
TORTICOLLIS	0	3 (0.7%)
DEAFNESS	5 (2.2%)	2 (0.5%)
EYE ABNORMALITY	4 (1.7%)	2 (0.5%)
BASAL CELL CARCINOMA	3 (1.3%)	2 (0.5%)
BLOOD UREA NITROGEN INCREASED	3 (1.3%)	2 (0.5%)
DERMATITIS FUNGAL	3 (1.3%)	2 (0.5%)
DIVERTICULITIS	2 (0.9%)	2 (0.5%)
DUODENAL ULCER	2 (0.9%)	2 (0.5%)
EDEMA GENERALISED	2 (0.9%)	2 (0.5%)
FEVER	2 (0.9%)	2 (0.5%)
HEPATIC FUNCTION ABNORMAL	2 (0.9%)	2 (0.5%)
NEUROPATHY	2 (0.9%)	2 (0.5%)
THERAPEUTIC RESPONSE INCREASED	2 (0.9%)	2 (0.5%)
VAGINITIS	2 (0.9%)	2 (0.5%)
AMNESIA	1 (0.4%)	2 (0.5%)
ARTHROPATHY	1 (0.4%)	2 (0.5%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
CARDIAC FAILURE LEFT	1 (0.4%)	2 (0.5%)
EDEMA PERIORBITAL	1 (0.4%)	2 (0.5%)
HEMORRHAGE RECTUM	1 (0.4%)	2 (0.5%)
MIGRAINE	1 (0.4%)	2 (0.5%)
OBESITY	1 (0.4%)	2 (0.5%)
RENAL CALCULUS	1 (0.4%)	2 (0.5%)
SEBORRHEA	1 (0.4%)	2 (0.5%)
SKIN HYPERTROPHY	1 (0.4%)	2 (0.5%)
TESTIS DISORDER	1 (0.4%)	2 (0.5%)
TINNITUS	1 (0.4%)	2 (0.5%)
TREMOR	1 (0.4%)	2 (0.5%)
BURSITIS	0	2 (0.5%)
CARCINOMA	0	2 (0.5%)
CHEST PAIN PRECORDIAL	0	2 (0.5%)
CHOLELITHIASIS	0	2 (0.5%)
EARACHE	0	2 (0.5%)
ECG ABNORMAL SPECIFIC	0	2 (0.5%)
EDEMA	0	2 (0.5%)
FACE EDEMA	0	2 (0.5%)
GALL BLADDER DISORDER	0	2 (0.5%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
GRANULOMATOUS LESION	0	2 (0.5%)
HEPATIC NEOPLASM MALIGNANT	0	2 (0.5%)
LACRIMATION ABNORMAL	0	2 (0.5%)
LYMPHEDEMA	0	2 (0.5%)
PHOTOSENSITIVITY REACTION	0	2 (0.5%)
PSORIASIS	0	2 (0.5%)
PURPURA	0	2 (0.5%)
RENAL PAIN	0	2 (0.5%)
RIGORS	0	2 (0.5%)
ROSACEA	0	2 (0.5%)
STOMATITIS ULCERATIVE	0	2 (0.5%)
THROMBOPHLEBITIS DEEP	0	2 (0.5%)
WEIGHT DECREASE	0	2 (0.5%)
NEUROPATHY PERIPHERAL	5 (2.2%)	1 (0.2%)
MALAISE	4 (1.7%)	1 (0.2%)
MONILIASIS GENITAL	4 (1.7%)	1 (0.2%)
SKIN DRY	4 (1.7%)	1 (0.2%)
FURUNCULOSIS	3 (1.3%)	1 (0.2%)
HYPERKERATOSIS	3 (1.3%)	1 (0.2%)
POLYURIA	3 (1.3%)	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
RASH ERYTHEMATOUS	3 (1.3%)	1 (0.2%)
SALIVARY GLAND ENLARGEMENT	3 (1.3%)	1 (0.2%)
THIRST	3 (1.3%)	1 (0.2%)
ABSCCESS	2 (0.9%)	1 (0.2%)
ALLERGY	2 (0.9%)	1 (0.2%)
EMBOLISM PULMONARY	2 (0.9%)	1 (0.2%)
ESOPHAGITIS	2 (0.9%)	1 (0.2%)
GI HEMORRHAGE	2 (0.9%)	1 (0.2%)
TOOTH CARIES	2 (0.9%)	1 (0.2%)
ALOPECIA	1 (0.4%)	1 (0.2%)
ARRHYTHMIA ATRIAL	1 (0.4%)	1 (0.2%)
ARTHRITIS RHEUMATOID	1 (0.4%)	1 (0.2%)
BLEPHARITIS	1 (0.4%)	1 (0.2%)
BONE DISORDER	1 (0.4%)	1 (0.2%)
EAR DISORDER NOS	1 (0.4%)	1 (0.2%)
ECG ABNORMAL	1 (0.4%)	1 (0.2%)
ENTERITIS	1 (0.4%)	1 (0.2%)
EOSINOPHILIA	1 (0.4%)	1 (0.2%)
ERYTHROCYTES ABNORMAL	1 (0.4%)	1 (0.2%)
HEART VALVE DISORDERS	1 (0.4%)	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
HYPOTENSION POSTURAL	1 (0.4%)	1 (0.2%)
INFLUENZA-LIKE SYMPTOMS	1 (0.4%)	1 (0.2%)
INTESTINAL PERFORATION	1 (0.4%)	1 (0.2%)
LIPOMA	1 (0.4%)	1 (0.2%)
LYMPHANGITIS	1 (0.4%)	1 (0.2%)
NEURITIS	1 (0.4%)	1 (0.2%)
PARESIS	1 (0.4%)	1 (0.2%)
RASH PUSTULAR	1 (0.4%)	1 (0.2%)
TETANY	1 (0.4%)	1 (0.2%)
THROMBOSIS CORONARY	1 (0.4%)	1 (0.2%)
VERRUCA	1 (0.4%)	1 (0.2%)
ANEMIA NORMOCHROMIC	0	1 (0.2%)
ANGIOEDEMA	0	1 (0.2%)
AORTIC STENOSIS	0	1 (0.2%)
APNEA	0	1 (0.2%)
ARRHYTHMIA VENTRICULAR	0	1 (0.2%)
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.2%)
BILIARY PAIN	0	1 (0.2%)
BRAIN NEOPLASM BENIGN	0	1 (0.2%)
BREAST NEOPLASM FEMALE	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
BULLOUS ERUPTION	0	1 (0.2%)
CHEST X-RAY ABNORMAL	0	1 (0.2%)
CHOLECYSTITIS	0	1 (0.2%)
CONJUNCTIVAL HEMORRHAGE	0	1 (0.2%)
CORNEAL OPACITY	0	1 (0.2%)
DEMENTIA	0	1 (0.2%)
EDEMA CEREBRAL	0	1 (0.2%)
EPIDIDYMITIS	0	1 (0.2%)
ESOPHAGEAL ULCERATION	0	1 (0.2%)
ESR INCREASED	0	1 (0.2%)
FECAL INCONTINENCE	0	1 (0.2%)
GASTRIC ULCER HEMORRHAGIC	0	1 (0.2%)
HEART DISORDER	0	1 (0.2%)
HEMOPTYSIS	0	1 (0.2%)
HEPATOMEGALY	0	1 (0.2%)
HYPERESTHESIA	0	1 (0.2%)
HYPERKALEMIA	0	1 (0.2%)
HYPERKINESIA	0	1 (0.2%)
HYPERURICEMIA	0	1 (0.2%)
HYPOCHOLESTEROLEMIA	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
HYPOGLYCEMIC REACTION	0	1 (0.2%)
INTESTINAL ISCHEMIA	0	1 (0.2%)
IRRITABLE BOWEL SYNDROME	0	1 (0.2%)
LYMPHADENOPATHY	0	1 (0.2%)
MELANOMA MALIGNANT	0	1 (0.2%)
MENORRHAGIA	0	1 (0.2%)
MICTURITION DISORDER	0	1 (0.2%)
NECROSIS ISCHEMIC	0	1 (0.2%)
NEOPLASM MALIGNANT	0	1 (0.2%)
NEUROSIS	0	1 (0.2%)
OSTEOMYELITIS	0	1 (0.2%)
OVARIAN DISORDER	0	1 (0.2%)
PALLOR	0	1 (0.2%)
PHARYNX NEOPLASM MALIGNANT	0	1 (0.2%)
PHLEBITIS SUPERFICIAL	0	1 (0.2%)
PHOTOSENSITIVITY ALLERGIC REACT	0	1 (0.2%)
PLEURAL EFFUSION	0	1 (0.2%)
PLEURISY	0	1 (0.2%)
PRURITUS GENITAL	0	1 (0.2%)
PTOSIS	0	1 (0.2%)

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
PYELONEPHRITIS	0	1 (0.2%)
RETINAL DETACHMENT	0	1 (0.2%)
SPEECH DISORDER	0	1 (0.2%)
STOMATITIS	0	1 (0.2%)
STRANGURY	0	1 (0.2%)
SUICIDE ATTEMPT	0	1 (0.2%)
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.2%)
THYROID ADENOMA	0	1 (0.2%)
THYROID DISORDER	0	1 (0.2%)
TONGUE EDEMA	0	1 (0.2%)
TONGUE ULCERATION	0	1 (0.2%)
TOOTH DISORDER	0	1 (0.2%)
TYMPANIC MEMBRANE PERFORATION	0	1 (0.2%)
URINARY INCONTINENCE	0	1 (0.2%)
UTERINE FIBROID	0	1 (0.2%)
VASCULITIS	0	1 (0.2%)
VITREOUS DETACHMENT	0	1 (0.2%)
TOOTH ACHE	4 (1.7%)	0
GINGIVITIS	3 (1.3%)	0
RENAL FAILURE ACUTE	3 (1.3%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
SKIN DISORDER	3 (1.3%)	0
ALKALOSIS RESPIRATORY	2 (0.9%)	0
EMOTIONAL LABILITY	2 (0.9%)	0
EYE PAIN	2 (0.9%)	0
HEPATIC ENZYMES INCREASED	2 (0.9%)	0
LIVER FATTY	2 (0.9%)	0
MYOSITIS	2 (0.9%)	0
QT INCREASED	2 (0.9%)	0
SGPT INCREASED	2 (0.9%)	0
URETHRAL DISORDER	2 (0.9%)	0
ACIDOSIS	1 (0.4%)	0
ALCOHOL INTOLERANCE	1 (0.4%)	0
ANEMIA B TWELVE DEFICIENCY	1 (0.4%)	0
ANGINA PECTORIS AGGRAVATED	1 (0.4%)	0
ATHEROSCLEROSIS	1 (0.4%)	0
BILIRUBINEMIA	1 (0.4%)	0
BONE DEVELOPMENT ABNORMAL	1 (0.4%)	0
BREAST PAIN MALE	1 (0.4%)	0
CALCITONIN SERUM LEVEL INCREASED	1 (0.4%)	0
CARDIOMYOPATHY	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
CONFUSION	1 (0.4%)	0
CONVULSIONS	1 (0.4%)	0
CORONARY ARTERY DISORDER	1 (0.4%)	0
DIPLOPIA	1 (0.4%)	0
GASTRIC CARCINOMA	1 (0.4%)	0
GRANULOCYTOPENIA	1 (0.4%)	0
HEMORRHAGE NOS	1 (0.4%)	0
HEPATITIS CHOLESTATIC	1 (0.4%)	0
HYDRONEPHROSIS	1 (0.4%)	0
HYPERPARATHYROIDISM	1 (0.4%)	0
HYPOKINESIA	1 (0.4%)	0
LEUKOCYTOSIS	1 (0.4%)	0
LYMPHADENOPATHY CERVICAL	1 (0.4%)	0
LYMPHOPENIA	1 (0.4%)	0
MACULA LUTEA DEGENERATION	1 (0.4%)	0
MIGRAINE AGGRAVATED	1 (0.4%)	0
MUSCLE WEAKNESS	1 (0.4%)	0
NEVUS	1 (0.4%)	0
NOCTURIA	1 (0.4%)	0
OTOSCLEROSIS	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4a

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences	189 (82.5%)	363 (84.4%)
Preferred Term		
OVARIAN CYST	1 (0.4%)	0
PENIS DISORDER	1 (0.4%)	0
PULMONARY CARCINOMA	1 (0.4%)	0
RESPIRATORY INSUFFICIENCY	1 (0.4%)	0
RETINITIS	1 (0.4%)	0
SKIN NEOPLASM MALIGNANT	1 (0.4%)	0
SUDDEN DEATH	1 (0.4%)	0
SYNOVITIS	1 (0.4%)	0
THROMBOPHLEBITIS	1 (0.4%)	0
TRIGEMINAL NEURALGIA	1 (0.4%)	0
URTICARIA	1 (0.4%)	0
VASOSPASM	1 (0.4%)	0
VESTIBULAR DISORDER	1 (0.4%)	0

Sort Order: descending order of 4bd Mono Total, 2bd Comb Total.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
HYPERGLYCEMIA	13 (21.3%)	12 (15.4%)	21 (23.3%)
INJURY	12 (19.7%)	10 (12.8%)	14 (15.6%)
UPPER RESP TRACT INFECTION	6 (9.8%)	9 (11.5%)	14 (15.6%)
URINARY TRACT INFECTION	4 (6.6%)	9 (11.5%)	11 (12.2%)
DIABETES MELLITUS AGGRAVATED	7 (11.5%)	6 (7.7%)	10 (11.1%)
RESPIRATORY DISORDER	3 (4.9%)	6 (7.7%)	10 (11.1%)
INFECTION VIRAL	10 (16.4%)	9 (11.5%)	9 (10.0%)
HYPERCHOLESTEROLEMIA	8 (13.1%)	3 (3.8%)	8 (8.9%)
ARTHRITIS	4 (6.6%)	3 (3.8%)	8 (8.9%)
BACK PAIN	6 (9.8%)	5 (6.4%)	7 (7.8%)
PHARYNGITIS	4 (6.6%)	4 (5.1%)	7 (7.8%)
ARTHRALGIA	8 (13.1%)	6 (7.7%)	6 (6.7%)
COUGHING	8 (13.1%)	5 (6.4%)	6 (6.7%)
DYSPNEA	1 (1.6%)	4 (5.1%)	6 (6.7%)
ANEMIA	1 (1.6%)	2 (2.6%)	6 (6.7%)
ANXIETY	0	2 (2.6%)	6 (6.7%)
HYPERLIPEMIA	4 (6.6%)	2 (2.6%)	5 (5.6%)
HYPERTENSION AGGRAVATED	3 (4.9%)	2 (2.6%)	5 (5.6%)
PAIN	7 (11.5%)	1 (1.3%)	5 (5.6%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
CONSTIPATION	3 (4.9%)	3 (3.8%)	4 (4.4%)
DIZZINESS	4 (6.6%)	2 (2.6%)	4 (4.4%)
HYPERTENSION	3 (4.9%)	2 (2.6%)	4 (4.4%)
CHEST PAIN	1 (1.6%)	2 (2.6%)	4 (4.4%)
HYPOGLYCEMIA	2 (3.3%)	9 (11.5%)	3 (3.3%)
DYSPEPSIA	0	6 (7.7%)	3 (3.3%)
ABDOMINAL PAIN	6 (9.8%)	4 (5.1%)	3 (3.3%)
TENDINITIS	3 (4.9%)	3 (3.8%)	3 (3.3%)
EDEMA LEGS	0	3 (3.8%)	3 (3.3%)
BRONCHITIS	4 (6.6%)	2 (2.6%)	3 (3.3%)
DEPRESSION	3 (4.9%)	2 (2.6%)	3 (3.3%)
NEURALGIA	3 (4.9%)	2 (2.6%)	3 (3.3%)
EDEMA DEPENDENT	1 (1.6%)	2 (2.6%)	3 (3.3%)
NPN INCREASED	1 (1.6%)	2 (2.6%)	3 (3.3%)
NEUROPATHY PERIPHERAL	0	2 (2.6%)	3 (3.3%)
RETINAL DISORDER	0	2 (2.6%)	3 (3.3%)
MYALGIA	3 (4.9%)	1 (1.3%)	3 (3.3%)
RASH	3 (4.9%)	1 (1.3%)	3 (3.3%)
DEAFNESS	1 (1.6%)	1 (1.3%)	3 (3.3%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
FIBRILLATION ATRIAL	0	1 (1.3%)	3 (3.3%)
MONILIASIS GENITAL	0	1 (1.3%)	3 (3.3%)
MYOCARDIAL INFARCTION	1 (1.6%)	0	3 (3.3%)
ANGINA PECTORIS	1 (1.6%)	6 (7.7%)	2 (2.2%)
HEADACHE	1 (1.6%)	5 (6.4%)	2 (2.2%)
ARTHRITIS AGGRAVATED	2 (3.3%)	2 (2.6%)	2 (2.2%)
GASTROENTERITIS	2 (3.3%)	2 (2.6%)	2 (2.2%)
PARESTHESIA	2 (3.3%)	2 (2.6%)	2 (2.2%)
VEIN DISORDER	2 (3.3%)	2 (2.6%)	2 (2.2%)
HEMATURIA	0	2 (2.6%)	2 (2.2%)
SINUSITIS	0	2 (2.6%)	2 (2.2%)
TOOTH ACHE	0	2 (2.6%)	2 (2.2%)
CATARACT	4 (6.6%)	1 (1.3%)	2 (2.2%)
SOMNOLENCE	3 (4.9%)	1 (1.3%)	2 (2.2%)
NAUSEA	2 (3.3%)	1 (1.3%)	2 (2.2%)
ARTHROSIS	1 (1.6%)	1 (1.3%)	2 (2.2%)
EYE ABNORMALITY	1 (1.6%)	1 (1.3%)	2 (2.2%)
WEIGHT INCREASE	1 (1.6%)	1 (1.3%)	2 (2.2%)
VERTIGO	0	1 (1.3%)	2 (2.2%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
ASTHENIA	2 (3.3%)	0	2 (2.2%)
FATIGUE	2 (3.3%)	0	2 (2.2%)
SKIN DRY	2 (3.3%)	0	2 (2.2%)
SYNCOPE	2 (3.3%)	0	2 (2.2%)
BLOOD UREA NITROGEN INCREASED	1 (1.6%)	0	2 (2.2%)
HYPERKERATOSIS	1 (1.6%)	0	2 (2.2%)
ABSCCESS	0	0	2 (2.2%)
ALKALOSIS RESPIRATORY	0	0	2 (2.2%)
CONJUNCTIVITIS	0	0	2 (2.2%)
INFECTION FUNGAL	0	0	2 (2.2%)
OTITIS MEDIA	0	0	2 (2.2%)
TOOTH CARIES	0	0	2 (2.2%)
URETHRAL DISORDER	0	0	2 (2.2%)
INFECTION	5 (8.2%)	4 (5.1%)	1 (1.1%)
DIARRHEA	3 (4.9%)	4 (5.1%)	1 (1.1%)
GAMMA-GT INCREASED	1 (1.6%)	4 (5.1%)	1 (1.1%)
HERPES ZOSTER	1 (1.6%)	4 (5.1%)	1 (1.1%)
PYURIA	1 (1.6%)	3 (3.8%)	1 (1.1%)
VASCULAR DISORDER	1 (1.6%)	3 (3.8%)	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
PRURITUS	4 (6.6%)	2 (2.6%)	1 (1.1%)
ECZEMA	2 (3.3%)	2 (2.6%)	1 (1.1%)
MALAISE	1 (1.6%)	2 (2.6%)	1 (1.1%)
PERIODONTITIS	1 (1.6%)	2 (2.6%)	1 (1.1%)
FURUNCULOSIS	0	2 (2.6%)	1 (1.1%)
MONILIASIS	0	2 (2.6%)	1 (1.1%)
CARDIAC FAILURE	3 (4.9%)	1 (1.3%)	1 (1.1%)
IMPOTENCE	3 (4.9%)	1 (1.3%)	1 (1.1%)
BASAL CELL CARCINOMA	1 (1.6%)	1 (1.3%)	1 (1.1%)
DERMATITIS FUNGAL	1 (1.6%)	1 (1.3%)	1 (1.1%)
GINGIVITIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
INSOMNIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
LEUKOPENIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
POLYURIA	1 (1.6%)	1 (1.3%)	1 (1.1%)
RHINITIS	1 (1.6%)	1 (1.3%)	1 (1.1%)
THIRST	1 (1.6%)	1 (1.3%)	1 (1.1%)
FLATULENCE	0	1 (1.3%)	1 (1.1%)
GASTRIC ULCER	0	1 (1.3%)	1 (1.1%)
HEPATIC FUNCTION ABNORMAL	0	1 (1.3%)	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
LIVER FATTY	0	1 (1.3%)	1 (1.1%)
OSTEOPOROSIS	0	1 (1.3%)	1 (1.1%)
PALPITATION	0	1 (1.3%)	1 (1.1%)
PERIPHERAL ISCHEMIA	0	1 (1.3%)	1 (1.1%)
SKELETAL PAIN	2 (3.3%)	0	1 (1.1%)
SKIN DISORDER	2 (3.3%)	0	1 (1.1%)
VEIN VARICOSE	2 (3.3%)	0	1 (1.1%)
CEREBROVASCULAR DISORDER	1 (1.6%)	0	1 (1.1%)
COLITIS	1 (1.6%)	0	1 (1.1%)
DERMATITIS	1 (1.6%)	0	1 (1.1%)
EMBOLISM PULMONARY	1 (1.6%)	0	1 (1.1%)
EMOTIONAL LABILITY	1 (1.6%)	0	1 (1.1%)
GI HEMORRHAGE	1 (1.6%)	0	1 (1.1%)
GLAUCOMA	1 (1.6%)	0	1 (1.1%)
GOITRE	1 (1.6%)	0	1 (1.1%)
NAIL DISORDER	1 (1.6%)	0	1 (1.1%)
PULMONARY EDEMA	1 (1.6%)	0	1 (1.1%)
THERAPEUTIC RESPONSE INCREASED	1 (1.6%)	0	1 (1.1%)
VISION ABNORMAL	1 (1.6%)	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
ACIDOSIS	0	0	1 (1.1%)
ANUS DISORDER	0	0	1 (1.1%)
APPETITE INCREASED	0	0	1 (1.1%)
ARRHYTHMIA ATRIAL	0	0	1 (1.1%)
ASTHMA	0	0	1 (1.1%)
ATHEROSCLEROSIS	0	0	1 (1.1%)
ATRIOVENTRICULAR BLOCK	0	0	1 (1.1%)
BRADYCARDIA	0	0	1 (1.1%)
BREAST PAIN MALE	0	0	1 (1.1%)
BUNDLE BRANCH BLOCK	0	0	1 (1.1%)
CALCITONIN SERUM LEVEL INCREASED	0	0	1 (1.1%)
CONVULSIONS	0	0	1 (1.1%)
CORONARY ARTERY DISORDER	0	0	1 (1.1%)
DIPLOPIA	0	0	1 (1.1%)
EAR DISORDER NOS	0	0	1 (1.1%)
EPISTAXIS	0	0	1 (1.1%)
GASTRITIS	0	0	1 (1.1%)
HEPATITIS CHOLESTATIC	0	0	1 (1.1%)
HYPOTENSION POSTURAL	0	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
LEUKOCYTOSIS	0	0	1 (1.1%)
LIPOMA	0	0	1 (1.1%)
MACULA LUTEA DEGENERATION	0	0	1 (1.1%)
MENSTRUAL DISORDER	0	0	1 (1.1%)
MIGRAINE	0	0	1 (1.1%)
MIGRAINE AGGRAVATED	0	0	1 (1.1%)
NERVOUSNESS	0	0	1 (1.1%)
NEVUS	0	0	1 (1.1%)
OBESITY	0	0	1 (1.1%)
OTOSCLEROSIS	0	0	1 (1.1%)
OVARIAN CYST	0	0	1 (1.1%)
PENIS DISORDER	0	0	1 (1.1%)
PULMONARY CARCINOMA	0	0	1 (1.1%)
RESPIRATORY INSUFFICIENCY	0	0	1 (1.1%)
RETINITIS	0	0	1 (1.1%)
SKIN ULCERATION	0	0	1 (1.1%)
SUDDEN DEATH	0	0	1 (1.1%)
SYNOVITIS	0	0	1 (1.1%)
THROMBOCYTOPENIA	0	0	1 (1.1%)

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
THROMBOPHLEBITIS	0	0	1 (1.1%)
TINNITUS	0	0	1 (1.1%)
TRIGEMINAL NEURALGIA	0	0	1 (1.1%)
PROSTATIC DISORDER	2 (3.3%)	5 (6.4%)	0
CRAMPS LEGS	2 (3.3%)	3 (3.8%)	0
MICTURITION FREQUENCY	0	3 (3.8%)	0
INFECTION BACTERIAL	2 (3.3%)	2 (2.6%)	0
ALLERGIC REACTION	1 (1.6%)	2 (2.6%)	0
RASH ERYTHEMATOUS	1 (1.6%)	2 (2.6%)	0
RENAL FAILURE ACUTE	1 (1.6%)	2 (2.6%)	0
SALIVARY GLAND ENLARGEMENT	1 (1.6%)	2 (2.6%)	0
TACHYCARDIA	1 (1.6%)	2 (2.6%)	0
VOMITING	1 (1.6%)	2 (2.6%)	0
QT INCREASED	0	2 (2.6%)	0
SGPT INCREASED	0	2 (2.6%)	0
ALLERGY	1 (1.6%)	1 (1.3%)	0
DIVERTICULITIS	1 (1.6%)	1 (1.3%)	0
DUODENAL ULCER	1 (1.6%)	1 (1.3%)	0
EDEMA GENERALISED	1 (1.6%)	1 (1.3%)	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
ESOPHAGITIS	1 (1.6%)	1 (1.3%)	0
EYE PAIN	1 (1.6%)	1 (1.3%)	0
FEVER	1 (1.6%)	1 (1.3%)	0
GASTROINTESTINAL DISORDER NOS	1 (1.6%)	1 (1.3%)	0
HEPATIC ENZYMES INCREASED	1 (1.6%)	1 (1.3%)	0
NEUROPATHY	1 (1.6%)	1 (1.3%)	0
ALCOHOL INTOLERANCE	0	1 (1.3%)	0
ALOPECIA	0	1 (1.3%)	0
ARTHRITIS RHEUMATOID	0	1 (1.3%)	0
ARTHROPATHY	0	1 (1.3%)	0
BONE DEVELOPMENT ABNORMAL	0	1 (1.3%)	0
BONE DISORDER	0	1 (1.3%)	0
CARDIOMYOPATHY	0	1 (1.3%)	0
EDEMA PERIORBITAL	0	1 (1.3%)	0
ENTERITIS	0	1 (1.3%)	0
ERYTHROCYTES ABNORMAL	0	1 (1.3%)	0
EXTRASYSTOLES	0	1 (1.3%)	0
GASTRIC CARCINOMA	0	1 (1.3%)	0
GRANULOCYTOPENIA	0	1 (1.3%)	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
HEMORRHAGE NOS	0	1 (1.3%)	0
HERPES SIMPLEX	0	1 (1.3%)	0
HYDRONEPHROSIS	0	1 (1.3%)	0
HYPERTRIGLYCERIDEMIA	0	1 (1.3%)	0
HYPOKINESIA	0	1 (1.3%)	0
INFLUENZA-LIKE SYMPTOMS	0	1 (1.3%)	0
INTESTINAL PERFORATION	0	1 (1.3%)	0
LYMPHANGITIS	0	1 (1.3%)	0
LYMPHOPENIA	0	1 (1.3%)	0
MUSCLE WEAKNESS	0	1 (1.3%)	0
NEOPLASM NOS	0	1 (1.3%)	0
NOCTURIA	0	1 (1.3%)	0
OTITIS EXTERNA	0	1 (1.3%)	0
PARESIS	0	1 (1.3%)	0
PHLEBITIS	0	1 (1.3%)	0
PNEUMONIA	0	1 (1.3%)	0
RASH PUSTULAR	0	1 (1.3%)	0
RENAL CALCULUS	0	1 (1.3%)	0
SEBORRHEA	0	1 (1.3%)	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
SKIN HYPERTROPHY	0	1 (1.3%)	0
TESTIS DISORDER	0	1 (1.3%)	0
TETANY	0	1 (1.3%)	0
THROMBOSIS CORONARY	0	1 (1.3%)	0
URTICARIA	0	1 (1.3%)	0
VASOSPASM	0	1 (1.3%)	0
DYSURIA	2 (3.3%)	0	0
MYOCARDIAL ISCHEMIA	2 (3.3%)	0	0
MYOSITIS	2 (3.3%)	0	0
VAGINITIS	2 (3.3%)	0	0
ALBUMINURIA	1 (1.6%)	0	0
AMNESIA	1 (1.6%)	0	0
ANEMIA B TWELVE DEFICIENCY	1 (1.6%)	0	0
ANEMIA HYPOCHROMIC	1 (1.6%)	0	0
ANGINA PECTORIS AGGRAVATED	1 (1.6%)	0	0
BILIRUBINEMIA	1 (1.6%)	0	0
BLEPHARITIS	1 (1.6%)	0	0
CARDIAC FAILURE LEFT	1 (1.6%)	0	0
CARPAL TUNNEL SYNDROME	1 (1.6%)	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
CONFUSION	1 (1.6%)	0	0
CYSTITIS	1 (1.6%)	0	0
ECG ABNORMAL	1 (1.6%)	0	0
EDEMA PERIPHERAL	1 (1.6%)	0	0
EOSINOPHILIA	1 (1.6%)	0	0
HEART VALVE DISORDERS	1 (1.6%)	0	0
HEMORRHAGE RECTUM	1 (1.6%)	0	0
HYPERPARATHYROIDISM	1 (1.6%)	0	0
HYPESTHESIA	1 (1.6%)	0	0
HYPOTHYROIDISM	1 (1.6%)	0	0
LARYNGITIS	1 (1.6%)	0	0
LYMPHADENOPATHY CERVICAL	1 (1.6%)	0	0
NEURITIS	1 (1.6%)	0	0
SKIN NEOPLASM MALIGNANT	1 (1.6%)	0	0
TREMOR	1 (1.6%)	0	0
VERRUCA	1 (1.6%)	0	0
VESTIBULAR DISORDER	1 (1.6%)	0	0
ANEMIA NORMOCHROMIC	0	0	0
ANGIOEDEMA	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
AORTIC STENOSIS	0	0	0
APNEA	0	0	0
ARRHYTHMIA VENTRICULAR	0	0	0
ARTERITIS	0	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	0	0
BILIARY PAIN	0	0	0
BLADDER CARCINOMA	0	0	0
BRAIN NEOPLASM BENIGN	0	0	0
BREAST NEOPLASM FEMALE	0	0	0
BULLOUS ERUPTION	0	0	0
BURSITIS	0	0	0
CALCINOSIS	0	0	0
CARCINOMA	0	0	0
CHEST PAIN PRECORDIAL	0	0	0
CHEST X-RAY ABNORMAL	0	0	0
CHOLECYSTITIS	0	0	0
CHOLELITHIASIS	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	0	0
CLAUDICATION INTERMITTENT	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
CONJUNCTIVAL HEMORRHAGE	0	0	0
CORNEAL OPACITY	0	0	0
CYSTITIS HEMORRHAGIC	0	0	0
DEMENTIA	0	0	0
EARACHE	0	0	0
ECG ABNORMAL SPECIFIC	0	0	0
EDEMA	0	0	0
EDEMA CEREBRAL	0	0	0
EPIDIDYMITIS	0	0	0
ESOPHAGEAL ULCERATION	0	0	0
ESR INCREASED	0	0	0
FACE EDEMA	0	0	0
FECAL INCONTINENCE	0	0	0
FOLLICULITIS	0	0	0
GALL BLADDER DISORDER	0	0	0
GASTRIC ULCER HEMORRHAGIC	0	0	0
GASTROESOPHAGEAL REFLUX	0	0	0
GOUT	0	0	0
GRANULOMATOUS LESION	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
GYNECOMASTIA	0	0	0
HEART DISORDER	0	0	0
HEMOPTYSIS	0	0	0
HEMORRHOIDS	0	0	0
HEPATIC NEOPLASM MALIGNANT	0	0	0
HEPATOMEGALY	0	0	0
HOT FLUSHES	0	0	0
HYPERESTHESIA	0	0	0
HYPERKALEMIA	0	0	0
HYPERKINESIA	0	0	0
HYPERURICEMIA	0	0	0
HYPOCHOLESTEROLEMIA	0	0	0
HYPOGLYCEMIC REACTION	0	0	0
HYPOKALEMIA	0	0	0
HYPOTENSION	0	0	0
INTESTINAL ISCHEMIA	0	0	0
IRRITABLE BOWEL SYNDROME	0	0	0
LACRIMATION ABNORMAL	0	0	0
LYMPHADENOPATHY	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
LYMPHEDEMA	0	0	0
MELANOMA MALIGNANT	0	0	0
MENORRHAGIA	0	0	0
MICTURITION DISORDER	0	0	0
MYOPATHY	0	0	0
NECROSIS ISCHEMIC	0	0	0
NEOPLASM MALIGNANT	0	0	0
NEUROSIS	0	0	0
OSTEOMYELITIS	0	0	0
OVARIAN DISORDER	0	0	0
PALLOR	0	0	0
PHARYNX NEOPLASM MALIGNANT	0	0	0
PHLEBITIS SUPERFICIAL	0	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	0	0
PHOTOSENSITIVITY REACTION	0	0	0
PLEURAL EFFUSION	0	0	0
PLEURISY	0	0	0
PRURITUS GENITAL	0	0	0
PSORIASIS	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
PSORIASIS AGGRAVATED	0	0	0
PTOSIS	0	0	0
PURPURA	0	0	0
PYELONEPHRITIS	0	0	0
RENAL PAIN	0	0	0
RETINAL DETACHMENT	0	0	0
RIGORS	0	0	0
ROSACEA	0	0	0
SEPSIS	0	0	0
SPEECH DISORDER	0	0	0
STOMATITIS	0	0	0
STOMATITIS ULCERATIVE	0	0	0
STRANGURY	0	0	0
SUICIDE ATTEMPT	0	0	0
SWEATING INCREASED	0	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	0	0
THROMBOPHLEBITIS DEEP	0	0	0
THYROID ADENOMA	0	0	0
THYROID DISORDER	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4b

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	-2bd Comb Total- 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences	51 (83.6%)	62 (79.5%)	76 (84.4%)
Preferred Term			
TONGUE EDEMA	0	0	0
TONGUE ULCERATION	0	0	0
TOOTH DISORDER	0	0	0
TORTICOLLIS	0	0	0
TRACHEITIS	0	0	0
TYMPANIC MEMBRANE PERFORATION	0	0	0
URINARY INCONTINENCE	0	0	0
UTERINE FIBROID	0	0	0
VASCULITIS	0	0	0
VITREOUS DETACHMENT	0	0	0
WEIGHT DECREASE	0	0	0

Sort Order: descending order of 015:2bd+S/2bd, 015:1bd+S/2bd, 015:S/2bd.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	-4bd Mono Total-			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
BRONCHITIS	18 (14.5%)	23 (16.9%)	27 (19.4%)	1 (3.3%)
INJURY	16 (12.9%)	26 (19.1%)	17 (12.2%)	1 (3.3%)
BACK PAIN	15 (12.1%)	20 (14.7%)	15 (10.8%)	0
HYPERCHOLESTEROLEMIA	14 (11.3%)	11 (8.1%)	9 (6.5%)	9 (30.0%)
INFECTION VIRAL	13 (10.5%)	10 (7.4%)	12 (8.6%)	3 (10.0%)
EDEMA LEGS	13 (10.5%)	6 (4.4%)	6 (4.3%)	0
ARTHRITIS	12 (9.7%)	17 (12.5%)	12 (8.6%)	1 (3.3%)
URINARY TRACT INFECTION	10 (8.1%)	10 (7.4%)	16 (11.5%)	4 (13.3%)
PHARYNGITIS	10 (8.1%)	8 (5.9%)	10 (7.2%)	0
RESPIRATORY DISORDER	10 (8.1%)	3 (2.2%)	11 (7.9%)	1 (3.3%)
ARTHRALGIA	9 (7.3%)	14 (10.3%)	7 (5.0%)	0
NEURALGIA	9 (7.3%)	12 (8.8%)	9 (6.5%)	1 (3.3%)
HYPERLIPEMIA	9 (7.3%)	6 (4.4%)	8 (5.8%)	0
WEIGHT INCREASE	7 (5.6%)	7 (5.1%)	1 (0.7%)	2 (6.7%)
ABDOMINAL PAIN	7 (5.6%)	6 (4.4%)	9 (6.5%)	0
CONSTIPATION	7 (5.6%)	5 (3.7%)	3 (2.2%)	0
ANEMIA	7 (5.6%)	4 (2.9%)	3 (2.2%)	6 (20.0%)
ARTHROSIS	6 (4.8%)	9 (6.6%)	7 (5.0%)	1 (3.3%)

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
PAIN	6 (4.8%)	8 (5.9%)	5 (3.6%)	0
DYSPNEA	6 (4.8%)	6 (4.4%)	1 (0.7%)	0
MYALGIA	6 (4.8%)	5 (3.7%)	9 (6.5%)	1 (3.3%)
DEPRESSION	6 (4.8%)	4 (2.9%)	4 (2.9%)	0
UPPER RESP TRACT INFECTION	5 (4.0%)	10 (7.4%)	11 (7.9%)	3 (10.0%)
HEADACHE	5 (4.0%)	6 (4.4%)	6 (4.3%)	2 (6.7%)
ASTHENIA	5 (4.0%)	6 (4.4%)	3 (2.2%)	0
DIABETES MELLITUS AGGRAVATED	5 (4.0%)	3 (2.2%)	4 (2.9%)	10 (33.3%)
PARESTHESIA	5 (4.0%)	3 (2.2%)	1 (0.7%)	1 (3.3%)
IMPOTENCE	5 (4.0%)	1 (0.7%)	0	0
VEIN DISORDER	4 (3.2%)	4 (2.9%)	6 (4.3%)	0
INFECTION	4 (3.2%)	4 (2.9%)	3 (2.2%)	0
INFECTION FUNGAL	4 (3.2%)	4 (2.9%)	3 (2.2%)	0
DYSPEPSIA	4 (3.2%)	4 (2.9%)	2 (1.4%)	2 (6.7%)
CONJUNCTIVITIS	4 (3.2%)	3 (2.2%)	10 (7.2%)	1 (3.3%)
HYPERGLYCEMIA	4 (3.2%)	3 (2.2%)	9 (6.5%)	0
ECZEMA	4 (3.2%)	3 (2.2%)	7 (5.0%)	0
GASTROINTESTINAL DISORDER NOS	4 (3.2%)	3 (2.2%)	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
RETINAL DISORDER	4 (3.2%)	2 (1.5%)	1 (0.7%)	0
RHINITIS	3 (2.4%)	6 (4.4%)	6 (4.3%)	1 (3.3%)
TENDINITIS	3 (2.4%)	6 (4.4%)	2 (1.4%)	0
OSTEOPOROSIS	3 (2.4%)	5 (3.7%)	1 (0.7%)	0
SINUSITIS	3 (2.4%)	4 (2.9%)	6 (4.3%)	0
VERTIGO	3 (2.4%)	4 (2.9%)	4 (2.9%)	0
NEOPLASM NOS	3 (2.4%)	4 (2.9%)	2 (1.4%)	0
COLITIS	3 (2.4%)	4 (2.9%)	1 (0.7%)	0
PERIODONTITIS	3 (2.4%)	3 (2.2%)	5 (3.6%)	3 (10.0%)
CYSTITIS	3 (2.4%)	2 (1.5%)	4 (2.9%)	0
HEMATURIA	3 (2.4%)	2 (1.5%)	3 (2.2%)	3 (10.0%)
DIZZINESS	3 (2.4%)	2 (1.5%)	3 (2.2%)	0
GASTRITIS	3 (2.4%)	2 (1.5%)	1 (0.7%)	0
ANXIETY	3 (2.4%)	1 (0.7%)	7 (5.0%)	0
FATIGUE	3 (2.4%)	1 (0.7%)	2 (1.4%)	1 (3.3%)
NAIL DISORDER	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
PHLEBITIS	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
GLAUCOMA	3 (2.4%)	0	2 (1.4%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

- 1023 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
SKIN ULCERATION	3 (2.4%)	0	1 (0.7%)	0
PERIPHERAL ISCHEMIA	3 (2.4%)	0	0	1 (3.3%)
CRAMPS LEGS	2 (1.6%)	7 (5.1%)	6 (4.3%)	1 (3.3%)
ANGINA PECTORIS	2 (1.6%)	7 (5.1%)	6 (4.3%)	0
COUGHING	2 (1.6%)	7 (5.1%)	4 (2.9%)	2 (6.7%)
GASTROENTERITIS	2 (1.6%)	7 (5.1%)	3 (2.2%)	0
INSOMNIA	2 (1.6%)	6 (4.4%)	6 (4.3%)	1 (3.3%)
HYPERTENSION	2 (1.6%)	6 (4.4%)	5 (3.6%)	0
HYPERTENSION AGGRAVATED	2 (1.6%)	5 (3.7%)	2 (1.4%)	0
PROSTATIC DISORDER	2 (1.6%)	5 (3.7%)	1 (0.7%)	0
CATARACT	2 (1.6%)	4 (2.9%)	3 (2.2%)	1 (3.3%)
NAUSEA	2 (1.6%)	3 (2.2%)	6 (4.3%)	0
OTITIS MEDIA	2 (1.6%)	3 (2.2%)	3 (2.2%)	0
SWEATING INCREASED	2 (1.6%)	3 (2.2%)	1 (0.7%)	0
GOITRE	2 (1.6%)	3 (2.2%)	0	0
EDEMA DEPENDENT	2 (1.6%)	2 (1.5%)	3 (2.2%)	0
ASTHMA	2 (1.6%)	2 (1.5%)	2 (1.4%)	0
EXTRASYSTOLES	2 (1.6%)	2 (1.5%)	2 (1.4%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

- 1024 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	-4bd Mono Total-			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
GOUT	2 (1.6%)	2 (1.5%)	1 (0.7%)	1 (3.3%)
BUNDLE BRANCH BLOCK	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
GASTRIC ULCER	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
NPN INCREASED	2 (1.6%)	2 (1.5%)	1 (0.7%)	0
ATRIOVENTRICULAR BLOCK	2 (1.6%)	2 (1.5%)	0	0
GYNECOMASTIA	2 (1.6%)	2 (1.5%)	0	0
LARYNGITIS	2 (1.6%)	2 (1.5%)	0	0
SOMNOLENCE	2 (1.6%)	2 (1.5%)	0	0
ANEMIA HYPOCHROMIC	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
SKELETAL PAIN	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
VISION ABNORMAL	2 (1.6%)	1 (0.7%)	2 (1.4%)	0
ARTHRITIS AGGRAVATED	2 (1.6%)	1 (0.7%)	0	0
TACHYCARDIA	2 (1.6%)	1 (0.7%)	0	0
SYNCOPE	2 (1.6%)	0	2 (1.4%)	1 (3.3%)
CALCINOSIS	2 (1.6%)	0	1 (0.7%)	0
CEREBROVASCULAR DISORDER	2 (1.6%)	0	1 (0.7%)	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	2 (1.6%)	0	1 (0.7%)	0
HYPOKALEMIA	2 (1.6%)	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

- 1025 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
MONILIASIS	2 (1.6%)	0	1 (0.7%)	0
CARCINOMA	2 (1.6%)	0	0	0
MIGRAINE	2 (1.6%)	0	0	0
ROSACEA	2 (1.6%)	0	0	0
TINNITUS	2 (1.6%)	0	0	0
TORTICOLLIS	2 (1.6%)	0	0	0
WEIGHT DECREASE	2 (1.6%)	0	0	0
DIARRHEA	1 (0.8%)	6 (4.4%)	4 (2.9%)	1 (3.3%)
TRACHEITIS	1 (0.8%)	5 (3.7%)	1 (0.7%)	0
MYOCARDIAL INFARCTION	1 (0.8%)	4 (2.9%)	5 (3.6%)	0
FIBRILLATION ATRIAL	1 (0.8%)	3 (2.2%)	6 (4.3%)	0
GASTROESOPHAGEAL REFLUX	1 (0.8%)	3 (2.2%)	1 (0.7%)	0
ANUS DISORDER	1 (0.8%)	3 (2.2%)	0	0
MICTURITION FREQUENCY	1 (0.8%)	3 (2.2%)	0	0
CHEST PAIN	1 (0.8%)	2 (1.5%)	6 (4.3%)	2 (6.7%)
RASH	1 (0.8%)	2 (1.5%)	3 (2.2%)	1 (3.3%)
VASCULAR DISORDER	1 (0.8%)	2 (1.5%)	3 (2.2%)	0
HEMORRHOIDS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
PRURITUS	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
LEUKOPENIA	1 (0.8%)	2 (1.5%)	0	4 (13.3%)
BRADYCARDIA	1 (0.8%)	2 (1.5%)	0	0
CARPAL TUNNEL SYNDROME	1 (0.8%)	2 (1.5%)	0	0
HYPOTENSION	1 (0.8%)	2 (1.5%)	0	0
HYPOTHYROIDISM	1 (0.8%)	2 (1.5%)	0	0
INFECTION BACTERIAL	1 (0.8%)	2 (1.5%)	0	0
MYOPATHY	1 (0.8%)	2 (1.5%)	0	0
THROMBOCYTOPENIA	1 (0.8%)	2 (1.5%)	0	0
CARDIAC FAILURE	1 (0.8%)	1 (0.7%)	5 (3.6%)	1 (3.3%)
PNEUMONIA	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ALBUMINURIA	1 (0.8%)	1 (0.7%)	1 (0.7%)	2 (6.7%)
APPETITE INCREASED	1 (0.8%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
HYPERTRIGLYCERIDEMIA	1 (0.8%)	1 (0.7%)	1 (0.7%)	1 (3.3%)
FLATULENCE	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
PSORIASIS AGGRAVATED	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
BURSITIS	1 (0.8%)	1 (0.7%)	0	0
DEAFNESS	1 (0.8%)	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
DIVERTICULITIS	1 (0.8%)	1 (0.7%)	0	0
DUODENAL ULCER	1 (0.8%)	1 (0.7%)	0	0
LYMPHEDEMA	1 (0.8%)	1 (0.7%)	0	0
NEUROPATHY	1 (0.8%)	1 (0.7%)	0	0
OBESITY	1 (0.8%)	1 (0.7%)	0	0
RIGORS	1 (0.8%)	1 (0.7%)	0	0
SKIN HYPERTROPHY	1 (0.8%)	1 (0.7%)	0	0
NERVOUSNESS	1 (0.8%)	0	3 (2.2%)	0
CLAUDICATION INTERMITTENT	1 (0.8%)	0	2 (1.4%)	0
CYSTITIS HEMORRHAGIC	1 (0.8%)	0	2 (1.4%)	0
HOT FLUSHES	1 (0.8%)	0	2 (1.4%)	0
VOMITING	1 (0.8%)	0	2 (1.4%)	0
HYPESTHESIA	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
PALPITATION	1 (0.8%)	0	1 (0.7%)	1 (3.3%)
EARACHE	1 (0.8%)	0	1 (0.7%)	0
EDEMA GENERALISED	1 (0.8%)	0	1 (0.7%)	0
GALL BLADDER DISORDER	1 (0.8%)	0	1 (0.7%)	0
HEMORRHAGE RECTUM	1 (0.8%)	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
HEPATIC NEOPLASM MALIGNANT	1 (0.8%)	0	1 (0.7%)	0
RENAL CALCULUS	1 (0.8%)	0	1 (0.7%)	0
RENAL PAIN	1 (0.8%)	0	1 (0.7%)	0
THERAPEUTIC RESPONSE INCREASED	1 (0.8%)	0	1 (0.7%)	0
HERPES ZOSTER	1 (0.8%)	0	0	2 (6.7%)
ABSCESS	1 (0.8%)	0	0	0
BONE DISORDER	1 (0.8%)	0	0	0
BULLOUS ERUPTION	1 (0.8%)	0	0	0
EAR DISORDER NOS	1 (0.8%)	0	0	0
EOSINOPHILIA	1 (0.8%)	0	0	0
EPIDIDYMITIS	1 (0.8%)	0	0	0
ESOPHAGITIS	1 (0.8%)	0	0	0
FECAL INCONTINENCE	1 (0.8%)	0	0	0
HYPERESTHESIA	1 (0.8%)	0	0	0
HYPERKERATOSIS	1 (0.8%)	0	0	0
HYPERKINESIA	1 (0.8%)	0	0	0
LYMPHANGITIS	1 (0.8%)	0	0	0
NECROSIS ISCHEMIC	1 (0.8%)	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
NEUROPATHY PERIPHERAL	1 (0.8%)	0	0	0
OSTEOMYELITIS	1 (0.8%)	0	0	0
RETINAL DETACHMENT	1 (0.8%)	0	0	0
SALIVARY GLAND ENLARGEMENT	1 (0.8%)	0	0	0
SKIN DRY	1 (0.8%)	0	0	0
TONGUE ULCERATION	1 (0.8%)	0	0	0
TOOTH DISORDER	1 (0.8%)	0	0	0
VERRUCA	1 (0.8%)	0	0	0
HYPOGLYCEMIA	0	5 (3.7%)	0	1 (3.3%)
VEIN VARICOSE	0	3 (2.2%)	1 (0.7%)	0
GAMMA-GT INCREASED	0	2 (1.5%)	3 (2.2%)	0
DERMATITIS	0	2 (1.5%)	2 (1.4%)	0
OTITIS EXTERNA	0	2 (1.5%)	2 (1.4%)	0
PULMONARY EDEMA	0	2 (1.5%)	1 (0.7%)	1 (3.3%)
DYSURIA	0	2 (1.5%)	1 (0.7%)	0
EDEMA PERIPHERAL	0	2 (1.5%)	1 (0.7%)	0
BASAL CELL CARCINOMA	0	2 (1.5%)	0	0
BLOOD UREA NITROGEN INCREASED	0	2 (1.5%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
EDEMA	0	2 (1.5%)	0	0
PURPURA	0	2 (1.5%)	0	0
ARTERITIS	0	1 (0.7%)	3 (2.2%)	0
EPISTAXIS	0	1 (0.7%)	2 (1.4%)	1 (3.3%)
ALLERGIC REACTION	0	1 (0.7%)	2 (1.4%)	0
BLADDER CARCINOMA	0	1 (0.7%)	2 (1.4%)	0
FOLLICULITIS	0	1 (0.7%)	2 (1.4%)	0
HERPES SIMPLEX	0	1 (0.7%)	2 (1.4%)	0
AMNESIA	0	1 (0.7%)	1 (0.7%)	0
CHEST PAIN PRECORDIAL	0	1 (0.7%)	1 (0.7%)	0
CHOLELITHIASIS	0	1 (0.7%)	1 (0.7%)	0
ECG ABNORMAL SPECIFIC	0	1 (0.7%)	1 (0.7%)	0
EYE ABNORMALITY	0	1 (0.7%)	1 (0.7%)	0
FACE EDEMA	0	1 (0.7%)	1 (0.7%)	0
FEVER	0	1 (0.7%)	1 (0.7%)	0
PHOTOSENSITIVITY REACTION	0	1 (0.7%)	1 (0.7%)	0
PSORIASIS	0	1 (0.7%)	1 (0.7%)	0
SEBORRHEA	0	1 (0.7%)	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
STOMATITIS ULCERATIVE	0	1 (0.7%)	1 (0.7%)	0
TESTIS DISORDER	0	1 (0.7%)	1 (0.7%)	0
TREMOR	0	1 (0.7%)	1 (0.7%)	0
VAGINITIS	0	1 (0.7%)	1 (0.7%)	0
SEPSIS	0	1 (0.7%)	0	2 (6.7%)
DERMATITIS FUNGAL	0	1 (0.7%)	0	1 (3.3%)
ALLERGY	0	1 (0.7%)	0	0
ALOPECIA	0	1 (0.7%)	0	0
ANGIOEDEMA	0	1 (0.7%)	0	0
APNEA	0	1 (0.7%)	0	0
ARTHRITIS RHEUMATOID	0	1 (0.7%)	0	0
ATRIOVENTRICULAR BLOCK COMPLETE	0	1 (0.7%)	0	0
CHOLECYSTITIS	0	1 (0.7%)	0	0
CORNEAL OPACITY	0	1 (0.7%)	0	0
EDEMA CEREBRAL	0	1 (0.7%)	0	0
ENTERITIS	0	1 (0.7%)	0	0
ESOPHAGEAL ULCERATION	0	1 (0.7%)	0	0
FURUNCULOSIS	0	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

- 1032 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
GASTRIC ULCER HEMORRHAGIC	0	1 (0.7%)	0	0
GI HEMORRHAGE	0	1 (0.7%)	0	0
HEART VALVE DISORDERS	0	1 (0.7%)	0	0
HYPOTENSION POSTURAL	0	1 (0.7%)	0	0
INFLUENZA-LIKE SYMPTOMS	0	1 (0.7%)	0	0
INTESTINAL PERFORATION	0	1 (0.7%)	0	0
NEOPLASM MALIGNANT	0	1 (0.7%)	0	0
NEURITIS	0	1 (0.7%)	0	0
PALLOR	0	1 (0.7%)	0	0
PARESIS	0	1 (0.7%)	0	0
PHLEBITIS SUPERFICIAL	0	1 (0.7%)	0	0
PHOTOSENSITIVITY ALLERGIC REACT	0	1 (0.7%)	0	0
PRURITUS GENITAL	0	1 (0.7%)	0	0
STOMATITIS	0	1 (0.7%)	0	0
SUICIDE ATTEMPT	0	1 (0.7%)	0	0
TACHYCARDIA SUPRAVENTRICULAR	0	1 (0.7%)	0	0
THROMBOSIS CORONARY	0	1 (0.7%)	0	0
THYROID ADENOMA	0	1 (0.7%)	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
THYROID DISORDER	0	1 (0.7%)	0	0
TOOTH CARIES	0	1 (0.7%)	0	0
TYMPANIC MEMBRANE PERFORATION	0	1 (0.7%)	0	0
URINARY INCONTINENCE	0	1 (0.7%)	0	0
VASCULITIS	0	1 (0.7%)	0	0
VITREOUS DETACHMENT	0	1 (0.7%)	0	0
MYOCARDIAL ISCHEMIA	0	0	4 (2.9%)	1 (3.3%)
MENSTRUAL DISORDER	0	0	2 (1.4%)	1 (3.3%)
ARTHROPATHY	0	0	2 (1.4%)	0
CARDIAC FAILURE LEFT	0	0	2 (1.4%)	0
GRANULOMATOUS LESION	0	0	2 (1.4%)	0
HEPATIC FUNCTION ABNORMAL	0	0	2 (1.4%)	0
THROMBOPHLEBITIS DEEP	0	0	2 (1.4%)	0
EDEMA PERIORBITAL	0	0	1 (0.7%)	1 (3.3%)
LACRIMATION ABNORMAL	0	0	1 (0.7%)	1 (3.3%)
ANEMIA NORMOCHROMIC	0	0	1 (0.7%)	0
AORTIC STENOSIS	0	0	1 (0.7%)	0
ARRHYTHMIA VENTRICULAR	0	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
BILIARY PAIN	0	0	1 (0.7%)	0
BLEPHARITIS	0	0	1 (0.7%)	0
BRAIN NEOPLASM BENIGN	0	0	1 (0.7%)	0
BREAST NEOPLASM FEMALE	0	0	1 (0.7%)	0
CHEST X-RAY ABNORMAL	0	0	1 (0.7%)	0
CONJUNCTIVAL HEMORRHAGE	0	0	1 (0.7%)	0
DEMENTIA	0	0	1 (0.7%)	0
EMBOLISM PULMONARY	0	0	1 (0.7%)	0
ESR INCREASED	0	0	1 (0.7%)	0
HEART DISORDER	0	0	1 (0.7%)	0
HEMOPTYSIS	0	0	1 (0.7%)	0
HEPATOMEGALY	0	0	1 (0.7%)	0
HYPERKALEMIA	0	0	1 (0.7%)	0
HYPERURICEMIA	0	0	1 (0.7%)	0
HYPOGLYCEMIC REACTION	0	0	1 (0.7%)	0
INTESTINAL ISCHEMIA	0	0	1 (0.7%)	0
IRRITABLE BOWEL SYNDROME	0	0	1 (0.7%)	0
LIPOMA	0	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
LYMPHADENOPATHY	0	0	1 (0.7%)	0
MALAISE	0	0	1 (0.7%)	0
MELANOMA MALIGNANT	0	0	1 (0.7%)	0
MENORRHAGIA	0	0	1 (0.7%)	0
MICTURITION DISORDER	0	0	1 (0.7%)	0
MONILIASIS GENITAL	0	0	1 (0.7%)	0
NEUROSIS	0	0	1 (0.7%)	0
OVARIAN DISORDER	0	0	1 (0.7%)	0
PHARYNX NEOPLASM MALIGNANT	0	0	1 (0.7%)	0
PLEURAL EFFUSION	0	0	1 (0.7%)	0
PLEURISY	0	0	1 (0.7%)	0
POLYURIA	0	0	1 (0.7%)	0
PTOSIS	0	0	1 (0.7%)	0
PYELONEPHRITIS	0	0	1 (0.7%)	0
RASH PUSTULAR	0	0	1 (0.7%)	0
SPEECH DISORDER	0	0	1 (0.7%)	0
STRANGURY	0	0	1 (0.7%)	0
TETANY	0	0	1 (0.7%)	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
THIRST	0	0	1 (0.7%)	0
TONGUE EDEMA	0	0	1 (0.7%)	0
UTERINE FIBROID	0	0	1 (0.7%)	0
PYURIA	0	0	0	3 (10.0%)
ARRHYTHMIA ATRIAL	0	0	0	1 (3.3%)
ECG ABNORMAL	0	0	0	1 (3.3%)
ERYTHROCYTES ABNORMAL	0	0	0	1 (3.3%)
HYPOCHOLESTEROLEMIA	0	0	0	1 (3.3%)
RASH ERYTHEMATOUS	0	0	0	1 (3.3%)
ACIDOSIS	0	0	0	0
ALCOHOL INTOLERANCE	0	0	0	0
ALKALOSIS RESPIRATORY	0	0	0	0
ANEMIA B TWELVE DEFICIENCY	0	0	0	0
ANGINA PECTORIS AGGRAVATED	0	0	0	0
ATHEROSCLEROSIS	0	0	0	0
BILIRUBINEMIA	0	0	0	0
BONE DEVELOPMENT ABNORMAL	0	0	0	0
BREAST PAIN MALE	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
CALCITONIN SERUM LEVEL INCREASED	0	0	0	0
CARDIOMYOPATHY	0	0	0	0
CONFUSION	0	0	0	0
CONVULSIONS	0	0	0	0
CORONARY ARTERY DISORDER	0	0	0	0
DIPLOPIA	0	0	0	0
EMOTIONAL LABILITY	0	0	0	0
EYE PAIN	0	0	0	0
GASTRIC CARCINOMA	0	0	0	0
GINGIVITIS	0	0	0	0
GRANULOCYTOPENIA	0	0	0	0
HEMORRHAGE NOS	0	0	0	0
HEPATIC ENZYMES INCREASED	0	0	0	0
HEPATITIS CHOLESTATIC	0	0	0	0
HYDRONEPHROSIS	0	0	0	0
HYPERPARATHYROIDISM	0	0	0	0
HYPOKINESIA	0	0	0	0
LEUKOCYTOSIS	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
LIVER FATTY	0	0	0	0
LYMPHADENOPATHY CERVICAL	0	0	0	0
LYMPHOPENIA	0	0	0	0
MACULA LUTEA DEGENERATION	0	0	0	0
MIGRAINE AGGRAVATED	0	0	0	0
MUSCLE WEAKNESS	0	0	0	0
MYOSITIS	0	0	0	0
NEVUS	0	0	0	0
NOCTURIA	0	0	0	0
OTOSCLEROSIS	0	0	0	0
OVARIAN CYST	0	0	0	0
PENIS DISORDER	0	0	0	0
PULMONARY CARCINOMA	0	0	0	0
QT INCREASED	0	0	0	0
RENAL FAILURE ACUTE	0	0	0	0
RESPIRATORY INSUFFICIENCY	0	0	0	0
RETINITIS	0	0	0	0
SGPT INCREASED	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

Data Source Table X15.2.4c

Summary of On-Therapy (Started During the Open Label Study) Adverse Experiences by Preferred Term
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	-4bd Mono Total- 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences	105 (84.7%)	114 (83.8%)	115 (82.7%)	28 (93.3%)
Preferred Term				
SKIN DISORDER	0	0	0	0
SKIN NEOPLASM MALIGNANT	0	0	0	0
SUDDEN DEATH	0	0	0	0
SYNOVITIS	0	0	0	0
THROMBOPHLEBITIS	0	0	0	0
TOOTH ACHE	0	0	0	0
TRIGEMINAL NEURALGIA	0	0	0	0
URETHRAL DISORDER	0	0	0	0
URTICARIA	0	0	0	0
VASOSPASM	0	0	0	0
VESTIBULAR DISORDER	0	0	0	0

Sort Order: descending order of 020:4bd/4bd, 020:2bd/4bd, 020:G/4bd, 025:Total.

BRL 49653C/009

Data Source Table 15.4

List of Fatal Adverse Experiences (During the Open Label Study)

PID	Treatment	Days From Last Dose	Total Time on Medication (days)*	Adverse Experience Preferred Term	Cause of Death	Comment
This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the Sponsor Clinical Study Register.						

- 1041 -

CONFIDENTIAL
BRL-049653/RSD-
100TV9/1/CPMS-009

* Time relative to start of RSG medication (open label study)

*This section contained patient narratives which are textual descriptions of medical history, treatment and outcome for individual patients who experienced a clinically important adverse event including serious adverse events during the trial. They have been excluded to protect patient privacy. This data may be made available subject to an approved research proposal and a determination of the ability to provide information from the specific narratives whilst protecting the patient's privacy. For further information please see the Patient Level Data section of the **GSK Clinical Study Register**.*

Data Source Table 15.5a

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences Leading To Withdrawal	26 (11.4%)	40 (9.3%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term		
BODY AS A WHOLE GENERAL	3 (1.3%)	3 (0.7%)
ALCOHOL INTOLERANCE	1 (0.4%)	0
ASTHENIA	0	1 (0.2%)
CHEST PAIN	1 (0.4%)	0
EDEMA LEGS	0	1 (0.2%)
FATIGUE	0	1 (0.2%)
HOT FLUSHES	0	1 (0.2%)
MALAISE	0	1 (0.2%)
SUDDEN DEATH	1 (0.4%)	0
CARDIOVASCULAR GENERAL	1 (0.4%)	3 (0.7%)
CARDIAC FAILURE	0	2 (0.5%)
CARDIAC FAILURE LEFT	1 (0.4%)	0
SYNCOPE	0	1 (0.2%)
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	1 (0.4%)	2 (0.5%)
DIZZINESS	0	1 (0.2%)
HEADACHE	1 (0.4%)	1 (0.2%)
PARESTHESIA	1 (0.4%)	0
ENDOCRINE	0	1 (0.2%)
GYNECOMASTIA	0	1 (0.2%)
GASTROINTESTINAL SYSTEM	6 (2.6%)	4 (0.9%)
ABDOMINAL PAIN	1 (0.4%)	1 (0.2%)
DIARRHEA	1 (0.4%)	0
GASTRIC ULCER	1 (0.4%)	0
GASTROINTESTINAL DISORDER NOS	1 (0.4%)	0
GI HEMORRHAGE	1 (0.4%)	0
INTESTINAL ISCHEMIA	0	1 (0.2%)
NAUSEA	1 (0.4%)	3 (0.7%)
VOMITING	0	1 (0.2%)
HEART RATE AND RHYTHM	2 (0.9%)	1 (0.2%)
ARRHYTHMIA ATRIAL	1 (0.4%)	0
BRADYCARDIA	0	1 (0.2%)
FIBRILLATION ATRIAL	1 (0.4%)	0
LIVER AND BILIARY SYSTEM	2 (0.9%)	1 (0.2%)
GAMMA-GT INCREASED	0	1 (0.2%)

Data Source Table 15.5a

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences Leading To Withdrawal	26 (11.4%)	40 (9.3%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term		
LIVER FATTY	1 (0.4%)	0
SGPT INCREASED	1 (0.4%)	0
METABOLIC AND NUTRITIONAL	7 (3.1%)	13 (3.0%)
DIABETES MELLITUS AGGRAVATED	2 (0.9%)	3 (0.7%)
HYPERGLYCEMIA	4 (1.7%)	2 (0.5%)
HYPOGLYCEMIA	0	2 (0.5%)
HYPOGLYCEMIC REACTION	0	1 (0.2%)
WEIGHT DECREASE	0	1 (0.2%)
WEIGHT INCREASE	1 (0.4%)	4 (0.9%)
MUSCULOSKELETAL SYSTEM	0	1 (0.2%)
ARTHRALGIA	0	1 (0.2%)
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	2 (0.9%)	6 (1.4%)
MYOCARDIAL INFARCTION	2 (0.9%)	6 (1.4%)
NEOPLASM	2 (0.9%)	1 (0.2%)
GASTRIC CARCINOMA	1 (0.4%)	0
HEPATIC NEOPLASM MALIGNANT	0	1 (0.2%)
PULMONARY CARCINOMA	1 (0.4%)	0
PSYCHIATRIC	1 (0.4%)	3 (0.7%)
DEMENTIA	0	1 (0.2%)
INSOMNIA	0	1 (0.2%)
NERVOUSNESS	0	1 (0.2%)
SOMNOLENCE	1 (0.4%)	0
SUICIDE ATTEMPT	0	1 (0.2%)
RED BLOOD CELL	0	2 (0.5%)
ANEMIA	0	2 (0.5%)
REPRODUCTIVE MALE	0	1 (0.2%)
PROSTATIC DISORDER	0	1 (0.2%)
RESISTANCE MECHANISM	0	1 (0.2%)
INFECTION	0	1 (0.2%)
RESPIRATORY SYSTEM	1 (0.4%)	2 (0.5%)
PULMONARY EDEMA	0	1 (0.2%)

Data Source Table 15.5a

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Patients with Adverse Experiences Leading To Withdrawal	26 (11.4%)	40 (9.3%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term		
RESPIRATORY DISORDER	0	1 (0.2%)
RESPIRATORY INSUFFICIENCY	1 (0.4%)	0
SKIN AND APPENDAGES	0	1 (0.2%)
PSORIASIS AGGRAVATED	0	1 (0.2%)
VASCULAR EXTRACARDIAC	1 (0.4%)	1 (0.2%)
EMBOLISM PULMONARY	1 (0.4%)	0
VASCULITIS	0	1 (0.2%)
VISION	1 (0.4%)	1 (0.2%)
EYE ABNORMALITY	1 (0.4%)	0
RETINAL DISORDER	0	1 (0.2%)

Data Source Table 15.5b

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences Leading To Withdrawal	6 (9.8%)	11 (14.1%)	9 (10.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term			
BODY AS A WHOLE GENERAL	0	2 (2.6%)	1 (1.1%)
ALCOHOL INTOLERANCE	0	1 (1.3%)	0
ASTHENIA	0	0	0
CHEST PAIN	0	1 (1.3%)	0
EDEMA LEGS	0	0	0
FATIGUE	0	0	0
HOT FLUSHES	0	0	0
MALAISE	0	0	0
SUDDEN DEATH	0	0	1 (1.1%)
CARDIOVASCULAR GENERAL	1 (1.6%)	0	0
CARDIAC FAILURE	0	0	0
CARDIAC FAILURE LEFT	1 (1.6%)	0	0
SYNCOPE	0	0	0
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	0	1 (1.3%)	0
DIZZINESS	0	0	0
HEADACHE	0	1 (1.3%)	0
PARESTHESIA	0	1 (1.3%)	0
ENDOCRINE	0	0	0
GYNECOMASTIA	0	0	0
GASTROINTESTINAL SYSTEM	1 (1.6%)	4 (5.1%)	1 (1.1%)
ABDOMINAL PAIN	0	0	1 (1.1%)
DIARRHEA	0	1 (1.3%)	0
GASTRIC ULCER	0	1 (1.3%)	0
GASTROINTESTINAL DISORDER NOS	0	1 (1.3%)	0
GI HEMORRHAGE	1 (1.6%)	0	0
INTESTINAL ISCHEMIA	0	0	0
NAUSEA	0	1 (1.3%)	0
VOMITING	0	0	0
HEART RATE AND RHYTHM	0	0	2 (2.2%)
ARRHYTHMIA ATRIAL	0	0	1 (1.1%)
BRADYCARDIA	0	0	0
FIBRILLATION ATRIAL	0	0	1 (1.1%)
LIVER AND BILIARY SYSTEM	0	2 (2.6%)	0

Data Source Table 15.5b

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences Leading To Withdrawal	6 (9.8%)	11 (14.1%)	9 (10.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term			
GAMMA-GT INCREASED	0	0	0
LIVER FATTY	0	1 (1.3%)	0
SGPT INCREASED	0	1 (1.3%)	0
METABOLIC AND NUTRITIONAL	3 (4.9%)	2 (2.6%)	2 (2.2%)
DIABETES MELLITUS AGGRAVATED	0	1 (1.3%)	1 (1.1%)
HYPERGLYCEMIA	2 (3.3%)	1 (1.3%)	1 (1.1%)
HYPOGLYCEMIA	0	0	0
HYPOGLYCEMIC REACTION	0	0	0
WEIGHT DECREASE	0	0	0
WEIGHT INCREASE	1 (1.6%)	0	0
MUSCULOSKELETAL SYSTEM	0	0	0
ARTHRALGIA	0	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	1 (1.6%)	0	1 (1.1%)
MYOCARDIAL INFARCTION	1 (1.6%)	0	1 (1.1%)
NEOPLASM	0	1 (1.3%)	1 (1.1%)
GASTRIC CARCINOMA	0	1 (1.3%)	0
HEPATIC NEOPLASM MALIGNANT	0	0	0
PULMONARY CARCINOMA	0	0	1 (1.1%)
PSYCHIATRIC	0	1 (1.3%)	0
DEMENTIA	0	0	0
INSOMNIA	0	0	0
NERVOUSNESS	0	0	0
SOMNOLENCE	0	1 (1.3%)	0
SUICIDE ATTEMPT	0	0	0
RED BLOOD CELL	0	0	0
ANEMIA	0	0	0
REPRODUCTIVE MALE	0	0	0
PROSTATIC DISORDER	0	0	0
RESISTANCE MECHANISM	0	0	0
INFECTION	0	0	0

Data Source Table 15.5b

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Patients with Adverse Experiences Leading To Withdrawal	6 (9.8%)	11 (14.1%)	9 (10.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term			
RESPIRATORY SYSTEM	0	0	1 (1.1%)
PULMONARY EDEMA	0	0	0
RESPIRATORY DISORDER	0	0	0
RESPIRATORY INSUFFICIENCY	0	0	1 (1.1%)
SKIN AND APPENDAGES	0	0	0
PSORIASIS AGGRAVATED	0	0	0
VASCULAR EXTRACARDIAC	1 (1.6%)	0	0
EMBOLISM PULMONARY	1 (1.6%)	0	0
VASCULITIS	0	0	0
VISION	0	1 (1.3%)	0
EYE ABNORMALITY	0	1 (1.3%)	0
RETINAL DISORDER	0	0	0

Data Source Table 15.5c

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	4bd Mono Total 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences Leading To Withdrawal	8 (6.5%)	10 (7.4%)	16 (11.5%)	6 (20.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term				
BODY AS A WHOLE GENERAL	0	1 (0.7%)	2 (1.4%)	0
ALCOHOL INTOLERANCE	0	0	0	0
ASTHENIA	0	0	1 (0.7%)	0
CHEST PAIN	0	0	0	0
EDEMA LEGS	0	1 (0.7%)	0	0
FATIGUE	0	0	1 (0.7%)	0
HOT FLUSHES	0	0	1 (0.7%)	0
MALAISE	0	0	1 (0.7%)	0
SUDDEN DEATH	0	0	0	0
CARDIOVASCULAR GENERAL	0	0	2 (1.4%)	1 (3.3%)
CARDIAC FAILURE	0	0	1 (0.7%)	1 (3.3%)
CARDIAC FAILURE LEFT	0	0	0	0
SYNCOPE	0	0	1 (0.7%)	0
CENTRAL AND PERIPHERAL NERVOUS SYSTEM	1 (0.8%)	0	1 (0.7%)	0
DIZZINESS	1 (0.8%)	0	0	0
HEADACHE	0	0	1 (0.7%)	0
PARESTHESIA	0	0	0	0
ENDOCRINE	1 (0.8%)	0	0	0
GYNECOMASTIA	1 (0.8%)	0	0	0
GASTROINTESTINAL SYSTEM	1 (0.8%)	1 (0.7%)	2 (1.4%)	0
ABDOMINAL PAIN	1 (0.8%)	0	0	0
DIARRHEA	0	0	0	0
GASTRIC ULCER	0	0	0	0
GASTROINTESTINAL DISORDER NOS	0	0	0	0
GI HEMORRHAGE	0	0	0	0
INTESTINAL ISCHEMIA	0	0	1 (0.7%)	0
NAUSEA	1 (0.8%)	1 (0.7%)	1 (0.7%)	0
VOMITING	1 (0.8%)	0	0	0
HEART RATE AND RHYTHM	0	1 (0.7%)	0	0
ARRHYTHMIA ATRIAL	0	0	0	0

Data Source Table 15.5c

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	4bd Mono 020:2bd/4bd (N=136)	Total 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences Leading To Withdrawal	8 (6.5%)	10 (7.4%)	16 (11.5%)	6 (20.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term				
BRADYCARDIA	0	1 (0.7%)	0	0
FIBRILLATION ATRIAL	0	0	0	0
LIVER AND BILIARY SYSTEM	0	0	1 (0.7%)	0
GAMMA-GT INCREASED	0	0	1 (0.7%)	0
LIVER FATTY	0	0	0	0
SGPT INCREASED	0	0	0	0
METABOLIC AND NUTRITIONAL	2 (1.6%)	3 (2.2%)	3 (2.2%)	5 (16.7%)
DIABETES MELLITUS AGGRAVATED	0	0	0	3 (10.0%)
HYPERGLYCEMIA	0	1 (0.7%)	1 (0.7%)	0
HYPOGLYCEMIA	0	2 (1.5%)	0	0
HYPOGLYCEMIC REACTION	0	0	1 (0.7%)	0
WEIGHT DECREASE	1 (0.8%)	0	0	0
WEIGHT INCREASE	1 (0.8%)	0	1 (0.7%)	2 (6.7%)
MUSCULOSKELETAL SYSTEM	0	1 (0.7%)	0	0
ARTHRALGIA	0	1 (0.7%)	0	0
MYOCARDIAL ENDOCARDIAL PERICARDIAL VALVE	1 (0.8%)	0	5 (3.6%)	0
MYOCARDIAL INFARCTION	1 (0.8%)	0	5 (3.6%)	0
NEOPLASM	1 (0.8%)	0	0	0
GASTRIC CARCINOMA	0	0	0	0
HEPATIC NEOPLASM MALIGNANT	1 (0.8%)	0	0	0
PULMONARY CARCINOMA	0	0	0	0
PSYCHIATRIC	0	1 (0.7%)	2 (1.4%)	0
DEMENTIA	0	0	1 (0.7%)	0
INSOMNIA	0	0	1 (0.7%)	0
NERVOUSNESS	0	0	1 (0.7%)	0
SOMNOLENCE	0	0	0	0
SUICIDE ATTEMPT	0	1 (0.7%)	0	0
RED BLOOD CELL	1 (0.8%)	0	1 (0.7%)	0

Data Source Table 15.5c

Summary of On-Therapy (During the Open Label Study) Withdrawals due to an Adverse Experience
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	4bd Mono Total 020:G/4bd (N=139)	025:Total (N=30)
Patients with Adverse Experiences Leading To Withdrawal	8 (6.5%)	10 (7.4%)	16 (11.5%)	6 (20.0%)
Adverse Experience Causing Withdrawal by WHO Body System/Preferred Term				
ANEMIA	1 (0.8%)	0	1 (0.7%)	0
REPRODUCTIVE MALE	0	1 (0.7%)	0	0
PROSTATIC DISORDER	0	1 (0.7%)	0	0
RESISTANCE MECHANISM	0	1 (0.7%)	0	0
INFECTION	0	1 (0.7%)	0	0
RESPIRATORY SYSTEM	1 (0.8%)	0	0	1 (3.3%)
PULMONARY EDEMA	0	0	0	1 (3.3%)
RESPIRATORY DISORDER	1 (0.8%)	0	0	0
RESPIRATORY INSUFFICIENCY	0	0	0	0
SKIN AND APPENDAGES	0	1 (0.7%)	0	0
PSORIASIS AGGRAVATED	0	1 (0.7%)	0	0
VASCULAR EXTRACARDIAC	0	1 (0.7%)	0	0
EMBOLISM PULMONARY	0	0	0	0
VASCULITIS	0	1 (0.7%)	0	0
VISION	1 (0.8%)	0	0	0
EYE ABNORMALITY	0	0	0	0
RETINAL DISORDER	1 (0.8%)	0	0	0

*This section contained patient narratives which are textual descriptions of medical history, treatment and outcome for individual patients who experienced a clinically important adverse event including serious adverse events during the trial. They have been excluded to protect patient privacy. This data may be made available subject to an approved research proposal and a determination of the ability to provide information from the specific narratives whilst protecting the patient's privacy. For further information please see the Patient Level Data section of the **GSK Clinical Study Register**.*

BRL 49653C/009

Data Source Table 15.6.2Ba

Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern
or Specified Change From Open Label Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Systolic Blood Pressure (mmHg)		
> 50 increase from baseline	8 (3.5%)	0
> 50 decrease from baseline	5 (2.2%)	2 (0.5%)
Diastolic Blood Pressure (mmHg)		
> 30 increase from baseline	4 (1.7%)	5 (1.2%)
> 30 decrease from baseline	5 (2.2%)	4 (0.9%)
Heart Rate (bpm)		
< 50	5 (2.2%)	12 (2.8%)
> 120	0	0

Data Source Table 15.6.2Bb

Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern
or Specified Change From Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Systolic Blood Pressure (mmHg)			
> 50 increase from baseline	2 (3.3%)	3 (3.8%)	3 (3.3%)
> 50 decrease from baseline	3 (4.9%)	1 (1.3%)	1 (1.1%)
Diastolic Blood Pressure (mmHg)			
> 30 increase from baseline	1 (1.6%)	1 (1.3%)	2 (2.2%)
> 30 decrease from baseline	2 (3.3%)	1 (1.3%)	2 (2.2%)
Heart Rate (bpm)			
< 50	2 (3.3%)	2 (2.6%)	1 (1.1%)
> 120	0	0	0

Data Source Table 15.6.2Bc

Summary of On-Therapy (During the Open Label Study) Vital Signs of Potential Clinical Concern
or Specified Change From Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Systolic Blood Pressure (mmHg)				
> 50 increase from baseline	0	0	0	0
> 50 decrease from baseline	1 (0.8%)	1 (0.7%)	0	0
Diastolic Blood Pressure (mmHg)				
> 30 increase from baseline	2 (1.6%)	0	2 (1.4%)	1 (3.3%)
> 30 decrease from baseline	1 (0.8%)	1 (0.7%)	0	2 (6.7%)
Heart Rate (bpm)				
< 50	3 (2.4%)	3 (2.2%)	3 (2.2%)	3 (10.0%)
> 120	0	0	0	0

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Double Blind Baseline		
Number of patients with values	229	430
Mean	141.5	139.1
SD	16.77	14.92
Median	140.0	140.0
Minimum	100	90
Maximum	185	195
Open Label Baseline		
Number of patients with values	229	430
Mean	141.4	138.8
SD	16.87	14.12
Median	140.0	140.0
Minimum	98	90
Maximum	208	190
Month 0		
Number of patients with values	229	428
Mean	141.4	138.8
SD	16.87	14.08
Median	140.0	140.0
Minimum	98	90
Maximum	208	190
Month 1		
Number of patients with values	225	421
Mean	141.1	139.0
SD	16.11	14.55
Median	140.0	140.0
Minimum	90	98
Maximum	180	190

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit

All Patients Who Entered Study 009

Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 2		
Number of patients with values	224	411
Mean	141.0	138.6
SD	16.81	13.61
Median	140.0	140.0
Minimum	90	100
Maximum	186	185
Month 3		
Number of patients with values	219	402
Mean	140.6	137.6
SD	15.48	13.84
Median	140.0	140.0
Minimum	98	99
Maximum	200	181
Month 6		
Number of patients with values	212	394
Mean	142.0	138.1
SD	17.58	13.65
Median	140.0	140.0
Minimum	100	102
Maximum	200	182
Month 9		
Number of patients with values	204	379
Mean	142.7	139.4
SD	16.51	13.74
Median	140.0	140.0
Minimum	98	100
Maximum	190	190

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 12		
Number of patients with values	188	345
Mean	144.6	140.5
SD	16.25	14.22
Median	142.0	140.0
Minimum	107	110
Maximum	192	182
Month 15		
Number of patients with values	174	325
Mean	143.4	139.1
SD	17.08	14.64
Median	140.0	140.0
Minimum	85	90
Maximum	200	190
Month 18		
Number of patients with values	157	302
Mean	141.1	138.1
SD	17.05	14.12
Median	140.0	138.0
Minimum	85	90
Maximum	190	180
Month 21		
Number of patients with values	153	285
Mean	142.5	137.7
SD	18.76	12.95
Median	140.0	140.0
Minimum	105	101
Maximum	210	180

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit

All Patients Who Entered Study 009

Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 24		
Number of patients with values	133	267
Mean	142.1	138.4
SD	16.66	13.66
Median	140.0	140.0
Minimum	110	100
Maximum	204	180
Month 27		
Number of patients with values	124	239
Mean	142.6	138.8
SD	17.56	13.45
Median	140.0	140.0
Minimum	97	105
Maximum	220	180
Month 30		
Number of patients with values	115	210
Mean	141.3	135.8
SD	16.42	13.20
Median	140.0	135.0
Minimum	100	100
Maximum	192	180
Month 33		
Number of patients with values	98	137
Mean	143.0	138.2
SD	18.37	12.51
Median	140.0	136.0
Minimum	110	110
Maximum	210	180

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit

All Patients Who Entered Study 009

Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 36		
Number of patients with values	84	85
Mean	141.6	136.8
SD	15.74	12.05
Median	140.0	138.0
Minimum	107	110
Maximum	190	170
Month 39		
Number of patients with values	52	0
Mean	143.3	
SD	19.83	
Median	140.0	
Minimum	105	
Maximum	213	
Month 42		
Number of patients with values	32	0
Mean	145.7	
SD	18.78	
Median	141.0	
Minimum	107	
Maximum	210	
Month 45		
Number of patients with values	11	0
Mean	140.9	
SD	7.35	
Median	140.0	
Minimum	130	
Maximum	150	

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit

All Patients Who Entered Study 009

Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Double Blind Baseline		
Number of patients with values	229	430
Mean	81.9	81.9
SD	8.66	8.42
Median	80.0	80.0
Minimum	60	55
Maximum	110	113
Open Label Baseline		
Number of patients with values	229	430
Mean	81.7	80.9
SD	8.60	8.60
Median	80.0	80.0
Minimum	60	56
Maximum	110	110
Month 0		
Number of patients with values	229	428
Mean	81.7	80.9
SD	8.60	8.60
Median	80.0	80.0
Minimum	60	56
Maximum	110	110
Month 1		
Number of patients with values	225	421
Mean	80.7	80.7
SD	8.39	8.60
Median	80.0	80.0
Minimum	50	60
Maximum	100	110

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 2		
Number of patients with values	224	411
Mean	81.1	80.4
SD	8.72	8.56
Median	80.0	80.0
Minimum	59	56
Maximum	106	120
Month 3		
Number of patients with values	219	402
Mean	80.7	80.1
SD	8.95	8.47
Median	80.0	80.0
Minimum	53	56
Maximum	100	116
Month 6		
Number of patients with values	212	394
Mean	80.7	80.1
SD	8.78	8.24
Median	80.0	80.0
Minimum	56	52
Maximum	110	106
Month 9		
Number of patients with values	204	379
Mean	80.4	80.1
SD	9.10	8.23
Median	80.0	80.0
Minimum	60	60
Maximum	113	108

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 12		
Number of patients with values	188	345
Mean	81.6	80.4
SD	8.02	8.31
Median	80.0	80.0
Minimum	60	60
Maximum	100	110
Month 15		
Number of patients with values	174	325
Mean	80.5	80.1
SD	7.47	7.60
Median	80.0	80.0
Minimum	65	60
Maximum	100	100
Month 18		
Number of patients with values	157	302
Mean	80.7	79.4
SD	8.17	7.63
Median	80.0	80.0
Minimum	60	59
Maximum	100	105
Month 21		
Number of patients with values	153	285
Mean	80.0	79.7
SD	8.82	7.83
Median	80.0	80.0
Minimum	60	60
Maximum	104	110

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 24		
Number of patients with values	133	267
Mean	79.0	79.4
SD	8.75	7.96
Median	80.0	80.0
Minimum	60	50
Maximum	103	105
Month 27		
Number of patients with values	124	239
Mean	79.7	79.6
SD	8.50	7.97
Median	80.0	80.0
Minimum	56	60
Maximum	101	110
Month 30		
Number of patients with values	115	210
Mean	78.4	78.5
SD	9.20	7.30
Median	80.0	80.0
Minimum	53	60
Maximum	100	100
Month 33		
Number of patients with values	98	137
Mean	79.7	80.0
SD	8.66	7.41
Median	80.0	80.0
Minimum	56	67
Maximum	104	100

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 36		
Number of patients with values	84	85
Mean	79.6	79.0
SD	8.25	7.50
Median	80.0	80.0
Minimum	54	50
Maximum	100	98
Month 39		
Number of patients with values	52	0
Mean	79.4	
SD	10.55	
Median	80.0	
Minimum	54	
Maximum	108	
Month 42		
Number of patients with values	32	0
Mean	81.4	
SD	10.46	
Median	80.0	
Minimum	60	
Maximum	106	
Month 45		
Number of patients with values	11	0
Mean	77.0	
SD	6.21	
Median	80.0	
Minimum	68	
Maximum	85	

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Double Blind Baseline		
Number of patients with values	229	430
Mean	73.0	71.5
SD	8.95	9.42
Median	72.0	71.5
Minimum	48	46
Maximum	113	102
Open Label Baseline		
Number of patients with values	229	430
Mean	72.5	72.4
SD	9.01	9.61
Median	72.0	72.0
Minimum	48	37
Maximum	102	102
Month 0		
Number of patients with values	229	425
Mean	72.5	72.4
SD	9.01	9.62
Median	72.0	72.0
Minimum	48	37
Maximum	102	102
Month 1		
Number of patients with values	225	420
Mean	72.7	71.9
SD	9.16	8.95
Median	72.0	72.0
Minimum	50	40
Maximum	120	100

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 2		
Number of patients with values	224	410
Mean	72.8	71.5
SD	8.86	8.80
Median	72.0	72.0
Minimum	50	37
Maximum	107	100
Month 3		
Number of patients with values	217	401
Mean	72.6	71.4
SD	9.15	8.91
Median	72.0	72.0
Minimum	49	42
Maximum	100	102
Month 6		
Number of patients with values	210	392
Mean	72.6	72.4
SD	9.75	9.12
Median	72.0	72.0
Minimum	50	47
Maximum	100	100
Month 9		
Number of patients with values	200	379
Mean	72.1	71.5
SD	9.14	8.74
Median	72.0	72.0
Minimum	49	44
Maximum	100	100

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 12		
Number of patients with values	188	345
Mean	72.7	72.0
SD	10.16	9.21
Median	72.0	72.0
Minimum	44	48
Maximum	120	104
Month 15		
Number of patients with values	172	323
Mean	72.6	72.2
SD	8.63	8.10
Median	72.0	72.0
Minimum	49	52
Maximum	100	100
Month 18		
Number of patients with values	157	302
Mean	72.3	71.2
SD	10.07	8.52
Median	72.0	72.0
Minimum	48	50
Maximum	100	98
Month 21		
Number of patients with values	153	284
Mean	72.3	71.4
SD	8.43	8.16
Median	72.0	72.0
Minimum	50	42
Maximum	96	96

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 24		
Number of patients with values	132	266
Mean	70.7	71.8
SD	8.94	9.26
Median	71.0	72.0
Minimum	47	49
Maximum	100	102
Month 27		
Number of patients with values	123	238
Mean	70.3	71.5
SD	8.19	8.55
Median	70.0	72.0
Minimum	50	48
Maximum	92	103
Month 30		
Number of patients with values	114	208
Mean	71.9	70.8
SD	8.89	9.45
Median	72.0	71.0
Minimum	56	50
Maximum	100	102
Month 33		
Number of patients with values	98	137
Mean	71.4	72.4
SD	8.39	8.53
Median	72.0	72.0
Minimum	52	48
Maximum	92	100

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 36		
Number of patients with values	83	82
Mean	71.2	71.8
SD	7.89	8.69
Median	72.0	72.0
Minimum	54	56
Maximum	88	90
Month 39		
Number of patients with values	52	0
Mean	75.0	
SD	8.87	
Median	74.0	
Minimum	56	
Maximum	100	
Month 42		
Number of patients with values	32	0
Mean	71.7	
SD	9.97	
Median	70.0	
Minimum	56	
Maximum	100	
Month 45		
Number of patients with values	11	0
Mean	68.2	
SD	5.90	
Median	68.0	
Minimum	60	
Maximum	80	

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Double Blind Baseline		
Number of patients with values	229	430
Mean	77.40	81.44
SD	14.143	13.334
Median	76.00	81.00
Minimum	49.5	50.5
Maximum	117.0	118.0
Open Label Baseline		
Number of patients with values	229	430
Mean	78.75	83.28
SD	14.111	13.989
Median	77.50	82.00
Minimum	50.0	49.0
Maximum	118.0	127.0
Month 0		
Number of patients with values	229	430
Mean	78.75	83.28
SD	14.111	13.989
Median	77.50	82.00
Minimum	50.0	49.0
Maximum	118.0	127.0
Month 1		
Number of patients with values	5	35
Mean	77.18	83.86
SD	12.977	12.442
Median	75.50	84.00
Minimum	64.5	62.0
Maximum	97.5	105.0

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 2		
Number of patients with values	19	30
Mean	85.70	82.35
SD	12.932	13.435
Median	85.70	80.50
Minimum	57.7	57.0
Maximum	109.0	109.0
Month 3		
Number of patients with values	148	355
Mean	78.59	83.43
SD	14.060	14.072
Median	76.40	82.40
Minimum	50.0	49.0
Maximum	118.0	127.4
Month 6		
Number of patients with values	158	366
Mean	79.62	83.95
SD	14.123	13.958
Median	78.85	83.00
Minimum	51.4	49.0
Maximum	117.0	122.0
Month 9		
Number of patients with values	168	361
Mean	79.89	84.06
SD	13.840	14.166
Median	78.85	83.00
Minimum	52.0	41.0
Maximum	119.0	125.0

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 12		
Number of patients with values	172	330
Mean	80.47	84.43
SD	13.875	14.035
Median	79.45	84.00
Minimum	53.0	50.0
Maximum	119.0	126.0
Month 15		
Number of patients with values	172	321
Mean	81.33	84.14
SD	14.416	14.139
Median	79.60	84.00
Minimum	53.5	50.0
Maximum	117.0	127.0
Month 18		
Number of patients with values	158	301
Mean	80.83	84.21
SD	14.438	14.519
Median	79.65	84.00
Minimum	47.7	50.0
Maximum	117.0	130.0
Month 21		
Number of patients with values	153	285
Mean	81.19	84.65
SD	14.317	14.601
Median	80.00	85.00
Minimum	54.0	50.0
Maximum	118.6	128.0

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 24		
Number of patients with values	133	265
Mean	81.73	85.06
SD	14.500	14.562
Median	80.00	84.80
Minimum	54.0	48.0
Maximum	117.0	130.0
Month 27		
Number of patients with values	123	239
Mean	83.52	85.59
SD	14.482	14.748
Median	82.00	85.50
Minimum	54.0	50.0
Maximum	120.2	130.0
Month 30		
Number of patients with values	115	210
Mean	82.96	85.89
SD	14.790	13.870
Median	81.00	85.60
Minimum	54.0	51.0
Maximum	124.6	130.0
Month 33		
Number of patients with values	98	138
Mean	83.11	86.29
SD	14.584	14.045
Median	82.05	87.00
Minimum	54.0	51.0
Maximum	116.0	124.4

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Entered Study 009
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Month 36		
Number of patients with values	84	85
Mean	83.16	86.85
SD	15.091	14.355
Median	81.75	88.00
Minimum	54.0	52.0
Maximum	119.0	132.0
Month 39		
Number of patients with values	52	0
Mean	83.90	
SD	15.619	
Median	82.50	
Minimum	54.0	
Maximum	122.0	
Month 42		
Number of patients with values	32	0
Mean	82.62	
SD	13.999	
Median	81.00	
Minimum	56.4	
Maximum	113.0	
Month 45		
Number of patients with values	11	0
Mean	79.35	
SD	16.845	
Median	80.00	
Minimum	57.4	
Maximum	104.0	

BRL 49653C/009

Data Source Table 15.6.3Ba

Summary Statistics for Vital Signs at Each Visit
All Patients Who Entered Study 009
Parameter: Waist/Hip Ratio

Time Relative to Start of Study Medication	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Double Blind Baseline		
Number of patients with values	226	428
Mean	0.949	0.955
SD	0.0737	0.0745
Median	0.950	0.960
Minimum	0.73	0.75
Maximum	1.24	1.17
Open Label Baseline		
Number of patients with values	211	397
Mean	0.946	0.952
SD	0.0720	0.0781
Median	0.950	0.950
Minimum	0.71	0.73
Maximum	1.13	1.19

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	139.0	142.6	142.2
SD	15.30	17.26	17.29
Median	140.0	140.0	140.0
Minimum	100	100	110
Maximum	185	185	185
Open Label Baseline			
Number of patients with values	61	78	90
Mean	143.8	139.9	141.0
SD	18.46	15.66	16.78
Median	140.0	140.0	140.0
Minimum	98	110	110
Maximum	208	197	200
Month 0			
Number of patients with values	61	78	90
Mean	143.8	139.9	141.0
SD	18.46	15.66	16.78
Median	140.0	140.0	140.0
Minimum	98	110	110
Maximum	208	197	200
Month 1			
Number of patients with values	60	76	89
Mean	139.7	141.8	141.5
SD	15.61	17.09	15.69
Median	140.0	140.0	140.0
Minimum	94	90	110
Maximum	170	180	180

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 2			
Number of patients with values	58	77	89
Mean	140.9	142.4	139.9
SD	17.95	16.48	16.44
Median	140.0	140.0	140.0
Minimum	90	110	108
Maximum	180	186	186
Month 3			
Number of patients with values	57	76	86
Mean	139.8	143.7	138.5
SD	14.37	16.33	15.16
Median	140.0	142.5	139.5
Minimum	98	100	100
Maximum	170	200	180
Month 6			
Number of patients with values	57	73	82
Mean	142.1	141.4	142.4
SD	16.12	17.63	18.66
Median	140.0	140.0	140.0
Minimum	105	100	110
Maximum	184	194	200
Month 9			
Number of patients with values	56	71	77
Mean	142.7	143.5	142.0
SD	16.13	17.46	16.07
Median	140.0	144.0	140.0
Minimum	98	110	110
Maximum	180	190	190

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 12			
Number of patients with values	54	62	72
Mean	144.4	145.5	144.0
SD	16.02	15.77	17.01
Median	147.0	145.0	140.0
Minimum	107	110	109
Maximum	180	180	192
Month 15			
Number of patients with values	50	57	67
Mean	142.2	143.5	144.3
SD	15.76	15.86	19.10
Median	140.5	142.0	140.0
Minimum	85	110	100
Maximum	180	180	200
Month 18			
Number of patients with values	45	52	60
Mean	140.6	139.6	142.7
SD	17.00	17.85	16.51
Median	140.0	140.0	140.0
Minimum	85	90	112
Maximum	175	190	190
Month 21			
Number of patients with values	44	50	59
Mean	144.2	141.3	142.1
SD	16.91	17.55	21.14
Median	141.0	141.0	140.0
Minimum	110	110	105
Maximum	200	180	210

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 24			
Number of patients with values	37	43	53
Mean	144.4	139.5	142.5
SD	21.26	13.56	15.29
Median	140.0	140.0	140.0
Minimum	110	110	117
Maximum	204	168	190
Month 27			
Number of patients with values	38	40	46
Mean	143.0	141.9	142.9
SD	16.74	14.92	20.46
Median	143.0	140.0	140.0
Minimum	97	112	120
Maximum	180	185	220
Month 30			
Number of patients with values	32	37	46
Mean	142.7	141.3	140.3
SD	15.96	16.35	17.07
Median	140.0	140.0	140.0
Minimum	100	104	110
Maximum	182	185	192
Month 33			
Number of patients with values	29	33	36
Mean	142.6	140.6	145.5
SD	15.04	15.99	22.55
Median	149.0	140.0	140.0
Minimum	110	110	113
Maximum	160	183	210

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 36			
Number of patients with values	24	27	33
Mean	141.6	143.4	140.2
SD	17.55	14.03	16.00
Median	140.0	145.0	140.0
Minimum	110	108	107
Maximum	190	174	187
Month 39			
Number of patients with values	17	18	17
Mean	143.2	144.1	142.5
SD	15.93	25.09	18.16
Median	140.0	135.5	140.0
Minimum	118	105	120
Maximum	180	213	194
Month 42			
Number of patients with values	10	12	10
Mean	151.7	146.1	139.2
SD	26.29	11.02	17.00
Median	150.0	145.0	140.0
Minimum	107	130	110
Maximum	210	166	172
Month 45			
Number of patients with values	3	3	5
Mean	145.0	143.3	137.0
SD	5.00	5.77	8.37
Median	145.0	140.0	135.0
Minimum	140	140	130
Maximum	150	150	150

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	82.6	81.3	81.9
SD	8.29	8.84	8.81
Median	80.0	80.0	80.0
Minimum	65	60	64
Maximum	102	100	110
Open Label Baseline			
Number of patients with values	61	78	90
Mean	82.8	82.3	80.6
SD	9.67	8.70	7.65
Median	80.0	80.0	80.0
Minimum	63	60	60
Maximum	110	110	100
Month 0			
Number of patients with values	61	78	90
Mean	82.8	82.3	80.6
SD	9.67	8.70	7.65
Median	80.0	80.0	80.0
Minimum	63	60	60
Maximum	110	110	100
Month 1			
Number of patients with values	60	76	89
Mean	80.7	80.4	81.0
SD	8.13	9.34	7.78
Median	80.0	80.0	80.0
Minimum	63	50	60
Maximum	100	100	100

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 2			
Number of patients with values	58	77	89
Mean	82.1	81.5	80.1
SD	8.38	9.30	8.41
Median	80.0	80.0	80.0
Minimum	67	59	60
Maximum	106	106	100
Month 3			
Number of patients with values	57	76	86
Mean	81.1	81.3	80.0
SD	9.14	8.96	8.87
Median	80.0	80.0	80.0
Minimum	60	53	55
Maximum	100	100	100
Month 6			
Number of patients with values	57	73	82
Mean	80.3	79.9	81.6
SD	8.56	8.62	9.09
Median	80.0	80.0	80.0
Minimum	68	56	60
Maximum	110	99	110
Month 9			
Number of patients with values	56	71	77
Mean	79.5	80.9	80.7
SD	7.97	9.63	9.43
Median	80.0	80.0	80.0
Minimum	60	60	60
Maximum	100	113	110

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 12			
Number of patients with values	54	62	72
Mean	82.0	81.7	81.2
SD	8.03	8.81	7.37
Median	80.0	80.0	80.0
Minimum	60	60	61
Maximum	100	100	95
Month 15			
Number of patients with values	50	57	67
Mean	79.5	80.5	81.2
SD	6.85	7.07	8.21
Median	80.0	80.0	80.0
Minimum	66	66	65
Maximum	91	100	100
Month 18			
Number of patients with values	45	52	60
Mean	83.3	79.2	80.1
SD	8.94	7.75	7.58
Median	85.0	80.0	80.0
Minimum	60	64	60
Maximum	100	95	95
Month 21			
Number of patients with values	44	50	59
Mean	80.4	79.1	80.4
SD	8.94	9.88	7.83
Median	80.0	80.0	80.0
Minimum	60	60	62
Maximum	102	104	100

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 24			
Number of patients with values	37	43	53
Mean	80.6	77.2	79.4
SD	9.64	7.90	8.66
Median	80.0	78.0	80.0
Minimum	60	60	62
Maximum	103	94	101
Month 27			
Number of patients with values	38	40	46
Mean	81.8	80.4	77.4
SD	7.94	8.38	8.67
Median	80.0	80.0	77.0
Minimum	63	63	56
Maximum	96	101	100
Month 30			
Number of patients with values	32	37	46
Mean	80.5	78.8	76.7
SD	9.46	9.83	8.32
Median	80.0	80.0	80.0
Minimum	60	53	56
Maximum	100	99	100
Month 33			
Number of patients with values	29	33	36
Mean	81.8	79.0	78.5
SD	8.19	8.31	9.25
Median	80.0	80.0	80.0
Minimum	65	60	56
Maximum	98	104	100

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 36			
Number of patients with values	24	27	33
Mean	80.7	79.3	79.1
SD	9.57	7.04	8.32
Median	80.0	80.0	80.0
Minimum	60	60	54
Maximum	100	95	98
Month 39			
Number of patients with values	17	18	17
Mean	79.5	79.1	79.5
SD	9.64	9.58	12.81
Median	80.0	80.0	80.0
Minimum	60	60	54
Maximum	100	95	108
Month 42			
Number of patients with values	10	12	10
Mean	83.4	80.3	80.6
SD	12.69	8.63	10.86
Median	80.0	80.0	80.0
Minimum	60	70	65
Maximum	106	99	104
Month 45			
Number of patients with values	3	3	5
Mean	81.3	74.3	76.0
SD	2.31	9.29	5.48
Median	80.0	70.0	80.0
Minimum	80	68	70
Maximum	84	85	80

- 1107 -

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 BRL-049653/RSD-
 100TV9/1/CPMS-009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	70.8	73.6	74.1
SD	6.91	10.59	8.44
Median	72.0	72.0	72.0
Minimum	56	48	56
Maximum	88	113	100
Open Label Baseline			
Number of patients with values	61	78	90
Mean	71.5	73.0	72.8
SD	9.08	9.39	8.67
Median	72.0	72.0	72.0
Minimum	48	52	60
Maximum	96	100	102
Month 0			
Number of patients with values	61	78	90
Mean	71.5	73.0	72.8
SD	9.08	9.39	8.67
Median	72.0	72.0	72.0
Minimum	48	52	60
Maximum	96	100	102
Month 1			
Number of patients with values	60	76	89
Mean	71.6	72.8	73.3
SD	10.28	8.99	8.51
Median	70.0	72.0	72.0
Minimum	50	52	54
Maximum	120	96	98

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 2			
Number of patients with values	58	77	89
Mean	71.4	73.0	73.6
SD	10.03	9.07	7.80
Median	71.0	72.0	74.0
Minimum	50	55	60
Maximum	106	107	92
Month 3			
Number of patients with values	56	75	86
Mean	71.0	73.6	72.9
SD	9.29	9.64	8.55
Median	71.0	74.0	72.0
Minimum	49	49	52
Maximum	92	100	100
Month 6			
Number of patients with values	55	73	82
Mean	71.2	72.7	73.4
SD	10.06	9.50	9.77
Median	72.0	72.0	72.0
Minimum	50	50	56
Maximum	100	100	100
Month 9			
Number of patients with values	54	70	76
Mean	70.0	72.8	73.0
SD	9.16	9.36	8.81
Median	70.0	72.0	72.0
Minimum	49	54	54
Maximum	100	96	98

- 1109 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/1/CPMS-009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 12			
Number of patients with values	54	62	72
Mean	70.7	73.4	73.6
SD	10.10	12.04	8.16
Median	72.0	72.0	72.0
Minimum	44	56	59
Maximum	93	120	96
Month 15			
Number of patients with values	49	56	67
Mean	71.6	72.8	73.2
SD	9.16	8.79	8.15
Median	70.0	72.0	72.0
Minimum	49	56	58
Maximum	100	92	96
Month 18			
Number of patients with values	45	52	60
Mean	71.1	72.7	72.9
SD	9.71	10.59	9.97
Median	70.0	73.0	72.0
Minimum	50	53	48
Maximum	100	98	90
Month 21			
Number of patients with values	44	50	59
Mean	69.8	73.1	73.4
SD	8.18	8.96	7.88
Median	70.0	72.0	72.0
Minimum	50	56	56
Maximum	88	93	96

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 24			
Number of patients with values	37	42	53
Mean	69.3	72.0	70.7
SD	8.67	9.35	8.80
Median	70.0	72.0	72.0
Minimum	56	47	50
Maximum	91	100	94
Month 27			
Number of patients with values	38	39	46
Mean	68.6	70.9	71.2
SD	8.60	8.06	7.92
Median	68.0	70.0	71.0
Minimum	50	60	50
Maximum	92	92	86
Month 30			
Number of patients with values	32	37	45
Mean	71.6	71.6	72.5
SD	8.18	8.07	10.10
Median	71.0	70.0	72.0
Minimum	56	57	56
Maximum	86	92	100
Month 33			
Number of patients with values	29	33	36
Mean	70.2	72.2	71.6
SD	7.83	8.99	8.39
Median	70.0	72.0	72.0
Minimum	56	52	56
Maximum	88	92	88

- 1111 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 36			
Number of patients with values	24	27	32
Mean	71.5	70.6	71.4
SD	8.29	8.37	7.38
Median	72.0	72.0	71.0
Minimum	54	56	60
Maximum	85	84	88
Month 39			
Number of patients with values	17	18	17
Mean	73.6	73.1	78.5
SD	6.82	9.68	9.27
Median	74.0	72.0	79.0
Minimum	60	56	64
Maximum	85	96	100
Month 42			
Number of patients with values	10	12	10
Mean	77.2	72.4	65.2
SD	8.05	11.52	5.83
Median	75.5	72.5	65.0
Minimum	68	58	56
Maximum	90	100	78
Month 45			
Number of patients with values	3	3	5
Mean	70.7	67.3	67.2
SD	4.62	1.15	8.32
Median	68.0	68.0	66.0
Minimum	68	66	60
Maximum	76	68	80

- 1112 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Double Blind Baseline			
Number of patients with values	61	78	90
Mean	78.11	77.80	76.58
SD	14.505	14.872	13.345
Median	77.00	76.40	74.80
Minimum	51.0	49.5	52.0
Maximum	111.5	117.0	112.0
Open Label Baseline			
Number of patients with values	61	78	90
Mean	78.09	79.16	78.85
SD	14.206	14.658	13.700
Median	76.00	79.00	77.45
Minimum	51.0	50.0	54.0
Maximum	111.5	118.0	113.0
Month 0			
Number of patients with values	61	78	90
Mean	78.09	79.16	78.85
SD	14.206	14.658	13.700
Median	76.00	79.00	77.45
Minimum	51.0	50.0	54.0
Maximum	111.5	118.0	113.0
Month 1			
Number of patients with values	1	1	3
Mean	64.50	97.50	74.63
SD			6.345
Median	64.50	97.50	75.50
Minimum	64.5	97.5	67.9
Maximum	64.5	97.5	80.5

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 2			
Number of patients with values	6	4	9
Mean	95.02	82.13	81.08
SD	12.803	17.065	8.311
Median	97.65	87.70	82.50
Minimum	71.7	57.7	68.3
Maximum	109.0	95.4	95.2
Month 3			
Number of patients with values	40	47	61
Mean	77.63	79.09	78.84
SD	13.610	15.298	13.552
Median	75.50	76.80	79.50
Minimum	53.0	50.0	54.0
Maximum	104.0	118.0	110.0
Month 6			
Number of patients with values	44	51	63
Mean	79.85	80.36	78.86
SD	14.869	14.490	13.465
Median	79.00	78.70	80.00
Minimum	54.0	53.4	51.4
Maximum	116.0	117.0	107.0
Month 9			
Number of patients with values	49	55	64
Mean	79.88	80.06	79.76
SD	14.964	14.435	12.588
Median	78.70	79.00	79.20
Minimum	55.0	52.0	56.0
Maximum	116.2	119.0	107.1

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 12			
Number of patients with values	49	54	69
Mean	79.99	81.28	80.17
SD	14.733	13.791	13.487
Median	79.00	79.50	79.90
Minimum	55.0	53.0	56.0
Maximum	115.1	119.0	108.3
Month 15			
Number of patients with values	49	57	66
Mean	81.71	80.98	81.35
SD	14.975	14.622	14.026
Median	82.00	79.20	79.00
Minimum	53.5	53.5	56.0
Maximum	113.5	117.0	114.0
Month 18			
Number of patients with values	45	52	61
Mean	78.91	81.68	81.51
SD	15.264	14.585	13.782
Median	79.00	80.00	81.00
Minimum	47.7	54.0	56.0
Maximum	116.7	117.0	114.8
Month 21			
Number of patients with values	44	50	59
Mean	80.30	80.98	82.02
SD	14.216	14.236	14.655
Median	80.50	80.25	80.00
Minimum	54.0	55.4	57.0
Maximum	114.7	116.0	118.6

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 24			
Number of patients with values	37	43	53
Mean	80.08	81.22	83.30
SD	14.166	15.137	14.321
Median	80.00	78.60	82.00
Minimum	54.0	56.6	56.5
Maximum	108.4	117.0	116.0
Month 27			
Number of patients with values	38	39	46
Mean	81.82	84.18	84.37
SD	15.301	15.053	13.460
Median	80.25	82.40	82.25
Minimum	54.0	55.8	59.0
Maximum	114.5	117.0	120.2
Month 30			
Number of patients with values	32	37	46
Mean	79.83	83.73	84.51
SD	14.692	15.600	14.172
Median	78.50	84.00	81.80
Minimum	54.0	54.8	59.0
Maximum	108.0	116.0	124.6
Month 33			
Number of patients with values	29	33	36
Mean	80.17	83.56	85.08
SD	14.653	16.159	12.946
Median	78.00	82.00	83.40
Minimum	54.0	54.0	63.8
Maximum	106.0	116.0	115.3

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Weight (kg)

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Month 36			
Number of patients with values	24	27	33
Mean	80.87	82.37	85.47
SD	15.617	16.454	13.618
Median	81.15	80.00	84.00
Minimum	54.0	54.0	60.0
Maximum	108.0	119.0	114.5
Month 39			
Number of patients with values	17	18	17
Mean	80.95	84.04	86.71
SD	14.528	17.336	15.149
Median	80.00	81.75	89.50
Minimum	54.0	55.4	59.0
Maximum	109.2	122.0	113.9
Month 42			
Number of patients with values	10	12	10
Mean	85.13	78.88	84.59
SD	12.846	14.238	15.243
Median	85.50	77.00	84.25
Minimum	68.0	56.4	62.0
Maximum	104.8	100.0	113.0
Month 45			
Number of patients with values	3	3	5
Mean	87.00	69.97	80.40
SD	19.313	14.612	17.459
Median	91.00	66.50	80.00
Minimum	66.0	57.4	60.0
Maximum	104.0	86.0	104.0

- 1117 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.6.3Bb

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Waist/Hip Ratio

Time Relative to Start of Study Medication	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Double Blind Baseline			
Number of patients with values	60	76	90
Mean	0.962	0.950	0.940
SD	0.0832	0.0657	0.0727
Median	0.960	0.950	0.940
Minimum	0.80	0.81	0.73
Maximum	1.24	1.10	1.12
Open Label Baseline			
Number of patients with values	56	72	83
Mean	0.952	0.945	0.942
SD	0.0633	0.0675	0.0813
Median	0.950	0.950	0.940
Minimum	0.80	0.81	0.71
Maximum	1.12	1.11	1.13

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	138.1	139.6	137.7	147.4
SD	15.25	14.96	13.29	18.11
Median	140.0	140.0	140.0	150.5
Minimum	90	100	110	113
Maximum	180	195	188	176
Open Label Baseline				
Number of patients with values	124	136	139	30
Mean	139.9	139.0	137.5	139.3
SD	13.59	14.46	13.65	17.09
Median	140.0	139.0	138.0	137.0
Minimum	104	90	105	111
Maximum	190	180	178	169
Month 0				
Number of patients with values	124	136	139	28
Mean	139.9	139.0	137.5	138.4
SD	13.59	14.46	13.65	16.79
Median	140.0	139.0	138.0	137.0
Minimum	104	90	105	111
Maximum	190	180	178	169
Month 1				
Number of patients with values	122	134	136	28
Mean	139.0	138.8	139.8	137.1
SD	14.58	14.67	14.76	13.47
Median	140.0	140.0	140.0	138.5
Minimum	98	105	110	110
Maximum	180	180	190	167

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 2				
Number of patients with values	119	131	134	26
Mean	139.4	138.9	137.6	138.8
SD	14.17	13.53	12.72	16.20
Median	140.0	140.0	140.0	136.0
Minimum	100	110	100	112
Maximum	185	174	175	169
Month 3				
Number of patients with values	117	130	131	23
Mean	137.5	137.5	137.1	141.8
SD	14.87	13.50	12.64	17.05
Median	140.0	140.0	140.0	140.0
Minimum	100	110	99	108
Maximum	172	170	170	181
Month 6				
Number of patients with values	116	130	127	20
Mean	139.8	137.4	137.2	138.4
SD	13.95	12.77	13.57	17.97
Median	140.0	140.0	140.0	132.5
Minimum	110	105	102	112
Maximum	180	182	180	180
Month 9				
Number of patients with values	116	127	117	18
Mean	138.3	139.2	139.9	144.1
SD	14.52	12.21	14.19	15.99
Median	140.0	140.0	140.0	141.0
Minimum	100	110	110	123
Maximum	180	190	180	175

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 12				
Number of patients with values	105	114	109	17
Mean	141.0	141.2	138.7	143.7
SD	13.71	13.77	15.02	14.95
Median	140.0	140.0	140.0	144.0
Minimum	110	110	110	116
Maximum	182	170	181	172
Month 15				
Number of patients with values	102	113	100	10
Mean	137.0	140.4	139.5	142.7
SD	13.77	15.23	13.63	23.83
Median	136.0	140.0	140.0	148.0
Minimum	90	105	110	104
Maximum	175	190	180	180
Month 18				
Number of patients with values	100	101	91	10
Mean	138.1	138.0	138.1	138.4
SD	14.28	13.73	13.80	20.62
Median	138.0	140.0	136.0	136.0
Minimum	110	90	107	111
Maximum	180	170	175	170
Month 21				
Number of patients with values	96	96	85	8
Mean	138.4	137.1	137.4	140.0
SD	12.43	12.49	13.39	20.33
Median	140.0	140.0	140.0	137.5
Minimum	107	110	101	108
Maximum	175	174	180	170

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 24				
Number of patients with values	90	89	81	7
Mean	140.4	137.3	136.9	145.9
SD	12.24	14.88	12.96	19.85
Median	140.0	140.0	135.0	147.0
Minimum	110	100	110	116
Maximum	168	170	170	180
Month 27				
Number of patients with values	76	81	77	5
Mean	138.5	137.8	139.2	151.8
SD	11.40	12.57	15.64	16.62
Median	140.0	140.0	140.0	140.0
Minimum	110	110	105	139
Maximum	170	170	180	170
Month 30				
Number of patients with values	66	73	66	5
Mean	134.6	136.5	136.0	140.6
SD	13.53	13.78	12.68	6.47
Median	131.5	134.0	135.0	140.0
Minimum	100	110	100	132
Maximum	176	180	174	150
Month 33				
Number of patients with values	43	47	44	3
Mean	137.7	140.4	135.9	144.0
SD	13.30	13.09	10.92	11.53
Median	135.0	140.0	136.5	145.0
Minimum	120	120	110	132
Maximum	176	180	160	155

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Systolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 36				
Number of patients with values	24	31	28	2
Mean	136.4	139.2	133.7	148.0
SD	12.39	11.88	11.27	16.97
Median	135.0	140.0	135.5	148.0
Minimum	110	120	110	136
Maximum	164	170	160	160
Month 39				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	82.1	81.3	81.3	86.6
SD	9.01	7.81	7.96	9.63
Median	80.0	80.0	80.0	85.5
Minimum	55	60	60	66
Maximum	113	100	110	104
Open Label Baseline				
Number of patients with values	124	136	139	30
Mean	81.2	80.6	80.4	84.1
SD	8.79	8.25	7.96	11.61
Median	80.0	80.0	80.0	84.5
Minimum	56	60	60	56
Maximum	100	102	100	110
Month 0				
Number of patients with values	124	136	139	28
Mean	81.2	80.6	80.4	83.8
SD	8.79	8.25	7.96	11.94
Median	80.0	80.0	80.0	84.0
Minimum	56	60	60	56
Maximum	100	102	100	110
Month 1				
Number of patients with values	122	134	136	28
Mean	79.8	79.9	81.3	86.0
SD	8.35	8.66	7.80	11.26
Median	80.0	80.0	80.0	85.5
Minimum	60	60	60	67
Maximum	105	108	110	109

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 2				
Number of patients with values	119	131	134	26
Mean	80.4	80.0	80.5	82.5
SD	8.10	8.36	8.71	10.90
Median	80.0	80.0	80.0	85.0
Minimum	60	56	60	62
Maximum	100	108	120	98
Month 3				
Number of patients with values	117	130	131	23
Mean	79.6	79.8	80.0	84.4
SD	8.37	7.83	7.92	13.49
Median	80.0	80.0	80.0	80.0
Minimum	60	60	56	64
Maximum	100	100	110	116
Month 6				
Number of patients with values	116	130	127	20
Mean	80.4	79.7	79.3	85.1
SD	7.88	8.41	7.74	10.87
Median	80.0	80.0	80.0	86.0
Minimum	60	52	60	60
Maximum	106	100	100	105
Month 9				
Number of patients with values	116	127	117	18
Mean	78.3	80.8	80.2	85.3
SD	8.71	7.50	7.40	12.19
Median	80.0	80.0	80.0	86.5
Minimum	60	60	60	67
Maximum	100	100	100	108

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Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 12				
Number of patients with values	105	114	109	17
Mean	80.5	79.5	80.4	86.5
SD	8.11	7.88	8.28	10.57
Median	80.0	80.0	80.0	87.0
Minimum	60	60	60	71
Maximum	100	100	110	110
Month 15				
Number of patients with values	102	113	100	10
Mean	79.3	80.3	80.5	81.7
SD	7.75	7.35	7.59	9.48
Median	80.0	80.0	80.0	79.5
Minimum	60	60	60	70
Maximum	100	100	100	98
Month 18				
Number of patients with values	100	101	91	10
Mean	78.6	80.1	79.4	79.9
SD	7.69	7.76	6.92	11.67
Median	80.0	80.0	80.0	84.0
Minimum	60	60	60	59
Maximum	100	100	105	90
Month 21				
Number of patients with values	96	96	85	8
Mean	79.8	79.5	79.5	83.1
SD	7.80	7.05	8.04	13.97
Median	80.0	80.0	80.0	86.5
Minimum	60	64	60	63
Maximum	110	100	105	98

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 24				
Number of patients with values	90	89	81	7
Mean	80.2	79.2	78.4	86.3
SD	7.81	7.16	8.63	9.03
Median	80.0	80.0	80.0	85.0
Minimum	50	55	55	75
Maximum	105	96	105	101
Month 27				
Number of patients with values	76	81	77	5
Mean	78.6	79.8	79.9	88.4
SD	7.37	7.53	8.69	8.68
Median	80.0	80.0	80.0	90.0
Minimum	60	62	60	78
Maximum	100	100	110	98
Month 30				
Number of patients with values	66	73	66	5
Mean	77.7	79.2	78.3	82.0
SD	7.01	7.19	7.48	10.72
Median	80.0	80.0	80.0	78.0
Minimum	60	70	60	71
Maximum	95	100	100	99
Month 33				
Number of patients with values	43	47	44	3
Mean	78.3	81.4	79.8	82.7
SD	7.17	7.54	7.50	4.62
Median	80.0	80.0	80.0	80.0
Minimum	70	70	67	80
Maximum	95	100	100	88

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Diastolic Blood Pressure (mmHg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 36				
Number of patients with values	24	31	28	2
Mean	79.2	79.2	78.0	86.5
SD	7.63	6.16	8.25	16.26
Median	80.0	80.0	80.0	86.5
Minimum	70	70	50	75
Maximum	95	95	90	98
Month 39				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	71.4	71.3	71.5	72.7
SD	8.78	8.86	10.24	10.81
Median	72.0	72.0	70.0	70.0
Minimum	52	46	50	60
Maximum	99	96	100	102
Open Label Baseline				
Number of patients with values	124	136	139	30
Mean	72.6	72.1	72.2	74.1
SD	9.14	9.51	9.86	11.19
Median	72.0	72.0	72.0	74.0
Minimum	47	37	50	54
Maximum	94	100	102	99
Month 0				
Number of patients with values	124	135	138	27
Mean	72.6	72.1	72.1	74.3
SD	9.14	9.55	9.87	11.19
Median	72.0	72.0	72.0	74.0
Minimum	47	37	50	54
Maximum	94	100	102	99
Month 1				
Number of patients with values	120	134	136	29
Mean	72.2	71.4	72.3	70.8
SD	8.78	8.35	8.98	12.10
Median	72.0	72.0	72.0	72.0
Minimum	50	46	50	40
Maximum	100	95	96	92

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 2				
Number of patients with values	118	131	134	26
Mean	71.8	71.4	71.2	72.3
SD	7.59	9.38	9.32	8.58
Median	72.0	72.0	71.0	71.5
Minimum	50	37	46	60
Maximum	91	100	96	89
Month 3				
Number of patients with values	117	129	131	23
Mean	71.2	71.5	71.8	69.8
SD	8.05	8.94	9.48	10.07
Median	72.0	72.0	72.0	70.0
Minimum	56	46	52	42
Maximum	102	95	92	87
Month 6				
Number of patients with values	114	130	127	20
Mean	72.2	72.5	72.3	73.5
SD	8.59	8.68	9.75	11.32
Median	72.0	72.0	72.0	73.5
Minimum	47	48	52	53
Maximum	92	96	100	96
Month 9				
Number of patients with values	116	127	117	18
Mean	71.4	71.4	72.0	69.7
SD	8.39	7.69	9.38	13.28
Median	72.0	72.0	72.0	66.0
Minimum	52	44	44	44
Maximum	96	88	100	95

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 12				
Number of patients with values	105	114	109	17
Mean	71.4	72.6	71.9	72.8
SD	8.99	7.73	9.64	15.53
Median	72.0	72.0	72.0	69.0
Minimum	48	56	48	50
Maximum	100	88	100	104
Month 15				
Number of patients with values	100	113	100	10
Mean	71.5	72.9	71.8	73.9
SD	7.64	7.00	8.95	14.07
Median	72.0	72.0	70.0	72.0
Minimum	56	52	56	55
Maximum	94	90	100	95
Month 18				
Number of patients with values	100	101	91	10
Mean	70.4	70.8	72.2	73.8
SD	8.14	7.74	9.29	11.82
Median	71.0	70.0	72.0	76.0
Minimum	52	50	54	52
Maximum	96	92	98	90
Month 21				
Number of patients with values	96	95	85	8
Mean	71.1	71.5	72.0	68.5
SD	7.76	7.39	8.64	15.23
Median	72.0	70.0	72.0	68.5
Minimum	52	52	56	42
Maximum	96	96	90	88

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 24				
Number of patients with values	89	89	81	7
Mean	70.9	71.8	72.4	75.6
SD	8.20	9.31	9.43	17.51
Median	72.0	72.0	72.0	69.0
Minimum	49	52	56	58
Maximum	94	96	100	102
Month 27				
Number of patients with values	76	81	76	5
Mean	70.2	71.2	73.2	71.4
SD	7.23	8.26	9.24	17.14
Median	70.0	72.0	72.0	72.0
Minimum	48	56	56	52
Maximum	88	96	103	98
Month 30				
Number of patients with values	66	72	65	5
Mean	68.6	71.2	72.4	75.4
SD	9.25	8.39	9.93	16.15
Median	69.0	72.0	72.0	74.0
Minimum	50	50	56	62
Maximum	100	92	100	102
Month 33				
Number of patients with values	43	46	45	3
Mean	71.1	71.7	73.7	79.7
SD	9.03	6.92	9.28	10.02
Median	72.0	72.0	72.0	76.0
Minimum	48	60	58	72
Maximum	100	88	93	91

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Heart Rate (bpm)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 36				
Number of patients with values	23	29	28	2
Mean	71.2	69.7	74.1	76.5
SD	8.88	7.83	9.20	6.36
Median	70.0	72.0	72.0	76.5
Minimum	58	56	56	72
Maximum	88	86	90	81
Month 39				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Double Blind Baseline				
Number of patients with values	124	136	139	30
Mean	80.95	82.00	81.71	79.83
SD	13.584	13.377	13.704	10.700
Median	80.45	82.00	80.50	81.75
Minimum	55.0	50.5	55.0	56.5
Maximum	112.3	116.2	118.0	107.0
Open Label Baseline				
Number of patients with values	124	136	139	30
Mean	83.50	83.58	83.50	80.07
SD	14.647	13.951	14.057	11.261
Median	81.75	82.80	82.00	80.45
Minimum	53.0	52.4	49.0	55.7
Maximum	127.0	114.8	125.0	110.0
Month 0				
Number of patients with values	124	136	139	30
Mean	83.50	83.58	83.50	80.07
SD	14.647	13.951	14.057	11.261
Median	81.75	82.80	82.00	80.45
Minimum	53.0	52.4	49.0	55.7
Maximum	127.0	114.8	125.0	110.0
Month 1				
Number of patients with values	13	9	12	1
Mean	80.95	88.04	84.69	74.00
SD	13.924	11.064	12.002	
Median	80.00	84.00	84.50	74.00
Minimum	63.0	72.0	62.0	74.0
Maximum	100.0	105.0	105.0	74.0

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 2				
Number of patients with values	9	9	12	0
Mean	77.08	90.79	79.98	
SD	15.474	10.016	11.900	
Median	75.00	89.00	77.50	
Minimum	57.0	77.0	62.7	
Maximum	97.0	109.0	103.0	
Month 3				
Number of patients with values	101	115	119	19
Mean	83.77	84.22	82.98	79.36
SD	14.162	14.158	14.521	10.208
Median	82.40	83.00	82.00	79.30
Minimum	53.0	53.4	49.0	60.2
Maximum	127.4	117.0	120.0	100.3
Month 6				
Number of patients with values	109	122	122	12
Mean	84.25	84.82	83.06	81.09
SD	13.948	13.936	14.278	12.137
Median	83.00	83.75	81.80	84.00
Minimum	52.0	53.2	49.0	60.1
Maximum	122.0	118.0	120.0	99.6
Month 9				
Number of patients with values	111	121	113	15
Mean	84.32	84.07	84.14	81.57
SD	14.114	14.549	14.391	10.750
Median	82.00	83.00	84.50	85.30
Minimum	50.0	41.0	50.5	60.1
Maximum	125.0	119.4	120.0	98.1

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 12				
Number of patients with values	101	111	105	12
Mean	84.49	85.03	83.89	83.48
SD	13.947	14.370	14.304	10.713
Median	84.00	84.50	83.70	86.70
Minimum	50.0	55.5	51.0	59.0
Maximum	126.0	121.0	125.0	96.2
Month 15				
Number of patients with values	102	111	99	9
Mean	83.35	84.72	84.44	82.59
SD	14.027	14.652	14.191	8.773
Median	82.60	84.50	84.00	84.10
Minimum	52.0	55.2	50.0	65.0
Maximum	127.0	122.0	125.0	91.0
Month 18				
Number of patients with values	100	100	91	10
Mean	84.02	84.88	84.28	78.71
SD	14.789	14.690	14.462	10.793
Median	83.50	85.00	84.00	78.85
Minimum	52.0	55.0	50.0	59.2
Maximum	130.0	124.6	125.0	90.4
Month 21				
Number of patients with values	96	96	85	8
Mean	84.10	85.43	85.01	78.00
SD	14.778	15.269	13.875	12.095
Median	82.75	85.25	85.00	80.90
Minimum	52.0	53.0	50.0	57.7
Maximum	123.0	128.0	112.0	92.7

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 24				
Number of patients with values	88	89	81	7
Mean	84.41	85.82	85.31	80.67
SD	15.348	14.842	13.826	9.873
Median	83.10	85.00	85.00	83.40
Minimum	48.0	55.0	51.0	66.2
Maximum	124.8	130.0	111.0	93.2
Month 27				
Number of patients with values	77	81	76	5
Mean	85.22	85.52	86.32	81.32
SD	15.842	15.314	13.353	10.151
Median	85.80	84.00	85.55	84.60
Minimum	56.0	54.0	50.0	67.6
Maximum	130.0	130.0	112.0	92.7
Month 30				
Number of patients with values	66	73	66	5
Mean	87.28	84.61	86.24	81.70
SD	15.003	13.133	13.834	9.650
Median	85.90	85.00	85.35	85.90
Minimum	61.0	54.0	51.0	67.4
Maximum	130.0	120.0	114.0	91.4
Month 33				
Number of patients with values	43	47	45	3
Mean	87.52	84.89	86.65	85.33
SD	15.268	12.608	14.790	8.198
Median	87.60	86.00	86.10	87.40
Minimum	61.5	60.5	51.0	76.3
Maximum	124.4	117.0	115.0	92.3

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Weight (kg)

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Month 36				
Number of patients with values	24	31	29	1
Mean	94.78	84.64	83.02	76.00
SD	16.760	11.662	12.774	
Median	92.10	87.00	83.60	76.00
Minimum	63.2	63.0	52.0	76.0
Maximum	132.0	118.0	109.0	76.0
Month 39				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 42				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				
Month 45				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.6.3Bc

Summary Statistics for Vital Signs at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Waist/Hip Ratio

Time Relative to Start of Study Medication	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Double Blind Baseline				
Number of patients with values	123	135	139	30
Mean	0.946	0.966	0.959	0.922
SD	0.0772	0.0701	0.0760	0.0643
Median	0.950	0.960	0.950	0.930
Minimum	0.75	0.79	0.79	0.75
Maximum	1.12	1.17	1.15	1.03
Open Label Baseline				
Number of patients with values	114	127	128	28
Mean	0.943	0.958	0.959	0.932
SD	0.0850	0.0735	0.0787	0.0604
Median	0.940	0.960	0.950	0.935
Minimum	0.73	0.77	0.73	0.82
Maximum	1.15	1.19	1.12	1.11

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	1 (4.3%)	0
With values below reference range	3 (13.0%)	3 (13.6%)
With values within reference range	19 (82.6%)	19 (86.4%)
Summary statistics:		
Number of patients with values	23	22
Mean	14.58	14.02
SD	1.125	1.289
Median	15.10	14.10
Minimum	12.0	10.5
Maximum	16.2	15.9
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	4 (1.7%)	7 (1.6%)
With values below reference range	19 (8.3%)	38 (8.9%)
With values within reference range	206 (90.0%)	382 (89.5%)
Summary statistics:		
Number of patients with values	229	427
Mean	14.24	14.12
SD	1.277	1.421
Median	14.30	14.20
Minimum	8.6	6.0
Maximum	16.9	19.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	2 (10.5%)
With values within reference range	2 (100.0%)	16 (84.2%)
Summary statistics:		
Number of patients with values	2	19
Mean	15.65	13.83
SD	0.212	1.645
Median	15.65	13.80
Minimum	15.5	10.7
Maximum	15.8	17.6
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	3 (33.3%)
With values within reference range	5 (100.0%)	6 (66.7%)
Summary statistics:		
Number of patients with values	5	9
Mean	14.40	13.10
SD	1.134	1.358
Median	14.90	13.10
Minimum	12.6	11.6
Maximum	15.4	14.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	385
With values above reference range	1 (0.5%)	2 (0.5%)
With values below reference range	24 (11.3%)	67 (17.4%)
With values within reference range	187 (88.2%)	316 (82.1%)

Summary statistics:

Number of patients with values	212	385
Mean	13.89	13.55
SD	1.196	1.262
Median	13.80	13.60
Minimum	10.8	8.5
Maximum	16.7	17.5

Month 6

Number of patients:

With values	203	374
With values above reference range	1 (0.5%)	2 (0.5%)
With values below reference range	22 (10.8%)	57 (15.2%)
With values within reference range	180 (88.7%)	315 (84.2%)

Summary statistics:

Number of patients with values	203	374
Mean	13.97	13.61
SD	1.250	1.333
Median	14.00	13.65
Minimum	8.5	6.9
Maximum	16.6	16.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	199	371
With values above reference range	3 (1.5%)	2 (0.5%)
With values below reference range	17 (8.5%)	50 (13.5%)
With values within reference range	179 (89.9%)	319 (86.0%)

Summary statistics:

Number of patients with values	199	371
Mean	13.95	13.65
SD	1.293	1.364
Median	14.00	13.80
Minimum	9.0	7.3
Maximum	17.0	16.9

Month 12

Number of patients:

With values	181	332
With values above reference range	2 (1.1%)	2 (0.6%)
With values below reference range	19 (10.5%)	48 (14.5%)
With values within reference range	160 (88.4%)	282 (84.9%)

Summary statistics:

Number of patients with values	181	332
Mean	13.85	13.69
SD	1.254	1.337
Median	13.80	13.70
Minimum	11.0	8.5
Maximum	17.2	17.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	164	314
With values above reference range	2 (1.2%)	3 (1.0%)
With values below reference range	16 (9.8%)	49 (15.6%)
With values within reference range	146 (89.0%)	262 (83.4%)

Summary statistics:

Number of patients with values	164	314
Mean	13.94	13.56
SD	1.299	1.354
Median	14.00	13.60
Minimum	10.5	8.7
Maximum	16.8	16.9

Month 18

Number of patients:

With values	155	290
With values above reference range	2 (1.3%)	2 (0.7%)
With values below reference range	16 (10.3%)	38 (13.1%)
With values within reference range	137 (88.4%)	250 (86.2%)

Summary statistics:

Number of patients with values	155	290
Mean	13.93	13.63
SD	1.225	1.326
Median	13.90	13.70
Minimum	10.9	8.7
Maximum	17.2	16.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	2 (1.3%)	3 (1.1%)
With values below reference range	14 (9.2%)	38 (13.9%)
With values within reference range	136 (89.5%)	233 (85.0%)
Summary statistics:		
Number of patients with values	152	274
Mean	13.99	13.60
SD	1.178	1.315
Median	14.00	13.70
Minimum	11.3	9.8
Maximum	17.3	17.8
Month 24		
Number of patients:		
With values	128	249
With values above reference range	2 (1.6%)	0
With values below reference range	13 (10.2%)	37 (14.9%)
With values within reference range	113 (88.3%)	212 (85.1%)
Summary statistics:		
Number of patients with values	128	249
Mean	14.03	13.56
SD	1.298	1.325
Median	14.10	13.50
Minimum	10.2	9.1
Maximum	17.2	16.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	118	227
With values above reference range	2 (1.7%)	2 (0.9%)
With values below reference range	8 (6.8%)	28 (12.3%)
With values within reference range	108 (91.5%)	197 (86.8%)
Summary statistics:		
Number of patients with values	118	227
Mean	14.10	13.58
SD	1.251	1.298
Median	13.95	13.60
Minimum	11.2	10.0
Maximum	16.8	16.9
Month 30		
Number of patients:		
With values	104	179
With values above reference range	3 (2.9%)	0
With values below reference range	9 (8.7%)	27 (15.1%)
With values within reference range	92 (88.5%)	152 (84.9%)
Summary statistics:		
Number of patients with values	104	179
Mean	13.97	13.54
SD	1.204	1.323
Median	13.80	13.60
Minimum	11.0	9.0
Maximum	17.4	17.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	3 (3.3%)	0
With values below reference range	9 (9.9%)	26 (17.0%)
With values within reference range	79 (86.8%)	127 (83.0%)
Summary statistics:		
Number of patients with values	91	153
Mean	13.95	13.51
SD	1.367	1.383
Median	14.00	13.60
Minimum	10.9	9.1
Maximum	17.8	17.1
Month 36		
Number of patients:		
With values	83	77
With values above reference range	3 (3.6%)	0
With values below reference range	9 (10.8%)	10 (13.0%)
With values within reference range	71 (85.5%)	67 (87.0%)
Summary statistics:		
Number of patients with values	83	77
Mean	13.72	13.42
SD	1.259	1.407
Median	13.70	13.50
Minimum	10.1	8.9
Maximum	17.4	15.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	2 (4.1%)	0
With values below reference range	3 (6.1%)	0
With values within reference range	44 (89.8%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	13.98	13.47
SD	1.364	1.087
Median	13.90	13.50
Minimum	11.2	12.1
Maximum	17.0	15.6
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	3 (9.4%)	
With values within reference range	29 (90.6%)	
Summary statistics:		
Number of patients with values	32	0
Mean	13.71	
SD	1.198	
Median	13.70	
Minimum	10.9	
Maximum	16.3	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	1 (5.3%)	
With values within reference range	16 (84.2%)	
Summary statistics:		
Number of patients with values	19	0
Mean	13.93	
SD	1.552	
Median	13.70	
Minimum	11.3	
Maximum	17.3	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	1 (4.3%)	0
With values below reference range	3 (13.0%)	5 (22.7%)
With values within reference range	19 (82.6%)	17 (77.3%)
Summary statistics:		
Number of patients with values	23	22
Mean	43.04	41.45
SD	3.512	3.702
Median	44.10	41.10
Minimum	35.3	32.3
Maximum	48.5	47.0
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	9 (3.9%)	5 (1.2%)
With values below reference range	20 (8.7%)	54 (12.6%)
With values within reference range	200 (87.3%)	368 (86.2%)
Summary statistics:		
Number of patients with values	229	427
Mean	42.44	41.11
SD	3.721	4.005
Median	42.60	41.40
Minimum	26.2	19.6
Maximum	52.0	60.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	3 (15.8%)
With values within reference range	2 (100.0%)	15 (78.9%)
Summary statistics:		
Number of patients with values	2	19
Mean	46.35	40.92
SD	0.919	4.807
Median	46.35	41.30
Minimum	45.7	31.6
Maximum	47.0	53.7
Month 2		
Number of patients:		
With values	5	9
With values above reference range	1 (20.0%)	0
With values below reference range	0	2 (22.2%)
With values within reference range	4 (80.0%)	7 (77.8%)
Summary statistics:		
Number of patients with values	5	9
Mean	43.42	39.11
SD	3.720	3.386
Median	44.70	38.50
Minimum	37.2	35.5
Maximum	47.0	43.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	385
With values above reference range	5 (2.4%)	3 (0.8%)
With values below reference range	28 (13.2%)	56 (14.5%)
With values within reference range	179 (84.4%)	326 (84.7%)
Summary statistics:		
Number of patients with values	212	385
Mean	41.14	40.33
SD	3.422	3.604
Median	41.00	40.50
Minimum	31.8	25.6
Maximum	49.2	51.3
Month 6		
Number of patients:		
With values	203	374
With values above reference range	6 (3.0%)	3 (0.8%)
With values below reference range	24 (11.8%)	57 (15.2%)
With values within reference range	173 (85.2%)	314 (84.0%)
Summary statistics:		
Number of patients with values	203	374
Mean	41.62	40.62
SD	3.630	3.859
Median	41.50	40.80
Minimum	27.4	20.6
Maximum	51.0	50.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	199	372
With values above reference range	5 (2.5%)	3 (0.8%)
With values below reference range	22 (11.1%)	50 (13.4%)
With values within reference range	172 (86.4%)	319 (85.8%)
Summary statistics:		
Number of patients with values	199	372
Mean	41.29	40.60
SD	3.612	3.904
Median	41.50	41.20
Minimum	29.0	22.0
Maximum	50.1	50.5
Month 12		
Number of patients:		
With values	181	332
With values above reference range	5 (2.8%)	8 (2.4%)
With values below reference range	18 (9.9%)	53 (16.0%)
With values within reference range	158 (87.3%)	271 (81.6%)
Summary statistics:		
Number of patients with values	181	332
Mean	41.36	40.87
SD	3.471	3.905
Median	41.30	41.00
Minimum	33.9	27.3
Maximum	50.9	51.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	164	315
With values above reference range	6 (3.7%)	6 (1.9%)
With values below reference range	16 (9.8%)	47 (14.9%)
With values within reference range	142 (86.6%)	262 (83.2%)
Summary statistics:		
Number of patients with values	164	315
Mean	41.70	40.79
SD	3.731	4.001
Median	41.85	41.10
Minimum	32.3	26.8
Maximum	50.1	51.0
Month 18		
Number of patients:		
With values	155	291
With values above reference range	3 (1.9%)	6 (2.1%)
With values below reference range	12 (7.7%)	32 (11.0%)
With values within reference range	140 (90.3%)	253 (86.9%)
Summary statistics:		
Number of patients with values	155	291
Mean	41.53	41.05
SD	3.435	3.908
Median	41.30	41.10
Minimum	32.8	27.8
Maximum	51.2	50.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	6 (3.9%)	8 (2.9%)
With values below reference range	11 (7.2%)	27 (9.9%)
With values within reference range	135 (88.8%)	239 (87.2%)
Summary statistics:		
Number of patients with values	152	274
Mean	41.83	41.30
SD	3.478	3.939
Median	41.75	41.60
Minimum	33.6	30.3
Maximum	53.8	55.3
Month 24		
Number of patients:		
With values	128	249
With values above reference range	5 (3.9%)	4 (1.6%)
With values below reference range	10 (7.8%)	24 (9.6%)
With values within reference range	113 (88.3%)	221 (88.8%)
Summary statistics:		
Number of patients with values	128	249
Mean	42.14	41.35
SD	3.888	3.992
Median	42.45	41.40
Minimum	31.6	27.8
Maximum	51.6	51.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	118	227
With values above reference range	7 (5.9%)	4 (1.8%)
With values below reference range	8 (6.8%)	15 (6.6%)
With values within reference range	103 (87.3%)	208 (91.6%)
Summary statistics:		
Number of patients with values	118	227
Mean	42.66	41.64
SD	3.798	3.928
Median	42.65	41.80
Minimum	35.3	29.5
Maximum	53.5	53.0
Month 30		
Number of patients:		
With values	104	179
With values above reference range	8 (7.7%)	3 (1.7%)
With values below reference range	7 (6.7%)	19 (10.6%)
With values within reference range	89 (85.6%)	157 (87.7%)
Summary statistics:		
Number of patients with values	104	179
Mean	42.55	41.37
SD	3.666	3.987
Median	42.15	41.40
Minimum	34.4	28.5
Maximum	52.4	50.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	6 (6.6%)	3 (2.0%)
With values below reference range	7 (7.7%)	17 (11.1%)
With values within reference range	78 (85.7%)	133 (86.9%)
Summary statistics:		
Number of patients with values	91	153
Mean	42.54	41.06
SD	4.147	4.073
Median	42.20	41.40
Minimum	32.8	29.0
Maximum	55.0	54.1
Month 36		
Number of patients:		
With values	83	77
With values above reference range	3 (3.6%)	0
With values below reference range	9 (10.8%)	9 (11.7%)
With values within reference range	71 (85.5%)	68 (88.3%)
Summary statistics:		
Number of patients with values	83	77
Mean	41.81	40.50
SD	3.871	4.121
Median	41.40	40.70
Minimum	32.1	26.6
Maximum	53.6	48.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	3 (6.1%)	1 (6.7%)
With values below reference range	5 (10.2%)	0
With values within reference range	41 (83.7%)	14 (93.3%)
Summary statistics:		
Number of patients with values	49	15
Mean	42.22	40.21
SD	3.775	2.959
Median	42.60	40.50
Minimum	34.7	36.3
Maximum	51.3	46.6
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	1 (3.1%)	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	41.58	
SD	3.236	
Median	41.50	
Minimum	35.2	
Maximum	48.6	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	1 (5.3%)	
With values within reference range	16 (84.2%)	
Summary statistics:		
Number of patients with values	19	0
Mean	41.95	
SD	4.730	
Median	40.90	
Minimum	35.2	
Maximum	51.9	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	2 (8.7%)	0
With values within reference range	21 (91.3%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	4.74	4.55
SD	0.413	0.389
Median	4.80	4.50
Minimum	3.8	3.6
Maximum	5.3	5.3
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	5 (2.2%)	8 (1.9%)
With values below reference range	9 (3.9%)	26 (6.1%)
With values within reference range	215 (93.9%)	393 (92.0%)
Summary statistics:		
Number of patients with values	229	427
Mean	4.66	4.59
SD	0.416	0.478
Median	4.70	4.60
Minimum	2.9	1.9
Maximum	5.7	6.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	1 (5.3%)
With values within reference range	2 (100.0%)	17 (89.5%)
Summary statistics:		
Number of patients with values	2	19
Mean	5.05	4.56
SD	0.071	0.565
Median	5.05	4.60
Minimum	5.0	3.6
Maximum	5.1	6.3
Month 2		
Number of patients:		
With values	5	9
With values above reference range	1 (20.0%)	0
With values below reference range	0	0
With values within reference range	4 (80.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	4.90	4.41
SD	0.464	0.362
Median	4.90	4.40
Minimum	4.2	3.8
Maximum	5.5	4.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	385
With values above reference range	3 (1.4%)	2 (0.5%)
With values below reference range	12 (5.7%)	40 (10.4%)
With values within reference range	197 (92.9%)	343 (89.1%)

Summary statistics:

Number of patients with values	212	385
Mean	4.53	4.44
SD	0.406	0.408
Median	4.50	4.40
Minimum	3.3	2.8
Maximum	5.6	5.9

Month 6

Number of patients:

With values	203	374
With values above reference range	3 (1.5%)	4 (1.1%)
With values below reference range	12 (5.9%)	46 (12.3%)
With values within reference range	188 (92.6%)	324 (86.6%)

Summary statistics:

Number of patients with values	203	374
Mean	4.60	4.43
SD	0.400	0.433
Median	4.60	4.50
Minimum	3.1	2.2
Maximum	5.6	6.0

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	199	371
With values above reference range	2 (1.0%)	2 (0.5%)
With values below reference range	11 (5.5%)	44 (11.9%)
With values within reference range	186 (93.5%)	325 (87.6%)

Summary statistics:

Number of patients with values	199	371
Mean	4.57	4.43
SD	0.407	0.439
Median	4.60	4.50
Minimum	3.5	2.3
Maximum	5.7	5.9

Month 12

Number of patients:

With values	181	332
With values above reference range	3 (1.7%)	1 (0.3%)
With values below reference range	11 (6.1%)	37 (11.1%)
With values within reference range	167 (92.3%)	294 (88.6%)

Summary statistics:

Number of patients with values	181	332
Mean	4.58	4.46
SD	0.421	0.431
Median	4.60	4.50
Minimum	3.7	3.4
Maximum	6.1	5.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	164	315
With values above reference range	4 (2.4%)	3 (1.0%)
With values below reference range	6 (3.7%)	38 (12.1%)
With values within reference range	154 (93.9%)	274 (87.0%)

Summary statistics:

Number of patients with values	164	315
Mean	4.57	4.43
SD	0.448	0.442
Median	4.50	4.50
Minimum	3.6	3.2
Maximum	5.8	6.1

Month 18

Number of patients:

With values	155	291
With values above reference range	3 (1.9%)	1 (0.3%)
With values below reference range	8 (5.2%)	29 (10.0%)
With values within reference range	144 (92.9%)	261 (89.7%)

Summary statistics:

Number of patients with values	155	291
Mean	4.56	4.41
SD	0.405	0.417
Median	4.50	4.40
Minimum	3.6	3.1
Maximum	6.1	5.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	152	274
With values above reference range	3 (2.0%)	1 (0.4%)
With values below reference range	7 (4.6%)	27 (9.9%)
With values within reference range	142 (93.4%)	246 (89.8%)

Summary statistics:

Number of patients with values	152	274
Mean	4.57	4.42
SD	0.413	0.436
Median	4.60	4.40
Minimum	3.6	3.2
Maximum	5.9	6.7

Month 24

Number of patients:

With values	128	249
With values above reference range	2 (1.6%)	1 (0.4%)
With values below reference range	6 (4.7%)	28 (11.2%)
With values within reference range	120 (93.8%)	220 (88.4%)

Summary statistics:

Number of patients with values	128	249
Mean	4.57	4.43
SD	0.437	0.451
Median	4.60	4.40
Minimum	3.5	3.3
Maximum	5.5	5.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	118	227
With values above reference range	3 (2.5%)	2 (0.9%)
With values below reference range	6 (5.1%)	18 (7.9%)
With values within reference range	109 (92.4%)	207 (91.2%)

Summary statistics:

Number of patients with values	118	227
Mean	4.61	4.45
SD	0.437	0.432
Median	4.60	4.50
Minimum	3.5	3.2
Maximum	5.6	5.9

Month 30

Number of patients:

With values	104	179
With values above reference range	3 (2.9%)	1 (0.6%)
With values below reference range	5 (4.8%)	22 (12.3%)
With values within reference range	96 (92.3%)	156 (87.2%)

Summary statistics:

Number of patients with values	104	179
Mean	4.60	4.40
SD	0.443	0.416
Median	4.55	4.40
Minimum	3.4	3.0
Maximum	5.9	5.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 33

Number of patients:

With values	91	153
With values above reference range	3 (3.3%)	1 (0.7%)
With values below reference range	6 (6.6%)	23 (15.0%)
With values within reference range	82 (90.1%)	129 (84.3%)

Summary statistics:

Number of patients with values	91	153
Mean	4.59	4.38
SD	0.482	0.478
Median	4.60	4.40
Minimum	3.5	3.0
Maximum	6.0	6.4

Month 36

Number of patients:

With values	83	77
With values above reference range	3 (3.6%)	0
With values below reference range	7 (8.4%)	7 (9.1%)
With values within reference range	73 (88.0%)	70 (90.9%)

Summary statistics:

Number of patients with values	83	77
Mean	4.52	4.36
SD	0.464	0.463
Median	4.50	4.40
Minimum	3.3	2.9
Maximum	5.9	5.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	3 (6.1%)	0
With values below reference range	4 (8.2%)	0
With values within reference range	42 (85.7%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	4.60	4.43
SD	0.484	0.289
Median	4.60	4.40
Minimum	3.5	3.9
Maximum	5.6	4.9
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	1 (3.1%)	
With values within reference range	30 (93.8%)	
Summary statistics:		
Number of patients with values	32	0
Mean	4.53	
SD	0.427	
Median	4.50	
Minimum	3.8	
Maximum	5.6	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	1 (5.3%)	
With values within reference range	16 (84.2%)	
Summary statistics:		
Number of patients with values	19	0
Mean	4.61	
SD	0.526	
Median	4.60	
Minimum	4.0	
Maximum	5.7	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	23 (100.0%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	90.8	91.2
SD	3.32	3.62
Median	91.0	90.5
Minimum	84	85
Maximum	98	100
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	1 (0.4%)	8 (1.9%)
With values below reference range	2 (0.9%)	11 (2.6%)
With values within reference range	226 (98.7%)	408 (95.6%)
Summary statistics:		
Number of patients with values	229	427
Mean	91.1	90.0
SD	4.08	5.13
Median	91.0	90.0
Minimum	74	60
Maximum	101	106

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	2 (100.0%)	19 (100.0%)
Summary statistics:		
Number of patients with values	2	19
Mean	92.0	90.0
SD	1.41	3.93
Median	92.0	89.0
Minimum	91	83
Maximum	93	99
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	5 (100.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	89.4	89.1
SD	2.30	4.34
Median	89.0	90.0
Minimum	86	82
Maximum	92	96

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	385
With values above reference range	2 (0.9%)	6 (1.6%)
With values below reference range	4 (1.9%)	9 (2.3%)
With values within reference range	206 (97.2%)	370 (96.1%)
Summary statistics:		
Number of patients with values	212	385
Mean	91.0	91.1
SD	4.32	4.86
Median	91.0	91.0
Minimum	77	61
Maximum	104	109
Month 6		
Number of patients:		
With values	203	374
With values above reference range	1 (0.5%)	10 (2.7%)
With values below reference range	2 (1.0%)	9 (2.4%)
With values within reference range	200 (98.5%)	355 (94.9%)
Summary statistics:		
Number of patients with values	203	374
Mean	90.8	92.0
SD	3.91	5.60
Median	91.0	92.0
Minimum	81	61
Maximum	101	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (fL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	199	371
With values above reference range	0	10 (2.7%)
With values below reference range	3 (1.5%)	9 (2.4%)
With values within reference range	196 (98.5%)	352 (94.9%)
Summary statistics:		
Number of patients with values	199	371
Mean	90.6	91.9
SD	3.85	5.53
Median	91.0	92.0
Minimum	79	62
Maximum	101	109
Month 12		
Number of patients:		
With values	181	332
With values above reference range	0	10 (3.0%)
With values below reference range	4 (2.2%)	8 (2.4%)
With values within reference range	177 (97.8%)	314 (94.6%)
Summary statistics:		
Number of patients with values	181	332
Mean	90.7	91.9
SD	4.50	5.38
Median	91.0	92.0
Minimum	62	65
Maximum	100	108

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	164	314
With values above reference range	0	14 (4.5%)
With values below reference range	0	7 (2.2%)
With values within reference range	164 (100.0%)	293 (93.3%)
Summary statistics:		
Number of patients with values	164	314
Mean	91.4	92.4
SD	4.02	5.81
Median	91.0	93.0
Minimum	80	62
Maximum	101	112
Month 18		
Number of patients:		
With values	155	290
With values above reference range	0	13 (4.5%)
With values below reference range	1 (0.6%)	5 (1.7%)
With values within reference range	154 (99.4%)	272 (93.8%)
Summary statistics:		
Number of patients with values	155	290
Mean	91.4	93.4
SD	3.70	5.57
Median	91.0	94.0
Minimum	81	63
Maximum	100	109

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (fL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	0	13 (4.7%)
With values below reference range	0	4 (1.5%)
With values within reference range	152 (100.0%)	257 (93.8%)
Summary statistics:		
Number of patients with values	152	274
Mean	91.7	93.7
SD	3.69	5.48
Median	92.0	94.0
Minimum	82	65
Maximum	100	111
Month 24		
Number of patients:		
With values	128	249
With values above reference range	1 (0.8%)	10 (4.0%)
With values below reference range	0	3 (1.2%)
With values within reference range	127 (99.2%)	236 (94.8%)
Summary statistics:		
Number of patients with values	128	249
Mean	92.4	93.7
SD	3.81	5.18
Median	92.0	94.0
Minimum	82	68
Maximum	102	110

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	118	227
With values above reference range	0	9 (4.0%)
With values below reference range	0	3 (1.3%)
With values within reference range	118 (100.0%)	215 (94.7%)
Summary statistics:		
Number of patients with values	118	227
Mean	92.7	93.9
SD	3.71	5.30
Median	93.0	94.0
Minimum	80	68
Maximum	102	114
Month 30		
Number of patients:		
With values	104	179
With values above reference range	1 (1.0%)	13 (7.3%)
With values below reference range	0	1 (0.6%)
With values within reference range	103 (99.0%)	165 (92.2%)
Summary statistics:		
Number of patients with values	104	179
Mean	92.8	94.3
SD	3.93	5.08
Median	93.0	94.0
Minimum	81	78
Maximum	104	116

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 33

Number of patients:

With values	91	153
With values above reference range	0	10 (6.5%)
With values below reference range	1 (1.1%)	1 (0.7%)
With values within reference range	90 (98.9%)	142 (92.8%)

Summary statistics:

Number of patients with values	91	153
Mean	92.9	93.9
SD	3.80	5.56
Median	92.0	93.0
Minimum	82	80
Maximum	102	117

Month 36

Number of patients:

With values	83	77
With values above reference range	1 (1.2%)	5 (6.5%)
With values below reference range	0	1 (1.3%)
With values within reference range	82 (98.8%)	71 (92.2%)

Summary statistics:

Number of patients with values	83	77
Mean	92.9	93.2
SD	3.82	5.61
Median	93.0	93.0
Minimum	82	79
Maximum	105	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	0	0
With values below reference range	0	1 (6.7%)
With values within reference range	49 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	49	15
Mean	92.0	91.3
SD	4.44	4.78
Median	93.0	91.0
Minimum	81	79
Maximum	103	97
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	92.1	
SD	4.40	
Median	92.0	
Minimum	81	
Maximum	100	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	91.2	
SD	4.02	
Median	90.0	
Minimum	82	
Maximum	98	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	23 (100.0%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	30.70	30.85
SD	1.473	1.338
Median	30.60	30.60
Minimum	28.2	28.2
Maximum	33.8	33.0
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	0	17 (4.0%)
With values below reference range	3 (1.3%)	11 (2.6%)
With values within reference range	226 (98.7%)	399 (93.4%)
Summary statistics:		
Number of patients with values	229	427
Mean	30.52	30.85
SD	1.475	1.942
Median	30.60	30.60
Minimum	23.4	19.3
Maximum	34.6	37.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	0
With values within reference range	2 (100.0%)	18 (94.7%)
Summary statistics:		
Number of patients with values	2	19
Mean	31.00	30.43
SD	0.566	1.720
Median	31.00	30.60
Minimum	30.6	27.4
Maximum	31.4	33.8
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	1 (11.1%)
With values within reference range	5 (100.0%)	8 (88.9%)
Summary statistics:		
Number of patients with values	5	9
Mean	29.64	29.89
SD	1.043	1.671
Median	29.80	29.80
Minimum	28.2	26.6
Maximum	30.6	32.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	385
With values above reference range	4 (1.9%)	8 (2.1%)
With values below reference range	4 (1.9%)	11 (2.9%)
With values within reference range	204 (96.2%)	366 (95.1%)
Summary statistics:		
Number of patients with values	212	385
Mean	30.70	30.53
SD	1.523	1.813
Median	30.60	30.60
Minimum	25.8	19.3
Maximum	35.4	36.3
Month 6		
Number of patients:		
With values	203	374
With values above reference range	0	14 (3.7%)
With values below reference range	5 (2.5%)	13 (3.5%)
With values within reference range	198 (97.5%)	347 (92.8%)
Summary statistics:		
Number of patients with values	203	374
Mean	30.44	30.80
SD	1.469	2.024
Median	30.60	30.60
Minimum	25.8	19.3
Maximum	33.8	37.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	199	371
With values above reference range	1 (0.5%)	15 (4.0%)
With values below reference range	5 (2.5%)	10 (2.7%)
With values within reference range	193 (97.0%)	346 (93.3%)
Summary statistics:		
Number of patients with values	199	371
Mean	30.53	30.86
SD	1.499	2.037
Median	30.60	30.60
Minimum	25.0	20.1
Maximum	34.6	37.9
Month 12		
Number of patients:		
With values	181	332
With values above reference range	1 (0.6%)	11 (3.3%)
With values below reference range	8 (4.4%)	8 (2.4%)
With values within reference range	172 (95.0%)	313 (94.3%)
Summary statistics:		
Number of patients with values	181	332
Mean	30.33	30.73
SD	1.779	2.014
Median	30.60	30.60
Minimum	19.3	20.9
Maximum	35.4	37.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	164	314
With values above reference range	2 (1.2%)	10 (3.2%)
With values below reference range	4 (2.4%)	11 (3.5%)
With values within reference range	158 (96.3%)	293 (93.3%)
Summary statistics:		
Number of patients with values	164	314
Mean	30.55	30.73
SD	1.525	2.131
Median	30.60	30.60
Minimum	25.8	19.3
Maximum	33.8	38.7
Month 18		
Number of patients:		
With values	155	290
With values above reference range	0	11 (3.8%)
With values below reference range	3 (1.9%)	8 (2.8%)
With values within reference range	152 (98.1%)	271 (93.4%)
Summary statistics:		
Number of patients with values	155	290
Mean	30.58	30.93
SD	1.351	1.972
Median	30.60	30.60
Minimum	26.6	19.3
Maximum	33.8	36.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	1 (0.7%)	7 (2.6%)
With values below reference range	3 (2.0%)	8 (2.9%)
With values within reference range	148 (97.4%)	259 (94.5%)
Summary statistics:		
Number of patients with values	152	274
Mean	30.66	30.82
SD	1.513	1.959
Median	30.60	30.60
Minimum	26.6	20.1
Maximum	34.6	37.9
Month 24		
Number of patients:		
With values	128	249
With values above reference range	1 (0.8%)	7 (2.8%)
With values below reference range	2 (1.6%)	4 (1.6%)
With values within reference range	125 (97.7%)	238 (95.6%)
Summary statistics:		
Number of patients with values	128	249
Mean	30.67	30.66
SD	1.451	1.861
Median	30.60	30.60
Minimum	26.6	20.9
Maximum	36.3	37.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	118	227
With values above reference range	1 (0.8%)	5 (2.2%)
With values below reference range	1 (0.8%)	6 (2.6%)
With values within reference range	116 (98.3%)	216 (95.2%)
Summary statistics:		
Number of patients with values	118	227
Mean	30.63	30.60
SD	1.457	1.922
Median	30.60	30.60
Minimum	26.6	20.9
Maximum	35.4	37.1
Month 30		
Number of patients:		
With values	104	179
With values above reference range	1 (1.0%)	5 (2.8%)
With values below reference range	1 (1.0%)	4 (2.2%)
With values within reference range	102 (98.1%)	170 (95.0%)
Summary statistics:		
Number of patients with values	104	179
Mean	30.43	30.88
SD	1.452	1.745
Median	30.60	30.60
Minimum	26.6	25.8
Maximum	35.4	37.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	1 (1.1%)	6 (3.9%)
With values below reference range	2 (2.2%)	6 (3.9%)
With values within reference range	88 (96.7%)	141 (92.2%)
Summary statistics:		
Number of patients with values	91	153
Mean	30.47	30.86
SD	1.412	1.976
Median	30.60	30.60
Minimum	25.8	25.8
Maximum	34.6	37.9
Month 36		
Number of patients:		
With values	83	77
With values above reference range	1 (1.2%)	4 (5.2%)
With values below reference range	2 (2.4%)	2 (2.6%)
With values within reference range	80 (96.4%)	71 (92.2%)
Summary statistics:		
Number of patients with values	83	77
Mean	30.46	30.83
SD	1.479	2.010
Median	30.60	30.60
Minimum	26.6	24.2
Maximum	35.4	37.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	0	0
With values below reference range	2 (4.1%)	1 (6.7%)
With values within reference range	47 (95.9%)	14 (93.3%)
Summary statistics:		
Number of patients with values	49	15
Mean	30.44	30.49
SD	1.673	1.733
Median	30.60	30.60
Minimum	26.6	25.8
Maximum	34.6	32.2
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	1 (3.1%)	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	30.30	
SD	1.610	
Median	30.20	
Minimum	25.8	
Maximum	33.8	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	1 (5.3%)	
With values within reference range	18 (94.7%)	
Summary statistics:		
Number of patients with values	19	0
Mean	30.18	
SD	1.630	
Median	29.80	
Minimum	25.8	
Maximum	32.2	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	23 (100.0%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	33.8	34.0
SD	0.90	0.49
Median	34.0	34.0
Minimum	32	32
Maximum	35	35
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	0	0
With values below reference range	1 (0.4%)	1 (0.2%)
With values within reference range	228 (99.6%)	426 (99.8%)
Summary statistics:		
Number of patients with values	229	427
Mean	33.6	34.2
SD	0.95	0.68
Median	34.0	34.0
Minimum	31	31
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	2	19
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	2 (100.0%)	19 (100.0%)
Summary statistics:		
Number of patients with values	2	19
Mean	34.0	33.5
SD	0.00	1.12
Median	34.0	34.0
Minimum	34	32
Maximum	34	35
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	5 (100.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	33.2	33.2
SD	1.10	1.20
Median	34.0	34.0
Minimum	32	32
Maximum	34	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	385
With values above reference range	0	0
With values below reference range	4 (1.9%)	1 (0.3%)
With values within reference range	208 (98.1%)	384 (99.7%)
Summary statistics:		
Number of patients with values	212	385
Mean	33.8	33.6
SD	0.95	0.91
Median	34.0	34.0
Minimum	31	31
Maximum	35	35
Month 6		
Number of patients:		
With values	203	374
With values above reference range	0	0
With values below reference range	3 (1.5%)	5 (1.3%)
With values within reference range	200 (98.5%)	369 (98.7%)
Summary statistics:		
Number of patients with values	203	374
Mean	33.6	33.5
SD	0.98	1.02
Median	34.0	34.0
Minimum	31	31
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	199	371
With values above reference range	0	0
With values below reference range	2 (1.0%)	0
With values within reference range	197 (99.0%)	371 (100.0%)
Summary statistics:		
Number of patients with values	199	371
Mean	33.8	33.7
SD	0.89	0.86
Median	34.0	34.0
Minimum	31	32
Maximum	35	35
Month 12		
Number of patients:		
With values	181	332
With values above reference range	0	0
With values below reference range	2 (1.1%)	2 (0.6%)
With values within reference range	179 (98.9%)	330 (99.4%)
Summary statistics:		
Number of patients with values	181	332
Mean	33.5	33.5
SD	1.03	0.96
Median	34.0	34.0
Minimum	31	31
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	164	314
With values above reference range	0	0
With values below reference range	5 (3.0%)	13 (4.1%)
With values within reference range	159 (97.0%)	301 (95.9%)
Summary statistics:		
Number of patients with values	164	314
Mean	33.5	33.3
SD	1.02	1.09
Median	34.0	34.0
Minimum	31	29
Maximum	35	35
Month 18		
Number of patients:		
With values	155	290
With values above reference range	0	0
With values below reference range	2 (1.3%)	7 (2.4%)
With values within reference range	153 (98.7%)	283 (97.6%)
Summary statistics:		
Number of patients with values	155	290
Mean	33.5	33.2
SD	0.97	1.06
Median	34.0	34.0
Minimum	31	31
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	0	0
With values below reference range	2 (1.3%)	10 (3.6%)
With values within reference range	150 (98.7%)	264 (96.4%)
Summary statistics:		
Number of patients with values	152	274
Mean	33.5	32.8
SD	0.96	1.06
Median	34.0	32.0
Minimum	31	31
Maximum	35	35
Month 24		
Number of patients:		
With values	128	249
With values above reference range	0	0
With values below reference range	3 (2.3%)	6 (2.4%)
With values within reference range	125 (97.7%)	243 (97.6%)
Summary statistics:		
Number of patients with values	128	249
Mean	33.2	32.7
SD	1.10	0.98
Median	34.0	32.0
Minimum	31	31
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	118	227
With values above reference range	0	0
With values below reference range	4 (3.4%)	9 (4.0%)
With values within reference range	114 (96.6%)	218 (96.0%)
Summary statistics:		
Number of patients with values	118	227
Mean	33.0	32.5
SD	1.10	0.91
Median	34.0	32.0
Minimum	31	31
Maximum	35	34
Month 30		
Number of patients:		
With values	104	179
With values above reference range	0	0
With values below reference range	5 (4.8%)	10 (5.6%)
With values within reference range	99 (95.2%)	169 (94.4%)
Summary statistics:		
Number of patients with values	104	179
Mean	32.6	32.7
SD	1.05	1.03
Median	32.0	32.0
Minimum	31	31
Maximum	35	34

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	0	0
With values below reference range	1 (1.1%)	5 (3.3%)
With values within reference range	90 (98.9%)	148 (96.7%)
Summary statistics:		
Number of patients with values	91	153
Mean	32.6	32.7
SD	0.97	1.06
Median	32.0	32.0
Minimum	31	31
Maximum	35	35
Month 36		
Number of patients:		
With values	83	77
With values above reference range	0	0
With values below reference range	2 (2.4%)	2 (2.6%)
With values within reference range	81 (97.6%)	75 (97.4%)
Summary statistics:		
Number of patients with values	83	77
Mean	32.7	33.0
SD	0.98	1.08
Median	32.0	34.0
Minimum	31	31
Maximum	34	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	49 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	33.1	33.5
SD	1.07	0.99
Median	34.0	34.0
Minimum	32	32
Maximum	35	35
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	2 (6.3%)	
With values within reference range	30 (93.8%)	
Summary statistics:		
Number of patients with values	32	0
Mean	32.8	
SD	1.18	
Median	32.0	
Minimum	31	
Maximum	35	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	33.1	
SD	1.10	
Median	34.0	
Minimum	32	
Maximum	35	

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	1 (4.5%)
With values below reference range	0	1 (4.5%)
With values within reference range	23 (100.0%)	20 (90.9%)
Summary statistics:		
Number of patients with values	23	22
Mean	6.38	6.43
SD	1.468	2.015
Median	6.60	5.95
Minimum	4.1	3.5
Maximum	9.5	12.2
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	4 (1.7%)	8 (1.9%)
With values below reference range	2 (0.9%)	17 (4.0%)
With values within reference range	223 (97.4%)	402 (94.1%)
Summary statistics:		
Number of patients with values	229	427
Mean	6.75	6.35
SD	1.722	1.921
Median	6.60	6.10
Minimum	3.0	3.0
Maximum	15.0	23.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	0
With values within reference range	1 (100.0%)	18 (94.7%)
Summary statistics:		
Number of patients with values	1	19
Mean	6.10	5.92
SD		1.651
Median	6.10	5.70
Minimum	6.1	4.2
Maximum	6.1	11.1
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	5 (100.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	7.20	5.64
SD	1.927	1.081
Median	7.20	5.50
Minimum	4.9	4.2
Maximum	10.1	7.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	385
With values above reference range	6 (2.8%)	6 (1.6%)
With values below reference range	1 (0.5%)	20 (5.2%)
With values within reference range	205 (96.7%)	359 (93.2%)

Summary statistics:

Number of patients with values	212	385
Mean	6.66	5.91
SD	1.777	1.858
Median	6.40	5.70
Minimum	3.5	2.8
Maximum	13.2	23.5

Month 6

Number of patients:

With values	203	374
With values above reference range	3 (1.5%)	7 (1.9%)
With values below reference range	4 (2.0%)	26 (7.0%)
With values within reference range	196 (96.6%)	341 (91.2%)

Summary statistics:

Number of patients with values	203	374
Mean	6.53	5.82
SD	1.681	1.879
Median	6.30	5.60
Minimum	3.3	2.6
Maximum	12.5	22.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	199	371
With values above reference range	3 (1.5%)	4 (1.1%)
With values below reference range	1 (0.5%)	20 (5.4%)
With values within reference range	195 (98.0%)	347 (93.5%)

Summary statistics:

Number of patients with values	199	371
Mean	6.48	5.89
SD	1.690	1.913
Median	6.20	5.60
Minimum	2.5	3.1
Maximum	15.0	22.7

Month 12

Number of patients:

With values	181	332
With values above reference range	5 (2.8%)	3 (0.9%)
With values below reference range	5 (2.8%)	23 (6.9%)
With values within reference range	171 (94.5%)	306 (92.2%)

Summary statistics:

Number of patients with values	181	332
Mean	6.52	5.74
SD	1.846	1.777
Median	6.30	5.50
Minimum	3.5	2.7
Maximum	15.3	19.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	164	315
With values above reference range	4 (2.4%)	5 (1.6%)
With values below reference range	1 (0.6%)	25 (7.9%)
With values within reference range	159 (97.0%)	285 (90.5%)

Summary statistics:

Number of patients with values	164	315
Mean	6.61	5.80
SD	1.737	1.962
Median	6.30	5.50
Minimum	3.7	2.6
Maximum	14.1	22.1

Month 18

Number of patients:

With values	155	291
With values above reference range	2 (1.3%)	4 (1.4%)
With values below reference range	2 (1.3%)	20 (6.9%)
With values within reference range	151 (97.4%)	267 (91.8%)

Summary statistics:

Number of patients with values	155	291
Mean	6.32	5.60
SD	1.551	1.779
Median	6.10	5.30
Minimum	3.5	2.5
Maximum	12.7	19.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	152	274
With values above reference range	4 (2.6%)	3 (1.1%)
With values below reference range	0	26 (9.5%)
With values within reference range	148 (97.4%)	245 (89.4%)

Summary statistics:

Number of patients with values	152	274
Mean	6.41	5.59
SD	1.596	1.707
Median	6.15	5.40
Minimum	3.9	2.3
Maximum	12.3	17.1

Month 24

Number of patients:

With values	128	249
With values above reference range	4 (3.1%)	1 (0.4%)
With values below reference range	5 (3.9%)	18 (7.2%)
With values within reference range	119 (93.0%)	230 (92.4%)

Summary statistics:

Number of patients with values	128	249
Mean	6.47	5.45
SD	1.879	1.364
Median	6.00	5.20
Minimum	3.0	2.5
Maximum	15.6	11.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	118	227
With values above reference range	0	3 (1.3%)
With values below reference range	2 (1.7%)	23 (10.1%)
With values within reference range	116 (98.3%)	201 (88.5%)

Summary statistics:

Number of patients with values	118	227
Mean	6.24	5.60
SD	1.367	2.011
Median	6.00	5.30
Minimum	3.5	2.8
Maximum	10.0	22.2

Month 30

Number of patients:

With values	104	179
With values above reference range	2 (1.9%)	3 (1.7%)
With values below reference range	1 (1.0%)	14 (7.8%)
With values within reference range	101 (97.1%)	162 (90.5%)

Summary statistics:

Number of patients with values	104	179
Mean	6.39	5.60
SD	1.651	1.799
Median	6.10	5.30
Minimum	3.4	2.6
Maximum	11.7	19.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 33

Number of patients:

With values	91	153
With values above reference range	2 (2.2%)	2 (1.3%)
With values below reference range	1 (1.1%)	12 (7.8%)
With values within reference range	88 (96.7%)	139 (90.8%)

Summary statistics:

Number of patients with values	91	153
Mean	6.41	5.63
SD	1.605	1.906
Median	6.10	5.30
Minimum	3.9	2.7
Maximum	12.2	20.7

Month 36

Number of patients:

With values	83	77
With values above reference range	3 (3.6%)	1 (1.3%)
With values below reference range	1 (1.2%)	10 (13.0%)
With values within reference range	79 (95.2%)	66 (85.7%)

Summary statistics:

Number of patients with values	83	77
Mean	6.29	5.54
SD	1.691	2.724
Median	6.10	5.10
Minimum	3.6	2.6
Maximum	12.1	25.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	1 (2.0%)	0
With values below reference range	1 (2.0%)	0
With values within reference range	47 (95.9%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	6.64	5.59
SD	1.697	0.882
Median	6.30	5.70
Minimum	3.7	4.1
Maximum	12.2	7.2
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	6.51	
SD	1.378	
Median	6.40	
Minimum	4.1	
Maximum	9.1	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: White Blood Cell Count (10⁹/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	6.76	
SD	1.340	
Median	6.70	
Minimum	4.4	
Maximum	9.4	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	3 (13.0%)	2 (9.1%)
With values within reference range	20 (87.0%)	20 (90.9%)
Summary statistics:		
Number of patients with values	23	22
Mean	52.79	56.01
SD	10.120	12.007
Median	53.60	55.70
Minimum	33.3	29.0
Maximum	71.4	72.1
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	2 (0.9%)	8 (1.9%)
With values below reference range	7 (3.1%)	17 (4.0%)
With values within reference range	220 (96.1%)	402 (94.1%)
Summary statistics:		
Number of patients with values	229	427
Mean	56.50	56.95
SD	8.979	9.264
Median	56.50	57.30
Minimum	19.4	19.4
Maximum	85.8	78.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	0
With values below reference range	0	2 (10.5%)
With values within reference range	1 (100.0%)	17 (89.5%)
Summary statistics:		
Number of patients with values	1	19
Mean	48.70	53.87
SD		12.439
Median	48.70	55.30
Minimum	48.7	13.5
Maximum	48.7	69.3
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	1 (11.1%)
With values within reference range	5 (100.0%)	8 (88.9%)
Summary statistics:		
Number of patients with values	5	9
Mean	58.80	51.89
SD	6.851	10.221
Median	58.00	53.60
Minimum	51.0	30.7
Maximum	69.6	64.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	382
With values above reference range	4 (1.9%)	5 (1.3%)
With values below reference range	8 (3.8%)	19 (5.0%)
With values within reference range	200 (94.3%)	358 (93.7%)
Summary statistics:		
Number of patients with values	212	382
Mean	56.23	55.17
SD	9.297	9.719
Median	55.65	54.85
Minimum	31.2	12.1
Maximum	82.5	87.7
Month 6		
Number of patients:		
With values	202	371
With values above reference range	5 (2.5%)	7 (1.9%)
With values below reference range	8 (4.0%)	19 (5.1%)
With values within reference range	189 (93.6%)	345 (93.0%)
Summary statistics:		
Number of patients with values	202	371
Mean	56.72	56.22
SD	9.246	9.358
Median	56.80	56.00
Minimum	29.4	19.2
Maximum	87.6	81.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	198	366
With values above reference range	5 (2.5%)	3 (0.8%)
With values below reference range	7 (3.5%)	16 (4.4%)
With values within reference range	186 (93.9%)	347 (94.8%)
Summary statistics:		
Number of patients with values	198	366
Mean	56.69	55.57
SD	9.429	8.685
Median	57.50	55.80
Minimum	0.9	25.1
Maximum	87.1	79.8
Month 12		
Number of patients:		
With values	180	332
With values above reference range	2 (1.1%)	4 (1.2%)
With values below reference range	7 (3.9%)	18 (5.4%)
With values within reference range	171 (95.0%)	310 (93.4%)
Summary statistics:		
Number of patients with values	180	332
Mean	56.90	55.22
SD	9.401	9.393
Median	57.25	56.25
Minimum	30.0	24.1
Maximum	77.0	90.5

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	163	312
With values above reference range	4 (2.5%)	5 (1.6%)
With values below reference range	8 (4.9%)	19 (6.1%)
With values within reference range	151 (92.6%)	288 (92.3%)
Summary statistics:		
Number of patients with values	163	312
Mean	56.24	55.62
SD	9.406	9.785
Median	56.20	56.55
Minimum	28.4	5.0
Maximum	81.6	81.4
Month 18		
Number of patients:		
With values	154	288
With values above reference range	3 (1.9%)	2 (0.7%)
With values below reference range	4 (2.6%)	16 (5.6%)
With values within reference range	147 (95.5%)	270 (93.8%)
Summary statistics:		
Number of patients with values	154	288
Mean	57.19	56.18
SD	8.912	9.426
Median	57.10	57.05
Minimum	17.8	13.6
Maximum	83.1	80.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	271
With values above reference range	0	2 (0.7%)
With values below reference range	6 (3.9%)	10 (3.7%)
With values within reference range	146 (96.1%)	259 (95.6%)
Summary statistics:		
Number of patients with values	152	271
Mean	57.27	56.42
SD	8.228	9.088
Median	58.25	56.40
Minimum	21.9	23.0
Maximum	74.4	77.9
Month 24		
Number of patients:		
With values	128	247
With values above reference range	4 (3.1%)	7 (2.8%)
With values below reference range	3 (2.3%)	6 (2.4%)
With values within reference range	121 (94.5%)	234 (94.7%)
Summary statistics:		
Number of patients with values	128	247
Mean	58.44	57.73
SD	10.306	8.907
Median	59.15	57.90
Minimum	6.7	30.0
Maximum	91.8	83.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	117	225
With values above reference range	0	4 (1.8%)
With values below reference range	1 (0.9%)	13 (5.8%)
With values within reference range	116 (99.1%)	208 (92.4%)
Summary statistics:		
Number of patients with values	117	225
Mean	57.51	56.35
SD	7.271	9.658
Median	57.50	56.60
Minimum	33.5	10.9
Maximum	73.3	79.1
Month 30		
Number of patients:		
With values	103	179
With values above reference range	4 (3.9%)	4 (2.2%)
With values below reference range	3 (2.9%)	7 (3.9%)
With values within reference range	96 (93.2%)	168 (93.9%)
Summary statistics:		
Number of patients with values	103	179
Mean	58.81	57.36
SD	8.731	9.265
Median	58.40	57.50
Minimum	37.2	32.3
Maximum	91.3	86.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	5 (5.5%)	1 (0.7%)
With values below reference range	1 (1.1%)	8 (5.2%)
With values within reference range	85 (93.4%)	144 (94.1%)
Summary statistics:		
Number of patients with values	91	153
Mean	59.04	56.29
SD	8.977	8.827
Median	59.20	56.80
Minimum	38.8	19.5
Maximum	79.6	76.6
Month 36		
Number of patients:		
With values	83	76
With values above reference range	3 (3.6%)	4 (5.3%)
With values below reference range	1 (1.2%)	3 (3.9%)
With values within reference range	79 (95.2%)	69 (90.8%)
Summary statistics:		
Number of patients with values	83	76
Mean	58.87	57.01
SD	8.992	9.755
Median	59.40	57.35
Minimum	35.8	35.0
Maximum	84.5	81.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	1 (2.0%)	0
With values below reference range	0	0
With values within reference range	48 (98.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	59.97	56.76
SD	7.445	9.802
Median	59.80	60.10
Minimum	46.0	41.0
Maximum	78.7	72.9
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	1 (3.1%)	
With values within reference range	30 (93.8%)	
Summary statistics:		
Number of patients with values	32	0
Mean	58.20	
SD	8.068	
Median	58.40	
Minimum	39.6	
Maximum	76.2	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	0	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	61.87	
SD	8.097	
Median	63.10	
Minimum	47.7	
Maximum	76.6	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	5 (21.7%)	2 (9.1%)
With values below reference range	0	0
With values within reference range	18 (78.3%)	20 (90.9%)
Summary statistics:		
Number of patients with values	23	22
Mean	36.59	33.45
SD	9.414	10.158
Median	35.80	34.90
Minimum	20.5	19.7
Maximum	55.8	54.5
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	17 (7.4%)	24 (5.6%)
With values below reference range	2 (0.9%)	9 (2.1%)
With values within reference range	210 (91.7%)	394 (92.3%)
Summary statistics:		
Number of patients with values	229	427
Mean	33.19	32.26
SD	8.517	8.544
Median	32.70	31.80
Minimum	6.4	13.3
Maximum	65.7	76.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	3 (15.8%)
With values below reference range	0	0
With values within reference range	1 (100.0%)	16 (84.2%)
Summary statistics:		
Number of patients with values	1	19
Mean	42.50	34.31
SD		11.124
Median	42.50	31.80
Minimum	42.5	20.2
Maximum	42.5	63.5
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	1 (11.1%)
With values below reference range	0	0
With values within reference range	5 (100.0%)	8 (88.9%)
Summary statistics:		
Number of patients with values	5	9
Mean	28.42	34.94
SD	6.990	8.837
Median	31.40	32.00
Minimum	18.6	23.9
Maximum	35.4	53.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	382
With values above reference range	17 (8.0%)	26 (6.8%)
With values below reference range	5 (2.4%)	7 (1.8%)
With values within reference range	190 (89.6%)	349 (91.4%)
Summary statistics:		
Number of patients with values	212	382
Mean	33.16	33.85
SD	9.137	9.123
Median	32.90	34.00
Minimum	7.8	5.1
Maximum	57.9	77.8
Month 6		
Number of patients:		
With values	202	371
With values above reference range	14 (6.9%)	26 (7.0%)
With values below reference range	8 (4.0%)	8 (2.2%)
With values within reference range	180 (89.1%)	337 (90.8%)
Summary statistics:		
Number of patients with values	202	371
Mean	32.85	33.15
SD	8.529	8.977
Median	32.30	33.00
Minimum	5.1	11.8
Maximum	52.9	76.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	198	366
With values above reference range	12 (6.1%)	23 (6.3%)
With values below reference range	4 (2.0%)	5 (1.4%)
With values within reference range	182 (91.9%)	338 (92.3%)
Summary statistics:		
Number of patients with values	198	366
Mean	32.93	33.46
SD	8.749	8.502
Median	32.35	32.75
Minimum	8.0	12.7
Maximum	72.9	71.2
Month 12		
Number of patients:		
With values	180	332
With values above reference range	15 (8.3%)	27 (8.1%)
With values below reference range	6 (3.3%)	4 (1.2%)
With values within reference range	159 (88.3%)	301 (90.7%)
Summary statistics:		
Number of patients with values	180	332
Mean	32.57	33.43
SD	8.876	8.736
Median	32.50	32.85
Minimum	7.7	3.9
Maximum	57.8	71.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	163	312
With values above reference range	16 (9.8%)	26 (8.3%)
With values below reference range	7 (4.3%)	6 (1.9%)
With values within reference range	140 (85.9%)	280 (89.7%)

Summary statistics:

Number of patients with values	163	312
Mean	33.38	33.51
SD	9.176	9.076
Median	33.40	32.95
Minimum	10.7	10.3
Maximum	57.8	75.8

Month 18

Number of patients:

With values	154	288
With values above reference range	7 (4.5%)	15 (5.2%)
With values below reference range	4 (2.6%)	4 (1.4%)
With values within reference range	143 (92.9%)	269 (93.4%)

Summary statistics:

Number of patients with values	154	288
Mean	32.36	33.27
SD	8.362	8.815
Median	32.20	32.80
Minimum	10.4	11.6
Maximum	61.5	75.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	271
With values above reference range	6 (3.9%)	16 (5.9%)
With values below reference range	2 (1.3%)	3 (1.1%)
With values within reference range	144 (94.7%)	252 (93.0%)
Summary statistics:		
Number of patients with values	152	271
Mean	32.29	32.74
SD	8.009	8.102
Median	32.10	32.60
Minimum	13.5	14.3
Maximum	67.3	54.3
Month 24		
Number of patients:		
With values	128	247
With values above reference range	7 (5.5%)	11 (4.5%)
With values below reference range	6 (4.7%)	7 (2.8%)
With values within reference range	115 (89.8%)	229 (92.7%)
Summary statistics:		
Number of patients with values	128	247
Mean	31.36	31.40
SD	9.199	8.225
Median	31.15	31.00
Minimum	5.0	8.3
Maximum	68.3	61.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	117	225
With values above reference range	3 (2.6%)	17 (7.6%)
With values below reference range	1 (0.9%)	3 (1.3%)
With values within reference range	113 (96.6%)	205 (91.1%)
Summary statistics:		
Number of patients with values	117	225
Mean	31.78	32.49
SD	6.907	9.070
Median	31.60	31.90
Minimum	14.5	11.2
Maximum	50.0	65.5
Month 30		
Number of patients:		
With values	103	179
With values above reference range	6 (5.8%)	13 (7.3%)
With values below reference range	5 (4.9%)	4 (2.2%)
With values within reference range	92 (89.3%)	162 (90.5%)
Summary statistics:		
Number of patients with values	103	179
Mean	31.17	32.37
SD	8.516	8.692
Median	30.70	32.00
Minimum	6.4	9.4
Maximum	55.0	57.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	3 (3.3%)	9 (5.9%)
With values below reference range	5 (5.5%)	4 (2.6%)
With values within reference range	83 (91.2%)	140 (91.5%)
Summary statistics:		
Number of patients with values	91	153
Mean	30.85	32.59
SD	8.368	9.507
Median	30.60	32.20
Minimum	11.0	5.0
Maximum	50.2	76.5
Month 36		
Number of patients:		
With values	83	76
With values above reference range	3 (3.6%)	5 (6.6%)
With values below reference range	6 (7.2%)	4 (5.3%)
With values within reference range	74 (89.2%)	67 (88.2%)
Summary statistics:		
Number of patients with values	83	76
Mean	30.52	32.03
SD	8.673	9.461
Median	30.60	31.45
Minimum	8.9	12.4
Maximum	51.7	52.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	0	1 (6.7%)
With values below reference range	1 (2.0%)	0
With values within reference range	48 (98.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	49	15
Mean	30.28	32.85
SD	6.627	8.575
Median	30.10	30.80
Minimum	11.7	17.6
Maximum	46.0	50.8
Month 42		
Number of patients:		
With values	32	0
With values above reference range	2 (6.3%)	
With values below reference range	1 (3.1%)	
With values within reference range	29 (90.6%)	
Summary statistics:		
Number of patients with values	32	0
Mean	31.72	
SD	8.420	
Median	32.25	
Minimum	12.6	
Maximum	52.8	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	2 (10.5%)	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	27.62	
SD	8.500	
Median	27.30	
Minimum	13.8	
Maximum	41.8	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	1 (4.5%)
With values below reference range	0	0
With values within reference range	23 (100.0%)	21 (95.5%)
Summary statistics:		
Number of patients with values	23	22
Mean	6.90	7.29
SD	1.467	2.113
Median	6.30	6.95
Minimum	5.0	3.9
Maximum	9.8	12.5
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	1 (0.4%)	11 (2.6%)
With values below reference range	0	0
With values within reference range	228 (99.6%)	416 (97.4%)
Summary statistics:		
Number of patients with values	229	427
Mean	6.56	7.35
SD	1.772	2.392
Median	6.40	7.00
Minimum	2.7	2.1
Maximum	12.7	30.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	2 (10.5%)
With values below reference range	0	0
With values within reference range	1 (100.0%)	17 (89.5%)
Summary statistics:		
Number of patients with values	1	19
Mean	6.30	8.10
SD		3.001
Median	6.30	7.40
Minimum	6.3	3.9
Maximum	6.3	16.1
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	2 (22.2%)
With values below reference range	0	0
With values within reference range	5 (100.0%)	7 (77.8%)
Summary statistics:		
Number of patients with values	5	9
Mean	7.96	8.24
SD	1.646	3.096
Median	8.30	7.40
Minimum	6.1	4.6
Maximum	10.3	13.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	382
With values above reference range	2 (0.9%)	7 (1.8%)
With values below reference range	0	0
With values within reference range	210 (99.1%)	375 (98.2%)
Summary statistics:		
Number of patients with values	212	382
Mean	7.07	7.11
SD	2.006	2.793
Median	7.10	6.80
Minimum	1.9	0.1
Maximum	14.6	42.9
Month 6		
Number of patients:		
With values	202	371
With values above reference range	3 (1.5%)	6 (1.6%)
With values below reference range	0	0
With values within reference range	199 (98.5%)	365 (98.4%)
Summary statistics:		
Number of patients with values	202	371
Mean	6.62	6.76
SD	1.941	2.439
Median	6.50	6.50
Minimum	2.9	1.9
Maximum	13.7	29.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	198	366
With values above reference range	1 (0.5%)	10 (2.7%)
With values below reference range	0	0
With values within reference range	197 (99.5%)	356 (97.3%)
Summary statistics:		
Number of patients with values	198	366
Mean	6.85	7.26
SD	1.987	2.161
Median	6.70	7.20
Minimum	2.1	1.1
Maximum	18.3	16.4
Month 12		
Number of patients:		
With values	180	332
With values above reference range	6 (3.3%)	11 (3.3%)
With values below reference range	0	0
With values within reference range	174 (96.7%)	321 (96.7%)
Summary statistics:		
Number of patients with values	180	332
Mean	6.74	7.53
SD	2.124	2.935
Median	6.40	7.15
Minimum	2.3	0.1
Maximum	14.4	36.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	163	312
With values above reference range	2 (1.2%)	7 (2.2%)
With values below reference range	0	0
With values within reference range	161 (98.8%)	305 (97.8%)
Summary statistics:		
Number of patients with values	163	312
Mean	6.76	7.00
SD	2.069	2.544
Median	6.70	6.70
Minimum	2.4	1.0
Maximum	14.1	31.9
Month 18		
Number of patients:		
With values	154	288
With values above reference range	2 (1.3%)	9 (3.1%)
With values below reference range	0	0
With values within reference range	152 (98.7%)	279 (96.9%)
Summary statistics:		
Number of patients with values	154	288
Mean	6.87	6.74
SD	1.895	2.672
Median	6.70	6.50
Minimum	1.5	1.1
Maximum	12.4	26.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	271
With values above reference range	3 (2.0%)	9 (3.3%)
With values below reference range	0	0
With values within reference range	149 (98.0%)	262 (96.7%)
Summary statistics:		
Number of patients with values	152	271
Mean	6.80	7.07
SD	2.118	2.515
Median	6.50	6.80
Minimum	2.0	2.5
Maximum	20.4	24.5
Month 24		
Number of patients:		
With values	128	247
With values above reference range	1 (0.8%)	8 (3.2%)
With values below reference range	0	0
With values within reference range	127 (99.2%)	239 (96.8%)
Summary statistics:		
Number of patients with values	128	247
Mean	6.66	7.34
SD	2.304	2.569
Median	6.65	7.00
Minimum	0.0	2.6
Maximum	18.3	28.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	117	225
With values above reference range	4 (3.4%)	7 (3.1%)
With values below reference range	0	0
With values within reference range	113 (96.6%)	218 (96.9%)
Summary statistics:		
Number of patients with values	117	225
Mean	7.00	7.45
SD	2.241	3.980
Median	6.80	6.80
Minimum	2.8	3.0
Maximum	17.8	55.1
Month 30		
Number of patients:		
With values	103	179
With values above reference range	1 (1.0%)	2 (1.1%)
With values below reference range	0	0
With values within reference range	102 (99.0%)	177 (98.9%)
Summary statistics:		
Number of patients with values	103	179
Mean	6.57	6.74
SD	1.979	2.139
Median	6.50	6.60
Minimum	2.1	0.5
Maximum	14.9	16.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	2 (2.2%)	2 (1.3%)
With values below reference range	0	0
With values within reference range	89 (97.8%)	151 (98.7%)
Summary statistics:		
Number of patients with values	91	153
Mean	6.61	7.35
SD	1.931	2.550
Median	6.50	7.10
Minimum	0.1	2.3
Maximum	12.2	28.1
Month 36		
Number of patients:		
With values	83	76
With values above reference range	3 (3.6%)	2 (2.6%)
With values below reference range	0	0
With values within reference range	80 (96.4%)	74 (97.4%)
Summary statistics:		
Number of patients with values	83	76
Mean	7.22	7.62
SD	2.109	1.938
Median	6.90	7.40
Minimum	3.7	4.0
Maximum	13.3	13.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	1 (2.0%)	0
With values below reference range	0	0
With values within reference range	48 (98.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	6.67	7.00
SD	2.042	1.838
Median	6.10	6.90
Minimum	3.1	4.6
Maximum	12.5	11.5
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	6.51	
SD	1.453	
Median	6.85	
Minimum	3.5	
Maximum	9.4	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	0	
With values within reference range	18 (94.7%)	
Summary statistics:		
Number of patients with values	19	0
Mean	7.37	
SD	1.804	
Median	7.00	
Minimum	4.6	
Maximum	12.2	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	1 (4.3%)	0
With values below reference range	0	0
With values within reference range	22 (95.7%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	3.26	2.81
SD	1.672	1.669
Median	2.80	2.65
Minimum	0.3	0.4
Maximum	7.6	6.1
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	9 (3.9%)	19 (4.4%)
With values below reference range	0	0
With values within reference range	220 (96.1%)	408 (95.6%)
Summary statistics:		
Number of patients with values	229	427
Mean	3.35	3.04
SD	1.809	1.997
Median	3.00	2.60
Minimum	0.3	0.0
Maximum	12.3	13.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	0
With values within reference range	1 (100.0%)	18 (94.7%)
Summary statistics:		
Number of patients with values	1	19
Mean	2.00	3.30
SD		1.796
Median	2.00	2.90
Minimum	2.0	1.1
Maximum	2.0	9.3
Month 2		
Number of patients:		
With values	5	9
With values above reference range	1 (20.0%)	2 (22.2%)
With values below reference range	0	0
With values within reference range	4 (80.0%)	7 (77.8%)
Summary statistics:		
Number of patients with values	5	9
Mean	4.48	4.58
SD	2.489	2.415
Median	4.80	3.60
Minimum	1.1	2.2
Maximum	7.7	8.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	382
With values above reference range	7 (3.3%)	17 (4.5%)
With values below reference range	0	0
With values within reference range	205 (96.7%)	365 (95.5%)
Summary statistics:		
Number of patients with values	212	382
Mean	3.14	3.47
SD	1.646	2.104
Median	2.75	3.00
Minimum	0.4	0.0
Maximum	10.0	14.8
Month 6		
Number of patients:		
With values	202	371
With values above reference range	15 (7.4%)	22 (5.9%)
With values below reference range	0	0
With values within reference range	187 (92.6%)	349 (94.1%)
Summary statistics:		
Number of patients with values	202	371
Mean	3.44	3.47
SD	1.984	2.017
Median	3.00	3.10
Minimum	0.3	0.0
Maximum	11.0	13.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	198	366
With values above reference range	6 (3.0%)	21 (5.7%)
With values below reference range	0	0
With values within reference range	192 (97.0%)	345 (94.3%)
Summary statistics:		
Number of patients with values	198	366
Mean	3.15	3.35
SD	1.739	1.964
Median	2.80	3.00
Minimum	0.3	0.1
Maximum	13.0	12.4
Month 12		
Number of patients:		
With values	180	332
With values above reference range	11 (6.1%)	25 (7.5%)
With values below reference range	0	0
With values within reference range	169 (93.9%)	307 (92.5%)
Summary statistics:		
Number of patients with values	180	332
Mean	3.42	3.47
SD	3.268	2.353
Median	2.95	2.80
Minimum	0.0	0.0
Maximum	37.5	15.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	163	312
With values above reference range	5 (3.1%)	18 (5.8%)
With values below reference range	0	0
With values within reference range	158 (96.9%)	294 (94.2%)
Summary statistics:		
Number of patients with values	163	312
Mean	3.24	3.50
SD	1.833	2.398
Median	2.90	3.05
Minimum	0.0	0.0
Maximum	11.6	19.0
Month 18		
Number of patients:		
With values	154	288
With values above reference range	6 (3.9%)	19 (6.6%)
With values below reference range	0	0
With values within reference range	148 (96.1%)	269 (93.4%)
Summary statistics:		
Number of patients with values	154	288
Mean	3.22	3.41
SD	1.683	2.419
Median	2.90	2.80
Minimum	0.1	0.0
Maximum	9.4	18.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	271
With values above reference range	9 (5.9%)	15 (5.5%)
With values below reference range	0	0
With values within reference range	143 (94.1%)	256 (94.5%)
Summary statistics:		
Number of patients with values	152	271
Mean	3.30	3.42
SD	1.930	2.506
Median	2.70	2.90
Minimum	0.2	0.1
Maximum	10.1	21.8
Month 24		
Number of patients:		
With values	128	247
With values above reference range	5 (3.9%)	11 (4.5%)
With values below reference range	0	0
With values within reference range	123 (96.1%)	236 (95.5%)
Summary statistics:		
Number of patients with values	128	247
Mean	3.17	3.16
SD	1.723	2.250
Median	2.90	2.80
Minimum	0.4	0.1
Maximum	9.1	22.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	117	225
With values above reference range	4 (3.4%)	14 (6.2%)
With values below reference range	0	0
With values within reference range	113 (96.6%)	211 (93.8%)
Summary statistics:		
Number of patients with values	117	225
Mean	3.35	3.32
SD	2.048	2.322
Median	2.90	2.70
Minimum	0.4	0.1
Maximum	14.0	20.7
Month 30		
Number of patients:		
With values	103	179
With values above reference range	5 (4.9%)	7 (3.9%)
With values below reference range	0	0
With values within reference range	98 (95.1%)	172 (96.1%)
Summary statistics:		
Number of patients with values	103	179
Mean	3.13	3.15
SD	1.800	1.778
Median	2.80	2.80
Minimum	0.0	0.2
Maximum	11.1	11.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	1 (1.1%)	6 (3.9%)
With values below reference range	0	0
With values within reference range	90 (98.9%)	147 (96.1%)
Summary statistics:		
Number of patients with values	91	153
Mean	3.14	3.38
SD	1.664	2.147
Median	2.90	3.10
Minimum	0.2	0.1
Maximum	9.1	18.6
Month 36		
Number of patients:		
With values	83	76
With values above reference range	1 (1.2%)	3 (3.9%)
With values below reference range	0	0
With values within reference range	82 (98.8%)	73 (96.1%)
Summary statistics:		
Number of patients with values	83	76
Mean	3.10	2.99
SD	1.688	1.819
Median	2.70	2.70
Minimum	0.2	0.2
Maximum	11.6	9.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	1 (2.0%)	0
With values below reference range	0	0
With values within reference range	48 (98.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	2.76	3.07
SD	1.505	1.262
Median	2.50	2.80
Minimum	0.4	1.6
Maximum	7.4	6.0
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	0	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	3.24	
SD	1.707	
Median	2.90	
Minimum	1.0	
Maximum	10.1	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	2.78	
SD	1.263	
Median	2.40	
Minimum	1.4	
Maximum	6.2	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	23 (100.0%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	0.46	0.44
SD	0.235	0.244
Median	0.40	0.30
Minimum	0.2	0.1
Maximum	1.2	1.0
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	0	2 (0.5%)
With values below reference range	0	0
With values within reference range	229 (100.0%)	425 (99.5%)
Summary statistics:		
Number of patients with values	229	427
Mean	0.41	0.40
SD	0.231	0.250
Median	0.40	0.40
Minimum	0.0	0.0
Maximum	1.4	2.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	1 (100.0%)	19 (100.0%)
Summary statistics:		
Number of patients with values	1	19
Mean	0.50	0.42
SD		0.232
Median	0.50	0.40
Minimum	0.5	0.1
Maximum	0.5	1.1
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	5 (100.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	0.34	0.34
SD	0.114	0.151
Median	0.30	0.30
Minimum	0.2	0.1
Maximum	0.5	0.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	382
With values above reference range	1 (0.5%)	0
With values below reference range	0	0
With values within reference range	211 (99.5%)	382 (100.0%)
Summary statistics:		
Number of patients with values	212	382
Mean	0.39	0.41
SD	0.251	0.194
Median	0.30	0.40
Minimum	0.0	0.1
Maximum	2.6	1.8
Month 6		
Number of patients:		
With values	202	371
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	202 (100.0%)	371 (100.0%)
Summary statistics:		
Number of patients with values	202	371
Mean	0.38	0.39
SD	0.194	0.205
Median	0.40	0.40
Minimum	0.0	0.0
Maximum	1.3	1.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	198	366
With values above reference range	0	1 (0.3%)
With values below reference range	0	0
With values within reference range	198 (100.0%)	365 (99.7%)
Summary statistics:		
Number of patients with values	198	366
Mean	0.38	0.37
SD	0.165	0.219
Median	0.40	0.30
Minimum	0.0	0.0
Maximum	1.0	2.1
Month 12		
Number of patients:		
With values	180	332
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	180 (100.0%)	332 (100.0%)
Summary statistics:		
Number of patients with values	180	332
Mean	0.36	0.36
SD	0.170	0.189
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	0.9	1.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	163	312
With values above reference range	1 (0.6%)	0
With values below reference range	0	0
With values within reference range	162 (99.4%)	312 (100.0%)
Summary statistics:		
Number of patients with values	163	312
Mean	0.39	0.35
SD	0.288	0.182
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	3.4	1.0
Month 18		
Number of patients:		
With values	154	288
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	154 (100.0%)	288 (100.0%)
Summary statistics:		
Number of patients with values	154	288
Mean	0.36	0.36
SD	0.174	0.175
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	1.0	1.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	271
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	152 (100.0%)	271 (100.0%)
Summary statistics:		
Number of patients with values	152	271
Mean	0.34	0.34
SD	0.154	0.203
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	1.0	1.7
Month 24		
Number of patients:		
With values	128	247
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	128 (100.0%)	247 (100.0%)
Summary statistics:		
Number of patients with values	128	247
Mean	0.37	0.36
SD	0.185	0.227
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	1.1	1.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	117	225
With values above reference range	0	1 (0.4%)
With values below reference range	0	0
With values within reference range	117 (100.0%)	224 (99.6%)
Summary statistics:		
Number of patients with values	117	225
Mean	0.36	0.39
SD	0.184	0.228
Median	0.30	0.40
Minimum	0.0	0.0
Maximum	1.0	2.3
Month 30		
Number of patients:		
With values	103	179
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	103 (100.0%)	179 (100.0%)
Summary statistics:		
Number of patients with values	103	179
Mean	0.32	0.39
SD	0.157	0.206
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	0.9	1.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	91 (100.0%)	153 (100.0%)
Summary statistics:		
Number of patients with values	91	153
Mean	0.35	0.38
SD	0.164	0.189
Median	0.30	0.40
Minimum	0.0	0.0
Maximum	0.9	1.1
Month 36		
Number of patients:		
With values	83	76
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	83 (100.0%)	76 (100.0%)
Summary statistics:		
Number of patients with values	83	76
Mean	0.35	0.35
SD	0.183	0.174
Median	0.30	0.30
Minimum	0.0	0.0
Maximum	0.9	0.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	49 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	0.32	0.31
SD	0.150	0.119
Median	0.30	0.30
Minimum	0.0	0.1
Maximum	0.7	0.5
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	0.33	
SD	0.145	
Median	0.30	
Minimum	0.1	
Maximum	0.7	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	0.35	
SD	0.158	
Median	0.40	
Minimum	0.0	
Maximum	0.7	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	22
With values above reference range	0	0
With values below reference range	1 (4.3%)	0
With values within reference range	22 (95.7%)	22 (100.0%)
Summary statistics:		
Number of patients with values	23	22
Mean	202.0	226.8
SD	39.65	38.55
Median	210.0	220.0
Minimum	110	131
Maximum	294	288
Open Label Baseline		
Number of patients:		
With values	229	427
With values above reference range	1 (0.4%)	2 (0.5%)
With values below reference range	8 (3.5%)	16 (3.7%)
With values within reference range	220 (96.1%)	409 (95.8%)
Summary statistics:		
Number of patients with values	229	427
Mean	214.7	212.6
SD	55.06	51.89
Median	210.0	210.0
Minimum	56	111
Maximum	421	512

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	19
With values above reference range	0	1 (5.3%)
With values below reference range	0	1 (5.3%)
With values within reference range	1 (100.0%)	17 (89.5%)
Summary statistics:		
Number of patients with values	1	19
Mean	191.0	221.3
SD		74.96
Median	191.0	213.0
Minimum	191	126
Maximum	191	480
Month 2		
Number of patients:		
With values	5	9
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	5 (100.0%)	9 (100.0%)
Summary statistics:		
Number of patients with values	5	9
Mean	210.0	214.0
SD	19.69	49.19
Median	212.0	208.0
Minimum	179	145
Maximum	230	294

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	385
With values above reference range	2 (0.9%)	1 (0.3%)
With values below reference range	6 (2.8%)	19 (4.9%)
With values within reference range	204 (96.2%)	365 (94.8%)

Summary statistics:

Number of patients with values	212	385
Mean	217.0	209.7
SD	53.81	52.70
Median	210.0	209.0
Minimum	105	101
Maximum	450	567

Month 6

Number of patients:

With values	203	374
With values above reference range	1 (0.5%)	1 (0.3%)
With values below reference range	4 (2.0%)	15 (4.0%)
With values within reference range	198 (97.5%)	358 (95.7%)

Summary statistics:

Number of patients with values	203	374
Mean	217.6	206.2
SD	55.60	51.37
Median	210.0	203.0
Minimum	115	96
Maximum	483	511

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	199	371
With values above reference range	2 (1.0%)	2 (0.5%)
With values below reference range	6 (3.0%)	19 (5.1%)
With values within reference range	191 (96.0%)	350 (94.3%)
Summary statistics:		
Number of patients with values	199	371
Mean	214.4	208.7
SD	54.55	54.37
Median	203.0	211.0
Minimum	113	69
Maximum	424	510
Month 12		
Number of patients:		
With values	181	332
With values above reference range	1 (0.6%)	1 (0.3%)
With values below reference range	7 (3.9%)	16 (4.8%)
With values within reference range	173 (95.6%)	315 (94.9%)
Summary statistics:		
Number of patients with values	181	332
Mean	215.2	216.6
SD	57.78	55.69
Median	208.0	214.5
Minimum	41	76
Maximum	521	539

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	164	315
With values above reference range	1 (0.6%)	4 (1.3%)
With values below reference range	5 (3.0%)	6 (1.9%)
With values within reference range	158 (96.3%)	305 (96.8%)

Summary statistics:

Number of patients with values	164	315
Mean	216.1	221.5
SD	55.98	57.83
Median	215.0	216.0
Minimum	44	101
Maximum	504	529

Month 18

Number of patients:

With values	155	291
With values above reference range	1 (0.6%)	3 (1.0%)
With values below reference range	7 (4.5%)	12 (4.1%)
With values within reference range	147 (94.8%)	276 (94.8%)

Summary statistics:

Number of patients with values	155	291
Mean	221.5	221.9
SD	57.73	58.39
Median	219.0	223.0
Minimum	110	99
Maximum	568	560

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	152	274
With values above reference range	1 (0.7%)	3 (1.1%)
With values below reference range	6 (3.9%)	10 (3.6%)
With values within reference range	145 (95.4%)	261 (95.3%)
Summary statistics:		
Number of patients with values	152	274
Mean	224.8	227.3
SD	59.00	62.37
Median	223.5	224.0
Minimum	96	49
Maximum	492	582
Month 24		
Number of patients:		
With values	128	249
With values above reference range	1 (0.8%)	3 (1.2%)
With values below reference range	5 (3.9%)	3 (1.2%)
With values within reference range	122 (95.3%)	243 (97.6%)
Summary statistics:		
Number of patients with values	128	249
Mean	225.2	229.1
SD	57.22	58.33
Median	221.0	226.0
Minimum	73	100
Maximum	488	545

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	118	227
With values above reference range	2 (1.7%)	3 (1.3%)
With values below reference range	7 (5.9%)	5 (2.2%)
With values within reference range	109 (92.4%)	219 (96.5%)

Summary statistics:

Number of patients with values	118	227
Mean	226.2	226.4
SD	67.70	58.18
Median	226.5	225.0
Minimum	43	105
Maximum	576	466

Month 30

Number of patients:

With values	104	179
With values above reference range	2 (1.9%)	0
With values below reference range	2 (1.9%)	6 (3.4%)
With values within reference range	100 (96.2%)	173 (96.6%)

Summary statistics:

Number of patients with values	104	179
Mean	232.9	222.0
SD	61.47	56.28
Median	222.0	217.0
Minimum	111	90
Maximum	485	390

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	91	153
With values above reference range	1 (1.1%)	2 (1.3%)
With values below reference range	2 (2.2%)	5 (3.3%)
With values within reference range	88 (96.7%)	146 (95.4%)
Summary statistics:		
Number of patients with values	91	153
Mean	235.8	226.0
SD	74.55	59.47
Median	230.0	226.0
Minimum	122	120
Maximum	686	463
Month 36		
Number of patients:		
With values	83	77
With values above reference range	1 (1.2%)	0
With values below reference range	3 (3.6%)	0
With values within reference range	79 (95.2%)	77 (100.0%)
Summary statistics:		
Number of patients with values	83	77
Mean	229.0	230.5
SD	65.69	57.55
Median	221.0	225.0
Minimum	56	136
Maximum	528	389

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	15
With values above reference range	2 (4.1%)	0
With values below reference range	2 (4.1%)	0
With values within reference range	45 (91.8%)	15 (100.0%)
Summary statistics:		
Number of patients with values	49	15
Mean	243.3	255.0
SD	72.47	55.01
Median	237.0	273.0
Minimum	121	161
Maximum	514	339
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	1 (3.1%)	
With values within reference range	30 (93.8%)	
Summary statistics:		
Number of patients with values	32	0
Mean	239.9	
SD	63.51	
Median	234.0	
Minimum	117	
Maximum	458	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	1 (5.3%)	
With values within reference range	16 (84.2%)	
Summary statistics:		
Number of patients with values	19	0
Mean	257.9	
SD	90.05	
Median	225.0	
Minimum	113	
Maximum	503	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	23	21
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	23 (100.0%)	21 (100.0%)
Summary statistics:		
Number of patients with values	23	21
Mean	1.29	1.23
SD	0.443	0.369
Median	1.10	1.20
Minimum	0.7	0.6
Maximum	2.2	2.1
Open Label Baseline		
Number of patients:		
With values	229	22
With values above reference range	5 (2.2%)	0
With values below reference range	0	0
With values within reference range	224 (97.8%)	22 (100.0%)
Summary statistics:		
Number of patients with values	229	22
Mean	1.41	1.22
SD	0.490	0.364
Median	1.30	1.15
Minimum	0.5	0.6
Maximum	5.0	2.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	1	11
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	1 (100.0%)	11 (100.0%)
Summary statistics:		
Number of patients with values	1	11
Mean	0.50	1.11
SD		0.359
Median	0.50	1.10
Minimum	0.5	0.5
Maximum	0.5	1.6
Month 2		
Number of patients:		
With values	2	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	2 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	2	5
Mean	0.80	0.96
SD	0.141	0.241
Median	0.80	0.90
Minimum	0.7	0.7
Maximum	0.9	1.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	75	352
With values above reference range	0	6 (1.7%)
With values below reference range	1 (1.3%)	1 (0.3%)
With values within reference range	74 (98.7%)	345 (98.0%)
Summary statistics:		
Number of patients with values	75	352
Mean	1.27	1.18
SD	0.379	0.449
Median	1.20	1.10
Minimum	0.4	0.3
Maximum	2.2	4.0
Month 6		
Number of patients:		
With values	197	374
With values above reference range	9 (4.6%)	13 (3.5%)
With values below reference range	0	1 (0.3%)
With values within reference range	188 (95.4%)	360 (96.3%)
Summary statistics:		
Number of patients with values	197	374
Mean	1.33	1.27
SD	0.511	0.545
Median	1.30	1.20
Minimum	0.5	0.4
Maximum	3.8	6.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	151	362
With values above reference range	6 (4.0%)	13 (3.6%)
With values below reference range	0	1 (0.3%)
With values within reference range	145 (96.0%)	348 (96.1%)
Summary statistics:		
Number of patients with values	151	362
Mean	1.38	1.23
SD	0.546	0.500
Median	1.30	1.10
Minimum	0.5	0.4
Maximum	4.1	5.2
Month 12		
Number of patients:		
With values	178	336
With values above reference range	6 (3.4%)	3 (0.9%)
With values below reference range	0	2 (0.6%)
With values within reference range	172 (96.6%)	331 (98.5%)
Summary statistics:		
Number of patients with values	178	336
Mean	1.32	1.18
SD	0.571	0.388
Median	1.20	1.10
Minimum	0.5	0.4
Maximum	4.6	2.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	308
With values above reference range	5 (3.0%)	2 (0.6%)
With values below reference range	0	0
With values within reference range	163 (97.0%)	306 (99.4%)
Summary statistics:		
Number of patients with values	168	308
Mean	1.30	1.15
SD	0.565	0.368
Median	1.30	1.10
Minimum	0.5	0.5
Maximum	6.1	2.5
Month 18		
Number of patients:		
With values	156	279
With values above reference range	0	4 (1.4%)
With values below reference range	0	0
With values within reference range	156 (100.0%)	275 (98.6%)
Summary statistics:		
Number of patients with values	156	279
Mean	1.26	1.17
SD	0.377	0.379
Median	1.20	1.10
Minimum	0.5	0.5
Maximum	2.3	2.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	150	263
With values above reference range	3 (2.0%)	4 (1.5%)
With values below reference range	0	0
With values within reference range	147 (98.0%)	259 (98.5%)
Summary statistics:		
Number of patients with values	150	263
Mean	1.24	1.18
SD	0.423	0.420
Median	1.20	1.10
Minimum	0.5	0.5
Maximum	2.8	3.1
Month 24		
Number of patients:		
With values	123	232
With values above reference range	3 (2.4%)	4 (1.7%)
With values below reference range	0	1 (0.4%)
With values within reference range	120 (97.6%)	227 (97.8%)
Summary statistics:		
Number of patients with values	123	232
Mean	1.23	1.20
SD	0.535	0.500
Median	1.10	1.10
Minimum	0.5	0.4
Maximum	4.6	5.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	110	221
With values above reference range	3 (2.7%)	3 (1.4%)
With values below reference range	1 (0.9%)	0
With values within reference range	106 (96.4%)	218 (98.6%)

Summary statistics:

Number of patients with values	110	221
Mean	1.25	1.12
SD	0.451	0.435
Median	1.20	1.10
Minimum	0.4	0.5
Maximum	3.0	3.6

Month 30

Number of patients:

With values	101	164
With values above reference range	0	2 (1.2%)
With values below reference range	1 (1.0%)	1 (0.6%)
With values within reference range	100 (99.0%)	161 (98.2%)

Summary statistics:

Number of patients with values	101	164
Mean	1.20	1.08
SD	0.397	0.374
Median	1.10	1.00
Minimum	0.4	0.4
Maximum	2.3	2.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	85	148
With values above reference range	3 (3.5%)	0
With values below reference range	1 (1.2%)	0
With values within reference range	81 (95.3%)	148 (100.0%)
Summary statistics:		
Number of patients with values	85	148
Mean	1.21	1.11
SD	0.445	0.341
Median	1.10	1.05
Minimum	0.4	0.5
Maximum	2.5	2.1
Month 36		
Number of patients:		
With values	78	77
With values above reference range	1 (1.3%)	1 (1.3%)
With values below reference range	0	0
With values within reference range	77 (98.7%)	76 (98.7%)
Summary statistics:		
Number of patients with values	78	77
Mean	1.21	1.25
SD	0.442	0.399
Median	1.10	1.20
Minimum	0.6	0.6
Maximum	2.9	2.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	45	14
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	45 (100.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	45	14
Mean	1.08	1.05
SD	0.327	0.199
Median	1.10	1.05
Minimum	0.6	0.8
Maximum	2.3	1.3
Month 42		
Number of patients:		
With values	27	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	27 (100.0%)	
Summary statistics:		
Number of patients with values	27	0
Mean	1.14	
SD	0.315	
Median	1.10	
Minimum	0.6	
Maximum	1.7	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	18	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	18 (100.0%)	
Summary statistics:		
Number of patients with values	18	0
Mean	1.13	
SD	0.303	
Median	1.10	
Minimum	0.6	
Maximum	1.7	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	12.8	11.7
SD	2.74	3.18
Median	12.0	11.5
Minimum	9	8
Maximum	21	19
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	5 (2.2%)	10 (2.3%)
With values below reference range	0	0
With values within reference range	224 (97.8%)	418 (97.7%)
Summary statistics:		
Number of patients with values	229	428
Mean	12.2	12.5
SD	4.36	4.00
Median	11.0	12.0
Minimum	6	6
Maximum	38	36

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	15.3	12.9
SD	4.04	6.16
Median	13.0	12.0
Minimum	13	6
Maximum	20	30
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	10.6	10.0
SD	2.72	2.12
Median	10.0	10.0
Minimum	7	7
Maximum	16	12

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	371
With values above reference range	2 (0.9%)	3 (0.8%)
With values below reference range	0	0
With values within reference range	210 (99.1%)	368 (99.2%)
Summary statistics:		
Number of patients with values	212	371
Mean	11.9	11.5
SD	3.13	3.24
Median	11.0	11.0
Minimum	6	3
Maximum	24	27
Month 6		
Number of patients:		
With values	205	369
With values above reference range	2 (1.0%)	2 (0.5%)
With values below reference range	0	0
With values within reference range	203 (99.0%)	367 (99.5%)
Summary statistics:		
Number of patients with values	205	369
Mean	11.4	11.0
SD	3.15	3.14
Median	11.0	10.0
Minimum	6	5
Maximum	24	27

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	3 (1.5%)	5 (1.4%)
With values below reference range	0	0
With values within reference range	193 (98.5%)	354 (98.6%)
Summary statistics:		
Number of patients with values	196	359
Mean	11.7	11.3
SD	3.45	3.17
Median	11.0	11.0
Minimum	6	7
Maximum	32	27
Month 12		
Number of patients:		
With values	177	325
With values above reference range	3 (1.7%)	4 (1.2%)
With values below reference range	0	0
With values within reference range	174 (98.3%)	321 (98.8%)
Summary statistics:		
Number of patients with values	177	325
Mean	11.7	10.8
SD	3.65	3.57
Median	11.0	10.0
Minimum	5	4
Maximum	30	31

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	167	316
With values above reference range	4 (2.4%)	4 (1.3%)
With values below reference range	0	0
With values within reference range	163 (97.6%)	312 (98.7%)
Summary statistics:		
Number of patients with values	167	316
Mean	11.4	10.2
SD	4.24	3.80
Median	11.0	9.5
Minimum	6	1
Maximum	34	25
Month 18		
Number of patients:		
With values	156	290
With values above reference range	2 (1.3%)	1 (0.3%)
With values below reference range	0	0
With values within reference range	154 (98.7%)	289 (99.7%)
Summary statistics:		
Number of patients with values	156	290
Mean	10.7	9.9
SD	3.95	3.71
Median	10.0	9.0
Minimum	3	3
Maximum	39	26

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	2 (1.4%)	4 (1.5%)
With values below reference range	0	0
With values within reference range	146 (98.6%)	270 (98.5%)
Summary statistics:		
Number of patients with values	148	274
Mean	10.6	9.9
SD	3.91	3.74
Median	10.0	9.0
Minimum	4	2
Maximum	40	27
Month 24		
Number of patients:		
With values	129	247
With values above reference range	1 (0.8%)	5 (2.0%)
With values below reference range	0	0
With values within reference range	128 (99.2%)	242 (98.0%)
Summary statistics:		
Number of patients with values	129	247
Mean	10.2	10.3
SD	3.50	4.49
Median	10.0	9.0
Minimum	4	1
Maximum	23	33

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	225
With values above reference range	3 (2.5%)	4 (1.8%)
With values below reference range	0	0
With values within reference range	117 (97.5%)	221 (98.2%)
Summary statistics:		
Number of patients with values	120	225
Mean	10.2	10.5
SD	3.90	3.95
Median	10.0	9.0
Minimum	5	4
Maximum	29	27
Month 30		
Number of patients:		
With values	106	180
With values above reference range	3 (2.8%)	1 (0.6%)
With values below reference range	0	0
With values within reference range	103 (97.2%)	179 (99.4%)
Summary statistics:		
Number of patients with values	106	180
Mean	10.4	10.1
SD	4.86	3.83
Median	9.0	9.0
Minimum	4	3
Maximum	41	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	155
With values above reference range	2 (2.2%)	1 (0.6%)
With values below reference range	0	0
With values within reference range	91 (97.8%)	154 (99.4%)
Summary statistics:		
Number of patients with values	93	155
Mean	10.1	9.7
SD	4.02	3.54
Median	9.0	9.0
Minimum	3	4
Maximum	24	23
Month 36		
Number of patients:		
With values	84	79
With values above reference range	3 (3.6%)	0
With values below reference range	0	0
With values within reference range	81 (96.4%)	79 (100.0%)
Summary statistics:		
Number of patients with values	84	79
Mean	10.5	9.3
SD	5.38	2.85
Median	10.0	9.0
Minimum	1	5
Maximum	37	19

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	1 (2.1%)	1 (7.1%)
With values below reference range	0	0
With values within reference range	47 (97.9%)	13 (92.9%)
Summary statistics:		
Number of patients with values	48	14
Mean	10.4	9.4
SD	4.81	5.23
Median	10.0	8.0
Minimum	4	3
Maximum	27	24
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	9.6	
SD	3.87	
Median	9.0	
Minimum	4	
Maximum	22	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	10.1	
SD	3.99	
Median	9.0	
Minimum	5	
Maximum	21	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	17
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	17 (100.0%)
Summary statistics:		
Number of patients with values	21	17
Mean	72.0	72.2
SD	3.88	3.98
Median	71.0	71.0
Minimum	65	65
Maximum	81	80
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	2 (0.9%)	5 (1.2%)
With values below reference range	0	0
With values within reference range	227 (99.1%)	423 (98.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	72.2	71.5
SD	4.15	4.63
Median	72.0	71.0
Minimum	62	58
Maximum	83	93

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	72.7	72.9
SD	2.08	2.49
Median	72.0	72.0
Minimum	71	69
Maximum	75	77
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	71.5	69.8
SD	1.51	6.06
Median	71.0	70.0
Minimum	69	61
Maximum	74	78

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	373
With values above reference range	0	2 (0.5%)
With values below reference range	0	1 (0.3%)
With values within reference range	212 (100.0%)	370 (99.2%)
Summary statistics:		
Number of patients with values	212	373
Mean	71.2	69.9
SD	4.15	4.67
Median	71.0	70.0
Minimum	61	53
Maximum	83	85
Month 6		
Number of patients:		
With values	204	363
With values above reference range	3 (1.5%)	3 (0.8%)
With values below reference range	0	2 (0.6%)
With values within reference range	201 (98.5%)	358 (98.6%)
Summary statistics:		
Number of patients with values	204	363
Mean	71.4	69.6
SD	4.24	4.50
Median	71.0	69.0
Minimum	62	56
Maximum	85	91

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	196	361
With values above reference range	2 (1.0%)	3 (0.8%)
With values below reference range	1 (0.5%)	0
With values within reference range	193 (98.5%)	358 (99.2%)

Summary statistics:

Number of patients with values	196	361
Mean	70.6	69.5
SD	4.35	4.52
Median	71.0	69.0
Minimum	59	59
Maximum	83	87

Month 12

Number of patients:

With values	175	324
With values above reference range	1 (0.6%)	5 (1.5%)
With values below reference range	0	1 (0.3%)
With values within reference range	174 (99.4%)	318 (98.1%)

Summary statistics:

Number of patients with values	175	324
Mean	70.1	70.7
SD	4.18	4.51
Median	70.0	70.0
Minimum	60	56
Maximum	82	88

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	166	316
With values above reference range	1 (0.6%)	1 (0.3%)
With values below reference range	1 (0.6%)	0
With values within reference range	164 (98.8%)	315 (99.7%)

Summary statistics:

Number of patients with values	166	316
Mean	70.3	70.9
SD	4.39	4.24
Median	70.0	71.0
Minimum	59	60
Maximum	91	82

Month 18

Number of patients:

With values	155	290
With values above reference range	2 (1.3%)	5 (1.7%)
With values below reference range	3 (1.9%)	0
With values within reference range	150 (96.8%)	285 (98.3%)

Summary statistics:

Number of patients with values	155	290
Mean	71.0	71.7
SD	4.45	4.50
Median	71.0	71.0
Minimum	56	58
Maximum	88	82

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	148	276
With values above reference range	1 (0.7%)	4 (1.4%)
With values below reference range	1 (0.7%)	0
With values within reference range	146 (98.6%)	272 (98.6%)

Summary statistics:

Number of patients with values	148	276
Mean	71.4	71.9
SD	4.63	4.33
Median	72.0	72.0
Minimum	58	60
Maximum	91	86

Month 24

Number of patients:

With values	129	248
With values above reference range	2 (1.6%)	7 (2.8%)
With values below reference range	1 (0.8%)	0
With values within reference range	126 (97.7%)	241 (97.2%)

Summary statistics:

Number of patients with values	129	248
Mean	72.6	72.3
SD	4.47	4.68
Median	72.0	72.0
Minimum	59	60
Maximum	82	89

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	120	225
With values above reference range	1 (0.8%)	3 (1.3%)
With values below reference range	0	0
With values within reference range	119 (99.2%)	222 (98.7%)

Summary statistics:

Number of patients with values	120	225
Mean	72.9	72.0
SD	3.94	4.27
Median	73.0	72.0
Minimum	60	61
Maximum	84	86

Month 30

Number of patients:

With values	108	180
With values above reference range	3 (2.8%)	2 (1.1%)
With values below reference range	0	1 (0.6%)
With values within reference range	105 (97.2%)	177 (98.3%)

Summary statistics:

Number of patients with values	108	180
Mean	72.5	71.6
SD	4.56	4.44
Median	73.0	72.0
Minimum	61	58
Maximum	84	83

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	155
With values above reference range	2 (2.1%)	1 (0.6%)
With values below reference range	0	0
With values within reference range	92 (97.9%)	154 (99.4%)
Summary statistics:		
Number of patients with values	94	155
Mean	72.2	71.2
SD	4.71	4.31
Median	72.0	71.0
Minimum	61	61
Maximum	84	84
Month 36		
Number of patients:		
With values	84	79
With values above reference range	3 (3.6%)	0
With values below reference range	0	0
With values within reference range	81 (96.4%)	79 (100.0%)
Summary statistics:		
Number of patients with values	84	79
Mean	72.4	71.1
SD	5.00	3.80
Median	73.0	71.0
Minimum	61	60
Maximum	94	79

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	49 (100.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	70.6	71.0
SD	4.25	4.35
Median	70.0	71.0
Minimum	60	65
Maximum	82	78
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	70.6	
SD	5.58	
Median	70.5	
Minimum	60	
Maximum	82	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	71.0	
SD	4.11	
Median	72.0	
Minimum	65	
Maximum	78	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	17
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	17 (100.0%)
Summary statistics:		
Number of patients with values	21	17
Mean	42.1	42.2
SD	2.24	1.70
Median	42.0	43.0
Minimum	37	39
Maximum	45	45
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	0	1 (0.2%)
With values below reference range	0	0
With values within reference range	229 (100.0%)	427 (99.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	42.8	42.7
SD	2.12	2.07
Median	43.0	43.0
Minimum	37	35
Maximum	49	51

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	44.7	42.8
SD	1.53	1.47
Median	45.0	43.0
Minimum	43	40
Maximum	46	46
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	43.0	42.0
SD	1.41	2.65
Median	43.0	43.0
Minimum	40	38
Maximum	45	45

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	374
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	212 (100.0%)	374 (100.0%)
Summary statistics:		
Number of patients with values	212	374
Mean	42.3	41.6
SD	2.16	1.94
Median	42.0	42.0
Minimum	36	34
Maximum	48	47
Month 6		
Number of patients:		
With values	203	364
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	203 (100.0%)	364 (100.0%)
Summary statistics:		
Number of patients with values	203	364
Mean	42.3	41.4
SD	2.07	1.85
Median	42.0	42.0
Minimum	35	34
Maximum	49	46

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	361
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	196 (100.0%)	361 (100.0%)
Summary statistics:		
Number of patients with values	196	361
Mean	41.8	41.2
SD	2.06	1.85
Median	42.0	41.0
Minimum	35	36
Maximum	48	46
Month 12		
Number of patients:		
With values	175	324
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	175 (100.0%)	324 (100.0%)
Summary statistics:		
Number of patients with values	175	324
Mean	41.7	41.7
SD	2.17	1.81
Median	41.0	42.0
Minimum	36	36
Maximum	47	47

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	166	316
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	166 (100.0%)	316 (100.0%)
Summary statistics:		
Number of patients with values	166	316
Mean	41.4	41.8
SD	2.00	2.19
Median	41.0	42.0
Minimum	36	33
Maximum	47	47
Month 18		
Number of patients:		
With values	155	290
With values above reference range	0	0
With values below reference range	0	1 (0.3%)
With values within reference range	155 (100.0%)	289 (99.7%)
Summary statistics:		
Number of patients with values	155	290
Mean	41.7	42.0
SD	2.07	2.11
Median	42.0	42.0
Minimum	33	31
Maximum	47	48

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	276
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	148 (100.0%)	276 (100.0%)
Summary statistics:		
Number of patients with values	148	276
Mean	41.8	42.0
SD	2.11	1.92
Median	42.0	42.0
Minimum	36	37
Maximum	49	46
Month 24		
Number of patients:		
With values	128	248
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	128 (100.0%)	248 (100.0%)
Summary statistics:		
Number of patients with values	128	248
Mean	42.1	41.7
SD	2.13	2.13
Median	42.0	42.0
Minimum	37	36
Maximum	47	48

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	225
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	120 (100.0%)	225 (100.0%)
Summary statistics:		
Number of patients with values	120	225
Mean	42.1	41.4
SD	1.82	1.94
Median	42.0	41.0
Minimum	38	34
Maximum	47	47
Month 30		
Number of patients:		
With values	108	179
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	108 (100.0%)	179 (100.0%)
Summary statistics:		
Number of patients with values	108	179
Mean	41.9	41.4
SD	1.93	1.99
Median	42.0	41.0
Minimum	37	35
Maximum	46	47

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	155
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	94 (100.0%)	155 (100.0%)
Summary statistics:		
Number of patients with values	94	155
Mean	41.7	41.8
SD	2.15	1.82
Median	42.0	42.0
Minimum	35	37
Maximum	47	48
Month 36		
Number of patients:		
With values	84	79
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	84 (100.0%)	79 (100.0%)
Summary statistics:		
Number of patients with values	84	79
Mean	41.9	42.2
SD	2.10	1.94
Median	42.0	42.0
Minimum	38	38
Maximum	48	47

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	49 (100.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	41.2	42.7
SD	2.59	1.77
Median	41.0	43.0
Minimum	36	40
Maximum	50	47
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	41.8	
SD	2.59	
Median	41.5	
Minimum	38	
Maximum	48	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	41.8	
SD	2.48	
Median	42.0	
Minimum	38	
Maximum	46	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	19.1	19.4
SD	8.14	4.55
Median	16.0	19.5
Minimum	12	12
Maximum	47	29
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	3 (1.3%)	12 (2.8%)
With values below reference range	0	0
With values within reference range	226 (98.7%)	416 (97.2%)
Summary statistics:		
Number of patients with values	229	428
Mean	19.8	20.9
SD	10.01	9.68
Median	18.0	18.0
Minimum	9	9
Maximum	103	90

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	19.7	23.1
SD	2.52	10.76
Median	20.0	18.0
Minimum	17	8
Maximum	22	50
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	18.0	16.8
SD	2.20	5.40
Median	18.0	20.0
Minimum	15	10
Maximum	22	22

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	369
With values above reference range	3 (1.4%)	5 (1.4%)
With values below reference range	0	0
With values within reference range	209 (98.6%)	364 (98.6%)
Summary statistics:		
Number of patients with values	212	369
Mean	19.9	20.1
SD	9.23	7.83
Median	17.5	18.0
Minimum	9	10
Maximum	98	86
Month 6		
Number of patients:		
With values	205	369
With values above reference range	2 (1.0%)	3 (0.8%)
With values below reference range	0	0
With values within reference range	203 (99.0%)	366 (99.2%)
Summary statistics:		
Number of patients with values	205	369
Mean	20.0	20.1
SD	9.51	7.86
Median	18.0	18.0
Minimum	9	9
Maximum	89	88

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	3 (1.5%)	4 (1.1%)
With values below reference range	0	0
With values within reference range	193 (98.5%)	355 (98.9%)
Summary statistics:		
Number of patients with values	196	359
Mean	19.6	19.8
SD	8.29	8.09
Median	18.0	18.0
Minimum	9	10
Maximum	74	74
Month 12		
Number of patients:		
With values	177	328
With values above reference range	3 (1.7%)	6 (1.8%)
With values below reference range	0	0
With values within reference range	174 (98.3%)	322 (98.2%)
Summary statistics:		
Number of patients with values	177	328
Mean	21.4	21.0
SD	18.63	15.10
Median	18.0	18.0
Minimum	8	9
Maximum	228	232

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	4 (2.4%)	3 (0.9%)
With values below reference range	0	0
With values within reference range	164 (97.6%)	313 (99.1%)
Summary statistics:		
Number of patients with values	168	316
Mean	20.3	20.2
SD	9.84	7.95
Median	18.0	18.0
Minimum	9	8
Maximum	84	76
Month 18		
Number of patients:		
With values	156	294
With values above reference range	4 (2.6%)	4 (1.4%)
With values below reference range	0	0
With values within reference range	152 (97.4%)	290 (98.6%)
Summary statistics:		
Number of patients with values	156	294
Mean	20.6	20.4
SD	9.73	8.18
Median	18.0	18.0
Minimum	9	9
Maximum	86	72

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	3 (2.0%)	4 (1.5%)
With values below reference range	0	0
With values within reference range	145 (98.0%)	270 (98.5%)
Summary statistics:		
Number of patients with values	148	274
Mean	20.4	20.4
SD	11.41	7.43
Median	18.0	19.0
Minimum	9	10
Maximum	99	60
Month 24		
Number of patients:		
With values	129	249
With values above reference range	5 (3.9%)	2 (0.8%)
With values below reference range	0	0
With values within reference range	124 (96.1%)	247 (99.2%)
Summary statistics:		
Number of patients with values	129	249
Mean	21.1	19.9
SD	11.07	7.45
Median	19.0	18.0
Minimum	9	11
Maximum	86	88

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	2 (1.7%)	4 (1.8%)
With values below reference range	0	0
With values within reference range	118 (98.3%)	222 (98.2%)
Summary statistics:		
Number of patients with values	120	226
Mean	21.4	20.6
SD	14.21	7.31
Median	19.0	19.0
Minimum	10	10
Maximum	156	60
Month 30		
Number of patients:		
With values	106	181
With values above reference range	3 (2.8%)	3 (1.7%)
With values below reference range	0	0
With values within reference range	103 (97.2%)	178 (98.3%)
Summary statistics:		
Number of patients with values	106	181
Mean	20.6	20.9
SD	9.66	7.57
Median	18.5	19.0
Minimum	10	9
Maximum	82	64

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 33

Number of patients:

With values	93	155
With values above reference range	1 (1.1%)	3 (1.9%)
With values below reference range	0	0
With values within reference range	92 (98.9%)	152 (98.1%)

Summary statistics:

Number of patients with values	93	155
Mean	19.5	20.4
SD	7.65	9.14
Median	18.0	19.0
Minimum	7	9
Maximum	73	92

Month 36

Number of patients:

With values	84	79
With values above reference range	2 (2.4%)	1 (1.3%)
With values below reference range	0	0
With values within reference range	82 (97.6%)	78 (98.7%)

Summary statistics:

Number of patients with values	84	79
Mean	20.9	20.4
SD	10.71	12.02
Median	19.0	18.0
Minimum	11	9
Maximum	101	111

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	1 (2.1%)	0
With values below reference range	0	0
With values within reference range	47 (97.9%)	14 (100.0%)
Summary statistics:		
Number of patients with values	48	14
Mean	19.9	19.1
SD	8.44	4.70
Median	18.5	18.0
Minimum	10	13
Maximum	59	31
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	20.0	
SD	7.72	
Median	18.0	
Minimum	11	
Maximum	50	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	20.2	
SD	8.82	
Median	17.0	
Minimum	12	
Maximum	47	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	2 (9.5%)	0
With values below reference range	0	0
With values within reference range	19 (90.5%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	22.9	20.8
SD	12.78	10.74
Median	19.0	16.0
Minimum	13	10
Maximum	64	44
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	9 (3.9%)	24 (5.6%)
With values below reference range	0	0
With values within reference range	220 (96.1%)	404 (94.4%)
Summary statistics:		
Number of patients with values	229	428
Mean	21.5	22.5
SD	12.29	13.72
Median	18.0	18.0
Minimum	5	7
Maximum	107	119

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	21.0	23.1
SD	1.73	13.54
Median	22.0	18.0
Minimum	19	5
Maximum	22	59
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	20.4	14.6
SD	10.21	4.39
Median	17.0	15.0
Minimum	10	8
Maximum	40	19

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	369
With values above reference range	3 (1.4%)	5 (1.4%)
With values below reference range	0	0
With values within reference range	209 (98.6%)	364 (98.6%)
Summary statistics:		
Number of patients with values	212	369
Mean	20.4	19.3
SD	9.50	9.09
Median	18.0	17.0
Minimum	9	6
Maximum	71	70
Month 6		
Number of patients:		
With values	205	369
With values above reference range	4 (2.0%)	5 (1.4%)
With values below reference range	0	0
With values within reference range	201 (98.0%)	364 (98.6%)
Summary statistics:		
Number of patients with values	205	369
Mean	20.7	19.2
SD	10.53	9.36
Median	18.0	17.0
Minimum	8	6
Maximum	79	77

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	4 (2.0%)	7 (1.9%)
With values below reference range	0	0
With values within reference range	192 (98.0%)	352 (98.1%)
Summary statistics:		
Number of patients with values	196	359
Mean	21.1	18.6
SD	11.92	9.24
Median	18.0	16.0
Minimum	8	5
Maximum	125	78
Month 12		
Number of patients:		
With values	177	328
With values above reference range	8 (4.5%)	7 (2.1%)
With values below reference range	0	0
With values within reference range	169 (95.5%)	321 (97.9%)
Summary statistics:		
Number of patients with values	177	328
Mean	22.1	18.9
SD	18.17	15.37
Median	18.0	16.0
Minimum	7	6
Maximum	211	240

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	5 (3.0%)	5 (1.6%)
With values below reference range	0	0
With values within reference range	163 (97.0%)	311 (98.4%)
Summary statistics:		
Number of patients with values	168	316
Mean	20.9	18.5
SD	12.01	9.73
Median	17.0	16.0
Minimum	7	4
Maximum	82	88
Month 18		
Number of patients:		
With values	156	294
With values above reference range	6 (3.8%)	7 (2.4%)
With values below reference range	0	0
With values within reference range	150 (96.2%)	287 (97.6%)
Summary statistics:		
Number of patients with values	156	294
Mean	21.1	18.5
SD	11.96	10.85
Median	17.0	16.0
Minimum	8	6
Maximum	90	92

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	6 (4.1%)	5 (1.8%)
With values below reference range	0	0
With values within reference range	142 (95.9%)	269 (98.2%)
Summary statistics:		
Number of patients with values	148	274
Mean	20.5	17.9
SD	11.47	8.77
Median	17.0	15.0
Minimum	8	6
Maximum	80	61
Month 24		
Number of patients:		
With values	129	249
With values above reference range	6 (4.7%)	5 (2.0%)
With values below reference range	0	0
With values within reference range	123 (95.3%)	244 (98.0%)
Summary statistics:		
Number of patients with values	129	249
Mean	21.4	17.9
SD	13.05	9.54
Median	18.0	16.0
Minimum	8	5
Maximum	88	82

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	220
With values above reference range	5 (4.2%)	5 (2.3%)
With values below reference range	0	0
With values within reference range	115 (95.8%)	215 (97.7%)
Summary statistics:		
Number of patients with values	120	220
Mean	21.9	18.2
SD	12.05	9.89
Median	19.5	16.0
Minimum	8	6
Maximum	95	84
Month 30		
Number of patients:		
With values	105	143
With values above reference range	4 (3.8%)	3 (2.1%)
With values below reference range	0	0
With values within reference range	101 (96.2%)	140 (97.9%)
Summary statistics:		
Number of patients with values	105	143
Mean	21.3	19.3
SD	11.21	10.63
Median	19.0	16.0
Minimum	8	6
Maximum	71	77

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	87	89
With values above reference range	2 (2.3%)	0
With values below reference range	0	0
With values within reference range	85 (97.7%)	89 (100.0%)
Summary statistics:		
Number of patients with values	87	89
Mean	20.8	16.6
SD	10.68	7.06
Median	18.0	15.0
Minimum	7	4
Maximum	65	40
Month 36		
Number of patients:		
With values	79	35
With values above reference range	1 (1.3%)	1 (2.9%)
With values below reference range	0	0
With values within reference range	78 (98.7%)	34 (97.1%)
Summary statistics:		
Number of patients with values	79	35
Mean	20.3	20.3
SD	9.61	14.61
Median	18.0	16.0
Minimum	7	7
Maximum	61	82

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	45	5
With values above reference range	1 (2.2%)	0
With values below reference range	0	0
With values within reference range	44 (97.8%)	5 (100.0%)
Summary statistics:		
Number of patients with values	45	5
Mean	19.4	16.6
SD	9.60	3.85
Median	17.0	18.0
Minimum	6	10
Maximum	56	20
Month 42		
Number of patients:		
With values	23	0
With values above reference range	2 (8.7%)	
With values below reference range	0	
With values within reference range	21 (91.3%)	
Summary statistics:		
Number of patients with values	23	0
Mean	22.6	
SD	13.35	
Median	19.0	
Minimum	9	
Maximum	62	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	14	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	14 (100.0%)	
Summary statistics:		
Number of patients with values	14	0
Mean	18.9	
SD	9.37	
Median	16.5	
Minimum	10	
Maximum	40	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	25.0	28.8
SD	9.15	15.82
Median	23.0	29.0
Minimum	9	5
Maximum	46	67
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	23 (10.0%)	48 (11.2%)
With values below reference range	0	0
With values within reference range	206 (90.0%)	380 (88.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	32.3	37.9
SD	26.28	43.90
Median	24.0	26.0
Minimum	6	3
Maximum	181	460

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	1 (33.3%)	2 (13.3%)
With values below reference range	0	0
With values within reference range	2 (66.7%)	13 (86.7%)
Summary statistics:		
Number of patients with values	3	15
Mean	40.7	46.7
SD	31.79	78.85
Median	51.0	23.0
Minimum	5	9
Maximum	66	325
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	24.5	21.4
SD	13.14	12.95
Median	21.5	14.0
Minimum	11	10
Maximum	55	36

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	370
With values above reference range	17 (8.0%)	24 (6.5%)
With values below reference range	0	0
With values within reference range	195 (92.0%)	346 (93.5%)

Summary statistics:

Number of patients with values	212	370
Mean	32.0	31.2
SD	41.46	28.26
Median	22.0	23.0
Minimum	6	5
Maximum	532	257

Month 6

Number of patients:

With values	204	368
With values above reference range	16 (7.8%)	29 (7.9%)
With values below reference range	0	0
With values within reference range	188 (92.2%)	339 (92.1%)

Summary statistics:

Number of patients with values	204	368
Mean	29.9	32.8
SD	24.92	42.76
Median	22.0	23.0
Minimum	7	2
Maximum	209	627

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	16 (8.2%)	31 (8.6%)
With values below reference range	0	0
With values within reference range	180 (91.8%)	328 (91.4%)
Summary statistics:		
Number of patients with values	196	359
Mean	31.9	34.1
SD	33.90	40.07
Median	22.0	24.0
Minimum	5	2
Maximum	350	519
Month 12		
Number of patients:		
With values	176	326
With values above reference range	14 (8.0%)	28 (8.6%)
With values below reference range	0	0
With values within reference range	162 (92.0%)	298 (91.4%)
Summary statistics:		
Number of patients with values	176	326
Mean	34.4	38.0
SD	46.43	51.82
Median	24.0	25.0
Minimum	4	5
Maximum	527	675

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	15 (8.9%)	31 (9.8%)
With values below reference range	0	0
With values within reference range	153 (91.1%)	285 (90.2%)
Summary statistics:		
Number of patients with values	168	316
Mean	35.8	38.2
SD	40.49	46.80
Median	25.0	26.0
Minimum	4	6
Maximum	313	552
Month 18		
Number of patients:		
With values	156	293
With values above reference range	13 (8.3%)	28 (9.6%)
With values below reference range	0	0
With values within reference range	143 (91.7%)	265 (90.4%)
Summary statistics:		
Number of patients with values	156	293
Mean	36.2	36.9
SD	51.76	37.55
Median	25.0	26.0
Minimum	8	7
Maximum	599	312

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	14 (9.5%)	29 (10.6%)
With values below reference range	0	0
With values within reference range	134 (90.5%)	245 (89.4%)
Summary statistics:		
Number of patients with values	148	274
Mean	42.2	36.5
SD	85.41	36.67
Median	25.5	27.0
Minimum	9	7
Maximum	996	280
Month 24		
Number of patients:		
With values	129	249
With values above reference range	17 (13.2%)	27 (10.8%)
With values below reference range	0	0
With values within reference range	112 (86.8%)	222 (89.2%)
Summary statistics:		
Number of patients with values	129	249
Mean	38.9	36.6
SD	38.61	35.00
Median	25.0	25.0
Minimum	6	7
Maximum	257	269

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	14 (11.7%)	20 (8.8%)
With values below reference range	0	0
With values within reference range	106 (88.3%)	206 (91.2%)
Summary statistics:		
Number of patients with values	120	226
Mean	38.2	37.7
SD	37.36	47.44
Median	27.0	26.0
Minimum	8	9
Maximum	276	531
Month 30		
Number of patients:		
With values	106	180
With values above reference range	10 (9.4%)	19 (10.6%)
With values below reference range	0	0
With values within reference range	96 (90.6%)	161 (89.4%)
Summary statistics:		
Number of patients with values	106	180
Mean	42.1	38.4
SD	76.81	43.69
Median	25.0	25.0
Minimum	11	7
Maximum	742	358

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	155
With values above reference range	9 (9.7%)	17 (11.0%)
With values below reference range	0	0
With values within reference range	84 (90.3%)	138 (89.0%)
Summary statistics:		
Number of patients with values	93	155
Mean	33.2	37.5
SD	22.46	37.58
Median	24.0	26.0
Minimum	10	9
Maximum	117	282
Month 36		
Number of patients:		
With values	84	79
With values above reference range	10 (11.9%)	5 (6.3%)
With values below reference range	0	0
With values within reference range	74 (88.1%)	74 (93.7%)
Summary statistics:		
Number of patients with values	84	79
Mean	43.3	31.9
SD	89.03	29.37
Median	24.0	25.0
Minimum	12	8
Maximum	790	235

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	5 (10.4%)	2 (14.3%)
With values below reference range	0	0
With values within reference range	43 (89.6%)	12 (85.7%)
Summary statistics:		
Number of patients with values	48	14
Mean	40.7	29.8
SD	54.89	25.32
Median	24.0	19.5
Minimum	10	10
Maximum	368	99
Month 42		
Number of patients:		
With values	32	0
With values above reference range	4 (12.5%)	
With values below reference range	0	
With values within reference range	28 (87.5%)	
Summary statistics:		
Number of patients with values	32	0
Mean	32.8	
SD	22.15	
Median	24.0	
Minimum	16	
Maximum	106	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	0	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	45.6	
SD	77.66	
Median	29.0	
Minimum	11	
Maximum	361	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	64.6	62.1
SD	15.29	17.17
Median	64.0	57.0
Minimum	39	39
Maximum	95	86
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	5 (2.2%)	4 (0.9%)
With values below reference range	0	1 (0.2%)
With values within reference range	224 (97.8%)	423 (98.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	66.6	63.3
SD	23.77	38.63
Median	64.0	58.0
Minimum	23	19
Maximum	241	712

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	81.3	62.3
SD	17.01	46.66
Median	88.0	51.0
Minimum	62	38
Maximum	94	228
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	66.5	59.8
SD	29.81	10.23
Median	60.0	57.0
Minimum	25	49
Maximum	122	72

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	369
With values above reference range	3 (1.4%)	1 (0.3%)
With values below reference range	0	0
With values within reference range	209 (98.6%)	368 (99.7%)
Summary statistics:		
Number of patients with values	212	369
Mean	62.4	56.0
SD	20.78	15.66
Median	61.0	54.0
Minimum	23	22
Maximum	204	141
Month 6		
Number of patients:		
With values	205	368
With values above reference range	2 (1.0%)	2 (0.5%)
With values below reference range	0	2 (0.5%)
With values within reference range	203 (99.0%)	364 (98.9%)
Summary statistics:		
Number of patients with values	205	368
Mean	62.4	56.5
SD	22.83	17.98
Median	60.0	54.0
Minimum	21	18
Maximum	233	217

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	3 (1.5%)	1 (0.3%)
With values below reference range	0	0
With values within reference range	193 (98.5%)	358 (99.7%)
Summary statistics:		
Number of patients with values	196	359
Mean	62.3	58.3
SD	21.92	17.72
Median	60.5	56.0
Minimum	24	21
Maximum	220	147
Month 12		
Number of patients:		
With values	177	324
With values above reference range	6 (3.4%)	6 (1.9%)
With values below reference range	0	0
With values within reference range	171 (96.6%)	318 (98.1%)
Summary statistics:		
Number of patients with values	177	324
Mean	65.0	61.8
SD	25.21	21.15
Median	62.0	58.0
Minimum	22	21
Maximum	231	205

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	314
With values above reference range	4 (2.4%)	3 (1.0%)
With values below reference range	1 (0.6%)	0
With values within reference range	163 (97.0%)	311 (99.0%)
Summary statistics:		
Number of patients with values	168	314
Mean	64.6	64.7
SD	24.45	40.14
Median	61.0	59.0
Minimum	18	22
Maximum	198	670
Month 18		
Number of patients:		
With values	156	288
With values above reference range	2 (1.3%)	4 (1.4%)
With values below reference range	0	0
With values within reference range	154 (98.7%)	284 (98.6%)
Summary statistics:		
Number of patients with values	156	288
Mean	65.2	63.0
SD	23.14	25.67
Median	61.0	59.0
Minimum	23	22
Maximum	190	256

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	271
With values above reference range	4 (2.7%)	6 (2.2%)
With values below reference range	0	0
With values within reference range	144 (97.3%)	265 (97.8%)
Summary statistics:		
Number of patients with values	148	271
Mean	67.9	62.2
SD	24.12	22.96
Median	65.0	59.0
Minimum	24	21
Maximum	187	243
Month 24		
Number of patients:		
With values	129	245
With values above reference range	4 (3.1%)	3 (1.2%)
With values below reference range	0	0
With values within reference range	125 (96.9%)	242 (98.8%)
Summary statistics:		
Number of patients with values	129	245
Mean	69.4	63.8
SD	25.18	25.00
Median	67.0	59.0
Minimum	20	22
Maximum	181	244

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	225
With values above reference range	5 (4.2%)	4 (1.8%)
With values below reference range	0	0
With values within reference range	115 (95.8%)	221 (98.2%)
Summary statistics:		
Number of patients with values	120	225
Mean	67.5	62.7
SD	25.76	28.39
Median	65.0	57.0
Minimum	23	23
Maximum	203	290
Month 30		
Number of patients:		
With values	106	177
With values above reference range	3 (2.8%)	1 (0.6%)
With values below reference range	0	0
With values within reference range	103 (97.2%)	176 (99.4%)
Summary statistics:		
Number of patients with values	106	177
Mean	66.1	61.0
SD	27.14	25.05
Median	63.0	57.0
Minimum	21	26
Maximum	215	291

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	153
With values above reference range	2 (2.2%)	2 (1.3%)
With values below reference range	0	0
With values within reference range	91 (97.8%)	151 (98.7%)
Summary statistics:		
Number of patients with values	93	153
Mean	65.5	62.8
SD	22.27	34.54
Median	62.0	57.0
Minimum	22	24
Maximum	160	344
Month 36		
Number of patients:		
With values	84	79
With values above reference range	2 (2.4%)	0
With values below reference range	1 (1.2%)	0
With values within reference range	81 (96.4%)	79 (100.0%)
Summary statistics:		
Number of patients with values	84	79
Mean	63.8	55.1
SD	25.19	15.72
Median	59.0	51.0
Minimum	19	29
Maximum	180	94

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	2 (4.2%)	0
With values below reference range	0	0
With values within reference range	46 (95.8%)	14 (100.0%)
Summary statistics:		
Number of patients with values	48	14
Mean	64.3	62.9
SD	26.45	17.01
Median	60.0	60.5
Minimum	22	40
Maximum	168	101
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	60.6	
SD	17.44	
Median	57.0	
Minimum	28	
Maximum	92	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	59.9	
SD	17.79	
Median	56.0	
Minimum	30	
Maximum	105	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	2 (11.1%)
With values below reference range	0	0
With values within reference range	21 (100.0%)	16 (88.9%)
Summary statistics:		
Number of patients with values	21	18
Mean	93.1	87.8
SD	16.47	19.27
Median	90.0	80.0
Minimum	60	70
Maximum	120	130
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	4 (1.7%)	10 (2.3%)
With values below reference range	8 (3.5%)	10 (2.3%)
With values within reference range	217 (94.8%)	408 (95.3%)
Summary statistics:		
Number of patients with values	229	428
Mean	89.2	90.4
SD	19.31	28.46
Median	87.0	87.0
Minimum	33	48
Maximum	176	548

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	1 (33.3%)	1 (6.7%)
With values below reference range	0	0
With values within reference range	2 (66.7%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	114.7	91.3
SD	40.07	18.07
Median	100.0	90.0
Minimum	84	60
Maximum	160	130
Month 2		
Number of patients:		
With values	8	5
With values above reference range	1 (12.5%)	0
With values below reference range	0	0
With values within reference range	7 (87.5%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	111.3	82.0
SD	25.88	10.95
Median	105.0	80.0
Minimum	90	70
Maximum	170	100

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	370
With values above reference range	7 (3.3%)	8 (2.2%)
With values below reference range	3 (1.4%)	5 (1.4%)
With values within reference range	202 (95.3%)	357 (96.5%)
Summary statistics:		
Number of patients with values	212	370
Mean	89.5	87.4
SD	19.65	16.52
Median	90.0	90.0
Minimum	50	40
Maximum	180	160
Month 6		
Number of patients:		
With values	204	367
With values above reference range	8 (3.9%)	11 (3.0%)
With values below reference range	1 (0.5%)	4 (1.1%)
With values within reference range	195 (95.6%)	352 (95.9%)
Summary statistics:		
Number of patients with values	204	367
Mean	92.0	88.8
SD	26.04	19.53
Median	90.0	90.0
Minimum	50	50
Maximum	320	230

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	7 (3.6%)	9 (2.5%)
With values below reference range	2 (1.0%)	2 (0.6%)
With values within reference range	187 (95.4%)	348 (96.9%)
Summary statistics:		
Number of patients with values	196	359
Mean	89.0	87.9
SD	18.37	17.79
Median	90.0	90.0
Minimum	50	50
Maximum	160	190
Month 12		
Number of patients:		
With values	176	326
With values above reference range	8 (4.5%)	12 (3.7%)
With values below reference range	2 (1.1%)	6 (1.8%)
With values within reference range	166 (94.3%)	308 (94.5%)
Summary statistics:		
Number of patients with values	176	326
Mean	89.8	87.7
SD	20.01	18.98
Median	90.0	90.0
Minimum	50	40
Maximum	160	190

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	8 (4.8%)	17 (5.4%)
With values below reference range	3 (1.8%)	5 (1.6%)
With values within reference range	157 (93.5%)	294 (93.0%)
Summary statistics:		
Number of patients with values	168	316
Mean	90.2	89.8
SD	21.06	21.24
Median	90.0	90.0
Minimum	50	40
Maximum	200	220
Month 18		
Number of patients:		
With values	156	293
With values above reference range	7 (4.5%)	19 (6.5%)
With values below reference range	4 (2.6%)	2 (0.7%)
With values within reference range	145 (92.9%)	272 (92.8%)
Summary statistics:		
Number of patients with values	156	293
Mean	90.4	92.8
SD	21.40	28.94
Median	90.0	90.0
Minimum	40	50
Maximum	190	330

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	10 (6.8%)	11 (4.0%)
With values below reference range	3 (2.0%)	6 (2.2%)
With values within reference range	135 (91.2%)	257 (93.8%)
Summary statistics:		
Number of patients with values	148	274
Mean	90.0	89.3
SD	21.16	21.25
Median	90.0	90.0
Minimum	50	40
Maximum	180	220
Month 24		
Number of patients:		
With values	128	249
With values above reference range	9 (7.0%)	13 (5.2%)
With values below reference range	1 (0.8%)	7 (2.8%)
With values within reference range	118 (92.2%)	229 (92.0%)
Summary statistics:		
Number of patients with values	128	249
Mean	91.3	88.2
SD	21.92	20.32
Median	90.0	90.0
Minimum	50	40
Maximum	170	170

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	6 (5.0%)	10 (4.4%)
With values below reference range	1 (0.8%)	5 (2.2%)
With values within reference range	113 (94.2%)	211 (93.4%)
Summary statistics:		
Number of patients with values	120	226
Mean	91.8	89.5
SD	20.81	21.01
Median	90.0	90.0
Minimum	50	50
Maximum	180	200
Month 30		
Number of patients:		
With values	106	180
With values above reference range	9 (8.5%)	10 (5.6%)
With values below reference range	1 (0.9%)	4 (2.2%)
With values within reference range	96 (90.6%)	166 (92.2%)
Summary statistics:		
Number of patients with values	106	180
Mean	90.2	87.9
SD	22.59	22.44
Median	90.0	90.0
Minimum	50	50
Maximum	180	240

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	155
With values above reference range	7 (7.5%)	8 (5.2%)
With values below reference range	4 (4.3%)	0
With values within reference range	82 (88.2%)	147 (94.8%)
Summary statistics:		
Number of patients with values	93	155
Mean	88.3	89.2
SD	21.14	20.95
Median	90.0	90.0
Minimum	40	60
Maximum	150	200
Month 36		
Number of patients:		
With values	84	79
With values above reference range	6 (7.1%)	7 (8.9%)
With values below reference range	4 (4.8%)	1 (1.3%)
With values within reference range	74 (88.1%)	71 (89.9%)
Summary statistics:		
Number of patients with values	84	79
Mean	88.1	93.3
SD	23.10	29.95
Median	90.0	90.0
Minimum	40	50
Maximum	190	260

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	1 (2.1%)	0
With values below reference range	1 (2.1%)	0
With values within reference range	46 (95.8%)	14 (100.0%)
Summary statistics:		
Number of patients with values	48	14
Mean	88.8	82.9
SD	18.06	15.90
Median	90.0	80.0
Minimum	50	60
Maximum	150	120
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	0	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	87.8	
SD	33.38	
Median	85.0	
Minimum	60	
Maximum	250	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	1 (5.3%)	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	86.8	
SD	19.16	
Median	90.0	
Minimum	50	
Maximum	140	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	1 (4.8%)	1 (5.6%)
With values below reference range	0	0
With values within reference range	20 (95.2%)	17 (94.4%)
Summary statistics:		
Number of patients with values	21	18
Mean	7.03	5.63
SD	1.618	1.639
Median	7.20	5.35
Minimum	4.2	3.3
Maximum	9.7	10.7
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	11 (4.8%)	13 (3.0%)
With values below reference range	0	1 (0.2%)
With values within reference range	218 (95.2%)	414 (96.7%)
Summary statistics:		
Number of patients with values	229	428
Mean	6.55	6.11
SD	1.731	1.909
Median	6.40	5.90
Minimum	2.5	2.1
Maximum	11.6	24.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	8.30	5.95
SD	1.800	1.403
Median	8.30	5.70
Minimum	6.5	3.7
Maximum	10.1	8.7
Month 2		
Number of patients:		
With values	8	5
With values above reference range	1 (12.5%)	1 (20.0%)
With values below reference range	0	0
With values within reference range	7 (87.5%)	4 (80.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	6.91	6.74
SD	2.514	1.847
Median	6.30	6.10
Minimum	4.6	5.0
Maximum	12.7	9.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	374
With values above reference range	13 (6.1%)	14 (3.7%)
With values below reference range	0	0
With values within reference range	199 (93.9%)	360 (96.3%)
Summary statistics:		
Number of patients with values	212	374
Mean	6.52	6.45
SD	1.798	1.942
Median	6.30	6.25
Minimum	2.7	2.6
Maximum	12.7	23.8
Month 6		
Number of patients:		
With values	205	366
With values above reference range	11 (5.4%)	13 (3.6%)
With values below reference range	0	0
With values within reference range	194 (94.6%)	353 (96.4%)
Summary statistics:		
Number of patients with values	205	366
Mean	6.59	6.54
SD	2.093	2.088
Median	6.30	6.20
Minimum	2.8	2.7
Maximum	19.8	30.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	361
With values above reference range	11 (5.6%)	14 (3.9%)
With values below reference range	0	0
With values within reference range	185 (94.4%)	347 (96.1%)
Summary statistics:		
Number of patients with values	196	361
Mean	6.70	6.37
SD	1.903	1.756
Median	6.40	6.10
Minimum	2.9	2.7
Maximum	14.6	18.8
Month 12		
Number of patients:		
With values	176	324
With values above reference range	13 (7.4%)	12 (3.7%)
With values below reference range	0	0
With values within reference range	163 (92.6%)	312 (96.3%)
Summary statistics:		
Number of patients with values	176	324
Mean	6.90	6.31
SD	2.090	1.832
Median	6.50	6.10
Minimum	3.5	2.6
Maximum	16.4	18.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	167	316
With values above reference range	13 (7.8%)	16 (5.1%)
With values below reference range	0	0
With values within reference range	154 (92.2%)	300 (94.9%)
Summary statistics:		
Number of patients with values	167	316
Mean	6.80	6.44
SD	2.058	1.915
Median	6.30	6.20
Minimum	3.2	2.6
Maximum	16.5	19.8
Month 18		
Number of patients:		
With values	156	290
With values above reference range	14 (9.0%)	15 (5.2%)
With values below reference range	0	1 (0.3%)
With values within reference range	142 (91.0%)	274 (94.5%)
Summary statistics:		
Number of patients with values	156	290
Mean	6.97	6.58
SD	2.023	1.977
Median	6.80	6.30
Minimum	2.6	2.4
Maximum	14.0	18.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	276
With values above reference range	8 (5.4%)	16 (5.8%)
With values below reference range	0	0
With values within reference range	140 (94.6%)	260 (94.2%)
Summary statistics:		
Number of patients with values	148	276
Mean	6.86	6.53
SD	1.982	2.013
Median	6.50	6.10
Minimum	3.2	3.1
Maximum	14.5	18.5
Month 24		
Number of patients:		
With values	129	248
With values above reference range	11 (8.5%)	7 (2.8%)
With values below reference range	0	0
With values within reference range	118 (91.5%)	241 (97.2%)
Summary statistics:		
Number of patients with values	129	248
Mean	6.86	6.39
SD	2.021	2.019
Median	6.40	6.10
Minimum	2.5	2.8
Maximum	14.9	24.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	120	225
With values above reference range	12 (10.0%)	12 (5.3%)
With values below reference range	0	0
With values within reference range	108 (90.0%)	213 (94.7%)

Summary statistics:

Number of patients with values	120	225
Mean	6.73	6.64
SD	2.064	2.367
Median	6.40	6.30
Minimum	3.7	2.9
Maximum	13.0	26.5

Month 30

Number of patients:

With values	108	180
With values above reference range	8 (7.4%)	9 (5.0%)
With values below reference range	0	1 (0.6%)
With values within reference range	100 (92.6%)	170 (94.4%)

Summary statistics:

Number of patients with values	108	180
Mean	6.86	6.52
SD	2.010	1.965
Median	6.70	6.30
Minimum	3.2	2.4
Maximum	13.1	17.2

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 33

Number of patients:

With values	94	155
With values above reference range	7 (7.4%)	12 (7.7%)
With values below reference range	0	0
With values within reference range	87 (92.6%)	143 (92.3%)

Summary statistics:

Number of patients with values	94	155
Mean	6.79	6.59
SD	1.987	2.059
Median	6.60	6.10
Minimum	3.2	2.8
Maximum	13.0	15.6

Month 36

Number of patients:

With values	84	79
With values above reference range	8 (9.5%)	7 (8.9%)
With values below reference range	0	0
With values within reference range	76 (90.5%)	72 (91.1%)

Summary statistics:

Number of patients with values	84	79
Mean	7.02	7.17
SD	2.300	3.850
Median	6.60	6.40
Minimum	2.9	3.3
Maximum	16.7	34.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	4 (8.2%)	0
With values below reference range	0	0
With values within reference range	45 (91.8%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	7.12	5.55
SD	1.805	1.446
Median	6.90	5.65
Minimum	3.4	2.8
Maximum	11.7	8.8
Month 42		
Number of patients:		
With values	32	0
With values above reference range	2 (6.3%)	
With values below reference range	0	
With values within reference range	30 (93.8%)	
Summary statistics:		
Number of patients with values	32	0
Mean	7.15	
SD	3.715	
Median	6.90	
Minimum	2.8	
Maximum	26.0	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	0	
With values within reference range	18 (94.7%)	
Summary statistics:		
Number of patients with values	19	0
Mean	6.46	
SD	2.089	
Median	6.60	
Minimum	3.5	
Maximum	12.5	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	1 (5.6%)
With values below reference range	3 (14.3%)	4 (22.2%)
With values within reference range	18 (85.7%)	13 (72.2%)
Summary statistics:		
Number of patients with values	21	18
Mean	287.1	297.9
SD	52.50	101.56
Median	278.0	279.0
Minimum	208	188
Maximum	394	595
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	2 (0.9%)	10 (2.3%)
With values below reference range	39 (17.0%)	74 (17.3%)
With values within reference range	188 (82.1%)	344 (80.4%)
Summary statistics:		
Number of patients with values	229	428
Mean	278.8	296.7
SD	72.91	90.52
Median	272.0	288.0
Minimum	83	83
Maximum	594	716

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	2 (13.3%)
With values below reference range	1 (33.3%)	3 (20.0%)
With values within reference range	2 (66.7%)	10 (66.7%)
Summary statistics:		
Number of patients with values	3	15
Mean	255.0	291.5
SD	20.30	95.48
Median	251.0	272.0
Minimum	237	195
Maximum	277	537
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	4 (50.0%)	2 (40.0%)
With values within reference range	4 (50.0%)	3 (60.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	239.9	256.6
SD	37.15	74.17
Median	234.0	280.0
Minimum	200	166
Maximum	287	353

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	374
With values above reference range	1 (0.5%)	8 (2.1%)
With values below reference range	40 (18.9%)	75 (20.1%)
With values within reference range	171 (80.7%)	291 (77.8%)
Summary statistics:		
Number of patients with values	212	374
Mean	273.3	276.1
SD	72.83	92.32
Median	271.0	266.0
Minimum	107	67
Maximum	558	789
Month 6		
Number of patients:		
With values	204	366
With values above reference range	1 (0.5%)	8 (2.2%)
With values below reference range	41 (20.1%)	60 (16.4%)
With values within reference range	162 (79.4%)	298 (81.4%)
Summary statistics:		
Number of patients with values	204	366
Mean	270.6	287.5
SD	73.24	84.95
Median	267.5	284.5
Minimum	95	75
Maximum	641	687

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	361
With values above reference range	0	6 (1.7%)
With values below reference range	40 (20.4%)	64 (17.7%)
With values within reference range	156 (79.6%)	291 (80.6%)
Summary statistics:		
Number of patients with values	196	361
Mean	271.8	282.8
SD	72.10	85.54
Median	266.5	277.0
Minimum	90	97
Maximum	485	797
Month 12		
Number of patients:		
With values	176	328
With values above reference range	2 (1.1%)	7 (2.1%)
With values below reference range	37 (21.0%)	52 (15.9%)
With values within reference range	137 (77.8%)	269 (82.0%)
Summary statistics:		
Number of patients with values	176	328
Mean	274.3	293.4
SD	77.61	91.16
Median	266.5	282.0
Minimum	90	83
Maximum	526	590

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	1 (0.6%)	10 (3.2%)
With values below reference range	35 (20.8%)	40 (12.7%)
With values within reference range	132 (78.6%)	266 (84.2%)
Summary statistics:		
Number of patients with values	168	316
Mean	274.4	305.0
SD	77.61	91.93
Median	270.5	300.0
Minimum	101	101
Maximum	599	666
Month 18		
Number of patients:		
With values	156	294
With values above reference range	2 (1.3%)	11 (3.7%)
With values below reference range	25 (16.0%)	28 (9.5%)
With values within reference range	129 (82.7%)	255 (86.7%)
Summary statistics:		
Number of patients with values	156	294
Mean	281.7	316.0
SD	79.62	86.52
Median	280.0	311.5
Minimum	130	85
Maximum	634	569

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	276
With values above reference range	2 (1.4%)	11 (4.0%)
With values below reference range	23 (15.5%)	34 (12.3%)
With values within reference range	123 (83.1%)	231 (83.7%)
Summary statistics:		
Number of patients with values	148	276
Mean	293.2	313.5
SD	83.27	91.69
Median	281.0	306.5
Minimum	102	61
Maximum	644	592
Month 24		
Number of patients:		
With values	129	250
With values above reference range	3 (2.3%)	6 (2.4%)
With values below reference range	13 (10.1%)	29 (11.6%)
With values within reference range	113 (87.6%)	215 (86.0%)
Summary statistics:		
Number of patients with values	129	250
Mean	296.4	306.0
SD	78.92	87.88
Median	289.0	297.5
Minimum	127	86
Maximum	577	650

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 27

Number of patients:

With values	120	226
With values above reference range	3 (2.5%)	12 (5.3%)
With values below reference range	13 (10.8%)	16 (7.1%)
With values within reference range	104 (86.7%)	198 (87.6%)

Summary statistics:

Number of patients with values	120	226
Mean	303.9	321.4
SD	80.20	95.94
Median	298.5	306.0
Minimum	132	104
Maximum	567	833

Month 30

Number of patients:

With values	108	181
With values above reference range	4 (3.7%)	8 (4.4%)
With values below reference range	11 (10.2%)	18 (9.9%)
With values within reference range	93 (86.1%)	155 (85.6%)

Summary statistics:

Number of patients with values	108	181
Mean	303.4	318.5
SD	80.05	88.20
Median	300.5	312.0
Minimum	141	112
Maximum	523	589

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	155
With values above reference range	3 (3.2%)	4 (2.6%)
With values below reference range	8 (8.5%)	16 (10.3%)
With values within reference range	83 (88.3%)	135 (87.1%)
Summary statistics:		
Number of patients with values	94	155
Mean	303.4	317.5
SD	82.28	87.26
Median	290.0	308.0
Minimum	136	128
Maximum	549	534
Month 36		
Number of patients:		
With values	84	79
With values above reference range	3 (3.6%)	3 (3.8%)
With values below reference range	12 (14.3%)	8 (10.1%)
With values within reference range	69 (82.1%)	68 (86.1%)
Summary statistics:		
Number of patients with values	84	79
Mean	308.5	312.6
SD	87.52	112.19
Median	306.5	293.0
Minimum	116	145
Maximum	602	885

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	1 (2.0%)	1 (7.1%)
With values below reference range	5 (10.2%)	1 (7.1%)
With values within reference range	43 (87.8%)	12 (85.7%)
Summary statistics:		
Number of patients with values	49	14
Mean	303.5	285.0
SD	75.63	96.90
Median	299.0	271.0
Minimum	182	121
Maximum	556	477
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	6 (18.8%)	
With values within reference range	25 (78.1%)	
Summary statistics:		
Number of patients with values	32	0
Mean	293.1	
SD	82.19	
Median	280.5	
Minimum	147	
Maximum	538	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	1 (5.3%)	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	307.5	
SD	83.77	
Median	278.0	
Minimum	212	
Maximum	486	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	139.0	139.9
SD	2.27	1.98
Median	139.0	140.0
Minimum	135	137
Maximum	144	145
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	1 (0.4%)	8 (1.9%)
With values below reference range	5 (2.2%)	6 (1.4%)
With values within reference range	223 (97.4%)	414 (96.7%)
Summary statistics:		
Number of patients with values	229	428
Mean	139.7	139.8
SD	2.61	2.73
Median	140.0	140.0
Minimum	133	120
Maximum	156	150

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	1 (6.7%)
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	140.3	139.3
SD	2.08	3.81
Median	141.0	139.0
Minimum	138	134
Maximum	142	146
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	141.4	140.6
SD	2.50	3.97
Median	141.0	140.0
Minimum	138	135
Maximum	145	146

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	373
With values above reference range	0	8 (2.1%)
With values below reference range	3 (1.4%)	7 (1.9%)
With values within reference range	209 (98.6%)	358 (96.0%)

Summary statistics:

Number of patients with values	212	373
Mean	139.2	139.5
SD	2.38	3.10
Median	139.0	139.0
Minimum	132	130
Maximum	146	167

Month 6

Number of patients:

With values	206	370
With values above reference range	3 (1.5%)	4 (1.1%)
With values below reference range	3 (1.5%)	5 (1.4%)
With values within reference range	200 (97.1%)	361 (97.6%)

Summary statistics:

Number of patients with values	206	370
Mean	139.5	139.7
SD	2.39	2.50
Median	139.0	139.0
Minimum	134	131
Maximum	147	148

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	196	361
With values above reference range	0	1 (0.3%)
With values below reference range	6 (3.1%)	7 (1.9%)
With values within reference range	190 (96.9%)	353 (97.8%)

Summary statistics:

Number of patients with values	196	361
Mean	139.2	139.8
SD	2.51	2.65
Median	139.0	140.0
Minimum	130	123
Maximum	146	147

Month 12

Number of patients:

With values	177	328
With values above reference range	1 (0.6%)	5 (1.5%)
With values below reference range	3 (1.7%)	8 (2.4%)
With values within reference range	173 (97.7%)	315 (96.0%)

Summary statistics:

Number of patients with values	177	328
Mean	139.2	140.0
SD	2.34	2.64
Median	139.0	140.0
Minimum	134	132
Maximum	147	152

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	168	316
With values above reference range	0	5 (1.6%)
With values below reference range	4 (2.4%)	4 (1.3%)
With values within reference range	164 (97.6%)	307 (97.2%)

Summary statistics:

Number of patients with values	168	316
Mean	139.4	140.3
SD	2.42	2.53
Median	140.0	140.0
Minimum	130	134
Maximum	146	150

Month 18

Number of patients:

With values	155	294
With values above reference range	0	8 (2.7%)
With values below reference range	7 (4.5%)	6 (2.0%)
With values within reference range	148 (95.5%)	280 (95.2%)

Summary statistics:

Number of patients with values	155	294
Mean	139.3	140.5
SD	2.93	2.87
Median	140.0	140.5
Minimum	118	130
Maximum	146	150

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	148	276
With values above reference range	1 (0.7%)	9 (3.3%)
With values below reference range	6 (4.1%)	6 (2.2%)
With values within reference range	141 (95.3%)	261 (94.6%)

Summary statistics:

Number of patients with values	148	276
Mean	139.8	140.8
SD	2.86	2.91
Median	140.0	140.0
Minimum	129	130
Maximum	148	151

Month 24

Number of patients:

With values	129	251
With values above reference range	3 (2.3%)	7 (2.8%)
With values below reference range	2 (1.6%)	1 (0.4%)
With values within reference range	124 (96.1%)	243 (96.8%)

Summary statistics:

Number of patients with values	129	251
Mean	140.2	140.8
SD	2.80	2.80
Median	140.0	141.0
Minimum	131	132
Maximum	147	149

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	3 (2.5%)	6 (2.7%)
With values below reference range	0	3 (1.3%)
With values within reference range	117 (97.5%)	217 (96.0%)
Summary statistics:		
Number of patients with values	120	226
Mean	140.3	140.4
SD	2.82	2.77
Median	140.0	140.0
Minimum	135	134
Maximum	149	154
Month 30		
Number of patients:		
With values	108	182
With values above reference range	0	3 (1.6%)
With values below reference range	2 (1.9%)	3 (1.6%)
With values within reference range	106 (98.1%)	176 (96.7%)
Summary statistics:		
Number of patients with values	108	182
Mean	140.1	139.7
SD	3.01	2.79
Median	140.0	140.0
Minimum	134	131
Maximum	146	151

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	155
With values above reference range	1 (1.1%)	2 (1.3%)
With values below reference range	0	4 (2.6%)
With values within reference range	93 (98.9%)	149 (96.1%)
Summary statistics:		
Number of patients with values	94	155
Mean	140.1	140.1
SD	2.41	2.53
Median	140.0	140.0
Minimum	135	133
Maximum	147	148
Month 36		
Number of patients:		
With values	84	79
With values above reference range	0	0
With values below reference range	3 (3.6%)	1 (1.3%)
With values within reference range	81 (96.4%)	78 (98.7%)
Summary statistics:		
Number of patients with values	84	79
Mean	139.6	140.9
SD	2.40	2.48
Median	140.0	141.0
Minimum	134	132
Maximum	144	146

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	0	0
With values below reference range	1 (2.0%)	0
With values within reference range	48 (98.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	139.8	141.5
SD	2.23	1.51
Median	140.0	142.0
Minimum	133	139
Maximum	144	144
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	1 (3.1%)	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	140.4	
SD	2.33	
Median	141.0	
Minimum	134	
Maximum	145	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	0	
With values within reference range	18 (94.7%)	
Summary statistics:		
Number of patients with values	19	0
Mean	141.4	
SD	2.67	
Median	141.0	
Minimum	137	
Maximum	148	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	4.49	4.41
SD	0.347	0.304
Median	4.40	4.40
Minimum	3.7	3.9
Maximum	5.0	5.2
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	4 (1.7%)	5 (1.2%)
With values below reference range	1 (0.4%)	1 (0.2%)
With values within reference range	224 (97.8%)	422 (98.6%)
Summary statistics:		
Number of patients with values	229	428
Mean	4.43	4.45
SD	0.358	0.363
Median	4.40	4.40
Minimum	3.2	3.4
Maximum	5.6	6.4

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	4.50	4.47
SD	0.200	0.526
Median	4.50	4.50
Minimum	4.3	3.8
Maximum	4.7	5.8
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	4.55	4.54
SD	0.431	0.351
Median	4.50	4.60
Minimum	4.0	4.1
Maximum	5.2	5.0

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	209	365
With values above reference range	3 (1.4%)	7 (1.9%)
With values below reference range	2 (1.0%)	0
With values within reference range	204 (97.6%)	358 (98.1%)
Summary statistics:		
Number of patients with values	209	365
Mean	4.43	4.45
SD	0.371	0.365
Median	4.40	4.40
Minimum	3.2	3.6
Maximum	5.8	6.3
Month 6		
Number of patients:		
With values	206	365
With values above reference range	3 (1.5%)	6 (1.6%)
With values below reference range	0	1 (0.3%)
With values within reference range	203 (98.5%)	358 (98.1%)
Summary statistics:		
Number of patients with values	206	365
Mean	4.46	4.44
SD	0.406	0.343
Median	4.40	4.40
Minimum	3.5	3.4
Maximum	6.9	5.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	195	355
With values above reference range	5 (2.6%)	7 (2.0%)
With values below reference range	2 (1.0%)	0
With values within reference range	188 (96.4%)	348 (98.0%)
Summary statistics:		
Number of patients with values	195	355
Mean	4.47	4.44
SD	0.391	0.359
Median	4.40	4.40
Minimum	3.4	3.5
Maximum	6.4	6.0
Month 12		
Number of patients:		
With values	176	322
With values above reference range	3 (1.7%)	6 (1.9%)
With values below reference range	0	3 (0.9%)
With values within reference range	173 (98.3%)	313 (97.2%)
Summary statistics:		
Number of patients with values	176	322
Mean	4.48	4.46
SD	0.355	0.384
Median	4.40	4.50
Minimum	3.6	2.7
Maximum	5.7	5.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	166	313
With values above reference range	4 (2.4%)	6 (1.9%)
With values below reference range	0	0
With values within reference range	162 (97.6%)	307 (98.1%)
Summary statistics:		
Number of patients with values	166	313
Mean	4.46	4.45
SD	0.340	0.388
Median	4.40	4.40
Minimum	3.5	3.5
Maximum	5.8	6.3
Month 18		
Number of patients:		
With values	154	287
With values above reference range	4 (2.6%)	6 (2.1%)
With values below reference range	1 (0.6%)	2 (0.7%)
With values within reference range	149 (96.8%)	279 (97.2%)
Summary statistics:		
Number of patients with values	154	287
Mean	4.51	4.45
SD	0.406	0.379
Median	4.50	4.40
Minimum	3.3	3.3
Maximum	6.7	6.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	270
With values above reference range	3 (2.0%)	6 (2.2%)
With values below reference range	1 (0.7%)	1 (0.4%)
With values within reference range	144 (97.3%)	263 (97.4%)
Summary statistics:		
Number of patients with values	148	270
Mean	4.51	4.46
SD	0.373	0.382
Median	4.50	4.40
Minimum	3.2	3.2
Maximum	5.9	5.8
Month 24		
Number of patients:		
With values	129	246
With values above reference range	6 (4.7%)	5 (2.0%)
With values below reference range	0	1 (0.4%)
With values within reference range	123 (95.3%)	240 (97.6%)
Summary statistics:		
Number of patients with values	129	246
Mean	4.51	4.49
SD	0.386	0.386
Median	4.50	4.50
Minimum	3.5	3.4
Maximum	5.7	5.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	224
With values above reference range	6 (5.0%)	7 (3.1%)
With values below reference range	0	0
With values within reference range	114 (95.0%)	217 (96.9%)
Summary statistics:		
Number of patients with values	120	224
Mean	4.51	4.48
SD	0.385	0.407
Median	4.50	4.40
Minimum	3.7	3.5
Maximum	5.9	5.9
Month 30		
Number of patients:		
With values	106	179
With values above reference range	0	6 (3.4%)
With values below reference range	0	0
With values within reference range	106 (100.0%)	173 (96.6%)
Summary statistics:		
Number of patients with values	106	179
Mean	4.44	4.43
SD	0.319	0.449
Median	4.40	4.40
Minimum	3.7	3.5
Maximum	5.2	6.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	154
With values above reference range	0	5 (3.2%)
With values below reference range	0	0
With values within reference range	93 (100.0%)	149 (96.8%)
Summary statistics:		
Number of patients with values	93	154
Mean	4.46	4.52
SD	0.365	0.615
Median	4.50	4.45
Minimum	3.6	3.7
Maximum	5.3	9.0
Month 36		
Number of patients:		
With values	84	79
With values above reference range	1 (1.2%)	2 (2.5%)
With values below reference range	0	0
With values within reference range	83 (98.8%)	77 (97.5%)
Summary statistics:		
Number of patients with values	84	79
Mean	4.46	4.57
SD	0.385	0.340
Median	4.40	4.50
Minimum	3.5	4.1
Maximum	5.5	5.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	48 (100.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	48	14
Mean	4.45	4.54
SD	0.336	0.295
Median	4.50	4.60
Minimum	3.7	4.1
Maximum	5.1	5.2
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	4.49	
SD	0.283	
Median	4.50	
Minimum	3.8	
Maximum	5.3	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	4.44	
SD	0.336	
Median	4.50	
Minimum	3.9	
Maximum	5.2	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	1 (5.6%)
With values below reference range	0	0
With values within reference range	21 (100.0%)	17 (94.4%)
Summary statistics:		
Number of patients with values	21	18
Mean	102.6	104.1
SD	1.72	2.85
Median	102.0	105.0
Minimum	100	99
Maximum	105	109
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	6 (2.6%)	17 (4.0%)
With values below reference range	0	1 (0.2%)
With values within reference range	223 (97.4%)	410 (95.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	103.2	103.6
SD	2.61	2.91
Median	103.0	104.0
Minimum	97	82
Maximum	110	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	2 (13.3%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	13 (86.7%)
Summary statistics:		
Number of patients with values	3	15
Mean	105.0	102.5
SD	2.65	3.72
Median	104.0	101.0
Minimum	103	100
Maximum	108	111
Month 2		
Number of patients:		
With values	8	5
With values above reference range	1 (12.5%)	0
With values below reference range	0	0
With values within reference range	7 (87.5%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	104.9	103.4
SD	2.64	3.36
Median	104.5	103.0
Minimum	102	99
Maximum	109	108

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	374
With values above reference range	8 (3.8%)	13 (3.5%)
With values below reference range	0	1 (0.3%)
With values within reference range	204 (96.2%)	360 (96.3%)
Summary statistics:		
Number of patients with values	212	374
Mean	103.6	103.5
SD	2.51	2.89
Median	103.0	104.0
Minimum	98	94
Maximum	110	113
Month 6		
Number of patients:		
With values	207	370
With values above reference range	6 (2.9%)	14 (3.8%)
With values below reference range	0	0
With values within reference range	201 (97.1%)	356 (96.2%)
Summary statistics:		
Number of patients with values	207	370
Mean	103.3	103.7
SD	2.60	2.71
Median	103.0	104.0
Minimum	96	96
Maximum	112	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	361
With values above reference range	6 (3.1%)	15 (4.2%)
With values below reference range	0	1 (0.3%)
With values within reference range	190 (96.9%)	345 (95.6%)
Summary statistics:		
Number of patients with values	196	361
Mean	103.6	103.7
SD	2.55	2.94
Median	104.0	104.0
Minimum	97	83
Maximum	110	110
Month 12		
Number of patients:		
With values	177	329
With values above reference range	5 (2.8%)	16 (4.9%)
With values below reference range	0	1 (0.3%)
With values within reference range	172 (97.2%)	312 (94.8%)
Summary statistics:		
Number of patients with values	177	329
Mean	103.1	103.7
SD	2.76	3.04
Median	103.0	104.0
Minimum	96	92
Maximum	111	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	168	316
With values above reference range	3 (1.8%)	19 (6.0%)
With values below reference range	1 (0.6%)	0
With values within reference range	164 (97.6%)	297 (94.0%)
Summary statistics:		
Number of patients with values	168	316
Mean	103.5	104.0
SD	3.03	2.82
Median	104.0	104.0
Minimum	87	95
Maximum	111	113
Month 18		
Number of patients:		
With values	155	294
With values above reference range	2 (1.3%)	17 (5.8%)
With values below reference range	1 (0.6%)	3 (1.0%)
With values within reference range	152 (98.1%)	274 (93.2%)
Summary statistics:		
Number of patients with values	155	294
Mean	102.9	103.5
SD	3.42	3.30
Median	103.0	104.0
Minimum	79	92
Maximum	110	114

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	276
With values above reference range	11 (7.4%)	14 (5.1%)
With values below reference range	2 (1.4%)	4 (1.4%)
With values within reference range	135 (91.2%)	258 (93.5%)
Summary statistics:		
Number of patients with values	148	276
Mean	103.6	103.5
SD	3.30	3.18
Median	104.0	104.0
Minimum	92	92
Maximum	111	112
Month 24		
Number of patients:		
With values	129	251
With values above reference range	7 (5.4%)	9 (3.6%)
With values below reference range	1 (0.8%)	0
With values within reference range	121 (93.8%)	242 (96.4%)
Summary statistics:		
Number of patients with values	129	251
Mean	103.2	103.4
SD	3.50	2.84
Median	103.0	103.0
Minimum	89	95
Maximum	112	112

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	4 (3.3%)	3 (1.3%)
With values below reference range	1 (0.8%)	0
With values within reference range	115 (95.8%)	223 (98.7%)
Summary statistics:		
Number of patients with values	120	226
Mean	103.0	103.5
SD	3.13	2.81
Median	103.0	104.0
Minimum	91	95
Maximum	113	111
Month 30		
Number of patients:		
With values	108	182
With values above reference range	2 (1.9%)	4 (2.2%)
With values below reference range	2 (1.9%)	0
With values within reference range	104 (96.3%)	178 (97.8%)
Summary statistics:		
Number of patients with values	108	182
Mean	103.0	103.5
SD	3.11	2.97
Median	103.0	104.0
Minimum	92	95
Maximum	111	111

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	155
With values above reference range	4 (4.3%)	3 (1.9%)
With values below reference range	1 (1.1%)	0
With values within reference range	89 (94.7%)	152 (98.1%)
Summary statistics:		
Number of patients with values	94	155
Mean	103.3	103.4
SD	3.06	2.73
Median	104.0	103.0
Minimum	94	95
Maximum	111	110
Month 36		
Number of patients:		
With values	84	79
With values above reference range	2 (2.4%)	2 (2.5%)
With values below reference range	1 (1.2%)	1 (1.3%)
With values within reference range	81 (96.4%)	76 (96.2%)
Summary statistics:		
Number of patients with values	84	79
Mean	102.8	103.4
SD	2.82	2.83
Median	103.0	104.0
Minimum	94	94
Maximum	110	109

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	0	0
With values below reference range	1 (2.0%)	0
With values within reference range	48 (98.0%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	103.2	104.0
SD	2.78	2.32
Median	103.0	103.5
Minimum	93	99
Maximum	108	107
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	0	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	103.2	
SD	3.08	
Median	104.0	
Minimum	97	
Maximum	109	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	103.8	
SD	2.39	
Median	104.0	
Minimum	98	
Maximum	108	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	1 (5.6%)
With values below reference range	0	1 (5.6%)
With values within reference range	21 (100.0%)	16 (88.9%)
Summary statistics:		
Number of patients with values	21	18
Mean	25.6	24.9
SD	2.89	3.15
Median	27.0	24.5
Minimum	20	19
Maximum	30	33
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	3 (1.3%)	9 (2.1%)
With values below reference range	6 (2.6%)	10 (2.3%)
With values within reference range	220 (96.1%)	409 (95.6%)
Summary statistics:		
Number of patients with values	229	428
Mean	25.5	25.9
SD	2.94	3.04
Median	25.0	26.0
Minimum	18	17
Maximum	37	39

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	28.3	25.2
SD	3.21	2.98
Median	27.0	25.0
Minimum	26	21
Maximum	32	30
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	26.3	26.0
SD	3.15	1.87
Median	27.5	27.0
Minimum	22	24
Maximum	30	28

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 3

Number of patients:

With values	212	372
With values above reference range	5 (2.4%)	15 (4.0%)
With values below reference range	7 (3.3%)	4 (1.1%)
With values within reference range	200 (94.3%)	353 (94.9%)

Summary statistics:

Number of patients with values	212	372
Mean	26.2	26.7
SD	3.18	3.21
Median	26.0	27.0
Minimum	14	12
Maximum	42	39

Month 6

Number of patients:

With values	205	370
With values above reference range	4 (2.0%)	9 (2.4%)
With values below reference range	5 (2.4%)	14 (3.8%)
With values within reference range	196 (95.6%)	347 (93.8%)

Summary statistics:

Number of patients with values	205	370
Mean	25.6	25.0
SD	3.15	3.36
Median	26.0	25.0
Minimum	16	12
Maximum	36	39

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	360
With values above reference range	1 (0.5%)	12 (3.3%)
With values below reference range	0	3 (0.8%)
With values within reference range	195 (99.5%)	345 (95.8%)
Summary statistics:		
Number of patients with values	196	360
Mean	26.2	26.7
SD	2.59	3.17
Median	26.0	27.0
Minimum	20	5
Maximum	33	36
Month 12		
Number of patients:		
With values	177	328
With values above reference range	4 (2.3%)	8 (2.4%)
With values below reference range	3 (1.7%)	4 (1.2%)
With values within reference range	170 (96.0%)	316 (96.3%)
Summary statistics:		
Number of patients with values	177	328
Mean	25.5	25.9
SD	3.18	3.16
Median	25.0	26.0
Minimum	16	16
Maximum	35	38

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	168	316
With values above reference range	3 (1.8%)	3 (0.9%)
With values below reference range	7 (4.2%)	3 (0.9%)
With values within reference range	158 (94.0%)	310 (98.1%)

Summary statistics:

Number of patients with values	168	316
Mean	25.7	26.1
SD	3.17	2.85
Median	26.0	26.0
Minimum	18	18
Maximum	35	36

Month 18

Number of patients:

With values	156	294
With values above reference range	3 (1.9%)	7 (2.4%)
With values below reference range	2 (1.3%)	6 (2.0%)
With values within reference range	151 (96.8%)	281 (95.6%)

Summary statistics:

Number of patients with values	156	294
Mean	25.1	25.7
SD	3.32	3.24
Median	25.0	26.0
Minimum	5	12
Maximum	35	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	148	276
With values above reference range	3 (2.0%)	9 (3.3%)
With values below reference range	2 (1.4%)	4 (1.4%)
With values within reference range	143 (96.6%)	263 (95.3%)

Summary statistics:

Number of patients with values	148	276
Mean	26.1	26.2
SD	3.05	3.06
Median	26.0	26.0
Minimum	17	17
Maximum	36	35

Month 24

Number of patients:

With values	129	250
With values above reference range	1 (0.8%)	4 (1.6%)
With values below reference range	3 (2.3%)	5 (2.0%)
With values within reference range	125 (96.9%)	241 (96.4%)

Summary statistics:

Number of patients with values	129	250
Mean	25.4	25.7
SD	3.15	3.00
Median	25.0	26.0
Minimum	19	18
Maximum	35	36

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	3 (2.5%)	2 (0.9%)
With values below reference range	5 (4.2%)	3 (1.3%)
With values within reference range	112 (93.3%)	221 (97.8%)
Summary statistics:		
Number of patients with values	120	226
Mean	25.6	26.0
SD	3.37	3.15
Median	25.0	26.0
Minimum	16	16
Maximum	35	33
Month 30		
Number of patients:		
With values	108	181
With values above reference range	2 (1.9%)	7 (3.9%)
With values below reference range	3 (2.8%)	7 (3.9%)
With values within reference range	103 (95.4%)	167 (92.3%)
Summary statistics:		
Number of patients with values	108	181
Mean	25.4	25.7
SD	3.40	3.44
Median	26.0	25.0
Minimum	12	18
Maximum	39	35

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	156
With values above reference range	5 (5.3%)	5 (3.2%)
With values below reference range	0	1 (0.6%)
With values within reference range	89 (94.7%)	150 (96.2%)
Summary statistics:		
Number of patients with values	94	156
Mean	26.2	27.2
SD	3.18	2.86
Median	26.0	27.5
Minimum	20	19
Maximum	35	34
Month 36		
Number of patients:		
With values	84	79
With values above reference range	2 (2.4%)	3 (3.8%)
With values below reference range	2 (2.4%)	0
With values within reference range	80 (95.2%)	76 (96.2%)
Summary statistics:		
Number of patients with values	84	79
Mean	25.9	26.8
SD	3.67	3.08
Median	26.0	27.0
Minimum	12	21
Maximum	36	37

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	1 (2.0%)	1 (7.1%)
With values below reference range	1 (2.0%)	0
With values within reference range	47 (95.9%)	13 (92.9%)
Summary statistics:		
Number of patients with values	49	14
Mean	26.0	26.9
SD	3.09	3.61
Median	26.0	26.5
Minimum	19	22
Maximum	35	33
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	0	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	27.1	
SD	3.08	
Median	27.0	
Minimum	20	
Maximum	33	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	2 (10.5%)	
With values below reference range	0	
With values within reference range	17 (89.5%)	
Summary statistics:		
Number of patients with values	19	0
Mean	26.7	
SD	3.61	
Median	27.0	
Minimum	20	
Maximum	34	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	22	21
With values above reference range	21 (95.5%)	15 (71.4%)
With values below reference range	0	0
With values within reference range	1 (4.5%)	6 (28.6%)
Summary statistics:		
Number of patients with values	22	21
Mean	182.0	153.0
SD	43.65	45.89
Median	184.5	137.0
Minimum	104	89
Maximum	280	252
Open Label Baseline		
Number of patients:		
With values	229	400
With values above reference range	194 (84.7%)	296 (74.0%)
With values below reference range	2 (0.9%)	2 (0.5%)
With values within reference range	33 (14.4%)	102 (25.5%)
Summary statistics:		
Number of patients with values	229	400
Mean	170.6	151.0
SD	41.59	39.28
Median	171.0	145.0
Minimum	66	61
Maximum	280	286

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	220	411
With values above reference range	181 (82.3%)	308 (74.9%)
With values below reference range	3 (1.4%)	0
With values within reference range	36 (16.4%)	103 (25.1%)
Summary statistics:		
Number of patients with values	220	411
Mean	163.8	157.1
SD	40.91	47.88
Median	164.0	145.0
Minimum	71	80
Maximum	341	521
Month 2		
Number of patients:		
With values	218	402
With values above reference range	178 (81.7%)	287 (71.4%)
With values below reference range	2 (0.9%)	1 (0.2%)
With values within reference range	38 (17.4%)	114 (28.4%)
Summary statistics:		
Number of patients with values	218	402
Mean	158.9	149.6
SD	39.90	38.73
Median	157.0	141.0
Minimum	71	73
Maximum	287	284

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	217	397
With values above reference range	179 (82.5%)	285 (71.8%)
With values below reference range	2 (0.9%)	0
With values within reference range	36 (16.6%)	112 (28.2%)
Summary statistics:		
Number of patients with values	217	397
Mean	161.2	148.3
SD	37.69	39.72
Median	162.0	139.0
Minimum	68	79
Maximum	250	298
Month 6		
Number of patients:		
With values	208	381
With values above reference range	173 (83.2%)	235 (61.7%)
With values below reference range	1 (0.5%)	0
With values within reference range	34 (16.3%)	146 (38.3%)
Summary statistics:		
Number of patients with values	208	381
Mean	160.9	141.5
SD	37.55	36.67
Median	160.0	132.0
Minimum	70	80
Maximum	307	312

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	200	374
With values above reference range	169 (84.5%)	246 (65.8%)
With values below reference range	0	2 (0.5%)
With values within reference range	31 (15.5%)	126 (33.7%)
Summary statistics:		
Number of patients with values	200	374
Mean	165.8	140.8
SD	39.18	34.51
Median	169.0	136.0
Minimum	80	64
Maximum	271	291
Month 12		
Number of patients:		
With values	182	343
With values above reference range	151 (83.0%)	222 (64.7%)
With values below reference range	3 (1.6%)	0
With values within reference range	28 (15.4%)	121 (35.3%)
Summary statistics:		
Number of patients with values	182	343
Mean	164.2	141.9
SD	43.39	35.39
Median	164.0	136.0
Minimum	71	79
Maximum	320	304

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	171	320
With values above reference range	140 (81.9%)	196 (61.3%)
With values below reference range	4 (2.3%)	2 (0.6%)
With values within reference range	27 (15.8%)	122 (38.1%)
Summary statistics:		
Number of patients with values	171	320
Mean	161.8	140.0
SD	43.94	36.11
Median	161.0	132.0
Minimum	75	30
Maximum	286	277
Month 18		
Number of patients:		
With values	154	295
With values above reference range	129 (83.8%)	184 (62.4%)
With values below reference range	3 (1.9%)	1 (0.3%)
With values within reference range	22 (14.3%)	110 (37.3%)
Summary statistics:		
Number of patients with values	154	295
Mean	161.2	142.1
SD	39.57	39.15
Median	160.0	134.0
Minimum	61	61
Maximum	271	280

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	151	279
With values above reference range	124 (82.1%)	188 (67.4%)
With values below reference range	2 (1.3%)	3 (1.1%)
With values within reference range	25 (16.6%)	88 (31.5%)
Summary statistics:		
Number of patients with values	151	279
Mean	160.7	141.3
SD	41.88	37.83
Median	161.0	134.0
Minimum	62	68
Maximum	327	318
Month 24		
Number of patients:		
With values	128	250
With values above reference range	103 (80.5%)	160 (64.0%)
With values below reference range	5 (3.9%)	2 (0.8%)
With values within reference range	20 (15.6%)	88 (35.2%)
Summary statistics:		
Number of patients with values	128	250
Mean	161.8	141.9
SD	48.85	37.92
Median	161.0	134.0
Minimum	50	70
Maximum	384	291

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	119	229
With values above reference range	96 (80.7%)	144 (62.9%)
With values below reference range	4 (3.4%)	1 (0.4%)
With values within reference range	19 (16.0%)	84 (36.7%)
Summary statistics:		
Number of patients with values	119	229
Mean	167.8	139.5
SD	50.12	35.94
Median	170.0	130.0
Minimum	20	61
Maximum	327	295
Month 30		
Number of patients:		
With values	107	180
With values above reference range	88 (82.2%)	112 (62.2%)
With values below reference range	2 (1.9%)	0
With values within reference range	17 (15.9%)	68 (37.8%)
Summary statistics:		
Number of patients with values	107	180
Mean	164.5	139.2
SD	44.93	34.16
Median	161.0	132.0
Minimum	68	82
Maximum	296	282

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	157
With values above reference range	78 (83.0%)	90 (57.3%)
With values below reference range	1 (1.1%)	1 (0.6%)
With values within reference range	15 (16.0%)	66 (42.0%)
Summary statistics:		
Number of patients with values	94	157
Mean	163.0	139.1
SD	40.15	36.55
Median	164.0	130.0
Minimum	66	71
Maximum	266	250
Month 36		
Number of patients:		
With values	83	77
With values above reference range	66 (79.5%)	44 (57.1%)
With values below reference range	0	0
With values within reference range	17 (20.5%)	33 (42.9%)
Summary statistics:		
Number of patients with values	83	77
Mean	160.0	137.8
SD	40.05	38.49
Median	162.0	127.0
Minimum	82	82
Maximum	270	320

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	16
With values above reference range	42 (85.7%)	8 (50.0%)
With values below reference range	0	0
With values within reference range	7 (14.3%)	8 (50.0%)
Summary statistics:		
Number of patients with values	49	16
Mean	168.4	130.4
SD	44.90	24.49
Median	166.0	125.0
Minimum	86	95
Maximum	275	179
Month 42		
Number of patients:		
With values	32	0
With values above reference range	25 (78.1%)	
With values below reference range	0	
With values within reference range	7 (21.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	160.8	
SD	48.07	
Median	149.0	
Minimum	82	
Maximum	271	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit

All Patients Who Entered Study 009

Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	18	0
With values above reference range	13 (72.2%)	
With values below reference range	1 (5.6%)	
With values within reference range	4 (22.2%)	
Summary statistics:		
Number of patients with values	18	0
Mean	145.9	
SD	45.42	
Median	146.0	
Minimum	73	
Maximum	245	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	0	0
With values below reference range	0	1 (5.6%)
With values within reference range	21 (100.0%)	17 (94.4%)
Summary statistics:		
Number of patients with values	21	18
Mean	1.04	1.04
SD	0.150	0.158
Median	1.00	1.05
Minimum	0.8	0.7
Maximum	1.4	1.3
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	5 (2.2%)	3 (0.7%)
With values below reference range	3 (1.3%)	8 (1.9%)
With values within reference range	221 (96.5%)	417 (97.4%)
Summary statistics:		
Number of patients with values	229	428
Mean	1.12	1.10
SD	0.160	0.159
Median	1.10	1.10
Minimum	0.7	0.6
Maximum	1.5	1.9

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	1 (6.7%)
With values below reference range	0	0
With values within reference range	3 (100.0%)	14 (93.3%)
Summary statistics:		
Number of patients with values	3	15
Mean	1.00	1.08
SD	0.100	0.197
Median	1.00	1.00
Minimum	0.9	0.8
Maximum	1.1	1.5
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	1.08	1.10
SD	0.149	0.158
Median	1.05	1.10
Minimum	0.9	0.9
Maximum	1.3	1.3

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	371
With values above reference range	2 (0.9%)	5 (1.3%)
With values below reference range	1 (0.5%)	6 (1.6%)
With values within reference range	209 (98.6%)	360 (97.0%)
Summary statistics:		
Number of patients with values	212	371
Mean	1.11	1.09
SD	0.154	0.160
Median	1.10	1.10
Minimum	0.8	0.6
Maximum	1.5	1.5
Month 6		
Number of patients:		
With values	204	368
With values above reference range	4 (2.0%)	4 (1.1%)
With values below reference range	4 (2.0%)	7 (1.9%)
With values within reference range	196 (96.1%)	357 (97.0%)
Summary statistics:		
Number of patients with values	204	368
Mean	1.10	1.08
SD	0.159	0.165
Median	1.10	1.10
Minimum	0.7	0.6
Maximum	1.7	1.8

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 9

Number of patients:

With values	196	359
With values above reference range	5 (2.6%)	2 (0.6%)
With values below reference range	1 (0.5%)	6 (1.7%)
With values within reference range	190 (96.9%)	351 (97.8%)

Summary statistics:

Number of patients with values	196	359
Mean	1.09	1.09
SD	0.149	0.150
Median	1.10	1.10
Minimum	0.8	0.6
Maximum	1.6	1.5

Month 12

Number of patients:

With values	176	326
With values above reference range	1 (0.6%)	2 (0.6%)
With values below reference range	1 (0.6%)	6 (1.8%)
With values within reference range	174 (98.9%)	318 (97.5%)

Summary statistics:

Number of patients with values	176	326
Mean	1.10	1.07
SD	0.145	0.150
Median	1.10	1.10
Minimum	0.7	0.7
Maximum	1.5	1.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	168	316
With values above reference range	2 (1.2%)	5 (1.6%)
With values below reference range	1 (0.6%)	2 (0.6%)
With values within reference range	165 (98.2%)	309 (97.8%)

Summary statistics:

Number of patients with values	168	316
Mean	1.09	1.09
SD	0.154	0.141
Median	1.10	1.10
Minimum	0.7	0.8
Maximum	1.6	1.5

Month 18

Number of patients:

With values	156	293
With values above reference range	2 (1.3%)	6 (2.0%)
With values below reference range	1 (0.6%)	4 (1.4%)
With values within reference range	153 (98.1%)	283 (96.6%)

Summary statistics:

Number of patients with values	156	293
Mean	1.10	1.09
SD	0.155	0.155
Median	1.10	1.10
Minimum	0.7	0.7
Maximum	1.8	1.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 21

Number of patients:

With values	148	274
With values above reference range	3 (2.0%)	5 (1.8%)
With values below reference range	0	4 (1.5%)
With values within reference range	145 (98.0%)	265 (96.7%)

Summary statistics:

Number of patients with values	148	274
Mean	1.10	1.10
SD	0.154	0.155
Median	1.10	1.10
Minimum	0.7	0.7
Maximum	1.5	1.5

Month 24

Number of patients:

With values	129	249
With values above reference range	2 (1.6%)	3 (1.2%)
With values below reference range	0	4 (1.6%)
With values within reference range	127 (98.4%)	242 (97.2%)

Summary statistics:

Number of patients with values	129	249
Mean	1.10	1.07
SD	0.147	0.143
Median	1.10	1.10
Minimum	0.8	0.6
Maximum	1.7	1.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	226
With values above reference range	3 (2.5%)	5 (2.2%)
With values below reference range	0	1 (0.4%)
With values within reference range	117 (97.5%)	220 (97.3%)
Summary statistics:		
Number of patients with values	120	226
Mean	1.09	1.10
SD	0.148	0.155
Median	1.10	1.10
Minimum	0.8	0.7
Maximum	1.6	1.7
Month 30		
Number of patients:		
With values	106	180
With values above reference range	2 (1.9%)	3 (1.7%)
With values below reference range	1 (0.9%)	1 (0.6%)
With values within reference range	103 (97.2%)	176 (97.8%)
Summary statistics:		
Number of patients with values	106	180
Mean	1.08	1.10
SD	0.151	0.154
Median	1.10	1.10
Minimum	0.7	0.7
Maximum	1.7	1.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	155
With values above reference range	1 (1.1%)	2 (1.3%)
With values below reference range	1 (1.1%)	0
With values within reference range	91 (97.8%)	153 (98.7%)
Summary statistics:		
Number of patients with values	93	155
Mean	1.07	1.08
SD	0.137	0.143
Median	1.10	1.10
Minimum	0.8	0.8
Maximum	1.4	1.5
Month 36		
Number of patients:		
With values	84	79
With values above reference range	1 (1.2%)	1 (1.3%)
With values below reference range	0	0
With values within reference range	83 (98.8%)	78 (98.7%)
Summary statistics:		
Number of patients with values	84	79
Mean	1.08	1.08
SD	0.166	0.148
Median	1.10	1.10
Minimum	0.7	0.8
Maximum	1.5	1.5

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	1 (2.1%)	0
With values below reference range	0	0
With values within reference range	47 (97.9%)	14 (100.0%)
Summary statistics:		
Number of patients with values	48	14
Mean	1.08	1.14
SD	0.158	0.160
Median	1.10	1.10
Minimum	0.8	0.8
Maximum	1.6	1.5
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	1 (3.1%)	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	1.08	
SD	0.146	
Median	1.05	
Minimum	0.8	
Maximum	1.4	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	1.05	
SD	0.143	
Median	1.00	
Minimum	0.8	
Maximum	1.3	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	17
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	21 (100.0%)	17 (100.0%)
Summary statistics:		
Number of patients with values	21	17
Mean	2.40	2.43
SD	0.100	0.077
Median	2.40	2.40
Minimum	2.2	2.3
Maximum	2.5	2.6
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	9 (3.9%)	21 (4.9%)
With values below reference range	0	2 (0.5%)
With values within reference range	220 (96.1%)	405 (94.6%)
Summary statistics:		
Number of patients with values	229	428
Mean	2.42	2.41
SD	0.096	0.106
Median	2.40	2.40
Minimum	2.2	1.8
Maximum	2.8	3.1

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	2.40	2.39
SD	0.100	0.080
Median	2.40	2.40
Minimum	2.3	2.2
Maximum	2.5	2.5
Month 2		
Number of patients:		
With values	8	5
With values above reference range	1 (12.5%)	1 (20.0%)
With values below reference range	0	0
With values within reference range	7 (87.5%)	4 (80.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	2.47	2.46
SD	0.149	0.114
Median	2.45	2.50
Minimum	2.3	2.3
Maximum	2.8	2.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	372
With values above reference range	7 (3.3%)	5 (1.3%)
With values below reference range	0	0
With values within reference range	205 (96.7%)	367 (98.7%)
Summary statistics:		
Number of patients with values	212	372
Mean	2.39	2.37
SD	0.101	0.086
Median	2.40	2.40
Minimum	2.1	2.2
Maximum	2.9	2.7
Month 6		
Number of patients:		
With values	202	363
With values above reference range	10 (5.0%)	12 (3.3%)
With values below reference range	0	0
With values within reference range	192 (95.0%)	351 (96.7%)
Summary statistics:		
Number of patients with values	202	363
Mean	2.41	2.39
SD	0.099	0.091
Median	2.40	2.40
Minimum	2.1	2.2
Maximum	2.9	2.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	360
With values above reference range	6 (3.1%)	11 (3.1%)
With values below reference range	0	1 (0.3%)
With values within reference range	190 (96.9%)	348 (96.7%)
Summary statistics:		
Number of patients with values	196	360
Mean	2.38	2.38
SD	0.097	0.099
Median	2.40	2.40
Minimum	2.2	1.6
Maximum	2.8	2.7
Month 12		
Number of patients:		
With values	175	323
With values above reference range	9 (5.1%)	11 (3.4%)
With values below reference range	0	0
With values within reference range	166 (94.9%)	312 (96.6%)
Summary statistics:		
Number of patients with values	175	323
Mean	2.40	2.40
SD	0.105	0.096
Median	2.40	2.40
Minimum	2.2	2.1
Maximum	3.0	2.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open
 Label Medication 2bd Comb Total 4bd Mono Total

Month 15

Number of patients:

With values	166	314
With values above reference range	2 (1.2%)	6 (1.9%)
With values below reference range	0	1 (0.3%)
With values within reference range	164 (98.8%)	307 (97.8%)

Summary statistics:

Number of patients with values	166	314
Mean	2.38	2.38
SD	0.097	0.092
Median	2.40	2.40
Minimum	2.1	2.1
Maximum	2.9	2.7

Month 18

Number of patients:

With values	155	285
With values above reference range	7 (4.5%)	8 (2.8%)
With values below reference range	1 (0.6%)	1 (0.4%)
With values within reference range	147 (94.8%)	276 (96.8%)

Summary statistics:

Number of patients with values	155	285
Mean	2.40	2.38
SD	0.116	0.094
Median	2.40	2.40
Minimum	1.8	2.1
Maximum	2.9	2.6

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	273
With values above reference range	3 (2.0%)	2 (0.7%)
With values below reference range	1 (0.7%)	1 (0.4%)
With values within reference range	144 (97.3%)	270 (98.9%)
Summary statistics:		
Number of patients with values	148	273
Mean	2.37	2.36
SD	0.111	0.093
Median	2.40	2.40
Minimum	2.1	2.1
Maximum	2.8	2.7
Month 24		
Number of patients:		
With values	128	244
With values above reference range	6 (4.7%)	7 (2.9%)
With values below reference range	0	0
With values within reference range	122 (95.3%)	237 (97.1%)
Summary statistics:		
Number of patients with values	128	244
Mean	2.38	2.38
SD	0.110	0.093
Median	2.40	2.40
Minimum	2.1	2.2
Maximum	2.9	2.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	224
With values above reference range	3 (2.5%)	4 (1.8%)
With values below reference range	0	0
With values within reference range	117 (97.5%)	220 (98.2%)
Summary statistics:		
Number of patients with values	120	224
Mean	2.39	2.37
SD	0.114	0.093
Median	2.40	2.40
Minimum	2.2	2.2
Maximum	3.1	2.6
Month 30		
Number of patients:		
With values	108	176
With values above reference range	5 (4.6%)	4 (2.3%)
With values below reference range	0	0
With values within reference range	103 (95.4%)	172 (97.7%)
Summary statistics:		
Number of patients with values	108	176
Mean	2.38	2.36
SD	0.114	0.100
Median	2.40	2.40
Minimum	2.2	2.2
Maximum	3.0	2.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	94	153
With values above reference range	2 (2.1%)	5 (3.3%)
With values below reference range	0	1 (0.7%)
With values within reference range	92 (97.9%)	147 (96.1%)
Summary statistics:		
Number of patients with values	94	153
Mean	2.37	2.35
SD	0.105	0.097
Median	2.40	2.30
Minimum	2.2	2.1
Maximum	2.8	2.6
Month 36		
Number of patients:		
With values	84	79
With values above reference range	1 (1.2%)	4 (5.1%)
With values below reference range	0	0
With values within reference range	83 (98.8%)	75 (94.9%)
Summary statistics:		
Number of patients with values	84	79
Mean	2.36	2.37
SD	0.088	0.097
Median	2.40	2.40
Minimum	2.2	2.2
Maximum	2.6	2.7

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	49	14
With values above reference range	2 (4.1%)	0
With values below reference range	0	0
With values within reference range	47 (95.9%)	14 (100.0%)
Summary statistics:		
Number of patients with values	49	14
Mean	2.37	2.39
SD	0.128	0.083
Median	2.30	2.40
Minimum	2.2	2.2
Maximum	2.9	2.5
Month 42		
Number of patients:		
With values	32	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	32 (100.0%)	
Summary statistics:		
Number of patients with values	32	0
Mean	2.34	
SD	0.110	
Median	2.30	
Minimum	2.1	
Maximum	2.6	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	0	
With values below reference range	0	
With values within reference range	19 (100.0%)	
Summary statistics:		
Number of patients with values	19	0
Mean	2.38	
SD	0.101	
Median	2.40	
Minimum	2.2	
Maximum	2.6	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	18
With values above reference range	1 (4.8%)	0
With values below reference range	0	0
With values within reference range	20 (95.2%)	18 (100.0%)
Summary statistics:		
Number of patients with values	21	18
Mean	160.7	162.9
SD	48.45	28.95
Median	158.0	165.5
Minimum	87	128
Maximum	298	235
Open Label Baseline		
Number of patients:		
With values	229	428
With values above reference range	5 (2.2%)	5 (1.2%)
With values below reference range	0	0
With values within reference range	224 (97.8%)	423 (98.8%)
Summary statistics:		
Number of patients with values	229	428
Mean	165.2	166.8
SD	34.42	38.16
Median	161.0	164.0
Minimum	63	82
Maximum	298	546

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	15
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	3 (100.0%)	15 (100.0%)
Summary statistics:		
Number of patients with values	3	15
Mean	167.0	160.1
SD	37.59	31.26
Median	164.0	160.0
Minimum	131	91
Maximum	206	207
Month 2		
Number of patients:		
With values	8	5
With values above reference range	0	0
With values below reference range	0	0
With values within reference range	8 (100.0%)	5 (100.0%)
Summary statistics:		
Number of patients with values	8	5
Mean	171.6	157.4
SD	25.10	37.41
Median	176.5	168.0
Minimum	134	93
Maximum	201	190

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	212	370
With values above reference range	5 (2.4%)	12 (3.2%)
With values below reference range	0	0
With values within reference range	207 (97.6%)	358 (96.8%)
Summary statistics:		
Number of patients with values	212	370
Mean	172.5	178.6
SD	34.33	42.44
Median	168.0	172.0
Minimum	80	81
Maximum	342	452
Month 6		
Number of patients:		
With values	204	365
With values above reference range	6 (2.9%)	12 (3.3%)
With values below reference range	0	0
With values within reference range	198 (97.1%)	353 (96.7%)
Summary statistics:		
Number of patients with values	204	365
Mean	171.7	178.6
SD	35.60	38.07
Median	165.0	176.0
Minimum	86	82
Maximum	305	327

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	196	359
With values above reference range	4 (2.0%)	5 (1.4%)
With values below reference range	0	0
With values within reference range	192 (98.0%)	354 (98.6%)
Summary statistics:		
Number of patients with values	196	359
Mean	170.3	173.8
SD	36.33	35.28
Median	164.5	171.0
Minimum	75	81
Maximum	335	299
Month 12		
Number of patients:		
With values	176	324
With values above reference range	5 (2.8%)	6 (1.9%)
With values below reference range	0	0
With values within reference range	171 (97.2%)	318 (98.1%)
Summary statistics:		
Number of patients with values	176	324
Mean	170.3	168.4
SD	43.19	38.56
Median	163.0	163.0
Minimum	73	67
Maximum	450	422

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	167	316
With values above reference range	2 (1.2%)	4 (1.3%)
With values below reference range	0	0
With values within reference range	165 (98.8%)	312 (98.7%)
Summary statistics:		
Number of patients with values	167	316
Mean	165.6	168.6
SD	37.06	31.94
Median	160.0	164.0
Minimum	86	79
Maximum	368	286
Month 18		
Number of patients:		
With values	156	290
With values above reference range	1 (0.6%)	5 (1.7%)
With values below reference range	0	0
With values within reference range	155 (99.4%)	285 (98.3%)
Summary statistics:		
Number of patients with values	156	290
Mean	163.9	171.8
SD	31.22	34.82
Median	163.5	167.0
Minimum	95	71
Maximum	292	315

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	148	274
With values above reference range	3 (2.0%)	4 (1.5%)
With values below reference range	0	0
With values within reference range	145 (98.0%)	270 (98.5%)
Summary statistics:		
Number of patients with values	148	274
Mean	162.0	172.4
SD	42.27	34.98
Median	155.5	169.5
Minimum	69	71
Maximum	428	290
Month 24		
Number of patients:		
With values	129	247
With values above reference range	1 (0.8%)	3 (1.2%)
With values below reference range	0	0
With values within reference range	128 (99.2%)	244 (98.8%)
Summary statistics:		
Number of patients with values	129	247
Mean	162.7	172.0
SD	35.53	36.17
Median	159.0	170.0
Minimum	79	67
Maximum	379	306

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	120	225
With values above reference range	3 (2.5%)	3 (1.3%)
With values below reference range	0	0
With values within reference range	117 (97.5%)	222 (98.7%)
Summary statistics:		
Number of patients with values	120	225
Mean	164.0	174.8
SD	37.98	40.41
Median	161.0	173.0
Minimum	61	78
Maximum	340	478
Month 30		
Number of patients:		
With values	106	180
With values above reference range	1 (0.9%)	5 (2.8%)
With values below reference range	0	0
With values within reference range	105 (99.1%)	175 (97.2%)
Summary statistics:		
Number of patients with values	106	180
Mean	166.0	178.2
SD	37.32	35.67
Median	161.0	175.5
Minimum	70	87
Maximum	419	317

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	93	155
With values above reference range	1 (1.1%)	1 (0.6%)
With values below reference range	0	0
With values within reference range	92 (98.9%)	154 (99.4%)
Summary statistics:		
Number of patients with values	93	155
Mean	165.1	174.4
SD	35.83	34.31
Median	162.0	171.0
Minimum	64	91
Maximum	328	270
Month 36		
Number of patients:		
With values	84	79
With values above reference range	2 (2.4%)	1 (1.3%)
With values below reference range	0	0
With values within reference range	82 (97.6%)	78 (98.7%)
Summary statistics:		
Number of patients with values	84	79
Mean	169.7	172.8
SD	35.85	33.29
Median	163.0	168.0
Minimum	99	111
Maximum	304	265

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	48	14
With values above reference range	1 (2.1%)	1 (7.1%)
With values below reference range	0	0
With values within reference range	47 (97.9%)	13 (92.9%)
Summary statistics:		
Number of patients with values	48	14
Mean	163.4	172.2
SD	37.20	41.66
Median	155.5	175.0
Minimum	110	114
Maximum	290	263
Month 42		
Number of patients:		
With values	32	0
With values above reference range	1 (3.1%)	
With values below reference range	0	
With values within reference range	31 (96.9%)	
Summary statistics:		
Number of patients with values	32	0
Mean	163.0	
SD	32.17	
Median	159.5	
Minimum	120	
Maximum	305	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	19	0
With values above reference range	1 (5.3%)	
With values below reference range	0	
With values within reference range	18 (94.7%)	
Summary statistics:		
Number of patients with values	19	0
Mean	162.8	
SD	63.76	
Median	137.0	
Minimum	96	
Maximum	360	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 0		
Number of patients:		
With values	21	22
With values above reference range	9 (42.9%)	9 (40.9%)
With values below reference range	0	0
With values within reference range	12 (57.1%)	13 (59.1%)
Summary statistics:		
Number of patients with values	21	22
Mean	220.6	193.3
SD	134.92	118.32
Median	182.0	173.5
Minimum	79	67
Maximum	558	487
Open Label Baseline		
Number of patients:		
With values	229	426
With values above reference range	78 (34.1%)	122 (28.6%)
With values below reference range	0	0
With values within reference range	151 (65.9%)	304 (71.4%)
Summary statistics:		
Number of patients with values	229	426
Mean	193.4	173.6
SD	119.09	108.88
Median	158.0	146.5
Minimum	35	42
Maximum	813	911

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 1		
Number of patients:		
With values	3	11
With values above reference range	1 (33.3%)	4 (36.4%)
With values below reference range	0	0
With values within reference range	2 (66.7%)	7 (63.6%)
Summary statistics:		
Number of patients with values	3	11
Mean	162.7	186.5
SD	87.30	125.27
Median	180.0	129.0
Minimum	68	80
Maximum	240	440
Month 2		
Number of patients:		
With values	6	5
With values above reference range	2 (33.3%)	1 (20.0%)
With values below reference range	0	0
With values within reference range	4 (66.7%)	4 (80.0%)
Summary statistics:		
Number of patients with values	6	5
Mean	182.8	133.0
SD	77.91	58.89
Median	160.0	115.0
Minimum	112	64
Maximum	313	223

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 3		
Number of patients:		
With values	13	26
With values above reference range	5 (38.5%)	9 (34.6%)
With values below reference range	0	0
With values within reference range	8 (61.5%)	17 (65.4%)
Summary statistics:		
Number of patients with values	13	26
Mean	158.5	173.8
SD	55.17	90.85
Median	150.0	140.0
Minimum	73	58
Maximum	246	388
Month 6		
Number of patients:		
With values	198	360
With values above reference range	70 (35.4%)	118 (32.8%)
With values below reference range	0	0
With values within reference range	128 (64.6%)	242 (67.2%)
Summary statistics:		
Number of patients with values	198	360
Mean	193.7	182.8
SD	113.41	123.32
Median	164.0	144.0
Minimum	38	37
Maximum	584	801

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 9		
Number of patients:		
With values	9	29
With values above reference range	3 (33.3%)	14 (48.3%)
With values below reference range	0	0
With values within reference range	6 (66.7%)	15 (51.7%)
Summary statistics:		
Number of patients with values	9	29
Mean	184.4	224.2
SD	52.23	156.53
Median	178.0	181.0
Minimum	94	33
Maximum	285	638
Month 12		
Number of patients:		
With values	176	321
With values above reference range	65 (36.9%)	94 (29.3%)
With values below reference range	0	0
With values within reference range	111 (63.1%)	227 (70.7%)
Summary statistics:		
Number of patients with values	176	321
Mean	195.0	175.9
SD	110.54	132.89
Median	161.0	142.0
Minimum	49	40
Maximum	598	1612

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 15		
Number of patients:		
With values	22	30
With values above reference range	5 (22.7%)	10 (33.3%)
With values below reference range	0	0
With values within reference range	17 (77.3%)	20 (66.7%)
Summary statistics:		
Number of patients with values	22	30
Mean	176.1	182.0
SD	115.04	118.39
Median	150.0	150.5
Minimum	56	51
Maximum	495	604
Month 18		
Number of patients:		
With values	150	274
With values above reference range	50 (33.3%)	71 (25.9%)
With values below reference range	0	0
With values within reference range	100 (66.7%)	203 (74.1%)
Summary statistics:		
Number of patients with values	150	274
Mean	183.6	173.2
SD	101.61	120.07
Median	158.5	134.5
Minimum	37	39
Maximum	558	897

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 21		
Number of patients:		
With values	13	13
With values above reference range	4 (30.8%)	4 (30.8%)
With values below reference range	0	0
With values within reference range	9 (69.2%)	9 (69.2%)
Summary statistics:		
Number of patients with values	13	13
Mean	174.4	195.8
SD	51.87	163.05
Median	183.0	135.0
Minimum	82	59
Maximum	250	684
Month 24		
Number of patients:		
With values	122	222
With values above reference range	43 (35.2%)	50 (22.5%)
With values below reference range	0	0
With values within reference range	79 (64.8%)	172 (77.5%)
Summary statistics:		
Number of patients with values	122	222
Mean	184.4	156.9
SD	111.57	101.75
Median	151.0	128.5
Minimum	54	53
Maximum	622	972

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 27		
Number of patients:		
With values	18	22
With values above reference range	10 (55.6%)	7 (31.8%)
With values below reference range	0	0
With values within reference range	8 (44.4%)	15 (68.2%)
Summary statistics:		
Number of patients with values	18	22
Mean	222.9	183.2
SD	124.01	135.97
Median	213.0	130.0
Minimum	63	43
Maximum	517	658
Month 30		
Number of patients:		
With values	99	157
With values above reference range	35 (35.4%)	35 (22.3%)
With values below reference range	0	0
With values within reference range	64 (64.6%)	122 (77.7%)
Summary statistics:		
Number of patients with values	99	157
Mean	197.7	159.4
SD	164.47	111.57
Median	152.0	129.0
Minimum	49	42
Maximum	1301	900

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 33		
Number of patients:		
With values	12	54
With values above reference range	5 (41.7%)	17 (31.5%)
With values below reference range	0	0
With values within reference range	7 (58.3%)	37 (68.5%)
Summary statistics:		
Number of patients with values	12	54
Mean	197.7	184.1
SD	118.94	97.77
Median	165.0	164.0
Minimum	90	40
Maximum	517	619
Month 36		
Number of patients:		
With values	71	61
With values above reference range	23 (32.4%)	7 (11.5%)
With values below reference range	0	0
With values within reference range	48 (67.6%)	54 (88.5%)
Summary statistics:		
Number of patients with values	71	61
Mean	182.2	137.2
SD	114.72	83.38
Median	161.0	127.0
Minimum	48	47
Maximum	882	596

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Entered Study 009
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 39		
Number of patients:		
With values	17	11
With values above reference range	7 (41.2%)	2 (18.2%)
With values below reference range	0	0
With values within reference range	10 (58.8%)	9 (81.8%)
Summary statistics:		
Number of patients with values	17	11
Mean	177.1	133.7
SD	81.29	86.95
Median	188.0	96.0
Minimum	73	35
Maximum	374	312
Month 42		
Number of patients:		
With values	28	0
With values above reference range	7 (25.0%)	
With values below reference range	0	
With values within reference range	21 (75.0%)	
Summary statistics:		
Number of patients with values	28	0
Mean	161.1	
SD	69.06	
Median	147.0	
Minimum	70	
Maximum	286	

BRL 49653C/009

Data Source Table 15.7.1a

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Entered Study 009
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	2bd Comb Total	4bd Mono Total
Month 45		
Number of patients:		
With values	14	0
With values above reference range	1 (7.1%)	
With values below reference range	0	
With values within reference range	13 (92.9%)	
Summary statistics:		
Number of patients with values	14	0
Mean	150.2	
SD	79.60	
Median	131.0	
Minimum	81	
Maximum	403	

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	1 (16.7%)	0	0
With values below reference range	0	1 (11.1%)	2 (25.0%)
With values within reference range	5 (83.3%)	8 (88.9%)	6 (75.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	15.07	14.90	13.86
SD	0.575	0.973	1.318
Median	15.25	15.20	13.70
Minimum	14.1	13.1	12.0
Maximum	15.6	16.2	15.7
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	2 (2.6%)	1 (1.1%)
With values below reference range	1 (1.6%)	8 (10.3%)	10 (11.1%)
With values within reference range	59 (96.7%)	68 (87.2%)	79 (87.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	14.80	14.27	13.83
SD	1.067	1.333	1.219
Median	14.90	14.30	13.90
Minimum	11.9	8.6	10.0
Maximum	16.9	16.8	16.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	15.65		
SD	0.212		
Median	15.65		
Minimum	15.5		
Maximum	15.8		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			14.40
SD			1.134
Median			14.90
Minimum			12.6
Maximum			15.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	1 (1.3%)	0
With values below reference range	4 (7.3%)	9 (11.8%)	11 (13.6%)
With values within reference range	51 (92.7%)	66 (86.8%)	70 (86.4%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	13.98	14.08	13.65
SD	1.191	1.221	1.148
Median	13.90	14.05	13.70
Minimum	11.3	10.9	10.8
Maximum	16.2	16.7	16.4
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	1 (1.4%)	0
With values below reference range	4 (7.3%)	6 (8.7%)	12 (15.2%)
With values within reference range	51 (92.7%)	62 (89.9%)	67 (84.8%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	14.14	14.15	13.70
SD	1.218	1.163	1.308
Median	14.30	14.30	13.70
Minimum	11.5	10.8	8.5
Maximum	16.5	16.6	16.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	1 (1.8%)	1 (1.5%)	1 (1.3%)
With values below reference range	4 (7.3%)	7 (10.3%)	6 (7.9%)
With values within reference range	50 (90.9%)	60 (88.2%)	69 (90.8%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	13.99	14.07	13.81
SD	1.425	1.181	1.292
Median	14.00	14.05	13.95
Minimum	9.0	11.2	9.5
Maximum	17.0	16.3	16.2
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	0	2 (3.3%)	0
With values below reference range	2 (3.8%)	8 (13.3%)	9 (13.2%)
With values within reference range	51 (96.2%)	50 (83.3%)	59 (86.8%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	13.95	13.91	13.72
SD	1.268	1.173	1.319
Median	13.90	13.95	13.60
Minimum	11.7	11.3	11.0
Maximum	16.6	16.9	17.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	0	1 (1.9%)	1 (1.6%)
With values below reference range	2 (4.3%)	8 (14.8%)	6 (9.5%)
With values within reference range	45 (95.7%)	45 (83.3%)	56 (88.9%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	14.21	13.94	13.75
SD	1.317	1.299	1.270
Median	14.30	14.10	13.70
Minimum	11.6	10.9	10.5
Maximum	16.8	16.7	16.4
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	1 (1.9%)	1 (1.7%)
With values below reference range	3 (6.7%)	7 (13.5%)	6 (10.3%)
With values within reference range	42 (93.3%)	44 (84.6%)	51 (87.9%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	14.11	14.01	13.71
SD	1.080	1.366	1.185
Median	14.00	13.85	13.60
Minimum	11.7	10.9	11.1
Maximum	16.7	17.2	16.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	2 (4.0%)	0
With values below reference range	3 (7.0%)	4 (8.0%)	7 (11.9%)
With values within reference range	40 (93.0%)	44 (88.0%)	52 (88.1%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	14.08	14.05	13.88
SD	1.160	1.306	1.085
Median	14.20	14.05	13.70
Minimum	11.6	11.3	11.9
Maximum	16.4	17.3	16.4
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	1 (2.6%)	1 (1.9%)
With values below reference range	3 (8.3%)	7 (17.9%)	3 (5.7%)
With values within reference range	33 (91.7%)	31 (79.5%)	49 (92.5%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	13.94	13.99	14.11
SD	1.300	1.348	1.280
Median	14.20	14.20	13.80
Minimum	10.2	10.9	11.6
Maximum	16.7	16.5	17.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	1 (2.6%)	1 (2.3%)
With values below reference range	2 (5.6%)	4 (10.3%)	2 (4.7%)
With values within reference range	34 (94.4%)	34 (87.2%)	40 (93.0%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	14.08	14.13	14.09
SD	1.119	1.308	1.330
Median	13.90	14.20	13.90
Minimum	11.4	11.6	11.2
Maximum	16.7	16.7	16.8
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	0	3 (6.8%)
With values below reference range	0	5 (15.6%)	4 (9.1%)
With values within reference range	28 (100.0%)	27 (84.4%)	37 (84.1%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	14.13	13.89	13.93
SD	1.205	1.035	1.328
Median	14.10	13.80	13.55
Minimum	12.1	11.0	11.8
Maximum	16.4	15.9	17.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	1 (4.0%)	1 (3.1%)	1 (2.9%)
With values below reference range	1 (4.0%)	5 (15.6%)	3 (8.8%)
With values within reference range	23 (92.0%)	26 (81.3%)	30 (88.2%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	14.38	13.99	13.60
SD	1.422	1.447	1.179
Median	14.20	14.25	13.35
Minimum	10.9	11.0	11.7
Maximum	17.8	16.5	16.5
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	1 (3.7%)	1 (3.8%)	1 (3.3%)
With values below reference range	1 (3.7%)	3 (11.5%)	5 (16.7%)
With values within reference range	25 (92.6%)	22 (84.6%)	24 (80.0%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	13.96	13.85	13.41
SD	1.293	1.169	1.280
Median	13.80	13.80	13.20
Minimum	11.6	11.5	10.1
Maximum	17.4	16.1	16.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	1 (6.7%)	1 (6.7%)	0
With values below reference range	0	2 (13.3%)	1 (5.3%)
With values within reference range	14 (93.3%)	12 (80.0%)	18 (94.7%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	14.38	13.73	13.87
SD	1.587	1.366	1.162
Median	14.50	13.70	13.80
Minimum	11.2	11.3	11.9
Maximum	17.0	16.4	16.0
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	2 (13.3%)	1 (11.1%)
With values within reference range	8 (100.0%)	13 (86.7%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	14.34	13.53	13.43
SD	1.207	1.141	1.213
Median	14.10	13.70	14.10
Minimum	12.9	11.4	10.9
Maximum	16.3	15.6	14.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	1 (14.3%)
With values below reference range	0	1 (20.0%)	0
With values within reference range	6 (85.7%)	4 (80.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	14.46	13.10	13.99
SD	1.771	0.660	1.702
Median	14.50	13.10	14.00
Minimum	11.7	12.3	11.3
Maximum	17.3	14.1	16.0

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	1 (11.1%)	0
With values below reference range	0	1 (11.1%)	2 (25.0%)
With values within reference range	6 (100.0%)	7 (77.8%)	6 (75.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	44.17	44.32	40.76
SD	1.433	3.195	4.062
Median	44.75	44.80	40.60
Minimum	41.4	38.9	35.3
Maximum	45.3	48.5	46.8
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	3 (4.9%)	4 (5.1%)	2 (2.2%)
With values below reference range	1 (1.6%)	9 (11.5%)	10 (11.1%)
With values within reference range	57 (93.4%)	65 (83.3%)	78 (86.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	44.05	42.41	41.37
SD	3.135	3.891	3.578
Median	44.50	42.80	41.70
Minimum	35.9	26.2	30.6
Maximum	50.6	52.0	50.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	46.35		
SD	0.919		
Median	46.35		
Minimum	45.7		
Maximum	47.0		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			1 (20.0%)
With values below reference range			0
With values within reference range			4 (80.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			43.42
SD			3.720
Median			44.70
Minimum			37.2
Maximum			47.0

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	1 (1.8%)	2 (2.6%)	2 (2.5%)
With values below reference range	6 (10.9%)	11 (14.5%)	11 (13.6%)
With values within reference range	48 (87.3%)	63 (82.9%)	68 (84.0%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	41.29	41.67	40.55
SD	3.282	3.416	3.471
Median	41.00	41.45	40.20
Minimum	34.2	32.2	31.8
Maximum	49.2	47.7	49.1
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	1 (1.8%)	3 (4.3%)	2 (2.5%)
With values below reference range	4 (7.3%)	9 (13.0%)	11 (13.9%)
With values within reference range	50 (90.9%)	57 (82.6%)	66 (83.5%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	41.89	42.19	40.95
SD	3.614	3.278	3.861
Median	42.10	42.60	40.50
Minimum	33.7	33.3	27.4
Maximum	49.2	48.7	51.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	1 (1.8%)	2 (2.9%)	2 (2.6%)
With values below reference range	6 (10.9%)	10 (14.7%)	6 (7.9%)
With values within reference range	48 (87.3%)	56 (82.4%)	68 (89.5%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	41.33	41.63	40.95
SD	3.970	3.305	3.622
Median	41.60	41.80	41.00
Minimum	29.0	33.1	30.3
Maximum	50.1	47.7	48.4
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	1 (1.9%)	2 (3.3%)	2 (2.9%)
With values below reference range	2 (3.8%)	8 (13.3%)	8 (11.8%)
With values within reference range	50 (94.3%)	50 (83.3%)	58 (85.3%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	41.68	41.44	41.05
SD	3.603	3.194	3.621
Median	41.50	41.70	40.55
Minimum	35.0	35.0	33.9
Maximum	50.2	50.1	50.9

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	3 (6.4%)	1 (1.9%)	2 (3.2%)
With values below reference range	4 (8.5%)	7 (13.0%)	5 (7.9%)
With values within reference range	40 (85.1%)	46 (85.2%)	56 (88.9%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	42.49	41.65	41.16
SD	3.709	3.747	3.689
Median	42.60	42.00	40.70
Minimum	34.8	32.7	32.3
Maximum	50.1	49.3	49.1
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	2 (3.8%)	1 (1.7%)
With values below reference range	1 (2.2%)	6 (11.5%)	5 (8.6%)
With values within reference range	44 (97.8%)	44 (84.6%)	52 (89.7%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	42.04	41.74	40.96
SD	3.050	3.746	3.401
Median	41.60	41.25	41.00
Minimum	35.2	32.8	34.4
Maximum	49.4	51.2	50.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	1 (2.3%)	4 (8.0%)	1 (1.7%)
With values below reference range	3 (7.0%)	3 (6.0%)	5 (8.5%)
With values within reference range	39 (90.7%)	43 (86.0%)	53 (89.8%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	42.09	42.07	41.45
SD	3.465	3.867	3.149
Median	42.70	41.95	41.00
Minimum	34.7	33.6	35.0
Maximum	49.7	53.8	48.7
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	1 (2.8%)	1 (2.6%)	3 (5.7%)
With values below reference range	2 (5.6%)	5 (12.8%)	3 (5.7%)
With values within reference range	33 (91.7%)	33 (84.6%)	47 (88.7%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	42.02	41.79	42.47
SD	3.681	4.074	3.932
Median	42.60	42.70	42.10
Minimum	31.6	33.5	35.6
Maximum	51.6	49.5	51.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	2 (5.6%)	2 (5.1%)	3 (7.0%)
With values below reference range	1 (2.8%)	4 (10.3%)	3 (7.0%)
With values within reference range	33 (91.7%)	33 (84.6%)	37 (86.0%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	42.62	42.61	42.75
SD	3.463	4.038	3.927
Median	42.15	42.30	42.80
Minimum	36.0	35.3	35.3
Maximum	53.5	50.8	50.7
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	1 (3.6%)	2 (6.3%)	5 (11.4%)
With values below reference range	0	3 (9.4%)	4 (9.1%)
With values within reference range	27 (96.4%)	27 (84.4%)	35 (79.5%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	42.81	42.33	42.55
SD	3.511	3.341	4.040
Median	42.75	41.85	41.70
Minimum	37.3	34.4	35.2
Maximum	52.4	50.7	50.9

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	2 (8.0%)	2 (6.3%)	2 (5.9%)
With values below reference range	0	3 (9.4%)	4 (11.8%)
With values within reference range	23 (92.0%)	27 (84.4%)	28 (82.4%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	43.84	42.61	41.51
SD	4.353	4.478	3.449
Median	43.40	42.90	40.90
Minimum	33.7	32.8	35.5
Maximum	55.0	50.2	51.0
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	1 (3.7%)	1 (3.8%)	1 (3.3%)
With values below reference range	0	3 (11.5%)	6 (20.0%)
With values within reference range	26 (96.3%)	22 (84.6%)	23 (76.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	42.45	42.22	40.88
SD	3.806	3.566	4.121
Median	42.10	41.60	40.30
Minimum	35.5	35.2	32.1
Maximum	53.6	48.8	49.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	1 (6.7%)	1 (6.7%)	1 (5.3%)
With values below reference range	0	3 (20.0%)	2 (10.5%)
With values within reference range	14 (93.3%)	11 (73.3%)	16 (84.2%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	43.23	41.39	42.09
SD	4.281	3.778	3.349
Median	44.10	41.40	42.30
Minimum	34.7	35.0	35.8
Maximum	51.3	49.0	48.2
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	1 (6.7%)	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	43.06	41.10	41.04
SD	3.199	3.473	2.751
Median	42.15	40.90	41.50
Minimum	39.2	35.2	35.3
Maximum	48.6	48.4	44.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	1 (14.3%)
With values below reference range	0	1 (20.0%)	0
With values within reference range	6 (85.7%)	4 (80.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	43.47	39.54	42.14
SD	5.168	2.629	5.313
Median	43.20	38.90	40.50
Minimum	35.9	37.2	35.2
Maximum	51.9	43.4	49.3

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	2 (25.0%)
With values within reference range	6 (100.0%)	9 (100.0%)	6 (75.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	4.80	4.97	4.45
SD	0.228	0.300	0.481
Median	4.80	5.10	4.40
Minimum	4.5	4.5	3.8
Maximum	5.1	5.3	5.1
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	2 (2.6%)	2 (2.2%)
With values below reference range	0	3 (3.8%)	6 (6.7%)
With values within reference range	60 (98.4%)	73 (93.6%)	82 (91.1%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	4.82	4.67	4.55
SD	0.374	0.419	0.411
Median	4.80	4.70	4.50
Minimum	4.0	2.9	3.4
Maximum	5.7	5.7	5.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	5.05		
SD	0.071		
Median	5.05		
Minimum	5.0		
Maximum	5.1		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			1 (20.0%)
With values below reference range			0
With values within reference range			4 (80.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			4.90
SD			0.464
Median			4.90
Minimum			4.2
Maximum			5.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	1 (1.3%)	2 (2.5%)
With values below reference range	3 (5.5%)	4 (5.3%)	5 (6.2%)
With values within reference range	52 (94.5%)	71 (93.4%)	74 (91.4%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	4.53	4.61	4.46
SD	0.396	0.417	0.395
Median	4.60	4.60	4.50
Minimum	3.7	3.6	3.3
Maximum	5.3	5.5	5.6
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	1 (1.4%)	2 (2.5%)
With values below reference range	2 (3.6%)	4 (5.8%)	6 (7.6%)
With values within reference range	53 (96.4%)	64 (92.8%)	71 (89.9%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	4.63	4.66	4.52
SD	0.378	0.383	0.422
Median	4.70	4.70	4.50
Minimum	3.8	3.7	3.1
Maximum	5.4	5.4	5.6

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	0	1 (1.5%)	1 (1.3%)
With values below reference range	2 (3.6%)	5 (7.4%)	4 (5.3%)
With values within reference range	53 (96.4%)	62 (91.2%)	71 (93.4%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	4.57	4.60	4.53
SD	0.425	0.387	0.413
Median	4.60	4.65	4.50
Minimum	3.7	3.7	3.5
Maximum	5.7	5.4	5.7
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	1 (1.9%)	1 (1.7%)	1 (1.5%)
With values below reference range	2 (3.8%)	3 (5.0%)	6 (8.8%)
With values within reference range	50 (94.3%)	56 (93.3%)	61 (89.7%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	4.62	4.58	4.54
SD	0.460	0.375	0.430
Median	4.60	4.60	4.45
Minimum	3.8	3.8	3.7
Maximum	6.1	5.4	5.8

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	1 (2.1%)	2 (3.7%)	1 (1.6%)
With values below reference range	1 (2.1%)	2 (3.7%)	3 (4.8%)
With values within reference range	45 (95.7%)	50 (92.6%)	59 (93.7%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	4.65	4.57	4.50
SD	0.435	0.452	0.450
Median	4.70	4.55	4.50
Minimum	3.8	3.6	3.6
Maximum	5.8	5.6	5.7
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	1 (2.2%)	1 (1.9%)	1 (1.7%)
With values below reference range	1 (2.2%)	3 (5.8%)	4 (6.9%)
With values within reference range	43 (95.6%)	48 (92.3%)	53 (91.4%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	4.61	4.58	4.49
SD	0.369	0.422	0.415
Median	4.50	4.50	4.40
Minimum	3.8	3.6	3.8
Maximum	5.4	5.6	6.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	2 (4.0%)	1 (1.7%)
With values below reference range	1 (2.3%)	2 (4.0%)	4 (6.8%)
With values within reference range	42 (97.7%)	46 (92.0%)	54 (91.5%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	4.59	4.61	4.53
SD	0.390	0.446	0.404
Median	4.60	4.60	4.50
Minimum	3.8	3.7	3.6
Maximum	5.5	5.9	5.6
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	1 (2.6%)	1 (1.9%)
With values below reference range	2 (5.6%)	2 (5.1%)	2 (3.8%)
With values within reference range	34 (94.4%)	36 (92.3%)	50 (94.3%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	4.56	4.56	4.59
SD	0.441	0.445	0.437
Median	4.60	4.60	4.50
Minimum	3.5	3.6	3.8
Maximum	5.5	5.3	5.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	1 (2.8%)	1 (2.6%)	1 (2.3%)
With values below reference range	1 (2.8%)	2 (5.1%)	3 (7.0%)
With values within reference range	34 (94.4%)	36 (92.3%)	39 (90.7%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	4.61	4.61	4.62
SD	0.394	0.439	0.477
Median	4.55	4.60	4.60
Minimum	3.7	3.9	3.5
Maximum	5.6	5.6	5.6
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	1 (3.1%)	2 (4.5%)
With values below reference range	0	2 (6.3%)	3 (6.8%)
With values within reference range	28 (100.0%)	29 (90.6%)	39 (88.6%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	4.62	4.59	4.59
SD	0.421	0.378	0.506
Median	4.60	4.60	4.50
Minimum	4.0	3.7	3.4
Maximum	5.5	5.7	5.9

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	1 (4.0%)	1 (3.1%)	1 (2.9%)
With values below reference range	0	2 (6.3%)	4 (11.8%)
With values within reference range	24 (96.0%)	29 (90.6%)	29 (85.3%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	4.73	4.60	4.48
SD	0.488	0.476	0.470
Median	4.70	4.70	4.45
Minimum	3.8	3.6	3.5
Maximum	6.0	5.4	5.8
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	1 (3.7%)	1 (3.8%)	1 (3.3%)
With values below reference range	1 (3.7%)	2 (7.7%)	4 (13.3%)
With values within reference range	25 (92.6%)	23 (88.5%)	25 (83.3%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	4.59	4.56	4.42
SD	0.461	0.419	0.502
Median	4.60	4.55	4.40
Minimum	3.8	3.8	3.3
Maximum	5.9	5.5	5.9

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	1 (6.7%)	1 (6.7%)	1 (5.3%)
With values below reference range	0	2 (13.3%)	2 (10.5%)
With values within reference range	14 (93.3%)	12 (80.0%)	16 (84.2%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	4.71	4.47	4.61
SD	0.482	0.479	0.490
Median	4.70	4.60	4.60
Minimum	3.9	3.7	3.5
Maximum	5.6	5.3	5.6
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	1 (12.5%)	0	0
With values within reference range	7 (87.5%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	4.76	4.47	4.40
SD	0.421	0.457	0.328
Median	4.70	4.40	4.30
Minimum	4.3	3.8	3.9
Maximum	5.4	5.6	4.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	1 (14.3%)
With values below reference range	0	1 (20.0%)	0
With values within reference range	6 (85.7%)	4 (80.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	4.71	4.32	4.70
SD	0.555	0.396	0.572
Median	4.60	4.10	4.60
Minimum	4.0	4.0	4.1
Maximum	5.7	4.8	5.7

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	92.2	89.2	91.5
SD	2.79	3.31	3.34
Median	92.5	89.0	91.5
Minimum	88	84	87
Maximum	95	94	98
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	0	0
With values below reference range	0	1 (1.3%)	1 (1.1%)
With values within reference range	60 (98.4%)	77 (98.7%)	89 (98.9%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	91.6	90.8	91.1
SD	4.01	3.96	4.24
Median	92.0	90.0	91.0
Minimum	83	80	74
Maximum	101	100	100

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	92.0		
SD	1.41		
Median	92.0		
Minimum	91		
Maximum	93		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			89.4
SD			2.30
Median			89.0
Minimum			86
Maximum			92

- 1501 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	0	2 (2.5%)
With values below reference range	1 (1.8%)	1 (1.3%)	2 (2.5%)
With values within reference range	54 (98.2%)	75 (98.7%)	77 (95.1%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	91.4	90.6	91.0
SD	4.55	3.80	4.62
Median	91.0	91.0	91.0
Minimum	81	77	78
Maximum	101	100	104
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	0	1 (1.3%)
With values below reference range	2 (3.6%)	0	0
With values within reference range	53 (96.4%)	69 (100.0%)	78 (98.7%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	90.6	90.9	90.8
SD	3.71	3.53	4.38
Median	91.0	91.0	91.0
Minimum	81	81	81
Maximum	100	100	101

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	0	0	0
With values below reference range	2 (3.6%)	0	1 (1.3%)
With values within reference range	53 (96.4%)	68 (100.0%)	75 (98.7%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	90.6	90.5	90.6
SD	4.05	3.58	3.98
Median	91.0	90.0	90.0
Minimum	79	80	81
Maximum	101	97	100
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	0	0	0
With values below reference range	3 (5.7%)	0	1 (1.5%)
With values within reference range	50 (94.3%)	60 (100.0%)	67 (98.5%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	90.6	90.7	90.7
SD	5.99	3.46	3.99
Median	91.0	91.0	91.0
Minimum	62	82	81
Maximum	100	100	100

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	47 (100.0%)	54 (100.0%)	63 (100.0%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	91.5	91.3	91.5
SD	3.82	4.04	4.20
Median	91.0	91.0	91.0
Minimum	84	80	82
Maximum	100	100	101
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	0	0
With values below reference range	0	0	1 (1.7%)
With values within reference range	45 (100.0%)	52 (100.0%)	57 (98.3%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	91.4	91.2	91.5
SD	3.29	3.24	4.37
Median	91.0	91.0	92.0
Minimum	84	82	81
Maximum	100	99	100

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	50 (100.0%)	59 (100.0%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	91.9	91.5	91.8
SD	3.74	3.77	3.63
Median	92.0	92.0	91.0
Minimum	83	82	83
Maximum	99	99	100
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	0	1 (1.9%)
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	39 (100.0%)	52 (98.1%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	92.7	91.8	92.6
SD	3.82	3.31	4.15
Median	93.0	92.0	92.0
Minimum	83	83	82
Maximum	102	99	102

- 1505 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	39 (100.0%)	43 (100.0%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	92.7	92.6	92.9
SD	3.15	3.68	4.21
Median	93.0	93.0	93.0
Minimum	86	80	85
Maximum	100	98	102
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	0	1 (2.3%)
With values below reference range	0	0	0
With values within reference range	28 (100.0%)	32 (100.0%)	43 (97.7%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	93.0	92.4	93.0
SD	3.70	4.15	3.99
Median	93.0	92.0	93.0
Minimum	85	81	84
Maximum	100	101	104

- 1506 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	0	0
With values below reference range	1 (4.0%)	0	0
With values within reference range	24 (96.0%)	32 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	92.8	92.8	93.0
SD	3.46	3.79	4.13
Median	93.0	92.0	92.0
Minimum	84	82	85
Maximum	99	100	102
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	0	1 (3.3%)
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	26 (100.0%)	29 (96.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	93.0	92.7	92.9
SD	3.58	3.83	4.14
Median	93.0	94.0	92.5
Minimum	85	82	85
Maximum	101	98	105

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	15 (100.0%)	19 (100.0%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	91.8	92.9	91.5
SD	3.45	4.72	5.02
Median	91.0	94.0	91.0
Minimum	84	81	82
Maximum	99	99	103
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	90.5	92.2	93.4
SD	3.25	4.41	5.22
Median	90.5	93.0	92.0
Minimum	85	81	84
Maximum	95	98	100

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	92.0	92.0	89.7
SD	2.38	4.00	5.31
Median	91.0	90.0	89.0
Minimum	90	88	82
Maximum	96	98	97

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	31.53	29.80	31.10
SD	1.178	1.442	1.278
Median	31.00	30.60	31.00
Minimum	30.6	28.2	29.8
Maximum	33.0	32.2	33.8
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	0
With values below reference range	0	2 (2.6%)	1 (1.1%)
With values within reference range	61 (100.0%)	76 (97.4%)	89 (98.9%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	30.73	30.52	30.38
SD	1.410	1.512	1.484
Median	30.60	30.60	30.60
Minimum	27.4	25.8	23.4
Maximum	33.8	34.6	33.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	31.00		
SD	0.566		
Median	31.00		
Minimum	30.6		
Maximum	31.4		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			29.64
SD			1.043
Median			29.80
Minimum			28.2
Maximum			30.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	3 (5.5%)	1 (1.3%)	0
With values below reference range	1 (1.8%)	2 (2.6%)	1 (1.2%)
With values within reference range	51 (92.7%)	73 (96.1%)	80 (98.8%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	30.89	30.66	30.60
SD	1.565	1.424	1.590
Median	30.60	30.60	30.60
Minimum	26.6	26.6	25.8
Maximum	34.6	35.4	33.8
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	0	0
With values below reference range	1 (1.8%)	2 (2.9%)	2 (2.5%)
With values within reference range	54 (98.2%)	67 (97.1%)	77 (97.5%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	30.56	30.45	30.35
SD	1.337	1.460	1.572
Median	30.60	30.60	30.60
Minimum	26.6	25.8	26.6
Maximum	33.0	33.8	33.8

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	1 (1.8%)	0	0
With values below reference range	3 (5.5%)	1 (1.5%)	1 (1.3%)
With values within reference range	51 (92.7%)	67 (98.5%)	75 (98.7%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	30.60	30.53	30.48
SD	1.637	1.408	1.494
Median	30.60	30.60	30.60
Minimum	25.0	26.6	26.6
Maximum	33.8	34.6	33.8
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	1 (1.9%)	0	0
With values below reference range	3 (5.7%)	2 (3.3%)	3 (4.4%)
With values within reference range	49 (92.5%)	58 (96.7%)	65 (95.6%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	30.34	30.37	30.28
SD	2.377	1.466	1.490
Median	30.60	30.60	30.60
Minimum	19.3	26.6	26.6
Maximum	35.4	34.6	33.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	1 (2.1%)	0	1 (1.6%)
With values below reference range	0	2 (3.7%)	2 (3.2%)
With values within reference range	46 (97.9%)	52 (96.3%)	60 (95.2%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	30.57	30.47	30.60
SD	1.547	1.544	1.514
Median	30.60	30.60	30.60
Minimum	27.4	26.6	25.8
Maximum	33.8	33.8	33.8
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	0	0
With values below reference range	0	1 (1.9%)	2 (3.4%)
With values within reference range	45 (100.0%)	51 (98.1%)	56 (96.6%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	30.64	30.52	30.60
SD	1.229	1.328	1.476
Median	30.60	30.60	30.60
Minimum	27.4	26.6	26.6
Maximum	33.8	33.8	33.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	1 (2.3%)	0	0
With values below reference range	0	2 (4.0%)	1 (1.7%)
With values within reference range	42 (97.7%)	48 (96.0%)	58 (98.3%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	30.69	30.52	30.75
SD	1.534	1.544	1.489
Median	30.60	30.60	30.60
Minimum	27.4	26.6	26.6
Maximum	34.6	34.6	34.6
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	0	1 (1.9%)
With values below reference range	0	1 (2.6%)	1 (1.9%)
With values within reference range	36 (100.0%)	38 (97.4%)	51 (96.2%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	30.64	30.66	30.69
SD	1.391	1.390	1.557
Median	30.60	30.60	30.60
Minimum	27.4	26.6	26.6
Maximum	33.8	33.8	36.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	0	1 (2.3%)
With values below reference range	0	1 (2.6%)	0
With values within reference range	36 (100.0%)	38 (97.4%)	42 (97.7%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	30.67	30.66	30.56
SD	1.316	1.378	1.656
Median	30.60	30.60	30.60
Minimum	27.4	26.6	27.4
Maximum	34.6	33.8	35.4
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	0	1 (2.3%)
With values below reference range	0	1 (3.1%)	0
With values within reference range	28 (100.0%)	31 (96.9%)	43 (97.7%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	30.66	30.32	30.36
SD	1.459	1.326	1.549
Median	30.60	30.20	30.60
Minimum	28.2	26.6	27.4
Maximum	34.6	33.8	35.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	0	1 (2.9%)
With values below reference range	1 (4.0%)	1 (3.1%)	0
With values within reference range	24 (96.0%)	31 (96.9%)	33 (97.1%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	30.41	30.53	30.46
SD	1.040	1.413	1.665
Median	30.60	30.60	30.60
Minimum	28.2	25.8	27.4
Maximum	33.0	33.0	34.6
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	0	1 (3.3%)
With values below reference range	0	1 (3.8%)	1 (3.3%)
With values within reference range	27 (100.0%)	25 (96.2%)	28 (93.3%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	30.54	30.32	30.49
SD	1.348	1.394	1.690
Median	30.60	30.60	30.60
Minimum	27.4	26.6	26.6
Maximum	33.8	33.0	35.4

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	0
With values below reference range	0	1 (6.7%)	1 (5.3%)
With values within reference range	15 (100.0%)	14 (93.3%)	18 (94.7%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	30.33	30.76	30.26
SD	1.158	1.768	1.965
Median	30.60	31.40	29.80
Minimum	29.0	26.6	26.6
Maximum	33.0	33.8	34.6
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	1 (11.1%)
With values within reference range	8 (100.0%)	15 (100.0%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	30.10	30.33	30.42
SD	1.126	1.532	2.183
Median	29.80	30.60	30.60
Minimum	28.2	27.4	25.8
Maximum	32.2	33.0	33.8

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	1 (14.3%)
With values within reference range	7 (100.0%)	5 (100.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	30.49	30.44	29.69
SD	0.855	1.824	2.138
Median	29.80	30.60	29.80
Minimum	29.8	28.2	25.8
Maximum	31.4	32.2	32.2

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	34.0	33.3	34.1
SD	1.10	1.00	0.35
Median	34.0	34.0	34.0
Minimum	32	32	34
Maximum	35	34	35
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	0
With values below reference range	0	1 (1.3%)	0
With values within reference range	61 (100.0%)	77 (98.7%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	33.7	33.6	33.5
SD	0.91	0.94	1.00
Median	34.0	34.0	34.0
Minimum	32	31	32
Maximum	35	35	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	2 (100.0%)		
Summary statistics:			
Number of patients with values	2	0	0
Mean	34.0		
SD	0.00		
Median	34.0		
Minimum	34		
Maximum	34		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			33.2
SD			1.10
Median			34.0
Minimum			32
Maximum			34

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	0	0
With values below reference range	1 (1.8%)	1 (1.3%)	2 (2.5%)
With values within reference range	54 (98.2%)	75 (98.7%)	79 (97.5%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	33.8	33.8	33.6
SD	0.83	0.91	1.06
Median	34.0	34.0	34.0
Minimum	31	31	31
Maximum	35	35	35
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	0	0
With values below reference range	0	1 (1.4%)	2 (2.5%)
With values within reference range	55 (100.0%)	68 (98.6%)	77 (97.5%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	33.8	33.6	33.5
SD	0.87	0.94	1.06
Median	34.0	34.0	34.0
Minimum	32	31	31
Maximum	35	35	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	0	0	0
With values below reference range	1 (1.8%)	0	1 (1.3%)
With values within reference range	54 (98.2%)	68 (100.0%)	75 (98.7%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	33.9	33.8	33.8
SD	0.86	0.88	0.92
Median	34.0	34.0	34.0
Minimum	31	32	31
Maximum	35	35	35
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	0	0	0
With values below reference range	2 (3.8%)	0	0
With values within reference range	51 (96.2%)	60 (100.0%)	68 (100.0%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	33.6	33.5	33.4
SD	1.05	0.98	1.05
Median	34.0	34.0	34.0
Minimum	31	32	32
Maximum	35	35	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	0	0	0
With values below reference range	1 (2.1%)	2 (3.7%)	2 (3.2%)
With values within reference range	46 (97.9%)	52 (96.3%)	61 (96.8%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	33.4	33.6	33.4
SD	1.04	1.02	1.01
Median	34.0	34.0	34.0
Minimum	31	31	31
Maximum	35	35	35
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	0	0
With values below reference range	0	1 (1.9%)	1 (1.7%)
With values within reference range	45 (100.0%)	51 (98.1%)	57 (98.3%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	33.5	33.6	33.3
SD	0.89	0.89	1.08
Median	34.0	34.0	34.0
Minimum	32	31	31
Maximum	35	35	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	0	0
With values below reference range	1 (2.3%)	1 (2.0%)	0
With values within reference range	42 (97.7%)	49 (98.0%)	59 (100.0%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	33.4	33.5	33.5
SD	1.03	1.01	0.88
Median	34.0	34.0	34.0
Minimum	31	31	32
Maximum	35	35	35
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	0	0
With values below reference range	1 (2.8%)	0	2 (3.8%)
With values within reference range	35 (97.2%)	39 (100.0%)	51 (96.2%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	32.9	33.4	33.2
SD	1.13	1.04	1.10
Median	32.0	34.0	34.0
Minimum	31	32	31
Maximum	35	35	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	0	0
With values below reference range	3 (8.3%)	0	1 (2.3%)
With values within reference range	33 (91.7%)	39 (100.0%)	42 (97.7%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	33.1	33.0	33.0
SD	1.17	1.09	1.08
Median	34.0	32.0	34.0
Minimum	31	32	31
Maximum	35	35	35
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	0	0
With values below reference range	1 (3.6%)	1 (3.1%)	3 (6.8%)
With values within reference range	27 (96.4%)	31 (96.9%)	41 (93.2%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	32.6	32.6	32.5
SD	1.16	1.04	1.00
Median	32.0	32.0	32.0
Minimum	31	31	31
Maximum	35	35	34

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	0	0
With values below reference range	0	0	1 (2.9%)
With values within reference range	25 (100.0%)	32 (100.0%)	33 (97.1%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	32.6	32.6	32.6
SD	0.95	0.94	1.04
Median	32.0	32.0	32.0
Minimum	32	32	31
Maximum	34	34	35
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	0	0
With values below reference range	1 (3.7%)	0	1 (3.3%)
With values within reference range	26 (96.3%)	26 (100.0%)	29 (96.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	32.8	32.6	32.6
SD	1.05	0.94	0.97
Median	32.0	32.0	32.0
Minimum	31	32	31
Maximum	34	34	34

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	15 (100.0%)	19 (100.0%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	33.3	32.9	33.1
SD	1.10	1.13	1.03
Median	34.0	32.0	34.0
Minimum	32	32	32
Maximum	35	35	34
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	1 (6.7%)	1 (11.1%)
With values within reference range	8 (100.0%)	14 (93.3%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	33.1	32.7	32.8
SD	1.25	1.18	1.20
Median	33.0	32.0	32.0
Minimum	32	31	31
Maximum	35	35	34

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	33.4	32.6	33.1
SD	0.98	1.34	1.07
Median	34.0	32.0	34.0
Minimum	32	32	32
Maximum	34	35	34

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	6.62	6.83	5.70
SD	0.458	1.856	1.358
Median	6.65	7.00	5.45
Minimum	5.8	4.1	4.1
Maximum	7.2	9.5	8.0
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	2 (2.6%)	2 (2.2%)
With values below reference range	1 (1.6%)	0	1 (1.1%)
With values within reference range	60 (98.4%)	76 (97.4%)	87 (96.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	6.74	6.88	6.63
SD	1.461	1.776	1.844
Median	6.80	6.60	6.20
Minimum	3.0	3.8	3.5
Maximum	10.5	15.0	13.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	6.10		
SD			
Median	6.10		
Minimum	6.1		
Maximum	6.1		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			7.20
SD			1.927
Median			7.20
Minimum			4.9
Maximum			10.1

- 1531 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	1 (1.8%)	2 (2.6%)	3 (3.7%)
With values below reference range	0	1 (1.3%)	0
With values within reference range	54 (98.2%)	73 (96.1%)	78 (96.3%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	6.38	6.86	6.66
SD	1.598	1.765	1.895
Median	6.20	6.70	6.30
Minimum	3.8	3.5	3.9
Maximum	11.8	11.9	13.2
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	1 (1.8%)	0	2 (2.5%)
With values below reference range	1 (1.8%)	2 (2.9%)	1 (1.3%)
With values within reference range	53 (96.4%)	67 (97.1%)	76 (96.2%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	6.59	6.54	6.48
SD	1.672	1.577	1.790
Median	6.50	6.30	6.20
Minimum	3.3	3.7	3.7
Maximum	11.1	10.8	12.5

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	2 (3.6%)	0	1 (1.3%)
With values below reference range	1 (1.8%)	0	0
With values within reference range	52 (94.5%)	68 (100.0%)	75 (98.7%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	6.43	6.55	6.46
SD	1.812	1.598	1.700
Median	6.50	6.25	6.15
Minimum	2.5	3.8	4.0
Maximum	12.8	10.8	15.0
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	2 (3.8%)	1 (1.7%)	2 (2.9%)
With values below reference range	2 (3.8%)	2 (3.3%)	1 (1.5%)
With values within reference range	49 (92.5%)	57 (95.0%)	65 (95.6%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	6.68	6.36	6.53
SD	1.937	1.616	1.975
Median	6.30	6.25	6.35
Minimum	3.5	3.5	3.6
Maximum	15.1	11.1	15.3

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	1 (2.1%)	0	3 (4.8%)
With values below reference range	0	1 (1.9%)	0
With values within reference range	46 (97.9%)	53 (98.1%)	60 (95.2%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	6.73	6.70	6.44
SD	1.646	1.772	1.786
Median	6.50	6.50	6.10
Minimum	4.4	3.7	3.8
Maximum	14.1	10.6	12.8
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	1 (1.9%)	1 (1.7%)
With values below reference range	0	0	2 (3.4%)
With values within reference range	45 (100.0%)	51 (98.1%)	55 (94.8%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	6.25	6.49	6.23
SD	1.468	1.600	1.584
Median	6.10	6.20	5.90
Minimum	4.0	3.8	3.5
Maximum	10.5	12.7	11.8

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	2 (4.0%)	2 (3.4%)
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	48 (96.0%)	57 (96.6%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	6.29	6.55	6.36
SD	1.273	1.743	1.692
Median	6.20	6.30	6.00
Minimum	4.0	4.0	3.9
Maximum	9.2	12.3	12.1
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	1 (2.8%)	2 (5.1%)	1 (1.9%)
With values below reference range	2 (5.6%)	1 (2.6%)	2 (3.8%)
With values within reference range	33 (91.7%)	36 (92.3%)	50 (94.3%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	6.28	6.46	6.60
SD	1.801	2.232	1.659
Median	5.95	6.00	6.20
Minimum	3.6	3.0	3.1
Maximum	12.1	15.6	12.2

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	0	0
With values below reference range	1 (2.8%)	1 (2.6%)	0
With values within reference range	35 (97.2%)	38 (97.4%)	43 (100.0%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	6.20	6.25	6.27
SD	1.383	1.402	1.355
Median	6.00	6.10	6.00
Minimum	3.5	3.7	3.9
Maximum	10.0	9.2	9.4
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	0	1 (3.1%)	1 (2.3%)
With values below reference range	1 (3.6%)	0	0
With values within reference range	27 (96.4%)	31 (96.9%)	43 (97.7%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	6.49	6.45	6.29
SD	1.387	1.758	1.753
Median	6.30	6.25	5.80
Minimum	3.4	3.9	3.8
Maximum	10.2	11.7	11.0

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	1 (4.0%)	0	1 (2.9%)
With values below reference range	1 (4.0%)	0	0
With values within reference range	23 (92.0%)	32 (100.0%)	33 (97.1%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	6.38	6.28	6.56
SD	1.641	1.521	1.688
Median	5.80	6.05	6.25
Minimum	4.5	3.9	3.9
Maximum	12.1	10.2	12.2
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	1 (3.7%)	1 (3.8%)	1 (3.3%)
With values below reference range	0	1 (3.8%)	0
With values within reference range	26 (96.3%)	24 (92.3%)	29 (96.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	6.14	6.50	6.23
SD	1.677	1.805	1.639
Median	5.90	6.15	6.05
Minimum	4.1	3.6	3.8
Maximum	11.4	11.5	12.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	1 (5.3%)
With values below reference range	0	1 (6.7%)	0
With values within reference range	15 (100.0%)	14 (93.3%)	18 (94.7%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	6.69	6.33	6.84
SD	1.753	1.546	1.816
Median	6.00	6.50	6.60
Minimum	4.8	3.7	4.9
Maximum	10.5	8.9	12.2
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	6.50	6.29	6.89
SD	1.507	1.372	1.349
Median	6.15	6.10	6.70
Minimum	4.8	4.1	5.1
Maximum	8.4	9.1	9.1

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	7.21	6.04	6.81
SD	1.265	1.278	1.421
Median	6.90	5.70	6.70
Minimum	5.9	4.4	5.2
Maximum	8.8	7.8	9.4

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	1 (16.7%)	1 (11.1%)	1 (12.5%)
With values within reference range	5 (83.3%)	8 (88.9%)	7 (87.5%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	52.37	52.48	53.46
SD	9.048	10.994	11.157
Median	52.60	54.80	53.95
Minimum	38.4	33.5	33.3
Maximum	65.8	71.4	66.9
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	0	1 (1.1%)
With values below reference range	3 (4.9%)	3 (3.8%)	1 (1.1%)
With values within reference range	57 (93.4%)	75 (96.2%)	88 (97.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	56.12	55.89	57.28
SD	10.202	8.782	8.282
Median	56.30	56.55	56.50
Minimum	19.4	33.5	33.3
Maximum	80.0	72.1	85.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	48.70		
SD			
Median	48.70		
Minimum	48.7		
Maximum	48.7		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			58.80
SD			6.851
Median			58.00
Minimum			51.0
Maximum			69.6

- 1541 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	2 (2.6%)	2 (2.5%)
With values below reference range	2 (3.6%)	3 (3.9%)	3 (3.7%)
With values within reference range	53 (96.4%)	71 (93.4%)	76 (93.8%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	54.98	55.53	57.74
SD	8.141	9.221	9.982
Median	55.60	54.15	57.10
Minimum	31.2	34.6	34.8
Maximum	71.4	82.5	80.9
Month 6			
Number of patients:			
With values	55	69	78
With values above reference range	2 (3.6%)	0	3 (3.8%)
With values below reference range	3 (5.5%)	4 (5.8%)	1 (1.3%)
With values within reference range	50 (90.9%)	65 (94.2%)	74 (94.9%)
Summary statistics:			
Number of patients with values	55	69	78
Mean	56.08	55.65	58.10
SD	9.203	8.699	9.680
Median	56.00	57.80	56.90
Minimum	33.7	29.4	38.9
Maximum	80.2	70.4	87.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	75
With values above reference range	0	0	5 (6.7%)
With values below reference range	3 (5.5%)	2 (2.9%)	2 (2.7%)
With values within reference range	52 (94.5%)	66 (97.1%)	68 (90.7%)
Summary statistics:			
Number of patients with values	55	68	75
Mean	55.05	55.34	59.12
SD	10.852	7.488	9.502
Median	55.80	55.15	59.20
Minimum	0.9	32.5	34.8
Maximum	71.6	69.2	87.1
Month 12			
Number of patients:			
With values	53	59	68
With values above reference range	1 (1.9%)	0	1 (1.5%)
With values below reference range	2 (3.8%)	3 (5.1%)	2 (2.9%)
With values within reference range	50 (94.3%)	56 (94.9%)	65 (95.6%)
Summary statistics:			
Number of patients with values	53	59	68
Mean	56.87	55.29	58.32
SD	9.051	8.563	10.235
Median	56.10	56.40	59.45
Minimum	35.4	32.7	30.0
Maximum	75.1	72.2	77.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	63
With values above reference range	1 (2.1%)	1 (1.9%)	2 (3.2%)
With values below reference range	3 (6.4%)	3 (5.7%)	2 (3.2%)
With values within reference range	43 (91.5%)	49 (92.5%)	59 (93.7%)
Summary statistics:			
Number of patients with values	47	53	63
Mean	56.84	55.53	56.38
SD	9.258	9.559	9.497
Median	56.50	56.10	56.50
Minimum	33.1	28.4	31.5
Maximum	81.6	79.8	80.5
Month 18			
Number of patients:			
With values	44	52	58
With values above reference range	0	0	3 (5.2%)
With values below reference range	1 (2.3%)	2 (3.8%)	1 (1.7%)
With values within reference range	43 (97.7%)	50 (96.2%)	54 (93.1%)
Summary statistics:			
Number of patients with values	44	52	58
Mean	57.35	55.97	58.16
SD	8.638	9.155	8.918
Median	57.75	56.60	57.05
Minimum	39.3	17.8	37.6
Maximum	72.8	71.9	83.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	0	0
With values below reference range	2 (4.7%)	2 (4.0%)	2 (3.4%)
With values within reference range	41 (95.3%)	48 (96.0%)	57 (96.6%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	56.79	57.88	57.11
SD	8.323	8.359	8.157
Median	58.40	58.85	56.90
Minimum	21.9	34.9	38.8
Maximum	71.7	74.4	73.4
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	1 (2.8%)	2 (5.1%)	1 (1.9%)
With values below reference range	1 (2.8%)	2 (5.1%)	0
With values within reference range	34 (94.4%)	35 (89.7%)	52 (98.1%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	57.02	59.11	58.91
SD	12.703	10.323	8.425
Median	58.30	60.10	58.20
Minimum	6.7	34.4	40.6
Maximum	77.8	91.8	80.1

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	35	39	43
With values above reference range	0	0	0
With values below reference range	0	1 (2.6%)	0
With values within reference range	35 (100.0%)	38 (97.4%)	43 (100.0%)
Summary statistics:			
Number of patients with values	35	39	43
Mean	58.37	56.11	58.08
SD	6.943	8.018	6.788
Median	60.10	56.90	56.80
Minimum	44.1	33.5	46.7
Maximum	73.3	70.1	72.9
Month 30			
Number of patients:			
With values	27	32	44
With values above reference range	1 (3.7%)	1 (3.1%)	2 (4.5%)
With values below reference range	1 (3.7%)	1 (3.1%)	1 (2.3%)
With values within reference range	25 (92.6%)	30 (93.8%)	41 (93.2%)
Summary statistics:			
Number of patients with values	27	32	44
Mean	60.53	57.04	59.05
SD	8.244	9.519	8.375
Median	60.50	56.40	58.85
Minimum	38.7	37.2	37.7
Maximum	78.6	91.3	77.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	1 (4.0%)	2 (6.3%)	2 (5.9%)
With values below reference range	0	0	1 (2.9%)
With values within reference range	24 (96.0%)	30 (93.8%)	31 (91.2%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	59.42	57.41	60.30
SD	8.043	8.912	9.685
Median	60.70	56.95	60.20
Minimum	42.8	41.1	38.8
Maximum	75.1	79.6	79.3
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	2 (7.4%)	1 (3.8%)	0
With values below reference range	0	0	1 (3.3%)
With values within reference range	25 (92.6%)	25 (96.2%)	29 (96.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	58.60	60.76	57.47
SD	8.596	8.925	9.401
Median	59.20	61.65	58.50
Minimum	42.5	41.6	35.8
Maximum	81.0	84.5	74.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	1 (5.3%)
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	15 (100.0%)	18 (94.7%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	60.54	58.78	60.45
SD	6.782	6.477	8.815
Median	59.90	59.40	59.80
Minimum	52.0	46.0	46.3
Maximum	71.4	66.6	78.7
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	1 (11.1%)
With values below reference range	0	1 (6.7%)	0
With values within reference range	8 (100.0%)	14 (93.3%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	59.08	56.61	60.09
SD	6.044	8.601	9.017
Median	59.40	57.90	58.60
Minimum	48.8	39.6	49.8
Maximum	65.6	69.9	76.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	1 (14.3%)
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	5 (100.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	64.40	59.50	61.04
SD	8.496	8.142	8.208
Median	64.10	61.40	58.80
Minimum	48.0	47.7	51.6
Maximum	76.0	69.0	76.6

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	1 (16.7%)	2 (22.2%)	2 (25.0%)
With values below reference range	0	0	0
With values within reference range	5 (83.3%)	7 (77.8%)	6 (75.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	37.82	36.53	35.73
SD	8.459	9.245	11.297
Median	37.50	38.60	33.50
Minimum	26.5	20.5	23.5
Maximum	51.1	48.5	55.8
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	5 (8.2%)	8 (10.3%)	4 (4.4%)
With values below reference range	1 (1.6%)	0	1 (1.1%)
With values within reference range	55 (90.2%)	70 (89.7%)	85 (94.4%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	34.16	33.53	32.25
SD	9.473	8.342	7.967
Median	34.10	32.75	31.70
Minimum	14.4	19.1	6.4
Maximum	65.7	51.3	55.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	42.50		
SD			
Median	42.50		
Minimum	42.5		
Maximum	42.5		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			28.42
SD			6.990
Median			31.40
Minimum			18.6
Maximum			35.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	4 (7.3%)	8 (10.5%)	5 (6.2%)
With values below reference range	0	2 (2.6%)	3 (3.7%)
With values within reference range	51 (92.7%)	66 (86.8%)	73 (90.1%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	34.21	33.62	32.02
SD	8.232	8.868	9.921
Median	34.20	33.55	32.40
Minimum	18.2	10.7	7.8
Maximum	57.9	56.1	57.2
Month 6			
Number of patients:			
With values	55	69	78
With values above reference range	3 (5.5%)	9 (13.0%)	2 (2.6%)
With values below reference range	2 (3.6%)	0	6 (7.7%)
With values within reference range	50 (90.9%)	60 (87.0%)	70 (89.7%)
Summary statistics:			
Number of patients with values	55	69	78
Mean	32.93	33.93	31.83
SD	8.246	8.436	8.789
Median	33.50	31.60	32.65
Minimum	13.3	19.4	5.1
Maximum	51.6	52.9	49.6

- 1552 -

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BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	75
With values above reference range	4 (7.3%)	5 (7.4%)	3 (4.0%)
With values below reference range	0	0	4 (5.3%)
With values within reference range	51 (92.7%)	63 (92.6%)	68 (90.7%)
Summary statistics:			
Number of patients with values	55	68	75
Mean	34.50	34.04	30.77
SD	9.515	7.619	8.799
Median	33.90	33.35	31.40
Minimum	16.3	21.8	8.0
Maximum	72.9	52.9	55.0
Month 12			
Number of patients:			
With values	53	59	68
With values above reference range	3 (5.7%)	8 (13.6%)	4 (5.9%)
With values below reference range	2 (3.8%)	0	4 (5.9%)
With values within reference range	48 (90.6%)	51 (86.4%)	60 (88.2%)
Summary statistics:			
Number of patients with values	53	59	68
Mean	32.29	34.43	31.19
SD	8.632	8.186	9.467
Median	32.30	33.10	31.90
Minimum	13.9	19.5	7.7
Maximum	56.0	51.3	57.8

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	63
With values above reference range	3 (6.4%)	8 (15.1%)	5 (7.9%)
With values below reference range	2 (4.3%)	1 (1.9%)	4 (6.3%)
With values within reference range	42 (89.4%)	44 (83.0%)	54 (85.7%)
Summary statistics:			
Number of patients with values	47	53	63
Mean	32.85	34.19	33.08
SD	8.978	9.317	9.302
Median	31.60	33.80	33.40
Minimum	10.7	13.0	11.7
Maximum	57.8	55.1	52.2
Month 18			
Number of patients:			
With values	44	52	58
With values above reference range	1 (2.3%)	4 (7.7%)	2 (3.4%)
With values below reference range	0	1 (1.9%)	3 (5.2%)
With values within reference range	43 (97.7%)	47 (90.4%)	53 (91.4%)
Summary statistics:			
Number of patients with values	44	52	58
Mean	32.26	33.26	31.64
SD	8.195	8.483	8.448
Median	32.20	32.35	32.05
Minimum	17.2	13.1	10.4
Maximum	47.5	61.5	52.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	2 (4.7%)	3 (6.0%)	1 (1.7%)
With values below reference range	0	0	2 (3.4%)
With values within reference range	41 (95.3%)	47 (94.0%)	56 (94.9%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	33.11	31.61	32.27
SD	8.426	7.831	7.931
Median	32.20	30.95	32.70
Minimum	18.7	18.1	13.5
Maximum	67.3	52.4	52.2
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	3 (8.3%)	3 (7.7%)	1 (1.9%)
With values below reference range	1 (2.8%)	2 (5.1%)	3 (5.7%)
With values within reference range	32 (88.9%)	34 (87.2%)	49 (92.5%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	32.58	30.59	31.11
SD	10.875	9.498	7.719
Median	32.70	29.90	31.40
Minimum	14.9	5.0	12.3
Maximum	68.3	58.0	48.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	35	39	43
With values above reference range	0	3 (7.7%)	0
With values below reference range	0	0	1 (2.3%)
With values within reference range	35 (100.0%)	36 (92.3%)	42 (97.7%)
Summary statistics:			
Number of patients with values	35	39	43
Mean	31.51	33.19	30.73
SD	6.501	7.873	6.201
Median	31.00	32.90	31.60
Minimum	19.7	21.3	14.5
Maximum	44.5	50.0	41.7
Month 30			
Number of patients:			
With values	27	32	44
With values above reference range	1 (3.7%)	3 (9.4%)	2 (4.5%)
With values below reference range	0	1 (3.1%)	4 (9.1%)
With values within reference range	26 (96.3%)	28 (87.5%)	38 (86.4%)
Summary statistics:			
Number of patients with values	27	32	44
Mean	29.86	32.37	31.10
SD	7.470	8.962	8.845
Median	30.00	31.40	30.85
Minimum	16.2	6.4	11.0
Maximum	49.4	55.0	51.5

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	2 (6.3%)	1 (2.9%)
With values below reference range	1 (4.0%)	1 (3.1%)	3 (8.8%)
With values within reference range	24 (96.0%)	29 (90.6%)	30 (88.2%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	30.72	31.85	30.01
SD	7.657	8.289	9.062
Median	30.50	31.45	30.55
Minimum	14.8	15.8	11.0
Maximum	44.6	50.2	48.3
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	1 (3.8%)	2 (6.7%)
With values below reference range	2 (7.4%)	2 (7.7%)	2 (6.7%)
With values within reference range	25 (92.6%)	23 (88.5%)	26 (86.7%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	31.06	28.28	31.96
SD	8.010	8.379	9.367
Median	32.30	28.00	31.85
Minimum	11.4	8.9	13.2
Maximum	43.7	49.0	51.7

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	0
With values below reference range	0	0	1 (5.3%)
With values within reference range	15 (100.0%)	15 (100.0%)	18 (94.7%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	29.79	30.66	30.37
SD	5.597	5.858	8.107
Median	30.10	30.10	29.60
Minimum	21.0	22.4	11.7
Maximum	37.9	45.5	46.0
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	2 (13.3%)	0
With values below reference range	0	0	1 (11.1%)
With values within reference range	8 (100.0%)	13 (86.7%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	31.23	32.85	30.27
SD	5.811	9.284	9.452
Median	32.35	32.10	32.40
Minimum	22.7	21.4	12.6
Maximum	39.9	52.8	40.5

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	1 (14.3%)	0	1 (14.3%)
With values within reference range	6 (85.7%)	5 (100.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	24.83	29.10	29.36
SD	8.567	9.441	8.337
Median	23.40	27.80	31.20
Minimum	14.4	16.5	13.8
Maximum	41.8	41.2	41.1

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	6.42	7.30	6.83
SD	0.975	1.619	1.637
Median	6.50	7.90	6.05
Minimum	5.2	5.0	5.3
Maximum	7.5	9.7	9.8
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	1 (1.3%)	0
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	77 (98.7%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	6.21	6.72	6.67
SD	1.833	1.751	1.735
Median	6.20	6.40	6.50
Minimum	2.7	3.3	2.7
Maximum	11.0	12.7	10.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	6.30		
SD			
Median	6.30		
Minimum	6.3		
Maximum	6.3		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			7.96
SD			1.646
Median			8.30
Minimum			6.1
Maximum			10.3

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	1 (1.3%)	1 (1.2%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	75 (98.7%)	80 (98.8%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	7.16	7.29	6.81
SD	1.769	1.834	2.287
Median	7.30	7.20	6.40
Minimum	4.1	3.4	1.9
Maximum	11.5	14.6	14.3
Month 6			
Number of patients:			
With values	55	69	78
With values above reference range	1 (1.8%)	2 (2.9%)	0
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	67 (97.1%)	78 (100.0%)
Summary statistics:			
Number of patients with values	55	69	78
Mean	6.87	6.79	6.29
SD	2.083	1.944	1.808
Median	6.60	6.70	6.00
Minimum	3.1	2.9	2.9
Maximum	13.7	12.9	11.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	75
With values above reference range	1 (1.8%)	0	0
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	68 (100.0%)	75 (100.0%)
Summary statistics:			
Number of patients with values	55	68	75
Mean	7.03	6.94	6.64
SD	2.270	1.627	2.067
Median	6.70	6.85	6.20
Minimum	3.7	2.4	2.1
Maximum	18.3	10.8	11.2
Month 12			
Number of patients:			
With values	53	59	68
With values above reference range	3 (5.7%)	0	3 (4.4%)
With values below reference range	0	0	0
With values within reference range	50 (94.3%)	59 (100.0%)	65 (95.6%)
Summary statistics:			
Number of patients with values	53	59	68
Mean	6.77	6.73	6.73
SD	2.284	1.751	2.313
Median	6.30	6.70	6.35
Minimum	2.3	3.3	3.3
Maximum	12.9	11.6	14.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	63
With values above reference range	0	1 (1.9%)	1 (1.6%)
With values below reference range	0	0	0
With values within reference range	47 (100.0%)	52 (98.1%)	62 (98.4%)
Summary statistics:			
Number of patients with values	47	53	63
Mean	6.90	6.54	6.84
SD	2.068	2.087	2.073
Median	7.00	6.30	6.90
Minimum	2.7	2.7	2.4
Maximum	11.8	14.1	12.1
Month 18			
Number of patients:			
With values	44	52	58
With values above reference range	0	1 (1.9%)	1 (1.7%)
With values below reference range	0	0	0
With values within reference range	44 (100.0%)	51 (98.1%)	57 (98.3%)
Summary statistics:			
Number of patients with values	44	52	58
Mean	6.98	7.10	6.59
SD	1.899	2.032	1.759
Median	6.75	6.75	6.30
Minimum	4.2	3.5	1.5
Maximum	11.5	12.4	12.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	1 (2.0%)	2 (3.4%)
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	49 (98.0%)	57 (96.6%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	6.54	6.96	6.84
SD	1.741	1.773	2.599
Median	6.50	6.85	6.30
Minimum	3.5	3.7	2.0
Maximum	11.5	13.4	20.4
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	1 (2.8%)	0	0
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (100.0%)	53 (100.0%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	6.84	6.66	6.54
SD	3.007	2.074	1.923
Median	6.80	6.60	6.30
Minimum	0.0	1.3	3.2
Maximum	18.3	10.6	11.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	35	39	43
With values above reference range	2 (5.7%)	0	2 (4.7%)
With values below reference range	0	0	0
With values within reference range	33 (94.3%)	39 (100.0%)	41 (95.3%)
Summary statistics:			
Number of patients with values	35	39	43
Mean	6.88	6.94	7.14
SD	2.113	1.544	2.840
Median	6.40	6.80	6.80
Minimum	3.7	2.8	3.1
Maximum	12.1	10.2	17.8
Month 30			
Number of patients:			
With values	27	32	44
With values above reference range	0	1 (3.1%)	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	31 (96.9%)	44 (100.0%)
Summary statistics:			
Number of patients with values	27	32	44
Mean	6.54	6.74	6.45
SD	1.639	2.378	1.885
Median	6.50	6.45	6.55
Minimum	4.3	2.1	2.7
Maximum	11.2	14.9	10.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	1 (4.0%)	1 (3.1%)	0
With values below reference range	0	0	0
With values within reference range	24 (96.0%)	31 (96.9%)	34 (100.0%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	6.36	7.33	6.13
SD	1.592	1.960	1.984
Median	6.10	7.10	6.10
Minimum	3.5	3.3	0.1
Maximum	9.6	12.2	9.8
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	1 (3.7%)	2 (7.7%)	0
With values below reference range	0	0	0
With values within reference range	26 (96.3%)	24 (92.3%)	30 (100.0%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	6.97	7.82	6.92
SD	2.111	2.447	1.717
Median	7.00	7.60	6.50
Minimum	3.7	3.8	4.0
Maximum	12.6	13.3	10.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	14 (93.3%)	19 (100.0%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	6.81	7.20	6.15
SD	2.341	2.072	1.727
Median	6.80	6.30	6.10
Minimum	3.1	4.5	3.6
Maximum	11.4	12.5	9.7
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	5.86	6.72	6.73
SD	1.889	1.365	1.115
Median	5.40	6.90	6.90
Minimum	3.5	3.8	5.2
Maximum	9.4	9.1	8.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	1 (20.0%)	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	4 (80.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	7.26	8.64	6.59
SD	1.001	2.452	1.636
Median	7.30	8.40	6.10
Minimum	6.1	5.9	4.6
Maximum	8.9	12.2	9.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	1 (11.1%)	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	8 (88.9%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	2.98	3.17	3.58
SD	1.294	2.424	0.829
Median	2.75	2.50	3.80
Minimum	1.5	0.3	2.5
Maximum	5.3	7.6	4.5
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	3 (3.8%)	5 (5.6%)
With values below reference range	0	0	0
With values within reference range	60 (98.4%)	75 (96.2%)	85 (94.4%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	3.15	3.43	3.41
SD	1.772	1.733	1.905
Median	2.70	3.20	2.90
Minimum	0.8	0.3	0.3
Maximum	11.5	9.1	12.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	2.00		
SD			
Median	2.00		
Minimum	2.0		
Maximum	2.0		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			1 (20.0%)
With values below reference range			0
With values within reference range			4 (80.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			4.48
SD			2.489
Median			4.80
Minimum			1.1
Maximum			7.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	4 (7.3%)	0	3 (3.7%)
With values below reference range	0	0	0
With values within reference range	51 (92.7%)	76 (100.0%)	78 (96.3%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	3.28	3.13	3.05
SD	1.855	1.414	1.712
Median	2.70	2.90	2.70
Minimum	1.0	0.7	0.4
Maximum	10.0	7.0	9.3
Month 6			
Number of patients:			
With values	55	69	78
With values above reference range	6 (10.9%)	5 (7.2%)	4 (5.1%)
With values below reference range	0	0	0
With values within reference range	49 (89.1%)	64 (92.8%)	74 (94.9%)
Summary statistics:			
Number of patients with values	55	69	78
Mean	3.72	3.26	3.39
SD	2.121	1.812	2.033
Median	3.30	2.80	3.00
Minimum	0.7	0.3	0.3
Maximum	10.6	7.5	11.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	75
With values above reference range	1 (1.8%)	4 (5.9%)	1 (1.3%)
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	64 (94.1%)	74 (98.7%)
Summary statistics:			
Number of patients with values	55	68	75
Mean	3.06	3.29	3.10
SD	1.632	2.083	1.467
Median	2.60	2.80	2.90
Minimum	0.7	0.3	0.8
Maximum	7.1	13.0	7.8
Month 12			
Number of patients:			
With values	53	59	68
With values above reference range	4 (7.5%)	2 (3.4%)	5 (7.4%)
With values below reference range	0	0	0
With values within reference range	49 (92.5%)	57 (96.6%)	63 (92.6%)
Summary statistics:			
Number of patients with values	53	59	68
Mean	3.73	3.17	3.40
SD	5.024	1.673	2.526
Median	3.00	2.70	2.80
Minimum	0.5	0.0	0.3
Maximum	37.5	8.4	15.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	63
With values above reference range	2 (4.3%)	2 (3.8%)	1 (1.6%)
With values below reference range	0	0	0
With values within reference range	45 (95.7%)	51 (96.2%)	62 (98.4%)
Summary statistics:			
Number of patients with values	47	53	63
Mean	3.07	3.36	3.27
SD	1.901	1.963	1.684
Median	2.60	3.00	3.00
Minimum	0.0	0.0	0.1
Maximum	10.4	11.6	9.8
Month 18			
Number of patients:			
With values	44	52	58
With values above reference range	3 (6.8%)	2 (3.8%)	1 (1.7%)
With values below reference range	0	0	0
With values within reference range	41 (93.2%)	50 (96.2%)	57 (98.3%)
Summary statistics:			
Number of patients with values	44	52	58
Mean	3.06	3.32	3.25
SD	1.712	1.826	1.542
Median	2.40	2.90	3.10
Minimum	0.9	0.1	0.7
Maximum	7.6	9.2	9.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	3 (7.0%)	2 (4.0%)	4 (6.8%)
With values below reference range	0	0	0
With values within reference range	40 (93.0%)	48 (96.0%)	55 (93.2%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	3.23	3.18	3.45
SD	2.003	1.965	1.868
Median	2.70	2.50	3.00
Minimum	0.2	0.5	0.5
Maximum	8.0	10.1	8.9
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	2 (5.6%)	1 (2.6%)	2 (3.8%)
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	38 (97.4%)	51 (96.2%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	3.19	3.28	3.08
SD	1.820	1.851	1.582
Median	2.95	2.90	2.90
Minimum	0.4	0.9	0.7
Maximum	7.7	7.1	9.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	35	39	43
With values above reference range	0	1 (2.6%)	3 (7.0%)
With values below reference range	0	0	0
With values within reference range	35 (100.0%)	38 (97.4%)	40 (93.0%)
Summary statistics:			
Number of patients with values	35	39	43
Mean	2.89	3.38	3.69
SD	1.521	2.071	2.354
Median	2.40	2.80	3.10
Minimum	0.4	0.6	1.3
Maximum	6.3	11.2	14.0
Month 30			
Number of patients:			
With values	27	32	44
With values above reference range	1 (3.7%)	3 (9.4%)	1 (2.3%)
With values below reference range	0	0	0
With values within reference range	26 (96.3%)	29 (90.6%)	43 (97.7%)
Summary statistics:			
Number of patients with values	27	32	44
Mean	2.75	3.48	3.11
SD	1.481	2.398	1.427
Median	2.60	3.05	2.90
Minimum	0.6	0.0	0.3
Maximum	7.3	11.1	7.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	1 (3.1%)	0
With values below reference range	0	0	0
With values within reference range	25 (100.0%)	31 (96.9%)	34 (100.0%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	3.18	3.07	3.18
SD	1.630	2.036	1.311
Median	2.90	2.50	3.10
Minimum	0.4	0.2	0.4
Maximum	6.3	9.1	6.3
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	1 (3.8%)	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	25 (96.2%)	30 (100.0%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	3.01	2.95	3.30
SD	1.520	2.225	1.286
Median	2.80	2.25	3.10
Minimum	0.2	0.4	0.6
Maximum	6.2	11.6	6.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	14 (93.3%)	19 (100.0%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	2.55	3.03	2.71
SD	1.439	1.481	1.619
Median	2.30	2.50	2.50
Minimum	0.4	1.2	0.8
Maximum	5.8	7.4	6.5
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	3.50	3.48	2.60
SD	1.224	2.170	1.055
Median	3.65	3.00	2.50
Minimum	1.2	1.7	1.0
Maximum	5.1	10.1	4.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	3.13	2.48	2.64
SD	1.110	1.018	1.620
Median	3.60	2.00	2.30
Minimum	1.7	1.4	1.5
Maximum	4.8	3.8	6.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	0.42	0.51	0.43
SD	0.147	0.196	0.328
Median	0.45	0.50	0.30
Minimum	0.2	0.3	0.2
Maximum	0.6	0.8	1.2
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	78 (100.0%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	0.36	0.45	0.41
SD	0.204	0.223	0.250
Median	0.30	0.40	0.30
Minimum	0.0	0.1	0.0
Maximum	1.1	1.2	1.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	0.50		
SD			
Median	0.50		
Minimum	0.5		
Maximum	0.5		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			0.34
SD			0.114
Median			0.30
Minimum			0.2
Maximum			0.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	0	1 (1.3%)	0
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	75 (98.7%)	81 (100.0%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	0.37	0.43	0.38
SD	0.174	0.326	0.212
Median	0.40	0.40	0.30
Minimum	0.0	0.0	0.0
Maximum	1.1	2.6	1.2
Month 6			
Number of patients:			
With values	55	69	78
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	69 (100.0%)	78 (100.0%)
Summary statistics:			
Number of patients with values	55	69	78
Mean	0.40	0.36	0.39
SD	0.205	0.150	0.220
Median	0.40	0.40	0.30
Minimum	0.1	0.0	0.0
Maximum	1.3	0.8	1.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	75
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	68 (100.0%)	75 (100.0%)
Summary statistics:			
Number of patients with values	55	68	75
Mean	0.36	0.39	0.37
SD	0.158	0.166	0.170
Median	0.30	0.40	0.40
Minimum	0.1	0.0	0.0
Maximum	0.8	1.0	0.8
Month 12			
Number of patients:			
With values	53	59	68
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	53 (100.0%)	59 (100.0%)	68 (100.0%)
Summary statistics:			
Number of patients with values	53	59	68
Mean	0.33	0.37	0.36
SD	0.159	0.148	0.194
Median	0.30	0.40	0.30
Minimum	0.1	0.1	0.0
Maximum	0.8	0.8	0.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	63
With values above reference range	0	0	1 (1.6%)
With values below reference range	0	0	0
With values within reference range	47 (100.0%)	53 (100.0%)	62 (98.4%)
Summary statistics:			
Number of patients with values	47	53	63
Mean	0.34	0.38	0.44
SD	0.134	0.177	0.415
Median	0.30	0.30	0.30
Minimum	0.1	0.0	0.1
Maximum	0.7	1.0	3.4
Month 18			
Number of patients:			
With values	44	52	58
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	44 (100.0%)	52 (100.0%)	58 (100.0%)
Summary statistics:			
Number of patients with values	44	52	58
Mean	0.36	0.36	0.35
SD	0.162	0.169	0.189
Median	0.30	0.30	0.30
Minimum	0.1	0.1	0.0
Maximum	0.8	0.9	1.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	50 (100.0%)	59 (100.0%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	0.32	0.36	0.32
SD	0.131	0.147	0.175
Median	0.30	0.40	0.30
Minimum	0.1	0.1	0.0
Maximum	0.6	0.8	1.0
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	39 (100.0%)	53 (100.0%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	0.37	0.36	0.37
SD	0.159	0.202	0.193
Median	0.40	0.30	0.30
Minimum	0.1	0.0	0.1
Maximum	0.7	1.1	1.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	35	39	43
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	35 (100.0%)	39 (100.0%)	43 (100.0%)
Summary statistics:			
Number of patients with values	35	39	43
Mean	0.35	0.38	0.36
SD	0.187	0.190	0.179
Median	0.40	0.30	0.30
Minimum	0.0	0.1	0.1
Maximum	0.8	1.0	1.0
Month 30			
Number of patients:			
With values	27	32	44
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	32 (100.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	27	32	44
Mean	0.32	0.38	0.29
SD	0.147	0.180	0.139
Median	0.30	0.40	0.30
Minimum	0.0	0.1	0.1
Maximum	0.7	0.9	0.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	25 (100.0%)	32 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	0.32	0.35	0.38
SD	0.128	0.178	0.172
Median	0.30	0.30	0.40
Minimum	0.1	0.1	0.0
Maximum	0.6	0.7	0.9
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	26 (100.0%)	30 (100.0%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	0.35	0.35	0.36
SD	0.181	0.198	0.177
Median	0.30	0.30	0.30
Minimum	0.1	0.0	0.1
Maximum	0.9	0.9	0.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	15 (100.0%)	19 (100.0%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	0.32	0.33	0.32
SD	0.197	0.118	0.138
Median	0.30	0.30	0.30
Minimum	0.0	0.1	0.1
Maximum	0.7	0.6	0.6
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	0.34	0.34	0.31
SD	0.130	0.145	0.169
Median	0.30	0.30	0.30
Minimum	0.2	0.1	0.1
Maximum	0.6	0.6	0.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	0.39	0.28	0.37
SD	0.069	0.148	0.221
Median	0.40	0.30	0.40
Minimum	0.3	0.1	0.0
Maximum	0.5	0.5	0.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	1 (16.7%)	0	0
With values within reference range	5 (83.3%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	193.3	193.6	218.0
SD	42.58	36.68	40.75
Median	209.5	194.0	218.0
Minimum	110	138	164
Maximum	223	254	294
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	1 (1.1%)
With values below reference range	2 (3.3%)	1 (1.3%)	5 (5.6%)
With values within reference range	59 (96.7%)	77 (98.7%)	84 (93.3%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	209.3	214.6	218.5
SD	54.41	48.91	60.55
Median	201.0	211.0	214.5
Minimum	74	113	56
Maximum	393	327	421

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	191.0		
SD			
Median	191.0		
Minimum	191		
Maximum	191		
Month 2			
Number of patients:			
With values	0	0	5
With values above reference range			0
With values below reference range			0
With values within reference range			5 (100.0%)
Summary statistics:			
Number of patients with values	0	0	5
Mean			210.0
SD			19.69
Median			212.0
Minimum			179
Maximum			230

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	55	76	81
With values above reference range	1 (1.8%)	0	1 (1.2%)
With values below reference range	2 (3.6%)	2 (2.6%)	2 (2.5%)
With values within reference range	52 (94.5%)	74 (97.4%)	78 (96.3%)
Summary statistics:			
Number of patients with values	55	76	81
Mean	219.0	217.6	215.0
SD	57.55	51.84	53.62
Median	210.0	212.5	206.0
Minimum	122	105	111
Maximum	407	329	450
Month 6			
Number of patients:			
With values	55	69	79
With values above reference range	0	0	1 (1.3%)
With values below reference range	1 (1.8%)	2 (2.9%)	1 (1.3%)
With values within reference range	54 (98.2%)	67 (97.1%)	77 (97.5%)
Summary statistics:			
Number of patients with values	55	69	79
Mean	220.9	213.3	219.0
SD	57.68	50.80	58.53
Median	212.0	210.0	209.0
Minimum	116	115	126
Maximum	397	322	483

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	68	76
With values above reference range	0	0	2 (2.6%)
With values below reference range	3 (5.5%)	1 (1.5%)	2 (2.6%)
With values within reference range	52 (94.5%)	67 (98.5%)	72 (94.7%)
Summary statistics:			
Number of patients with values	55	68	76
Mean	214.4	212.9	215.8
SD	61.52	46.15	56.79
Median	200.0	213.5	202.0
Minimum	113	121	118
Maximum	391	308	424
Month 12			
Number of patients:			
With values	53	60	68
With values above reference range	0	0	1 (1.5%)
With values below reference range	1 (1.9%)	4 (6.7%)	2 (2.9%)
With values within reference range	52 (98.1%)	56 (93.3%)	65 (95.6%)
Summary statistics:			
Number of patients with values	53	60	68
Mean	219.3	209.6	216.9
SD	56.41	57.38	59.64
Median	208.0	210.0	203.0
Minimum	116	41	112
Maximum	394	333	521

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	63
With values above reference range	0	0	1 (1.6%)
With values below reference range	1 (2.1%)	1 (1.9%)	3 (4.8%)
With values within reference range	46 (97.9%)	53 (98.1%)	59 (93.7%)
Summary statistics:			
Number of patients with values	47	54	63
Mean	217.2	210.3	220.2
SD	50.79	44.17	67.90
Median	214.0	216.5	215.0
Minimum	120	109	44
Maximum	372	324	504
Month 18			
Number of patients:			
With values	45	52	58
With values above reference range	0	0	1 (1.7%)
With values below reference range	0	3 (5.8%)	4 (6.9%)
With values within reference range	45 (100.0%)	49 (94.2%)	53 (91.4%)
Summary statistics:			
Number of patients with values	45	52	58
Mean	217.5	220.1	225.8
SD	49.83	51.85	68.19
Median	211.0	223.0	220.5
Minimum	139	126	110
Maximum	352	347	568

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	59
With values above reference range	0	0	1 (1.7%)
With values below reference range	3 (7.0%)	1 (2.0%)	2 (3.4%)
With values within reference range	40 (93.0%)	49 (98.0%)	56 (94.9%)
Summary statistics:			
Number of patients with values	43	50	59
Mean	224.4	228.5	222.0
SD	58.17	57.42	61.71
Median	226.0	226.5	217.0
Minimum	116	122	96
Maximum	379	352	492
Month 24			
Number of patients:			
With values	36	39	53
With values above reference range	0	0	1 (1.9%)
With values below reference range	2 (5.6%)	0	3 (5.7%)
With values within reference range	34 (94.4%)	39 (100.0%)	49 (92.5%)
Summary statistics:			
Number of patients with values	36	39	53
Mean	228.6	218.2	228.0
SD	52.26	49.98	65.41
Median	230.5	220.0	221.0
Minimum	122	130	73
Maximum	342	329	488

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	43
With values above reference range	0	0	2 (4.7%)
With values below reference range	2 (5.6%)	2 (5.1%)	3 (7.0%)
With values within reference range	34 (94.4%)	37 (94.9%)	38 (88.4%)
Summary statistics:			
Number of patients with values	36	39	43
Mean	225.8	223.0	229.4
SD	54.50	53.57	87.61
Median	226.5	216.0	229.0
Minimum	119	128	43
Maximum	359	318	576
Month 30			
Number of patients:			
With values	28	32	44
With values above reference range	1 (3.6%)	0	1 (2.3%)
With values below reference range	0	1 (3.1%)	1 (2.3%)
With values within reference range	27 (96.4%)	31 (96.9%)	42 (95.5%)
Summary statistics:			
Number of patients with values	28	32	44
Mean	235.8	236.8	228.2
SD	63.78	58.22	63.35
Median	224.5	231.5	220.0
Minimum	164	126	111
Maximum	485	348	432

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	25	32	34
With values above reference range	0	0	1 (2.9%)
With values below reference range	0	2 (6.3%)	0
With values within reference range	25 (100.0%)	30 (93.8%)	33 (97.1%)
Summary statistics:			
Number of patients with values	25	32	34
Mean	238.8	237.6	232.0
SD	57.01	63.64	94.68
Median	235.0	229.5	223.5
Minimum	144	122	131
Maximum	368	357	686
Month 36			
Number of patients:			
With values	27	26	30
With values above reference range	0	0	1 (3.3%)
With values below reference range	0	1 (3.8%)	2 (6.7%)
With values within reference range	27 (100.0%)	25 (96.2%)	27 (90.0%)
Summary statistics:			
Number of patients with values	27	26	30
Mean	235.3	229.8	222.5
SD	55.72	55.19	81.91
Median	224.0	222.0	213.0
Minimum	154	110	56
Maximum	383	340	528

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count (10⁹/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	15	19
With values above reference range	0	1 (6.7%)	1 (5.3%)
With values below reference range	0	1 (6.7%)	1 (5.3%)
With values within reference range	15 (100.0%)	13 (86.7%)	17 (89.5%)
Summary statistics:			
Number of patients with values	15	15	19
Mean	235.4	244.8	248.4
SD	63.44	74.43	80.52
Median	237.0	243.0	231.0
Minimum	140	121	129
Maximum	386	419	514
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	1 (11.1%)
With values below reference range	1 (12.5%)	0	0
With values within reference range	7 (87.5%)	15 (100.0%)	8 (88.9%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	217.9	245.4	250.2
SD	64.19	48.52	85.11
Median	211.0	236.0	241.0
Minimum	117	169	168
Maximum	322	361	458

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	1 (14.3%)
With values below reference range	0	1 (20.0%)	0
With values within reference range	6 (85.7%)	4 (80.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	285.4	206.0	267.6
SD	76.55	77.71	105.84
Median	255.0	215.0	228.0
Minimum	219	113	198
Maximum	414	322	503

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	6 (100.0%)	9 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	6	9	8
Mean	1.35	1.34	1.18
SD	0.356	0.546	0.406
Median	1.30	1.10	1.00
Minimum	0.9	0.8	0.7
Maximum	1.9	2.2	1.9
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	2 (3.3%)	1 (1.3%)	2 (2.2%)
With values below reference range	0	0	0
With values within reference range	59 (96.7%)	77 (98.7%)	88 (97.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	1.42	1.46	1.36
SD	0.636	0.455	0.397
Median	1.30	1.40	1.30
Minimum	0.5	0.6	0.6
Maximum	5.0	2.5	2.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	1	0	0
With values above reference range	0		
With values below reference range	0		
With values within reference range	1 (100.0%)		
Summary statistics:			
Number of patients with values	1	0	0
Mean	0.50		
SD			
Median	0.50		
Minimum	0.5		
Maximum	0.5		
Month 2			
Number of patients:			
With values	0	0	2
With values above reference range			0
With values below reference range			0
With values within reference range			2 (100.0%)
Summary statistics:			
Number of patients with values	0	0	2
Mean			0.80
SD			0.141
Median			0.80
Minimum			0.7
Maximum			0.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	20	23	32
With values above reference range	0	0	0
With values below reference range	0	0	1 (3.1%)
With values within reference range	20 (100.0%)	23 (100.0%)	31 (96.9%)
Summary statistics:			
Number of patients with values	20	23	32
Mean	1.32	1.15	1.33
SD	0.296	0.331	0.444
Median	1.30	1.20	1.15
Minimum	0.8	0.6	0.4
Maximum	1.9	1.7	2.2
Month 6			
Number of patients:			
With values	53	68	76
With values above reference range	2 (3.8%)	3 (4.4%)	4 (5.3%)
With values below reference range	0	0	0
With values within reference range	51 (96.2%)	65 (95.6%)	72 (94.7%)
Summary statistics:			
Number of patients with values	53	68	76
Mean	1.28	1.39	1.31
SD	0.427	0.548	0.531
Median	1.30	1.35	1.20
Minimum	0.5	0.6	0.5
Maximum	2.7	3.8	3.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	42	52	57
With values above reference range	1 (2.4%)	2 (3.8%)	3 (5.3%)
With values below reference range	0	0	0
With values within reference range	41 (97.6%)	50 (96.2%)	54 (94.7%)
Summary statistics:			
Number of patients with values	42	52	57
Mean	1.33	1.40	1.39
SD	0.428	0.595	0.581
Median	1.30	1.30	1.20
Minimum	0.5	0.7	0.7
Maximum	2.6	3.8	4.1
Month 12			
Number of patients:			
With values	53	57	68
With values above reference range	1 (1.9%)	1 (1.8%)	4 (5.9%)
With values below reference range	0	0	0
With values within reference range	52 (98.1%)	56 (98.2%)	64 (94.1%)
Summary statistics:			
Number of patients with values	53	57	68
Mean	1.29	1.26	1.39
SD	0.632	0.495	0.579
Median	1.20	1.20	1.30
Minimum	0.5	0.6	0.7
Maximum	4.6	3.9	3.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	56	65
With values above reference range	2 (4.3%)	0	3 (4.6%)
With values below reference range	0	0	0
With values within reference range	45 (95.7%)	56 (100.0%)	62 (95.4%)
Summary statistics:			
Number of patients with values	47	56	65
Mean	1.30	1.27	1.34
SD	0.510	0.385	0.718
Median	1.20	1.30	1.30
Minimum	0.5	0.5	0.6
Maximum	3.1	2.0	6.1
Month 18			
Number of patients:			
With values	45	52	59
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	45 (100.0%)	52 (100.0%)	59 (100.0%)
Summary statistics:			
Number of patients with values	45	52	59
Mean	1.32	1.21	1.25
SD	0.420	0.291	0.407
Median	1.30	1.20	1.20
Minimum	0.7	0.7	0.5
Maximum	2.2	2.3	2.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	57
With values above reference range	0	0	3 (5.3%)
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	50 (100.0%)	54 (94.7%)
Summary statistics:			
Number of patients with values	43	50	57
Mean	1.24	1.17	1.29
SD	0.430	0.332	0.483
Median	1.10	1.20	1.20
Minimum	0.6	0.5	0.5
Maximum	2.3	1.9	2.8
Month 24			
Number of patients:			
With values	34	39	50
With values above reference range	1 (2.9%)	0	2 (4.0%)
With values below reference range	0	0	0
With values within reference range	33 (97.1%)	39 (100.0%)	48 (96.0%)
Summary statistics:			
Number of patients with values	34	39	50
Mean	1.26	1.11	1.31
SD	0.499	0.380	0.643
Median	1.10	1.00	1.20
Minimum	0.6	0.6	0.5
Maximum	3.1	2.1	4.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	34	36	40
With values above reference range	1 (2.9%)	1 (2.8%)	1 (2.5%)
With values below reference range	0	1 (2.8%)	0
With values within reference range	33 (97.1%)	34 (94.4%)	39 (97.5%)
Summary statistics:			
Number of patients with values	34	36	40
Mean	1.21	1.29	1.25
SD	0.444	0.456	0.460
Median	1.10	1.30	1.20
Minimum	0.6	0.4	0.6
Maximum	3.0	2.8	2.7
Month 30			
Number of patients:			
With values	26	31	44
With values above reference range	0	0	0
With values below reference range	0	0	1 (2.3%)
With values within reference range	26 (100.0%)	31 (100.0%)	43 (97.7%)
Summary statistics:			
Number of patients with values	26	31	44
Mean	1.23	1.19	1.18
SD	0.427	0.377	0.401
Median	1.10	1.10	1.15
Minimum	0.5	0.6	0.4
Maximum	2.3	2.3	2.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	23	28	34
With values above reference range	1 (4.3%)	0	2 (5.9%)
With values below reference range	0	0	1 (2.9%)
With values within reference range	22 (95.7%)	28 (100.0%)	31 (91.2%)
Summary statistics:			
Number of patients with values	23	28	34
Mean	1.10	1.25	1.26
SD	0.415	0.389	0.503
Median	1.00	1.30	1.10
Minimum	0.7	0.6	0.4
Maximum	2.5	2.0	2.4
Month 36			
Number of patients:			
With values	25	24	29
With values above reference range	1 (4.0%)	0	0
With values below reference range	0	0	0
With values within reference range	24 (96.0%)	24 (100.0%)	29 (100.0%)
Summary statistics:			
Number of patients with values	25	24	29
Mean	1.15	1.17	1.28
SD	0.525	0.256	0.487
Median	1.00	1.10	1.20
Minimum	0.6	0.8	0.6
Maximum	2.9	1.7	2.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	13	13	19
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	13 (100.0%)	13 (100.0%)	19 (100.0%)
Summary statistics:			
Number of patients with values	13	13	19
Mean	1.09	1.02	1.10
SD	0.423	0.303	0.279
Median	1.00	1.10	1.10
Minimum	0.6	0.6	0.6
Maximum	2.3	1.6	1.7
Month 42			
Number of patients:			
With values	7	13	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	13 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	13	7
Mean	1.04	1.18	1.19
SD	0.282	0.274	0.430
Median	0.90	1.10	1.20
Minimum	0.8	0.8	0.6
Maximum	1.4	1.6	1.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	8	4	6
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	4 (100.0%)	6 (100.0%)
Summary statistics:			
Number of patients with values	8	4	6
Mean	1.19	1.08	1.10
SD	0.285	0.359	0.335
Median	1.10	0.95	1.10
Minimum	0.8	0.8	0.6
Maximum	1.7	1.6	1.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	15.4	11.8	12.1
SD	3.78	1.91	1.73
Median	16.0	11.0	11.5
Minimum	11	9	10
Maximum	21	15	15
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	3 (4.9%)	2 (2.6%)	0
With values below reference range	0	0	0
With values within reference range	58 (95.1%)	76 (97.4%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	14.1	12.2	10.8
SD	5.34	4.40	2.88
Median	13.0	11.0	10.5
Minimum	6	7	6
Maximum	38	36	21

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	16.5	13.0	
SD	4.95		
Median	16.5	13.0	
Minimum	13	13	
Maximum	20	13	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	7.0	11.0	11.2
SD		1.41	2.95
Median	7.0	11.0	10.0
Minimum	7	10	9
Maximum	7	12	16

- 1611 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	1 (1.8%)	1 (1.4%)	0
With values below reference range	0	0	0
With values within reference range	55 (98.2%)	73 (98.6%)	82 (100.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	12.4	12.3	11.3
SD	3.48	3.13	2.80
Median	12.0	11.0	10.0
Minimum	6	8	7
Maximum	24	24	19
Month 6			
Number of patients:			
With values	55	70	80
With values above reference range	2 (3.6%)	0	0
With values below reference range	0	0	0
With values within reference range	53 (96.4%)	70 (100.0%)	80 (100.0%)
Summary statistics:			
Number of patients with values	55	70	80
Mean	12.1	11.7	10.8
SD	3.57	3.14	2.74
Median	11.0	11.0	10.0
Minimum	7	6	6
Maximum	24	22	18

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	2 (3.6%)	1 (1.5%)	0
With values below reference range	0	0	0
With values within reference range	53 (96.4%)	66 (98.5%)	74 (100.0%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	12.5	11.8	11.1
SD	4.37	3.07	2.87
Median	11.0	11.0	11.0
Minimum	8	7	6
Maximum	32	24	19
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	1 (1.9%)	1 (1.7%)	1 (1.5%)
With values below reference range	0	0	0
With values within reference range	51 (98.1%)	57 (98.3%)	66 (98.5%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	12.3	11.7	11.2
SD	4.17	3.41	3.39
Median	12.0	11.0	10.0
Minimum	7	6	5
Maximum	30	25	23

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	66
With values above reference range	2 (4.3%)	1 (1.9%)	1 (1.5%)
With values below reference range	0	0	0
With values within reference range	45 (95.7%)	53 (98.1%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	54	66
Mean	12.7	11.3	10.6
SD	5.33	3.94	3.35
Median	11.0	10.0	10.0
Minimum	7	7	6
Maximum	34	33	23
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	1 (2.2%)	1 (2.0%)	0
With values below reference range	0	0	0
With values within reference range	44 (97.8%)	50 (98.0%)	60 (100.0%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	11.5	11.0	9.8
SD	5.46	3.46	2.67
Median	11.0	10.0	9.0
Minimum	3	6	5
Maximum	39	25	17

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	1 (2.0%)	0
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	49 (98.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	11.6	10.7	9.6
SD	5.13	3.60	2.78
Median	11.0	10.0	10.0
Minimum	6	4	4
Maximum	40	24	16
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	0	0
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	41 (100.0%)	52 (100.0%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	10.6	10.7	9.7
SD	3.74	3.74	3.11
Median	10.5	10.0	10.0
Minimum	5	6	4
Maximum	23	22	18

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	2 (5.0%)	0
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	38 (95.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	10.2	11.3	9.2
SD	3.79	4.76	2.76
Median	10.0	10.0	9.0
Minimum	6	6	5
Maximum	26	29	15
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	0	3 (8.6%)	0
With values below reference range	0	0	0
With values within reference range	29 (100.0%)	32 (91.4%)	42 (100.0%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	10.2	11.5	9.6
SD	2.98	7.39	2.74
Median	10.0	9.0	10.0
Minimum	5	4	5
Maximum	19	41	16

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	1 (3.8%)	1 (3.0%)	0
With values below reference range	0	0	0
With values within reference range	25 (96.2%)	32 (97.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	10.5	10.5	9.5
SD	4.27	4.15	3.74
Median	10.0	10.0	9.0
Minimum	5	5	3
Maximum	24	24	22
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	3 (11.5%)	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	23 (88.5%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	10.3	11.7	9.6
SD	3.47	8.30	3.15
Median	10.0	9.0	10.0
Minimum	5	1	4
Maximum	21	37	21

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	1 (7.1%)	0
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	13 (92.9%)	20 (100.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	10.6	11.6	9.4
SD	4.68	6.36	3.53
Median	11.0	9.0	9.0
Minimum	5	4	5
Maximum	21	27	18
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	8.8	10.1	9.3
SD	2.38	4.91	3.08
Median	9.0	9.0	10.0
Minimum	6	6	4
Maximum	13	22	13

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	9.3	11.0	10.1
SD	2.98	6.20	3.44
Median	9.0	8.0	10.0
Minimum	5	6	5
Maximum	13	21	15

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	72.8	72.6	70.8
SD	3.42	5.13	2.71
Median	73.0	72.0	71.0
Minimum	68	67	65
Maximum	76	81	74
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	2 (2.6%)	0
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	76 (97.4%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	72.1	72.4	72.0
SD	3.64	4.61	4.08
Median	72.0	72.0	72.0
Minimum	64	62	63
Maximum	81	83	81

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	73.0	72.0	
SD	2.83		
Median	73.0	72.0	
Minimum	71	72	
Maximum	75	72	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	69.0	71.0	72.2
SD		0.00	1.30
Median	69.0	71.0	72.0
Minimum	69	71	71
Maximum	69	71	74

- 1621 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	56 (100.0%)	74 (100.0%)	82 (100.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	71.3	71.4	71.0
SD	3.49	4.54	4.25
Median	71.0	71.0	71.0
Minimum	64	63	61
Maximum	80	83	80
Month 6			
Number of patients:			
With values	54	71	79
With values above reference range	1 (1.9%)	1 (1.4%)	1 (1.3%)
With values below reference range	0	0	0
With values within reference range	53 (98.1%)	70 (98.6%)	78 (98.7%)
Summary statistics:			
Number of patients with values	54	71	79
Mean	71.3	71.9	71.0
SD	3.84	4.65	4.12
Median	71.0	72.0	70.0
Minimum	63	63	62
Maximum	83	85	82

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	2 (3.0%)	0
With values below reference range	0	1 (1.5%)	0
With values within reference range	55 (100.0%)	64 (95.5%)	74 (100.0%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	70.3	71.5	70.1
SD	4.02	4.71	4.18
Median	71.0	71.0	70.0
Minimum	61	59	61
Maximum	80	83	82
Month 12			
Number of patients:			
With values	51	58	66
With values above reference range	0	1 (1.7%)	0
With values below reference range	0	0	0
With values within reference range	51 (100.0%)	57 (98.3%)	66 (100.0%)
Summary statistics:			
Number of patients with values	51	58	66
Mean	70.2	70.3	69.9
SD	3.76	4.57	4.20
Median	70.0	69.5	70.0
Minimum	63	62	60
Maximum	79	82	78

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	66
With values above reference range	0	0	1 (1.5%)
With values below reference range	0	1 (1.9%)	0
With values within reference range	47 (100.0%)	52 (98.1%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	53	66
Mean	70.7	70.5	70.0
SD	3.11	4.71	4.91
Median	71.0	70.0	70.0
Minimum	63	59	61
Maximum	77	83	91
Month 18			
Number of patients:			
With values	44	51	60
With values above reference range	0	1 (2.0%)	1 (1.7%)
With values below reference range	0	2 (3.9%)	1 (1.7%)
With values within reference range	44 (100.0%)	48 (94.1%)	58 (96.7%)
Summary statistics:			
Number of patients with values	44	51	60
Mean	71.5	71.1	70.6
SD	3.01	5.45	4.43
Median	71.5	71.0	70.0
Minimum	65	56	59
Maximum	78	88	82

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	0	1 (2.0%)	0
With values below reference range	0	1 (2.0%)	0
With values within reference range	43 (100.0%)	48 (96.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	71.4	72.3	70.5
SD	3.22	5.61	4.49
Median	72.0	73.0	70.0
Minimum	65	58	61
Maximum	79	91	81
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	1 (2.4%)	0
With values below reference range	0	1 (2.4%)	0
With values within reference range	35 (97.2%)	39 (95.1%)	52 (100.0%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	72.4	72.9	72.4
SD	3.84	4.70	4.76
Median	72.5	72.0	72.0
Minimum	65	59	60
Maximum	82	82	82

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	1 (2.5%)	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	39 (97.5%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	73.0	73.3	72.4
SD	3.22	4.66	3.81
Median	74.0	73.0	72.5
Minimum	67	60	63
Maximum	80	84	81
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	1 (3.4%)	2 (5.7%)	0
With values below reference range	0	0	0
With values within reference range	28 (96.6%)	33 (94.3%)	44 (100.0%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	72.5	73.2	72.1
SD	4.17	4.88	4.58
Median	72.0	74.0	72.0
Minimum	64	61	63
Maximum	82	84	80

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	1 (3.8%)	1 (2.9%)	0
With values below reference range	0	0	0
With values within reference range	25 (96.2%)	33 (97.1%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	72.3	73.1	71.3
SD	4.31	5.31	4.33
Median	71.5	74.0	71.5
Minimum	67	61	61
Maximum	84	83	79
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	3 (11.5%)	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	23 (88.5%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	71.7	73.4	72.0
SD	3.28	6.92	4.30
Median	73.0	73.0	73.0
Minimum	63	61	61
Maximum	76	94	79

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	14 (100.0%)	20 (100.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	71.6	70.2	70.2
SD	3.91	4.54	4.38
Median	73.0	69.0	70.0
Minimum	62	64	60
Maximum	76	82	79
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	70.5	72.5	67.6
SD	4.57	5.95	4.82
Median	70.0	72.0	67.0
Minimum	65	61	60
Maximum	80	82	75

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	72.3	68.8	71.3
SD	3.68	3.49	4.79
Median	73.0	67.0	69.0
Minimum	66	65	66
Maximum	78	73	78

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	42.8	42.3	41.6
SD	2.17	2.49	2.20
Median	44.0	42.5	42.0
Minimum	40	37	38
Maximum	45	45	45
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	78 (100.0%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	43.0	42.7	42.7
SD	2.19	2.24	1.99
Median	43.0	43.0	43.0
Minimum	37	37	38
Maximum	47	49	48

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	45.5	43.0	
SD	0.71		
Median	45.5	43.0	
Minimum	45	43	
Maximum	46	43	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	44.0	43.0	42.8
SD		0.00	1.79
Median	44.0	43.0	43.0
Minimum	44	43	40
Maximum	44	43	45

- 1631 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	56 (100.0%)	74 (100.0%)	82 (100.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	42.5	42.1	42.2
SD	1.87	2.32	2.22
Median	43.0	42.0	42.0
Minimum	37	36	38
Maximum	48	48	48
Month 6			
Number of patients:			
With values	54	70	79
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	54 (100.0%)	70 (100.0%)	79 (100.0%)
Summary statistics:			
Number of patients with values	54	70	79
Mean	42.4	42.3	42.2
SD	2.19	2.18	1.90
Median	42.5	42.0	42.0
Minimum	35	38	37
Maximum	46	49	46

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	67 (100.0%)	74 (100.0%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	41.7	41.9	41.6
SD	2.13	2.26	1.83
Median	42.0	42.0	42.0
Minimum	35	38	38
Maximum	48	47	45
Month 12			
Number of patients:			
With values	51	58	66
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	51 (100.0%)	58 (100.0%)	66 (100.0%)
Summary statistics:			
Number of patients with values	51	58	66
Mean	41.8	41.5	41.8
SD	1.96	2.27	2.24
Median	42.0	41.0	42.0
Minimum	36	37	37
Maximum	47	47	47

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	66
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	47 (100.0%)	53 (100.0%)	66 (100.0%)
Summary statistics:			
Number of patients with values	47	53	66
Mean	41.9	41.1	41.3
SD	1.92	1.95	2.05
Median	42.0	41.0	41.0
Minimum	37	37	36
Maximum	46	46	47
Month 18			
Number of patients:			
With values	44	51	60
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	44 (100.0%)	51 (100.0%)	60 (100.0%)
Summary statistics:			
Number of patients with values	44	51	60
Mean	41.9	41.4	41.7
SD	1.39	2.32	2.26
Median	42.0	41.0	41.0
Minimum	39	33	37
Maximum	45	46	47

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	50 (100.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	41.9	41.8	41.9
SD	1.49	2.31	2.36
Median	42.0	42.0	42.0
Minimum	39	36	37
Maximum	45	46	49
Month 24			
Number of patients:			
With values	36	41	51
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	41 (100.0%)	51 (100.0%)
Summary statistics:			
Number of patients with values	36	41	51
Mean	42.1	41.9	42.2
SD	1.48	2.32	2.37
Median	42.0	42.0	42.0
Minimum	39	37	37
Maximum	45	47	47

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	40 (100.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	42.1	42.2	42.1
SD	1.35	2.11	1.90
Median	42.0	42.0	42.0
Minimum	39	38	38
Maximum	45	47	46
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	29 (100.0%)	35 (100.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	42.0	41.8	41.9
SD	1.67	1.78	2.22
Median	42.0	42.0	42.0
Minimum	38	39	37
Maximum	46	45	46

- 1636 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	34 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	41.7	41.9	41.5
SD	1.87	2.44	2.06
Median	42.0	42.0	41.0
Minimum	38	35	38
Maximum	47	46	47
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	26 (100.0%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	41.6	41.9	42.2
SD	1.67	2.31	2.27
Median	42.0	41.5	43.0
Minimum	38	39	38
Maximum	44	48	47

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	14 (100.0%)	20 (100.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	41.3	40.4	41.7
SD	2.46	2.44	2.78
Median	41.0	40.0	41.0
Minimum	36	36	37
Maximum	46	44	50
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	42.1	42.3	40.8
SD	2.03	2.92	2.39
Median	42.0	41.0	40.0
Minimum	39	38	38
Maximum	46	48	45

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	42.0	40.4	42.7
SD	2.58	2.19	2.43
Median	43.0	40.0	42.0
Minimum	39	38	39
Maximum	45	44	46

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	15.4	23.4	17.1
SD	1.14	10.77	6.10
Median	15.0	22.0	14.5
Minimum	14	12	12
Maximum	17	47	30
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	2 (2.6%)	0
With values below reference range	0	0	0
With values within reference range	60 (98.4%)	76 (97.4%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	18.0	23.0	18.3
SD	6.15	14.30	6.40
Median	16.0	20.0	17.0
Minimum	11	10	9
Maximum	53	103	51

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	21.0	17.0	
SD	1.41		
Median	21.0	17.0	
Minimum	20	17	
Maximum	22	17	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	18.0	19.0	17.6
SD		1.41	2.70
Median	18.0	19.0	17.0
Minimum	18	18	15
Maximum	18	20	22

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	3 (4.1%)	0
With values below reference range	0	0	0
With values within reference range	56 (100.0%)	71 (95.9%)	82 (100.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	17.9	22.6	18.9
SD	4.30	12.96	6.88
Median	17.0	19.0	17.0
Minimum	12	11	9
Maximum	30	98	50
Month 6			
Number of patients:			
With values	55	70	80
With values above reference range	1 (1.8%)	1 (1.4%)	0
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	69 (98.6%)	80 (100.0%)
Summary statistics:			
Number of patients with values	55	70	80
Mean	19.9	21.9	18.5
SD	10.76	11.46	5.85
Median	18.0	19.0	17.5
Minimum	9	11	9
Maximum	89	87	46

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	3 (4.5%)	0
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	64 (95.5%)	74 (100.0%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	18.9	21.9	18.1
SD	5.43	11.22	6.36
Median	18.0	19.0	16.0
Minimum	11	11	9
Maximum	35	74	47
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	0	2 (3.4%)	1 (1.5%)
With values below reference range	0	0	0
With values within reference range	52 (100.0%)	56 (96.6%)	66 (98.5%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	18.9	26.3	19.2
SD	5.65	30.63	7.74
Median	18.0	19.5	17.0
Minimum	10	11	8
Maximum	32	228	59

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	0	2 (3.6%)	2 (3.0%)
With values below reference range	0	0	0
With values within reference range	47 (100.0%)	53 (96.4%)	64 (97.0%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	20.3	22.4	18.7
SD	7.67	13.88	6.40
Median	19.0	19.0	17.0
Minimum	9	10	10
Maximum	52	84	46
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	0	2 (3.9%)	2 (3.3%)
With values below reference range	0	0	0
With values within reference range	45 (100.0%)	49 (96.1%)	58 (96.7%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	19.1	23.8	19.1
SD	5.07	13.98	7.15
Median	19.0	20.0	17.5
Minimum	11	10	9
Maximum	37	86	45

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	0	3 (6.0%)	0
With values below reference range	0	0	0
With values within reference range	43 (100.0%)	47 (94.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	19.1	24.5	17.8
SD	5.07	17.82	4.77
Median	17.0	19.0	17.0
Minimum	12	9	9
Maximum	35	99	35
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	3 (7.3%)	1 (1.9%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	38 (92.7%)	51 (98.1%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	21.0	24.7	18.4
SD	8.45	15.96	6.41
Median	19.0	21.0	17.5
Minimum	12	10	9
Maximum	61	86	50

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	2 (5.0%)	0
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	38 (95.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	19.6	26.2	18.4
SD	5.20	23.01	4.83
Median	17.5	21.5	18.0
Minimum	13	12	10
Maximum	38	156	34
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	0	2 (5.7%)	1 (2.4%)
With values below reference range	0	0	0
With values within reference range	29 (100.0%)	33 (94.3%)	41 (97.6%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	19.2	23.0	19.7
SD	6.00	13.92	6.80
Median	17.0	19.0	19.0
Minimum	10	10	11
Maximum	35	82	48

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	0	1 (3.0%)	0
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	32 (97.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	18.6	22.3	17.5
SD	3.95	11.20	4.17
Median	17.5	20.0	17.0
Minimum	13	7	10
Maximum	26	73	26
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	2 (7.7%)	0
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	24 (92.3%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	19.6	24.0	19.3
SD	5.75	17.44	4.74
Median	19.0	20.0	19.0
Minimum	11	11	12
Maximum	35	101	32

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	1 (7.1%)	0
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	13 (92.9%)	20 (100.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	18.4	23.0	18.9
SD	6.06	12.51	5.83
Median	17.0	20.0	17.5
Minimum	11	13	10
Maximum	31	59	35
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	17.8	21.5	19.6
SD	3.24	9.71	6.89
Median	17.5	19.0	17.0
Minimum	12	11	14
Maximum	21	50	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	18.3	25.8	18.1
SD	5.06	15.25	4.18
Median	16.0	17.0	17.0
Minimum	12	14	13
Maximum	25	47	23

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	2 (25.0%)	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	6 (75.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	21.0	27.8	19.1
SD	4.47	19.15	6.56
Median	21.0	18.5	18.0
Minimum	15	13	13
Maximum	27	64	34
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	2 (3.3%)	7 (9.0%)	0
With values below reference range	0	0	0
With values within reference range	59 (96.7%)	71 (91.0%)	90 (100.0%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	21.4	24.7	18.9
SD	11.64	15.83	7.93
Median	18.0	19.0	17.0
Minimum	10	9	5
Maximum	82	107	40

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	20.5	22.0	
SD	2.12		
Median	20.5	22.0	
Minimum	19	22	
Maximum	22	22	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	13.0	26.5	19.4
SD		3.54	12.07
Median	13.0	26.5	14.0
Minimum	13	24	10
Maximum	13	29	40

- 1651 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	3 (4.1%)	0
With values below reference range	0	0	0
With values within reference range	56 (100.0%)	71 (95.9%)	82 (100.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	18.1	23.2	19.5
SD	6.70	12.31	7.49
Median	16.0	19.0	18.0
Minimum	9	10	9
Maximum	40	71	37
Month 6			
Number of patients:			
With values	55	70	80
With values above reference range	1 (1.8%)	3 (4.3%)	0
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	67 (95.7%)	80 (100.0%)
Summary statistics:			
Number of patients with values	55	70	80
Mean	19.3	23.2	19.4
SD	10.26	12.90	7.77
Median	17.0	20.0	18.0
Minimum	9	10	8
Maximum	72	79	43

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	3 (4.5%)	1 (1.4%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	64 (95.5%)	73 (98.6%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	19.2	23.0	20.8
SD	8.07	11.62	14.24
Median	17.0	21.0	17.5
Minimum	9	10	8
Maximum	48	71	125
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	0	6 (10.3%)	2 (3.0%)
With values below reference range	0	0	0
With values within reference range	52 (100.0%)	52 (89.7%)	65 (97.0%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	19.1	26.7	20.4
SD	7.88	28.79	9.35
Median	16.0	19.5	18.0
Minimum	9	10	7
Maximum	41	211	59

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	1 (2.1%)	4 (7.3%)	0
With values below reference range	0	0	0
With values within reference range	46 (97.9%)	51 (92.7%)	66 (100.0%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	21.3	22.3	19.5
SD	12.47	15.13	8.17
Median	17.0	19.0	17.0
Minimum	7	8	9
Maximum	82	77	42
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	1 (2.2%)	4 (7.8%)	1 (1.7%)
With values below reference range	0	0	0
With values within reference range	44 (97.8%)	47 (92.2%)	59 (98.3%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	19.4	23.8	20.2
SD	9.03	16.07	9.29
Median	16.0	19.0	18.0
Minimum	10	9	8
Maximum	52	90	49

- 1654 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	4 (8.0%)	1 (1.8%)
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	46 (92.0%)	54 (98.2%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	19.7	22.8	19.2
SD	10.56	14.78	8.13
Median	16.0	17.0	17.0
Minimum	10	9	8
Maximum	54	80	54
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	2 (5.6%)	4 (9.8%)	0
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	37 (90.2%)	52 (100.0%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	21.5	22.8	20.2
SD	14.67	16.32	8.23
Median	16.5	19.0	17.5
Minimum	11	8	8
Maximum	88	88	45

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	2 (5.6%)	3 (7.5%)	0
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	37 (92.5%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	20.1	25.4	20.3
SD	10.36	16.19	7.73
Median	18.0	23.0	19.5
Minimum	9	9	8
Maximum	60	95	43
Month 30			
Number of patients:			
With values	29	35	41
With values above reference range	1 (3.4%)	3 (8.6%)	0
With values below reference range	0	0	0
With values within reference range	28 (96.6%)	32 (91.4%)	41 (100.0%)
Summary statistics:			
Number of patients with values	29	35	41
Mean	20.8	23.6	19.7
SD	12.31	12.73	8.69
Median	17.0	20.0	17.0
Minimum	10	9	8
Maximum	71	68	41

- 1656 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	24	31	32
With values above reference range	1 (4.2%)	1 (3.2%)	0
With values below reference range	0	0	0
With values within reference range	23 (95.8%)	30 (96.8%)	32 (100.0%)
Summary statistics:			
Number of patients with values	24	31	32
Mean	18.7	24.5	18.9
SD	8.91	12.95	8.65
Median	16.5	22.0	17.5
Minimum	12	9	7
Maximum	52	65	47
Month 36			
Number of patients:			
With values	26	23	30
With values above reference range	0	1 (4.3%)	0
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	22 (95.7%)	30 (100.0%)
Summary statistics:			
Number of patients with values	26	23	30
Mean	19.2	22.4	19.7
SD	9.13	12.00	7.89
Median	16.5	19.0	19.0
Minimum	9	10	7
Maximum	47	61	47

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	12	14	19
With values above reference range	0	1 (7.1%)	0
With values below reference range	0	0	0
With values within reference range	12 (100.0%)	13 (92.9%)	19 (100.0%)
Summary statistics:			
Number of patients with values	12	14	19
Mean	16.9	21.6	19.4
SD	7.61	12.63	8.17
Median	14.5	17.5	18.0
Minimum	11	12	6
Maximum	39	56	44
Month 42			
Number of patients:			
With values	5	13	5
With values above reference range	1 (20.0%)	1 (7.7%)	0
With values below reference range	0	0	0
With values within reference range	4 (80.0%)	12 (92.3%)	5 (100.0%)
Summary statistics:			
Number of patients with values	5	13	5
Mean	25.4	22.9	19.0
SD	15.42	14.59	8.86
Median	24.0	19.0	18.0
Minimum	11	11	9
Maximum	50	62	33

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	3	5	6
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	3 (100.0%)	5 (100.0%)	6 (100.0%)
Summary statistics:			
Number of patients with values	3	5	6
Mean	15.3	19.2	20.3
SD	2.89	11.39	10.54
Median	17.0	16.0	18.0
Minimum	12	10	10
Maximum	17	39	40

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	33.2	26.4	18.4
SD	4.55	9.52	6.05
Median	35.0	24.5	18.5
Minimum	27	18	9
Maximum	38	46	28
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	9 (14.8%)	7 (9.0%)	7 (7.8%)
With values below reference range	0	0	0
With values within reference range	52 (85.2%)	71 (91.0%)	83 (92.2%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	36.5	35.9	26.5
SD	29.36	30.15	18.55
Median	27.0	25.0	21.0
Minimum	6	10	6
Maximum	151	181	105

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	1 (50.0%)	0	
With values below reference range	0	0	
With values within reference range	1 (50.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	35.5	51.0	
SD	43.13		
Median	35.5	51.0	
Minimum	5	51	
Maximum	66	51	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	11.0	37.0	22.2
SD		25.46	3.11
Median	11.0	37.0	23.0
Minimum	11	19	18
Maximum	11	55	25

- 1661 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	1 (1.8%)	7 (9.5%)	9 (11.0%)
With values below reference range	0	0	0
With values within reference range	55 (98.2%)	67 (90.5%)	73 (89.0%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	26.5	39.7	28.9
SD	19.58	62.65	24.40
Median	22.0	24.0	21.0
Minimum	6	12	7
Maximum	112	532	142
Month 6			
Number of patients:			
With values	54	70	80
With values above reference range	1 (1.9%)	7 (10.0%)	8 (10.0%)
With values below reference range	0	0	0
With values within reference range	53 (98.1%)	63 (90.0%)	72 (90.0%)
Summary statistics:			
Number of patients with values	54	70	80
Mean	25.4	34.6	28.7
SD	18.22	31.55	21.67
Median	19.0	24.0	22.0
Minimum	7	12	7
Maximum	96	209	118

- 1662 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	2 (3.6%)	5 (7.5%)	9 (12.2%)
With values below reference range	0	0	0
With values within reference range	53 (96.4%)	62 (92.5%)	65 (87.8%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	26.1	38.2	30.6
SD	18.07	47.20	27.38
Median	20.0	25.0	21.0
Minimum	7	5	7
Maximum	89	350	160
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	1 (2.0%)	6 (10.3%)	7 (10.4%)
With values below reference range	0	0	0
With values within reference range	50 (98.0%)	52 (89.7%)	60 (89.6%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	25.9	42.8	33.5
SD	15.47	71.71	31.24
Median	23.0	25.5	24.0
Minimum	6	9	4
Maximum	77	527	185

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	3 (6.4%)	7 (12.7%)	5 (7.6%)
With values below reference range	0	0	0
With values within reference range	44 (93.6%)	48 (87.3%)	61 (92.4%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	34.1	38.6	34.7
SD	44.80	39.65	38.40
Median	26.0	26.0	24.0
Minimum	4	9	9
Maximum	313	270	249
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	3 (6.7%)	6 (11.8%)	4 (6.7%)
With values below reference range	0	0	0
With values within reference range	42 (93.3%)	45 (88.2%)	56 (93.3%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	29.6	48.1	31.1
SD	19.15	83.93	24.76
Median	24.0	28.0	25.0
Minimum	8	12	9
Maximum	93	599	169

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	3 (7.0%)	9 (18.0%)	2 (3.6%)
With values below reference range	0	0	0
With values within reference range	40 (93.0%)	41 (82.0%)	53 (96.4%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	32.8	61.5	32.1
SD	25.80	140.17	31.51
Median	25.0	27.0	25.0
Minimum	9	13	9
Maximum	119	996	204
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	4 (11.1%)	8 (19.5%)	5 (9.6%)
With values below reference range	0	0	0
With values within reference range	32 (88.9%)	33 (80.5%)	47 (90.4%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	32.6	48.0	36.1
SD	27.25	45.86	38.47
Median	23.5	28.0	24.5
Minimum	6	12	10
Maximum	126	178	257

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	3 (8.3%)	8 (20.0%)	3 (6.8%)
With values below reference range	0	0	0
With values within reference range	33 (91.7%)	32 (80.0%)	41 (93.2%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	32.2	48.0	34.2
SD	23.37	49.07	33.12
Median	24.0	31.5	27.0
Minimum	8	12	11
Maximum	113	276	230
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	2 (6.9%)	5 (14.3%)	3 (7.1%)
With values below reference range	0	0	0
With values within reference range	27 (93.1%)	30 (85.7%)	39 (92.9%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	33.3	64.0	29.8
SD	29.60	128.33	15.34
Median	22.0	31.0	24.0
Minimum	11	13	12
Maximum	136	742	77

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	0	6 (18.2%)	3 (8.8%)
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	27 (81.8%)	31 (91.2%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	28.0	39.9	30.7
SD	17.72	26.58	20.26
Median	23.0	27.0	24.5
Minimum	10	12	10
Maximum	73	117	94
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	2 (7.4%)	4 (15.4%)	4 (12.9%)
With values below reference range	0	0	0
With values within reference range	25 (92.6%)	22 (84.6%)	27 (87.1%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	27.9	63.7	39.7
SD	21.19	150.03	46.84
Median	20.0	25.5	28.0
Minimum	12	15	12
Maximum	104	790	262

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	3 (21.4%)	2 (10.0%)
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	11 (78.6%)	18 (90.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	24.9	66.9	33.5
SD	14.42	92.98	25.56
Median	22.5	36.0	25.0
Minimum	12	15	10
Maximum	60	368	106
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	2 (13.3%)	2 (22.2%)
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	13 (86.7%)	7 (77.8%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	27.6	31.4	39.8
SD	14.60	21.64	28.47
Median	25.5	20.0	26.0
Minimum	17	16	16
Maximum	62	89	106

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	1 (20.0%)	0
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	4 (80.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	27.1	94.4	29.3
SD	20.67	149.13	12.02
Median	20.0	29.0	29.0
Minimum	11	19	16
Maximum	71	361	54

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	71.8	66.5	58.1
SD	16.21	17.07	11.73
Median	66.0	64.0	64.0
Minimum	54	48	39
Maximum	95	92	69
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	3 (4.9%)	1 (1.3%)	1 (1.1%)
With values below reference range	0	0	0
With values within reference range	58 (95.1%)	77 (98.7%)	89 (98.9%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	76.6	64.5	61.5
SD	24.77	26.80	17.70
Median	76.0	62.5	60.5
Minimum	36	23	30
Maximum	175	241	129

- 1670 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	75.0	94.0	
SD	18.38		
Median	75.0	94.0	
Minimum	62	94	
Maximum	88	94	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	60.0	74.5	64.6
SD		31.82	35.43
Median	60.0	74.5	60.0
Minimum	60	52	25
Maximum	60	97	122

- 1671 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	1 (1.8%)	1 (1.4%)	1 (1.2%)
With values below reference range	0	0	0
With values within reference range	55 (98.2%)	73 (98.6%)	81 (98.8%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	62.3	62.6	62.2
SD	18.46	24.48	18.80
Median	59.5	61.0	61.0
Minimum	33	23	28
Maximum	143	204	145
Month 6			
Number of patients:			
With values	55	70	80
With values above reference range	0	1 (1.4%)	1 (1.3%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	69 (98.6%)	79 (98.8%)
Summary statistics:			
Number of patients with values	55	70	80
Mean	62.8	61.9	62.7
SD	18.18	27.90	20.98
Median	64.0	58.0	59.5
Minimum	30	21	28
Maximum	125	233	154

- 1672 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	1 (1.5%)	2 (2.7%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	66 (98.5%)	72 (97.3%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	60.5	63.0	63.0
SD	16.35	26.36	21.31
Median	61.0	59.0	59.5
Minimum	30	24	25
Maximum	99	220	141
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	2 (3.8%)	1 (1.7%)	3 (4.5%)
With values below reference range	0	0	0
With values within reference range	50 (96.2%)	57 (98.3%)	64 (95.5%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	66.0	64.7	64.5
SD	23.26	28.99	23.45
Median	66.0	60.5	61.0
Minimum	36	22	27
Maximum	173	231	152

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	3 (6.4%)	0	1 (1.5%)
With values below reference range	0	1 (1.8%)	0
With values within reference range	44 (93.6%)	54 (98.2%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	68.8	61.9	63.9
SD	33.40	16.83	22.17
Median	64.0	62.0	58.0
Minimum	26	18	34
Maximum	198	102	162
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	1 (2.2%)	0	1 (1.7%)
With values below reference range	0	0	0
With values within reference range	44 (97.8%)	51 (100.0%)	59 (98.3%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	66.9	64.2	64.8
SD	25.47	20.77	23.54
Median	64.0	61.0	59.0
Minimum	31	23	31
Maximum	190	122	171

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	1 (2.0%)	2 (3.6%)
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	49 (98.0%)	53 (96.4%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	66.9	68.2	68.3
SD	25.78	20.83	25.93
Median	62.0	66.0	68.0
Minimum	36	24	29
Maximum	187	129	177
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	0	3 (5.8%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	41 (100.0%)	49 (94.2%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	71.8	69.1	68.1
SD	23.36	22.68	28.42
Median	70.5	68.0	59.0
Minimum	39	20	27
Maximum	177	120	181

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	1 (2.5%)	3 (6.8%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (97.5%)	41 (93.2%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	68.8	64.6	69.1
SD	28.53	20.58	27.88
Median	66.0	62.0	66.0
Minimum	27	23	29
Maximum	203	138	177
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	1 (3.4%)	1 (2.9%)	1 (2.4%)
With values below reference range	0	0	0
With values within reference range	28 (96.6%)	34 (97.1%)	41 (97.6%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	70.0	66.8	62.9
SD	32.86	22.78	26.39
Median	63.0	65.0	59.0
Minimum	33	23	21
Maximum	215	145	174

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	0	1 (3.0%)	1 (2.9%)
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	32 (97.0%)	33 (97.1%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	65.5	66.8	64.2
SD	17.64	24.22	23.97
Median	62.0	66.0	61.0
Minimum	30	22	27
Maximum	93	160	160
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	1 (3.7%)	0	1 (3.2%)
With values below reference range	0	1 (3.8%)	0
With values within reference range	26 (96.3%)	25 (96.2%)	30 (96.8%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	68.8	62.8	60.3
SD	28.48	20.71	25.65
Median	63.0	63.5	54.0
Minimum	32	19	23
Maximum	180	111	152

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	1 (7.1%)	1 (5.0%)
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	13 (92.9%)	19 (95.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	58.3	71.1	63.8
SD	12.71	32.80	28.68
Median	59.0	68.5	58.5
Minimum	35	22	25
Maximum	80	168	163
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	62.5	65.4	50.8
SD	15.35	18.07	15.68
Median	61.0	57.0	53.0
Minimum	44	39	28
Maximum	92	91	78

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	54.6	65.2	61.4
SD	17.08	16.81	20.24
Median	55.0	57.0	54.0
Minimum	30	53	45
Maximum	79	94	105

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	84.0	87.5	104.4
SD	13.42	14.88	14.50
Median	90.0	85.0	105.0
Minimum	60	70	80
Maximum	90	110	120
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	1 (1.3%)	3 (3.3%)
With values below reference range	2 (3.3%)	3 (3.8%)	3 (3.3%)
With values within reference range	59 (96.7%)	74 (94.9%)	84 (93.3%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	87.7	86.6	92.6
SD	16.15	18.27	21.71
Median	88.0	85.0	89.5
Minimum	33	46	54
Maximum	114	167	176

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	1 (100.0%)	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	0	
Summary statistics:			
Number of patients with values	2	1	0
Mean	92.0	160.0	
SD	11.31		
Median	92.0	160.0	
Minimum	84	160	
Maximum	100	160	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	1 (50.0%)	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	1 (50.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	110.0	130.0	104.0
SD		56.57	11.40
Median	110.0	130.0	100.0
Minimum	110	90	90
Maximum	110	170	120

- 1681 -

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BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	3 (4.1%)	4 (4.9%)
With values below reference range	1 (1.8%)	0	2 (2.4%)
With values within reference range	55 (98.2%)	71 (95.9%)	76 (92.7%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	88.6	90.1	89.5
SD	15.89	19.12	22.44
Median	90.0	90.0	90.0
Minimum	50	60	50
Maximum	120	180	170
Month 6			
Number of patients:			
With values	54	70	80
With values above reference range	1 (1.9%)	1 (1.4%)	6 (7.5%)
With values below reference range	0	0	1 (1.3%)
With values within reference range	53 (98.1%)	69 (98.6%)	73 (91.3%)
Summary statistics:			
Number of patients with values	54	70	80
Mean	90.7	90.3	94.3
SD	19.70	17.19	34.85
Median	90.0	90.0	90.0
Minimum	60	60	50
Maximum	180	170	320

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	1 (1.8%)	3 (4.5%)	3 (4.1%)
With values below reference range	0	1 (1.5%)	1 (1.4%)
With values within reference range	54 (98.2%)	63 (94.0%)	70 (94.6%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	89.5	89.4	88.2
SD	16.82	18.16	19.82
Median	90.0	90.0	90.0
Minimum	60	50	50
Maximum	130	160	150
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	1 (2.0%)	3 (5.2%)	4 (6.0%)
With values below reference range	0	0	2 (3.0%)
With values within reference range	50 (98.0%)	55 (94.8%)	61 (91.0%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	87.8	91.0	90.3
SD	16.65	18.89	23.22
Median	90.0	90.0	90.0
Minimum	60	60	50
Maximum	140	150	160

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	2 (4.3%)	2 (3.6%)	4 (6.1%)
With values below reference range	1 (2.1%)	0	2 (3.0%)
With values within reference range	44 (93.6%)	53 (96.4%)	60 (90.9%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	90.6	89.5	90.5
SD	22.78	18.70	21.94
Median	90.0	90.0	90.0
Minimum	50	60	50
Maximum	200	140	160
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	0	2 (3.9%)	5 (8.3%)
With values below reference range	2 (4.4%)	1 (2.0%)	1 (1.7%)
With values within reference range	43 (95.6%)	48 (94.1%)	54 (90.0%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	88.9	91.0	91.0
SD	16.82	19.21	26.02
Median	90.0	90.0	90.0
Minimum	50	40	50
Maximum	120	160	190

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	4 (8.0%)	5 (9.1%)
With values below reference range	1 (2.3%)	0	2 (3.6%)
With values within reference range	41 (95.3%)	46 (92.0%)	48 (87.3%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	87.2	91.0	91.3
SD	17.09	21.78	23.50
Median	90.0	90.0	90.0
Minimum	50	60	50
Maximum	130	180	160
Month 24			
Number of patients:			
With values	36	41	51
With values above reference range	0	3 (7.3%)	6 (11.8%)
With values below reference range	0	0	1 (2.0%)
With values within reference range	36 (100.0%)	38 (92.7%)	44 (86.3%)
Summary statistics:			
Number of patients with values	36	41	51
Mean	86.9	90.5	94.9
SD	15.27	22.13	25.25
Median	85.0	80.0	90.0
Minimum	60	60	50
Maximum	110	170	170

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	1 (2.5%)	5 (11.4%)
With values below reference range	0	0	1 (2.3%)
With values within reference range	36 (100.0%)	39 (97.5%)	38 (86.4%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	89.4	89.5	95.7
SD	15.85	18.39	25.74
Median	90.0	90.0	100.0
Minimum	60	60	50
Maximum	120	160	180
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	1 (3.4%)	2 (5.7%)	6 (14.3%)
With values below reference range	0	0	1 (2.4%)
With values within reference range	28 (96.6%)	33 (94.3%)	35 (83.3%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	88.6	86.9	94.0
SD	15.97	17.78	29.05
Median	90.0	80.0	90.0
Minimum	60	60	50
Maximum	130	150	180

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	2 (7.7%)	2 (6.1%)	3 (8.8%)
With values below reference range	1 (3.8%)	1 (3.0%)	2 (5.9%)
With values within reference range	23 (88.5%)	30 (90.9%)	29 (85.3%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	84.6	89.7	89.7
SD	17.72	21.28	23.55
Median	80.0	90.0	90.0
Minimum	40	50	50
Maximum	130	150	150
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	1 (3.7%)	2 (7.7%)	3 (9.7%)
With values below reference range	2 (7.4%)	0	2 (6.5%)
With values within reference range	24 (88.9%)	24 (92.3%)	26 (83.9%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	85.6	89.2	89.4
SD	18.67	26.82	23.80
Median	80.0	90.0	90.0
Minimum	40	60	50
Maximum	130	190	150

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	0	1 (5.0%)
With values below reference range	0	0	1 (5.0%)
With values within reference range	14 (100.0%)	14 (100.0%)	18 (90.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	95.0	87.1	85.5
SD	14.54	18.16	19.86
Median	90.0	90.0	85.0
Minimum	70	60	50
Maximum	120	120	150
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	81.3	92.0	86.7
SD	20.31	45.07	18.03
Median	80.0	80.0	90.0
Minimum	60	60	60
Maximum	120	250	110

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	0
With values below reference range	0	0	1 (14.3%)
With values within reference range	6 (85.7%)	5 (100.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	97.1	82.0	80.0
SD	21.38	17.89	15.28
Median	90.0	70.0	90.0
Minimum	80	70	50
Maximum	140	110	90

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	1 (12.5%)
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	7 (87.5%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	5.94	6.71	8.03
SD	1.381	1.689	1.201
Median	6.30	6.15	8.40
Minimum	4.2	4.7	6.0
Maximum	7.2	9.1	9.7
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	4 (5.1%)	7 (7.8%)
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	74 (94.9%)	83 (92.2%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	6.26	6.22	7.03
SD	1.466	1.767	1.774
Median	6.30	5.85	6.70
Minimum	3.6	2.5	2.7
Maximum	10.5	10.6	11.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	7.40	10.10	
SD	1.273		
Median	7.40	10.10	
Minimum	6.5	10.1	
Maximum	8.3	10.1	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	1 (50.0%)	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	1 (50.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	7.60	9.30	5.82
SD		4.808	0.907
Median	7.60	9.30	6.00
Minimum	7.6	5.9	4.6
Maximum	7.6	12.7	6.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	3 (5.4%)	2 (2.7%)	8 (9.8%)
With values below reference range	0	0	0
With values within reference range	53 (94.6%)	72 (97.3%)	74 (90.2%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	6.44	6.30	6.78
SD	1.833	1.721	1.832
Median	6.25	6.15	6.60
Minimum	3.5	2.7	3.4
Maximum	11.5	10.5	12.7
Month 6			
Number of patients:			
With values	54	71	80
With values above reference range	1 (1.9%)	5 (7.0%)	5 (6.3%)
With values below reference range	0	0	0
With values within reference range	53 (98.1%)	66 (93.0%)	75 (93.8%)
Summary statistics:			
Number of patients with values	54	71	80
Mean	6.44	6.32	6.93
SD	1.715	1.850	2.470
Median	6.25	6.20	6.40
Minimum	3.7	2.8	2.9
Maximum	11.5	12.0	19.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	2 (3.6%)	6 (9.0%)	3 (4.1%)
With values below reference range	0	0	0
With values within reference range	53 (96.4%)	61 (91.0%)	71 (95.9%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	6.49	6.65	6.90
SD	1.874	1.868	1.960
Median	6.40	6.40	6.60
Minimum	2.9	3.1	3.5
Maximum	11.6	11.1	14.6
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	2 (3.9%)	3 (5.2%)	8 (11.9%)
With values below reference range	0	0	0
With values within reference range	49 (96.1%)	55 (94.8%)	59 (88.1%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	6.65	6.59	7.36
SD	1.955	1.624	2.462
Median	6.30	6.50	7.10
Minimum	3.5	3.7	3.5
Maximum	12.3	10.7	16.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	66
With values above reference range	5 (10.6%)	3 (5.6%)	5 (7.6%)
With values below reference range	0	0	0
With values within reference range	42 (89.4%)	51 (94.4%)	61 (92.4%)
Summary statistics:			
Number of patients with values	47	54	66
Mean	6.84	6.52	7.00
SD	2.314	1.843	2.036
Median	6.30	6.25	6.60
Minimum	4.2	3.7	3.2
Maximum	16.5	12.6	13.6
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	2 (4.4%)	4 (7.8%)	8 (13.3%)
With values below reference range	0	0	0
With values within reference range	43 (95.6%)	47 (92.2%)	52 (86.7%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	6.64	6.57	7.56
SD	1.889	2.086	1.956
Median	6.30	5.90	7.35
Minimum	3.3	2.6	4.7
Maximum	13.0	14.0	13.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	5 (10.0%)	2 (3.6%)
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	45 (90.0%)	53 (96.4%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	6.60	6.93	7.00
SD	1.847	2.196	1.893
Median	6.20	6.25	6.80
Minimum	3.2	3.7	3.5
Maximum	10.8	13.1	14.5
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	2 (5.6%)	3 (7.3%)	6 (11.5%)
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	38 (92.7%)	46 (88.5%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	6.58	6.42	7.41
SD	1.932	1.948	2.047
Median	6.25	6.00	6.90
Minimum	3.4	2.5	3.5
Maximum	11.0	11.3	14.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	3 (8.3%)	3 (7.5%)	6 (13.6%)
With values below reference range	0	0	0
With values within reference range	33 (91.7%)	37 (92.5%)	38 (86.4%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	6.63	6.28	7.21
SD	2.060	1.835	2.200
Median	6.25	5.95	7.05
Minimum	3.9	3.7	3.9
Maximum	11.8	11.8	13.0
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	2 (6.9%)	1 (2.9%)	5 (11.4%)
With values below reference range	0	0	0
With values within reference range	27 (93.1%)	34 (97.1%)	39 (88.6%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	6.74	6.28	7.40
SD	2.041	1.682	2.127
Median	6.90	5.80	7.10
Minimum	3.2	3.3	3.8
Maximum	12.2	11.2	13.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	2 (7.7%)	2 (5.9%)	3 (8.8%)
With values below reference range	0	0	0
With values within reference range	24 (92.3%)	32 (94.1%)	31 (91.2%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	6.74	6.51	7.11
SD	2.164	1.940	1.905
Median	6.25	6.10	7.00
Minimum	3.2	3.5	3.7
Maximum	12.1	13.0	12.4
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	2 (7.4%)	2 (7.7%)	4 (12.9%)
With values below reference range	0	0	0
With values within reference range	25 (92.6%)	24 (92.3%)	27 (87.1%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	6.72	7.09	7.21
SD	2.214	2.638	2.113
Median	6.60	6.35	7.20
Minimum	3.1	2.9	3.3
Maximum	12.9	16.7	11.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	1 (6.7%)	1 (7.1%)	2 (10.0%)
With values below reference range	0	0	0
With values within reference range	14 (93.3%)	13 (92.9%)	18 (90.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	6.80	7.36	7.19
SD	1.932	1.758	1.801
Median	6.30	6.95	7.10
Minimum	3.4	5.4	3.8
Maximum	10.8	11.7	10.9
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	2 (13.3%)	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	13 (86.7%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	6.03	7.90	6.89
SD	2.034	5.131	1.184
Median	6.05	6.50	7.00
Minimum	2.8	5.0	4.8
Maximum	8.7	26.0	8.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	0
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	7.06	6.00	6.19
SD	2.865	2.038	1.195
Median	6.80	5.40	6.60
Minimum	4.1	3.5	4.4
Maximum	12.5	8.6	7.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	1 (20.0%)	2 (25.0%)	0
With values within reference range	4 (80.0%)	6 (75.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	283.8	279.1	297.1
SD	51.82	65.79	42.64
Median	275.0	275.5	284.0
Minimum	214	208	243
Maximum	357	394	362
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	0	2 (2.2%)
With values below reference range	13 (21.3%)	14 (17.9%)	12 (13.3%)
With values within reference range	48 (78.7%)	64 (82.1%)	76 (84.4%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	268.4	280.6	284.2
SD	65.34	67.87	81.54
Median	272.0	261.0	285.0
Minimum	83	137	100
Maximum	459	435	594

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	1 (50.0%)	0	
With values within reference range	1 (50.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	257.0	251.0	
SD	28.28		
Median	257.0	251.0	
Minimum	237	251	
Maximum	277	251	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	2 (100.0%)	2 (40.0%)
With values within reference range	1 (100.0%)	0	3 (60.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	287.0	203.0	245.2
SD		4.24	33.76
Median	287.0	203.0	246.0
Minimum	287	200	202
Maximum	287	206	279

- 1701 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	0	1 (1.2%)
With values below reference range	9 (16.1%)	16 (21.6%)	15 (18.3%)
With values within reference range	47 (83.9%)	58 (78.4%)	66 (80.5%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	273.7	271.4	274.8
SD	68.21	68.04	80.49
Median	281.0	255.5	273.5
Minimum	112	141	107
Maximum	435	409	558
Month 6			
Number of patients:			
With values	54	70	80
With values above reference range	0	0	1 (1.3%)
With values below reference range	8 (14.8%)	19 (27.1%)	14 (17.5%)
With values within reference range	46 (85.2%)	51 (72.9%)	65 (81.3%)
Summary statistics:			
Number of patients with values	54	70	80
Mean	270.6	270.4	271.0
SD	67.69	69.35	80.69
Median	286.5	260.0	262.0
Minimum	95	125	98
Maximum	391	485	641

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	0	0
With values below reference range	11 (20.0%)	17 (25.4%)	12 (16.2%)
With values within reference range	44 (80.0%)	50 (74.6%)	62 (83.8%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	269.0	277.2	268.9
SD	77.40	73.44	67.36
Median	281.0	270.0	254.5
Minimum	90	161	162
Maximum	423	485	463
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	0	0	2 (3.0%)
With values below reference range	8 (15.7%)	15 (25.9%)	14 (20.9%)
With values within reference range	43 (84.3%)	43 (74.1%)	51 (76.1%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	284.3	274.0	267.0
SD	79.46	77.24	76.84
Median	288.0	264.0	257.0
Minimum	98	92	90
Maximum	451	487	526

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	0	0	1 (1.5%)
With values below reference range	10 (21.3%)	12 (21.8%)	13 (19.7%)
With values within reference range	37 (78.7%)	43 (78.2%)	52 (78.8%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	282.9	271.8	270.6
SD	74.93	75.79	81.60
Median	282.0	250.0	274.5
Minimum	138	124	101
Maximum	481	429	599
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	0	0	2 (3.3%)
With values below reference range	4 (8.9%)	12 (23.5%)	9 (15.0%)
With values within reference range	41 (91.1%)	39 (76.5%)	49 (81.7%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	287.2	272.7	285.2
SD	65.74	77.01	91.10
Median	296.0	253.0	273.0
Minimum	134	149	130
Maximum	437	458	634

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	0	1 (2.0%)	1 (1.8%)
With values below reference range	5 (11.6%)	10 (20.0%)	8 (14.5%)
With values within reference range	38 (88.4%)	39 (78.0%)	46 (83.6%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	294.2	295.1	290.7
SD	74.45	92.38	82.51
Median	306.0	276.0	273.0
Minimum	102	141	147
Maximum	436	595	644
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	1 (2.4%)	1 (1.9%)
With values below reference range	2 (5.6%)	6 (14.6%)	5 (9.6%)
With values within reference range	33 (91.7%)	34 (82.9%)	46 (88.5%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	307.7	292.2	291.9
SD	72.11	86.80	77.66
Median	309.5	272.0	291.5
Minimum	180	173	127
Maximum	508	577	546

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	2 (5.6%)	0	1 (2.3%)
With values below reference range	2 (5.6%)	6 (15.0%)	5 (11.4%)
With values within reference range	32 (88.9%)	34 (85.0%)	38 (86.4%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	315.0	302.9	295.7
SD	88.73	70.11	82.22
Median	307.0	299.5	287.5
Minimum	135	132	170
Maximum	518	429	567
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	2 (6.9%)	0	2 (4.5%)
With values below reference range	2 (6.9%)	7 (20.0%)	2 (4.5%)
With values within reference range	25 (86.2%)	28 (80.0%)	40 (90.9%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	305.8	291.4	311.3
SD	81.45	76.46	82.57
Median	315.0	280.0	303.0
Minimum	141	170	173
Maximum	490	471	523

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	2 (7.7%)	0	1 (2.9%)
With values below reference range	3 (11.5%)	4 (11.8%)	1 (2.9%)
With values within reference range	21 (80.8%)	30 (88.2%)	32 (94.1%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	306.3	305.9	298.7
SD	81.79	87.97	78.96
Median	303.0	288.0	285.0
Minimum	136	175	156
Maximum	507	502	549
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	1 (3.7%)	2 (7.7%)	0
With values below reference range	5 (18.5%)	5 (19.2%)	2 (6.5%)
With values within reference range	21 (77.8%)	19 (73.1%)	29 (93.5%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	295.7	312.2	316.5
SD	86.73	106.19	71.09
Median	309.0	301.5	314.0
Minimum	116	177	213
Maximum	497	602	450

- 1707 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	1 (6.7%)	0	0
With values below reference range	1 (6.7%)	2 (14.3%)	2 (10.0%)
With values within reference range	13 (86.7%)	12 (85.7%)	18 (90.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	331.6	311.1	277.1
SD	89.75	68.91	62.16
Median	334.0	304.0	274.0
Minimum	182	224	183
Maximum	556	455	389
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	1 (12.5%)	3 (20.0%)	2 (22.2%)
With values within reference range	7 (87.5%)	11 (73.3%)	7 (77.8%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	290.1	312.0	264.2
SD	67.85	104.16	39.33
Median	284.0	289.0	276.0
Minimum	207	147	200
Maximum	425	538	315

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	0
With values below reference range	0	0	1 (14.3%)
With values within reference range	6 (85.7%)	5 (100.0%)	6 (85.7%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	368.3	290.4	258.9
SD	89.12	88.06	25.00
Median	356.0	250.0	250.0
Minimum	254	212	222
Maximum	486	416	294

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	137.6	139.5	139.5
SD	2.07	2.27	2.27
Median	138.0	139.5	139.0
Minimum	135	136	137
Maximum	140	143	144
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	1 (1.3%)	0
With values below reference range	2 (3.3%)	1 (1.3%)	2 (2.2%)
With values within reference range	59 (96.7%)	76 (97.4%)	88 (97.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	139.3	139.8	139.9
SD	2.57	2.66	2.59
Median	139.0	140.0	140.0
Minimum	133	134	134
Maximum	146	156	146

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	139.5	142.0	
SD	2.12		
Median	139.5	142.0	
Minimum	138	142	
Maximum	141	142	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	144.0	142.5	140.4
SD		3.54	2.07
Median	144.0	142.5	140.0
Minimum	144	140	138
Maximum	144	145	143

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	0	0
With values below reference range	0	1 (1.4%)	2 (2.4%)
With values within reference range	56 (100.0%)	73 (98.6%)	80 (97.6%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	139.5	139.3	139.0
SD	2.44	2.35	2.38
Median	139.0	139.0	139.0
Minimum	135	134	132
Maximum	146	145	146
Month 6			
Number of patients:			
With values	54	72	80
With values above reference range	1 (1.9%)	1 (1.4%)	1 (1.3%)
With values below reference range	0	0	3 (3.8%)
With values within reference range	53 (98.1%)	71 (98.6%)	76 (95.0%)
Summary statistics:			
Number of patients with values	54	72	80
Mean	139.7	139.4	139.4
SD	2.48	2.27	2.45
Median	139.0	139.0	139.0
Minimum	135	136	134
Maximum	147	147	147

- 1712 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	0	0
With values below reference range	1 (1.8%)	3 (4.5%)	2 (2.7%)
With values within reference range	54 (98.2%)	64 (95.5%)	72 (97.3%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	139.6	139.0	139.1
SD	2.53	2.56	2.45
Median	139.0	139.0	139.0
Minimum	134	130	133
Maximum	146	144	144
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	1 (1.9%)	0	0
With values below reference range	0	2 (3.4%)	1 (1.5%)
With values within reference range	51 (98.1%)	56 (96.6%)	66 (98.5%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	139.2	139.0	139.4
SD	2.66	2.22	2.17
Median	139.0	139.0	139.0
Minimum	135	134	134
Maximum	147	143	144

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	0	0	0
With values below reference range	2 (4.3%)	1 (1.8%)	1 (1.5%)
With values within reference range	45 (95.7%)	54 (98.2%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	139.2	139.5	139.4
SD	2.72	2.47	2.18
Median	139.0	140.0	140.0
Minimum	130	131	134
Maximum	144	146	143
Month 18			
Number of patients:			
With values	44	51	60
With values above reference range	0	0	0
With values below reference range	2 (4.5%)	3 (5.9%)	2 (3.3%)
With values within reference range	42 (95.5%)	48 (94.1%)	58 (96.7%)
Summary statistics:			
Number of patients with values	44	51	60
Mean	139.8	138.5	139.5
SD	2.25	3.82	2.37
Median	140.0	138.0	140.0
Minimum	134	118	134
Maximum	146	143	144

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	0	0	1 (1.8%)
With values below reference range	1 (2.3%)	3 (6.0%)	2 (3.6%)
With values within reference range	42 (97.7%)	47 (94.0%)	52 (94.5%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	139.5	139.8	140.1
SD	2.50	3.09	2.93
Median	139.0	140.0	141.0
Minimum	134	130	129
Maximum	146	146	148
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	2 (5.6%)	0	1 (1.9%)
With values below reference range	0	0	2 (3.8%)
With values within reference range	34 (94.4%)	41 (100.0%)	49 (94.2%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	140.5	139.3	140.7
SD	2.79	2.57	2.85
Median	140.5	139.0	141.0
Minimum	136	135	131
Maximum	147	145	147

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	1 (2.5%)	1 (2.3%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (97.5%)	43 (97.7%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	140.8	140.0	140.2
SD	2.63	2.83	2.98
Median	141.0	140.0	140.0
Minimum	135	135	135
Maximum	147	149	147
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	0	0	0
With values below reference range	0	0	2 (4.5%)
With values within reference range	29 (100.0%)	35 (100.0%)	42 (95.5%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	139.7	140.8	139.9
SD	2.49	2.87	3.38
Median	139.0	140.0	140.0
Minimum	136	135	134
Maximum	146	146	146

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	1 (3.8%)	0	0
With values below reference range	0	0	0
With values within reference range	25 (96.2%)	34 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	139.9	140.1	140.2
SD	2.62	2.36	2.35
Median	140.0	140.0	140.0
Minimum	135	135	136
Maximum	147	144	146
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	0	0
With values below reference range	1 (3.7%)	2 (7.7%)	0
With values within reference range	26 (96.3%)	24 (92.3%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	139.6	139.2	140.1
SD	2.87	2.36	1.92
Median	139.0	140.0	140.0
Minimum	134	134	137
Maximum	144	142	144

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	0
With values below reference range	0	1 (7.1%)	0
With values within reference range	15 (100.0%)	13 (92.9%)	20 (100.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	139.9	139.2	140.0
SD	2.15	2.64	2.03
Median	139.0	139.5	140.0
Minimum	137	133	137
Maximum	144	144	144
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	1 (6.7%)	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	140.9	140.0	140.7
SD	2.36	2.70	1.66
Median	141.5	140.0	141.0
Minimum	137	134	138
Maximum	143	145	143

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	0
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	142.3	141.2	140.6
SD	3.20	1.92	2.64
Median	141.0	141.0	141.0
Minimum	139	139	137
Maximum	148	144	144

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	4.36	4.60	4.45
SD	0.493	0.251	0.338
Median	4.40	4.55	4.35
Minimum	3.7	4.3	4.1
Maximum	5.0	5.0	4.9
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	2 (2.6%)	2 (2.2%)
With values below reference range	0	1 (1.3%)	0
With values within reference range	61 (100.0%)	75 (96.2%)	88 (97.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	4.39	4.41	4.47
SD	0.331	0.356	0.376
Median	4.40	4.40	4.40
Minimum	3.7	3.2	3.5
Maximum	5.3	5.5	5.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	4.60	4.30	
SD	0.141		
Median	4.60	4.30	
Minimum	4.5	4.3	
Maximum	4.7	4.3	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	5.20	4.35	4.50
SD		0.212	0.430
Median	5.20	4.35	4.50
Minimum	5.2	4.2	4.0
Maximum	5.2	4.5	5.1

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	54	74	81
With values above reference range	0	0	3 (3.7%)
With values below reference range	1 (1.9%)	0	1 (1.2%)
With values within reference range	53 (98.1%)	74 (100.0%)	77 (95.1%)
Summary statistics:			
Number of patients with values	54	74	81
Mean	4.44	4.35	4.49
SD	0.368	0.331	0.398
Median	4.50	4.40	4.40
Minimum	3.2	3.6	3.4
Maximum	5.2	5.3	5.8
Month 6			
Number of patients:			
With values	55	72	79
With values above reference range	0	0	3 (3.8%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	72 (100.0%)	76 (96.2%)
Summary statistics:			
Number of patients with values	55	72	79
Mean	4.43	4.41	4.53
SD	0.398	0.332	0.465
Median	4.40	4.40	4.40
Minimum	3.5	3.6	3.5
Maximum	5.1	5.1	6.9

- 1722 -

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BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	66	74
With values above reference range	3 (5.5%)	0	2 (2.7%)
With values below reference range	0	1 (1.5%)	1 (1.4%)
With values within reference range	52 (94.5%)	65 (98.5%)	71 (95.9%)
Summary statistics:			
Number of patients with values	55	66	74
Mean	4.50	4.43	4.49
SD	0.397	0.323	0.441
Median	4.40	4.45	4.45
Minimum	3.8	3.4	3.4
Maximum	5.6	5.3	6.4
Month 12			
Number of patients:			
With values	52	58	66
With values above reference range	1 (1.9%)	0	2 (3.0%)
With values below reference range	0	0	0
With values within reference range	51 (98.1%)	58 (100.0%)	64 (97.0%)
Summary statistics:			
Number of patients with values	52	58	66
Mean	4.45	4.44	4.54
SD	0.321	0.345	0.387
Median	4.40	4.40	4.50
Minimum	3.7	3.6	3.6
Maximum	5.4	5.2	5.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	46	55	65
With values above reference range	0	1 (1.8%)	3 (4.6%)
With values below reference range	0	0	0
With values within reference range	46 (100.0%)	54 (98.2%)	62 (95.4%)
Summary statistics:			
Number of patients with values	46	55	65
Mean	4.40	4.43	4.53
SD	0.302	0.294	0.389
Median	4.40	4.40	4.50
Minimum	3.5	3.8	3.6
Maximum	5.0	5.6	5.8
Month 18			
Number of patients:			
With values	43	51	60
With values above reference range	1 (2.3%)	2 (3.9%)	1 (1.7%)
With values below reference range	0	1 (2.0%)	0
With values within reference range	42 (97.7%)	48 (94.1%)	59 (98.3%)
Summary statistics:			
Number of patients with values	43	51	60
Mean	4.52	4.45	4.55
SD	0.351	0.499	0.353
Median	4.50	4.40	4.50
Minimum	3.8	3.3	3.5
Maximum	5.5	6.7	5.4

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	2 (4.0%)	0
With values below reference range	0	0	1 (1.8%)
With values within reference range	42 (97.7%)	48 (96.0%)	54 (98.2%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	4.46	4.53	4.54
SD	0.355	0.415	0.349
Median	4.40	4.50	4.60
Minimum	3.8	3.5	3.2
Maximum	5.6	5.9	5.2
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	2 (4.9%)	3 (5.8%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (95.1%)	49 (94.2%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	4.39	4.50	4.60
SD	0.377	0.362	0.393
Median	4.40	4.40	4.50
Minimum	3.5	3.9	3.6
Maximum	5.5	5.4	5.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	1 (2.5%)	4 (9.1%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (97.5%)	40 (90.9%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	4.46	4.41	4.65
SD	0.356	0.303	0.437
Median	4.45	4.40	4.50
Minimum	3.7	3.9	4.0
Maximum	5.4	5.5	5.9
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	29 (100.0%)	35 (100.0%)	42 (100.0%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	4.39	4.41	4.50
SD	0.253	0.354	0.325
Median	4.40	4.50	4.40
Minimum	3.9	3.7	3.8
Maximum	5.1	5.2	5.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	33 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	4.41	4.44	4.51
SD	0.392	0.318	0.389
Median	4.50	4.40	4.50
Minimum	3.7	3.8	3.6
Maximum	5.1	5.0	5.3
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	1 (3.7%)	0	0
With values below reference range	0	0	0
With values within reference range	26 (96.3%)	26 (100.0%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	4.49	4.34	4.53
SD	0.415	0.365	0.363
Median	4.40	4.35	4.50
Minimum	3.9	3.5	3.6
Maximum	5.5	4.9	5.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	14 (100.0%)	20 (100.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	4.26	4.53	4.52
SD	0.354	0.289	0.317
Median	4.35	4.50	4.50
Minimum	3.7	4.1	4.0
Maximum	4.9	5.0	5.1
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	4.40	4.55	4.48
SD	0.312	0.295	0.244
Median	4.40	4.60	4.50
Minimum	3.8	4.0	4.1
Maximum	4.7	5.3	4.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	4.31	4.54	4.50
SD	0.291	0.371	0.361
Median	4.40	4.60	4.50
Minimum	3.9	3.9	4.2
Maximum	4.7	4.8	5.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	101.2	102.8	103.3
SD	0.84	1.83	1.67
Median	101.0	102.5	103.5
Minimum	100	100	100
Maximum	102	105	105
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	3 (4.9%)	1 (1.3%)	2 (2.2%)
With values below reference range	0	0	0
With values within reference range	58 (95.1%)	77 (98.7%)	88 (97.8%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	102.9	103.2	103.3
SD	2.73	2.39	2.72
Median	103.0	103.0	103.5
Minimum	97	98	98
Maximum	110	109	109

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	103.5	108.0	
SD	0.71		
Median	103.5	108.0	
Minimum	103	108	
Maximum	104	108	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	1 (100.0%)	0	0
With values below reference range	0	0	0
With values within reference range	0	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	109.0	105.5	103.8
SD		3.54	1.79
Median	109.0	105.5	104.0
Minimum	109	103	102
Maximum	109	108	106

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	2 (3.6%)	3 (4.1%)	3 (3.7%)
With values below reference range	0	0	0
With values within reference range	54 (96.4%)	71 (95.9%)	79 (96.3%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	103.9	103.4	103.6
SD	2.46	2.67	2.40
Median	104.0	103.0	103.5
Minimum	98	98	98
Maximum	110	110	110
Month 6			
Number of patients:			
With values	55	72	80
With values above reference range	4 (7.3%)	1 (1.4%)	1 (1.3%)
With values below reference range	0	0	0
With values within reference range	51 (92.7%)	71 (98.6%)	79 (98.8%)
Summary statistics:			
Number of patients with values	55	72	80
Mean	103.7	102.9	103.2
SD	2.71	2.46	2.64
Median	103.0	103.0	103.0
Minimum	99	97	96
Maximum	112	109	110

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	2 (3.6%)	2 (3.0%)	2 (2.7%)
With values below reference range	0	0	0
With values within reference range	53 (96.4%)	65 (97.0%)	72 (97.3%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	103.9	103.4	103.4
SD	2.28	2.67	2.62
Median	104.0	104.0	103.0
Minimum	99	98	97
Maximum	110	110	109
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	2 (3.8%)	2 (3.4%)	1 (1.5%)
With values below reference range	0	0	0
With values within reference range	50 (96.2%)	56 (96.6%)	66 (98.5%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	103.3	102.9	103.1
SD	2.96	2.70	2.68
Median	103.5	103.0	103.0
Minimum	96	97	98
Maximum	111	110	109

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	1 (2.1%)	1 (1.8%)	1 (1.5%)
With values below reference range	1 (2.1%)	0	0
With values within reference range	45 (95.7%)	54 (98.2%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	102.9	104.1	103.4
SD	3.53	2.84	2.74
Median	103.0	105.0	103.5
Minimum	87	96	97
Maximum	109	110	111
Month 18			
Number of patients:			
With values	44	51	60
With values above reference range	0	1 (2.0%)	1 (1.7%)
With values below reference range	0	1 (2.0%)	0
With values within reference range	44 (100.0%)	49 (96.1%)	59 (98.3%)
Summary statistics:			
Number of patients with values	44	51	60
Mean	103.2	102.4	103.3
SD	2.35	4.57	2.90
Median	103.0	103.0	103.5
Minimum	97	79	96
Maximum	107	109	110

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	5 (11.6%)	1 (2.0%)	5 (9.1%)
With values below reference range	1 (2.3%)	1 (2.0%)	0
With values within reference range	37 (86.0%)	48 (96.0%)	50 (90.9%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	103.7	103.0	104.1
SD	3.64	3.29	3.00
Median	103.0	103.5	105.0
Minimum	92	92	96
Maximum	111	110	109
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	1 (2.4%)	5 (9.6%)
With values below reference range	1 (2.8%)	0	0
With values within reference range	34 (94.4%)	40 (97.6%)	47 (90.4%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	102.8	102.9	103.7
SD	3.91	3.22	3.42
Median	103.0	103.0	104.0
Minimum	89	96	95
Maximum	109	112	111

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	3 (7.5%)	0
With values below reference range	0	1 (2.5%)	0
With values within reference range	35 (97.2%)	36 (90.0%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	102.7	103.1	103.1
SD	3.05	3.80	2.51
Median	103.0	103.0	103.0
Minimum	95	91	97
Maximum	110	113	108
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	0	1 (2.9%)	1 (2.3%)
With values below reference range	1 (3.4%)	1 (2.9%)	0
With values within reference range	28 (96.6%)	33 (94.3%)	43 (97.7%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	102.9	102.5	103.3
SD	3.09	3.42	2.88
Median	103.0	103.0	103.0
Minimum	94	92	98
Maximum	108	110	111

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	1 (3.8%)	1 (2.9%)	2 (5.9%)
With values below reference range	0	1 (2.9%)	0
With values within reference range	25 (96.2%)	32 (94.1%)	32 (94.1%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	103.8	102.7	103.5
SD	2.48	3.42	3.06
Median	104.0	103.5	103.5
Minimum	99	94	96
Maximum	111	109	109
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	2 (7.4%)	0	0
With values below reference range	0	1 (3.8%)	0
With values within reference range	25 (92.6%)	25 (96.2%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	103.1	102.1	103.1
SD	3.06	3.06	2.32
Median	102.0	102.0	103.0
Minimum	99	94	97
Maximum	110	108	107

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	0
With values below reference range	0	1 (7.1%)	0
With values within reference range	15 (100.0%)	13 (92.9%)	20 (100.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	103.5	102.8	103.3
SD	2.75	3.58	2.25
Median	103.0	103.5	103.0
Minimum	99	93	100
Maximum	108	107	107
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	103.0	103.3	103.1
SD	2.73	3.28	3.37
Median	102.5	104.0	104.0
Minimum	100	97	97
Maximum	107	109	107

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	103.7	103.4	104.3
SD	2.87	3.13	1.38
Median	104.0	104.0	105.0
Minimum	99	98	102
Maximum	108	106	106

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	26.2	26.3	24.6
SD	3.42	2.31	3.16
Median	27.0	27.0	26.0
Minimum	21	23	20
Maximum	30	29	28
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	1 (1.6%)	1 (1.3%)	1 (1.1%)
With values below reference range	1 (1.6%)	3 (3.8%)	2 (2.2%)
With values within reference range	59 (96.7%)	74 (94.9%)	87 (96.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	25.3	25.5	25.5
SD	3.04	2.77	3.04
Median	25.0	25.5	26.0
Minimum	19	19	18
Maximum	37	33	33

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	29.0	27.0	
SD	4.24		
Median	29.0	27.0	
Minimum	26	27	
Maximum	32	27	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	28.0	23.0	27.2
SD		1.41	3.11
Median	28.0	23.0	28.0
Minimum	28	22	22
Maximum	28	24	30

- 1741 -

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BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	3 (5.4%)	0	2 (2.4%)
With values below reference range	1 (1.8%)	3 (4.1%)	3 (3.7%)
With values within reference range	52 (92.9%)	71 (95.9%)	77 (93.9%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	26.6	26.0	26.0
SD	3.46	3.04	3.11
Median	26.0	26.0	26.0
Minimum	19	18	14
Maximum	42	32	34
Month 6			
Number of patients:			
With values	55	70	80
With values above reference range	0	3 (4.3%)	1 (1.3%)
With values below reference range	2 (3.6%)	1 (1.4%)	2 (2.5%)
With values within reference range	53 (96.4%)	66 (94.3%)	77 (96.3%)
Summary statistics:			
Number of patients with values	55	70	80
Mean	25.1	26.5	25.1
SD	2.99	3.19	3.09
Median	26.0	27.0	25.5
Minimum	16	19	18
Maximum	31	34	36

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	1 (1.8%)	0	0
With values below reference range	0	0	0
With values within reference range	54 (98.2%)	67 (100.0%)	74 (100.0%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	26.5	26.0	26.2
SD	2.15	2.75	2.75
Median	26.0	26.0	26.0
Minimum	21	21	20
Maximum	33	32	32
Month 12			
Number of patients:			
With values	52	58	67
With values above reference range	1 (1.9%)	0	3 (4.5%)
With values below reference range	1 (1.9%)	1 (1.7%)	1 (1.5%)
With values within reference range	50 (96.2%)	57 (98.3%)	63 (94.0%)
Summary statistics:			
Number of patients with values	52	58	67
Mean	25.3	25.6	25.6
SD	3.02	3.11	3.39
Median	25.5	25.0	25.0
Minimum	16	19	19
Maximum	33	32	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	0	1 (1.8%)	2 (3.0%)
With values below reference range	0	5 (9.1%)	2 (3.0%)
With values within reference range	47 (100.0%)	49 (89.1%)	62 (93.9%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	25.9	25.5	25.8
SD	2.58	3.80	3.00
Median	26.0	25.0	26.0
Minimum	20	18	19
Maximum	32	34	35
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	0	2 (3.9%)	1 (1.7%)
With values below reference range	0	1 (2.0%)	1 (1.7%)
With values within reference range	45 (100.0%)	48 (94.1%)	58 (96.7%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	25.6	25.0	24.9
SD	2.40	4.08	3.20
Median	25.0	25.0	25.0
Minimum	21	5	18
Maximum	31	34	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	2 (4.7%)	1 (2.0%)	0
With values below reference range	1 (2.3%)	1 (2.0%)	0
With values within reference range	40 (93.0%)	48 (96.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	25.9	26.1	26.1
SD	3.28	2.93	3.01
Median	25.0	26.0	26.0
Minimum	18	17	21
Maximum	34	36	32
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	0	0	1 (1.9%)
With values below reference range	0	1 (2.4%)	2 (3.8%)
With values within reference range	36 (100.0%)	40 (97.6%)	49 (94.2%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	26.3	24.9	25.1
SD	3.16	2.61	3.42
Median	26.0	25.0	25.0
Minimum	20	19	19
Maximum	32	30	35

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	2 (5.0%)	1 (2.3%)
With values below reference range	0	2 (5.0%)	3 (6.8%)
With values within reference range	36 (100.0%)	36 (90.0%)	40 (90.9%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	25.8	25.6	25.4
SD	2.84	3.81	3.42
Median	25.0	25.0	26.0
Minimum	21	18	16
Maximum	32	34	35
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	1 (3.4%)	0	1 (2.3%)
With values below reference range	0	1 (2.9%)	2 (4.5%)
With values within reference range	28 (96.6%)	34 (97.1%)	41 (93.2%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	25.4	25.5	25.2
SD	2.41	2.64	4.41
Median	25.0	26.0	26.0
Minimum	21	18	12
Maximum	33	29	39

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	2 (7.7%)	2 (5.9%)	1 (2.9%)
With values below reference range	0	0	0
With values within reference range	24 (92.3%)	32 (94.1%)	33 (97.1%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	26.3	26.3	26.0
SD	3.44	3.20	3.03
Median	26.0	26.5	26.0
Minimum	21	21	20
Maximum	35	34	34
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	1 (3.8%)	1 (3.2%)
With values below reference range	1 (3.7%)	1 (3.8%)	0
With values within reference range	26 (96.3%)	24 (92.3%)	30 (96.8%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	26.3	25.4	25.8
SD	3.31	4.34	3.43
Median	27.0	25.0	25.0
Minimum	19	12	20
Maximum	32	36	33

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	1 (5.0%)
With values below reference range	0	1 (7.1%)	0
With values within reference range	15 (100.0%)	13 (92.9%)	19 (95.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	26.0	25.8	26.2
SD	3.12	3.12	3.20
Median	26.0	25.0	25.5
Minimum	21	19	22
Maximum	31	31	35
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	1 (12.5%)	0	0
With values below reference range	0	0	0
With values within reference range	7 (87.5%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	27.4	26.9	27.0
SD	2.67	3.75	2.40
Median	27.5	27.0	26.0
Minimum	25	20	23
Maximum	33	32	30

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	1 (20.0%)	0
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	4 (80.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	27.3	28.2	25.0
SD	3.68	3.42	3.46
Median	27.0	27.0	25.0
Minimum	22	24	20
Maximum	34	33	29

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	9	7
With values above reference range	6 (100.0%)	9 (100.0%)	6 (85.7%)
With values below reference range	0	0	0
With values within reference range	0	0	1 (14.3%)
Summary statistics:			
Number of patients with values	6	9	7
Mean	214.2	184.3	151.6
SD	23.07	49.41	29.09
Median	208.0	187.0	155.0
Minimum	182	125	104
Maximum	243	280	191
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	59 (96.7%)	69 (88.5%)	66 (73.3%)
With values below reference range	0	0	2 (2.2%)
With values within reference range	2 (3.3%)	9 (11.5%)	22 (24.4%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	195.4	170.2	154.2
SD	36.46	36.77	40.86
Median	198.0	170.5	152.0
Minimum	116	87	66
Maximum	264	280	250

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	59	74	87
With values above reference range	52 (88.1%)	62 (83.8%)	67 (77.0%)
With values below reference range	0	1 (1.4%)	2 (2.3%)
With values within reference range	7 (11.9%)	11 (14.9%)	18 (20.7%)
Summary statistics:			
Number of patients with values	59	74	87
Mean	170.1	163.3	159.9
SD	41.86	36.98	43.33
Median	173.0	165.0	159.0
Minimum	91	77	71
Maximum	341	243	270
Month 2			
Number of patients:			
With values	55	77	86
With values above reference range	44 (80.0%)	62 (80.5%)	72 (83.7%)
With values below reference range	2 (3.6%)	0	0
With values within reference range	9 (16.4%)	15 (19.5%)	14 (16.3%)
Summary statistics:			
Number of patients with values	55	77	86
Mean	155.4	157.8	162.2
SD	36.63	38.00	43.59
Median	155.0	157.0	158.5
Minimum	71	80	80
Maximum	225	246	287

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	57	75	85
With values above reference range	50 (87.7%)	59 (78.7%)	70 (82.4%)
With values below reference range	1 (1.8%)	0	1 (1.2%)
With values within reference range	6 (10.5%)	16 (21.3%)	14 (16.5%)
Summary statistics:			
Number of patients with values	57	75	85
Mean	163.2	162.1	159.2
SD	36.52	39.22	37.44
Median	166.0	162.0	159.0
Minimum	77	79	68
Maximum	229	246	250
Month 6			
Number of patients:			
With values	55	73	80
With values above reference range	45 (81.8%)	59 (80.8%)	69 (86.3%)
With values below reference range	1 (1.8%)	0	0
With values within reference range	9 (16.4%)	14 (19.2%)	11 (13.8%)
Summary statistics:			
Number of patients with values	55	73	80
Mean	158.3	162.4	161.3
SD	36.29	37.86	38.47
Median	155.0	164.0	154.0
Minimum	70	87	79
Maximum	221	252	307

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	70	75
With values above reference range	48 (87.3%)	57 (81.4%)	64 (85.3%)
With values below reference range	0	0	0
With values within reference range	7 (12.7%)	13 (18.6%)	11 (14.7%)
Summary statistics:			
Number of patients with values	55	70	75
Mean	162.3	165.8	168.4
SD	34.81	41.67	40.11
Median	168.0	169.0	171.0
Minimum	82	80	100
Maximum	254	271	271
Month 12			
Number of patients:			
With values	52	60	70
With values above reference range	49 (94.2%)	45 (75.0%)	57 (81.4%)
With values below reference range	0	2 (3.3%)	1 (1.4%)
With values within reference range	3 (5.8%)	13 (21.7%)	12 (17.1%)
Summary statistics:			
Number of patients with values	52	60	70
Mean	168.2	162.2	163.1
SD	37.72	45.72	45.64
Median	165.0	168.0	154.5
Minimum	105	71	77
Maximum	261	320	280

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	48	55	68
With values above reference range	40 (83.3%)	46 (83.6%)	54 (79.4%)
With values below reference range	1 (2.1%)	1 (1.8%)	2 (2.9%)
With values within reference range	7 (14.6%)	8 (14.5%)	12 (17.6%)
Summary statistics:			
Number of patients with values	48	55	68
Mean	162.9	162.9	160.1
SD	42.38	36.16	50.79
Median	159.0	166.0	148.0
Minimum	77	77	75
Maximum	261	257	286
Month 18			
Number of patients:			
With values	43	51	60
With values above reference range	36 (83.7%)	43 (84.3%)	50 (83.3%)
With values below reference range	1 (2.3%)	1 (2.0%)	1 (1.7%)
With values within reference range	6 (14.0%)	7 (13.7%)	9 (15.0%)
Summary statistics:			
Number of patients with values	43	51	60
Mean	157.9	164.4	161.0
SD	38.56	40.32	40.09
Median	150.0	166.0	158.0
Minimum	71	61	64
Maximum	234	268	271

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	58
With values above reference range	36 (83.7%)	42 (84.0%)	46 (79.3%)
With values below reference range	0	0	2 (3.4%)
With values within reference range	7 (16.3%)	8 (16.0%)	10 (17.2%)
Summary statistics:			
Number of patients with values	43	50	58
Mean	161.1	166.0	155.7
SD	36.90	39.69	46.99
Median	159.0	171.0	154.0
Minimum	98	79	62
Maximum	239	254	327
Month 24			
Number of patients:			
With values	36	40	52
With values above reference range	32 (88.9%)	31 (77.5%)	40 (76.9%)
With values below reference range	1 (2.8%)	1 (2.5%)	3 (5.8%)
With values within reference range	3 (8.3%)	8 (20.0%)	9 (17.3%)
Summary statistics:			
Number of patients with values	36	40	52
Mean	158.1	164.7	162.1
SD	36.75	56.82	50.31
Median	158.0	159.5	162.0
Minimum	73	71	50
Maximum	229	384	287

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	39	44
With values above reference range	32 (88.9%)	30 (76.9%)	34 (77.3%)
With values below reference range	1 (2.8%)	1 (2.6%)	2 (4.5%)
With values within reference range	3 (8.3%)	8 (20.5%)	8 (18.2%)
Summary statistics:			
Number of patients with values	36	39	44
Mean	170.1	166.9	166.7
SD	43.59	46.35	58.67
Median	170.0	171.0	170.5
Minimum	64	70	20
Maximum	275	268	327
Month 30			
Number of patients:			
With values	28	35	44
With values above reference range	25 (89.3%)	29 (82.9%)	34 (77.3%)
With values below reference range	1 (3.6%)	0	1 (2.3%)
With values within reference range	2 (7.1%)	6 (17.1%)	9 (20.5%)
Summary statistics:			
Number of patients with values	28	35	44
Mean	162.2	162.6	167.4
SD	37.80	42.35	51.45
Median	164.0	154.0	164.5
Minimum	68	84	70
Maximum	252	252	296

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	22 (84.6%)	26 (76.5%)	30 (88.2%)
With values below reference range	0	0	1 (2.9%)
With values within reference range	4 (15.4%)	8 (23.5%)	3 (8.8%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	164.5	161.9	163.0
SD	33.40	39.67	46.04
Median	170.0	162.5	158.0
Minimum	95	89	66
Maximum	229	261	266
Month 36			
Number of patients:			
With values	27	25	31
With values above reference range	23 (85.2%)	19 (76.0%)	24 (77.4%)
With values below reference range	0	0	0
With values within reference range	4 (14.8%)	6 (24.0%)	7 (22.6%)
Summary statistics:			
Number of patients with values	27	25	31
Mean	166.3	159.4	155.1
SD	36.91	45.08	38.95
Median	168.0	168.0	155.0
Minimum	91	82	86
Maximum	229	229	270

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	15	20
With values above reference range	12 (85.7%)	13 (86.7%)	17 (85.0%)
With values below reference range	0	0	0
With values within reference range	2 (14.3%)	2 (13.3%)	3 (15.0%)
Summary statistics:			
Number of patients with values	14	15	20
Mean	165.2	164.5	173.6
SD	36.44	45.06	51.38
Median	174.0	157.0	181.0
Minimum	98	89	86
Maximum	230	270	275
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	7 (87.5%)	11 (73.3%)	7 (77.8%)
With values below reference range	0	0	0
With values within reference range	1 (12.5%)	4 (26.7%)	2 (22.2%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	162.9	153.1	171.9
SD	31.20	46.69	63.51
Median	163.5	143.0	148.0
Minimum	109	82	91
Maximum	202	232	271

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	6	5	7
With values above reference range	4 (66.7%)	3 (60.0%)	6 (85.7%)
With values below reference range	0	1 (20.0%)	0
With values within reference range	2 (33.3%)	1 (20.0%)	1 (14.3%)
Summary statistics:			
Number of patients with values	6	5	7
Mean	137.7	134.8	161.0
SD	49.69	46.59	43.64
Median	134.0	157.0	154.0
Minimum	89	73	109
Maximum	227	180	245

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	1.02	1.03	1.08
SD	0.148	0.139	0.175
Median	1.00	1.00	1.05
Minimum	0.8	0.9	0.8
Maximum	1.2	1.3	1.4
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	2 (3.3%)	1 (1.3%)	2 (2.2%)
With values below reference range	2 (3.3%)	0	1 (1.1%)
With values within reference range	57 (93.4%)	77 (98.7%)	87 (96.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	1.11	1.11	1.14
SD	0.189	0.139	0.158
Median	1.10	1.10	1.10
Minimum	0.7	0.8	0.8
Maximum	1.5	1.4	1.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	0.95	1.10	
SD	0.071		
Median	0.95	1.10	
Minimum	0.9	1.1	
Maximum	1.0	1.1	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	1.00	1.10	1.08
SD		0.283	0.130
Median	1.00	1.10	1.10
Minimum	1.0	0.9	0.9
Maximum	1.0	1.3	1.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	1 (1.8%)	0	1 (1.2%)
With values below reference range	0	1 (1.4%)	0
With values within reference range	55 (98.2%)	73 (98.6%)	81 (98.8%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	1.12	1.10	1.12
SD	0.168	0.139	0.158
Median	1.10	1.10	1.10
Minimum	0.8	0.8	0.8
Maximum	1.5	1.4	1.5
Month 6			
Number of patients:			
With values	54	70	80
With values above reference range	1 (1.9%)	1 (1.4%)	2 (2.5%)
With values below reference range	1 (1.9%)	2 (2.9%)	1 (1.3%)
With values within reference range	52 (96.3%)	67 (95.7%)	77 (96.3%)
Summary statistics:			
Number of patients with values	54	70	80
Mean	1.11	1.09	1.10
SD	0.182	0.140	0.159
Median	1.20	1.10	1.10
Minimum	0.7	0.8	0.8
Maximum	1.5	1.5	1.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	2 (3.6%)	0	3 (4.1%)
With values below reference range	1 (1.8%)	0	0
With values within reference range	52 (94.5%)	67 (100.0%)	71 (95.9%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	1.09	1.07	1.10
SD	0.171	0.134	0.146
Median	1.10	1.10	1.10
Minimum	0.8	0.8	0.8
Maximum	1.6	1.4	1.6
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	0	0	1 (1.5%)
With values below reference range	0	1 (1.7%)	0
With values within reference range	51 (100.0%)	57 (98.3%)	66 (98.5%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	1.10	1.08	1.11
SD	0.157	0.134	0.147
Median	1.10	1.10	1.10
Minimum	0.8	0.7	0.8
Maximum	1.4	1.4	1.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	55	66
With values above reference range	0	0	2 (3.0%)
With values below reference range	1 (2.1%)	0	0
With values within reference range	46 (97.9%)	55 (100.0%)	64 (97.0%)
Summary statistics:			
Number of patients with values	47	55	66
Mean	1.08	1.07	1.12
SD	0.163	0.138	0.158
Median	1.10	1.10	1.10
Minimum	0.7	0.8	0.8
Maximum	1.4	1.4	1.6
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	1 (2.2%)	0	1 (1.7%)
With values below reference range	0	1 (2.0%)	0
With values within reference range	44 (97.8%)	50 (98.0%)	59 (98.3%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	1.11	1.08	1.10
SD	0.163	0.133	0.167
Median	1.10	1.10	1.10
Minimum	0.8	0.7	0.8
Maximum	1.5	1.3	1.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	0	2 (3.6%)
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	50 (100.0%)	53 (96.4%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	1.08	1.10	1.12
SD	0.165	0.147	0.152
Median	1.10	1.10	1.10
Minimum	0.7	0.8	0.8
Maximum	1.4	1.4	1.5
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	0	0	2 (3.8%)
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	41 (100.0%)	50 (96.2%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	1.11	1.10	1.10
SD	0.151	0.127	0.161
Median	1.10	1.10	1.10
Minimum	0.8	0.8	0.8
Maximum	1.4	1.3	1.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	0	1 (2.5%)	2 (4.5%)
With values below reference range	0	0	0
With values within reference range	36 (100.0%)	39 (97.5%)	42 (95.5%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	1.07	1.10	1.08
SD	0.142	0.157	0.148
Median	1.00	1.10	1.10
Minimum	0.8	0.8	0.8
Maximum	1.3	1.6	1.5
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	0	0	2 (4.8%)
With values below reference range	0	0	1 (2.4%)
With values within reference range	29 (100.0%)	35 (100.0%)	39 (92.9%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	1.08	1.09	1.07
SD	0.145	0.135	0.170
Median	1.10	1.10	1.05
Minimum	0.8	0.8	0.7
Maximum	1.3	1.4	1.7

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	0	0	1 (2.9%)
With values below reference range	1 (3.8%)	0	0
With values within reference range	25 (96.2%)	33 (100.0%)	33 (97.1%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	1.05	1.09	1.08
SD	0.114	0.119	0.167
Median	1.05	1.10	1.00
Minimum	0.8	0.9	0.9
Maximum	1.2	1.4	1.4
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	0	1 (3.2%)
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	26 (100.0%)	30 (96.8%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	1.07	1.04	1.14
SD	0.173	0.158	0.158
Median	1.10	1.05	1.10
Minimum	0.7	0.8	0.9
Maximum	1.4	1.3	1.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	0	1 (7.1%)	0
With values below reference range	0	0	0
With values within reference range	14 (100.0%)	13 (92.9%)	20 (100.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	1.01	1.15	1.09
SD	0.092	0.214	0.129
Median	1.00	1.15	1.10
Minimum	0.8	0.8	0.9
Maximum	1.1	1.6	1.4
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	1 (6.7%)	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	1.01	1.08	1.12
SD	0.083	0.157	0.164
Median	1.00	1.00	1.10
Minimum	0.9	0.8	0.9
Maximum	1.1	1.4	1.3

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	0.99	1.20	1.01
SD	0.107	0.141	0.107
Median	1.00	1.30	1.00
Minimum	0.8	1.0	0.9
Maximum	1.1	1.3	1.2

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	8 (100.0%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	2.42	2.39	2.40
SD	0.084	0.113	0.107
Median	2.40	2.40	2.40
Minimum	2.3	2.2	2.2
Maximum	2.5	2.5	2.5
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	4 (6.6%)	2 (2.6%)	3 (3.3%)
With values below reference range	0	0	0
With values within reference range	57 (93.4%)	76 (97.4%)	87 (96.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	2.42	2.41	2.42
SD	0.105	0.092	0.095
Median	2.40	2.40	2.40
Minimum	2.2	2.2	2.2
Maximum	2.7	2.7	2.8

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	2.40	2.40	
SD	0.141		
Median	2.40	2.40	
Minimum	2.3	2.4	
Maximum	2.5	2.4	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	1 (100.0%)	0	0
With values below reference range	0	0	0
With values within reference range	0	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	2.80	2.40	2.44
SD		0.000	0.089
Median	2.80	2.40	2.50
Minimum	2.8	2.4	2.3
Maximum	2.8	2.4	2.5

- 1771 -

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BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	3 (5.4%)	2 (2.7%)	2 (2.4%)
With values below reference range	0	0	0
With values within reference range	53 (94.6%)	72 (97.3%)	80 (97.6%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	2.41	2.38	2.39
SD	0.102	0.091	0.108
Median	2.40	2.40	2.40
Minimum	2.2	2.1	2.2
Maximum	2.8	2.6	2.9
Month 6			
Number of patients:			
With values	54	70	78
With values above reference range	3 (5.6%)	5 (7.1%)	2 (2.6%)
With values below reference range	0	0	0
With values within reference range	51 (94.4%)	65 (92.9%)	76 (97.4%)
Summary statistics:			
Number of patients with values	54	70	78
Mean	2.41	2.40	2.42
SD	0.098	0.088	0.109
Median	2.40	2.40	2.40
Minimum	2.2	2.2	2.1
Maximum	2.7	2.6	2.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	4 (7.3%)	1 (1.5%)	1 (1.4%)
With values below reference range	0	0	0
With values within reference range	51 (92.7%)	66 (98.5%)	73 (98.6%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	2.39	2.37	2.39
SD	0.110	0.095	0.088
Median	2.40	2.40	2.40
Minimum	2.2	2.2	2.2
Maximum	2.7	2.6	2.8
Month 12			
Number of patients:			
With values	51	58	66
With values above reference range	2 (3.9%)	2 (3.4%)	5 (7.6%)
With values below reference range	0	0	0
With values within reference range	49 (96.1%)	56 (96.6%)	61 (92.4%)
Summary statistics:			
Number of patients with values	51	58	66
Mean	2.38	2.39	2.43
SD	0.099	0.079	0.126
Median	2.40	2.40	2.40
Minimum	2.2	2.2	2.2
Maximum	2.7	2.6	3.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	53	66
With values above reference range	1 (2.1%)	0	1 (1.5%)
With values below reference range	0	0	0
With values within reference range	46 (97.9%)	53 (100.0%)	65 (98.5%)
Summary statistics:			
Number of patients with values	47	53	66
Mean	2.39	2.37	2.39
SD	0.096	0.085	0.107
Median	2.40	2.40	2.40
Minimum	2.2	2.1	2.2
Maximum	2.7	2.5	2.9
Month 18			
Number of patients:			
With values	44	51	60
With values above reference range	3 (6.8%)	1 (2.0%)	3 (5.0%)
With values below reference range	0	1 (2.0%)	0
With values within reference range	41 (93.2%)	49 (96.1%)	57 (95.0%)
Summary statistics:			
Number of patients with values	44	51	60
Mean	2.41	2.39	2.42
SD	0.099	0.137	0.107
Median	2.40	2.40	2.40
Minimum	2.2	1.8	2.2
Maximum	2.7	2.7	2.9

- 1774 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	1 (2.0%)	1 (1.8%)
With values below reference range	0	1 (2.0%)	0
With values within reference range	42 (97.7%)	48 (96.0%)	54 (98.2%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	2.37	2.37	2.38
SD	0.115	0.110	0.110
Median	2.40	2.40	2.40
Minimum	2.1	2.1	2.2
Maximum	2.7	2.6	2.8
Month 24			
Number of patients:			
With values	36	41	51
With values above reference range	2 (5.6%)	2 (4.9%)	2 (3.9%)
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	39 (95.1%)	49 (96.1%)
Summary statistics:			
Number of patients with values	36	41	51
Mean	2.38	2.38	2.39
SD	0.096	0.101	0.126
Median	2.40	2.40	2.40
Minimum	2.2	2.1	2.1
Maximum	2.6	2.6	2.9

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	1 (2.8%)	1 (2.5%)	1 (2.3%)
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	39 (97.5%)	43 (97.7%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	2.38	2.38	2.39
SD	0.088	0.101	0.143
Median	2.40	2.40	2.40
Minimum	2.3	2.2	2.2
Maximum	2.6	2.6	3.1
Month 30			
Number of patients:			
With values	29	35	44
With values above reference range	1 (3.4%)	0	4 (9.1%)
With values below reference range	0	0	0
With values within reference range	28 (96.6%)	35 (100.0%)	40 (90.9%)
Summary statistics:			
Number of patients with values	29	35	44
Mean	2.37	2.37	2.39
SD	0.093	0.074	0.148
Median	2.40	2.40	2.40
Minimum	2.2	2.3	2.2
Maximum	2.7	2.5	3.0

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	34	34
With values above reference range	0	0	2 (5.9%)
With values below reference range	0	0	0
With values within reference range	26 (100.0%)	34 (100.0%)	32 (94.1%)
Summary statistics:			
Number of patients with values	26	34	34
Mean	2.35	2.36	2.38
SD	0.086	0.102	0.122
Median	2.30	2.40	2.40
Minimum	2.2	2.2	2.2
Maximum	2.6	2.6	2.8
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	0	0	1 (3.2%)
With values below reference range	0	0	0
With values within reference range	27 (100.0%)	26 (100.0%)	30 (96.8%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	2.34	2.36	2.38
SD	0.080	0.099	0.084
Median	2.30	2.30	2.40
Minimum	2.2	2.2	2.2
Maximum	2.5	2.5	2.6

- 1777 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	15	14	20
With values above reference range	0	0	2 (10.0%)
With values below reference range	0	0	0
With values within reference range	15 (100.0%)	14 (100.0%)	18 (90.0%)
Summary statistics:			
Number of patients with values	15	14	20
Mean	2.35	2.36	2.38
SD	0.092	0.084	0.173
Median	2.30	2.40	2.30
Minimum	2.2	2.2	2.2
Maximum	2.5	2.5	2.9
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	15 (100.0%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	2.35	2.35	2.32
SD	0.107	0.113	0.120
Median	2.30	2.30	2.30
Minimum	2.3	2.2	2.1
Maximum	2.6	2.5	2.5

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	7 (100.0%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	2.39	2.38	2.39
SD	0.107	0.084	0.121
Median	2.30	2.40	2.40
Minimum	2.3	2.3	2.2
Maximum	2.5	2.5	2.6

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	5	8	8
With values above reference range	0	1 (12.5%)	0
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	7 (87.5%)	8 (100.0%)
Summary statistics:			
Number of patients with values	5	8	8
Mean	129.8	186.4	154.3
SD	34.56	50.59	44.51
Median	124.0	166.0	159.0
Minimum	87	145	95
Maximum	177	298	243
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	0	2 (2.6%)	3 (3.3%)
With values below reference range	0	0	0
With values within reference range	61 (100.0%)	76 (97.4%)	87 (96.7%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	151.5	171.8	168.7
SD	27.22	34.53	36.41
Median	149.0	167.0	162.0
Minimum	87	63	88
Maximum	221	298	289

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	0	0	
With values below reference range	0	0	
With values within reference range	2 (100.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	147.5	206.0	
SD	23.33		
Median	147.5	206.0	
Minimum	131	206	
Maximum	164	206	
Month 2			
Number of patients:			
With values	1	2	5
With values above reference range	0	0	0
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	5 (100.0%)
Summary statistics:			
Number of patients with values	1	2	5
Mean	134.0	181.0	175.4
SD		4.24	26.12
Median	134.0	181.0	175.0
Minimum	134	178	136
Maximum	134	184	201

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	56	74	82
With values above reference range	0	2 (2.7%)	3 (3.7%)
With values below reference range	0	0	0
With values within reference range	56 (100.0%)	72 (97.3%)	79 (96.3%)
Summary statistics:			
Number of patients with values	56	74	82
Mean	168.6	174.8	173.2
SD	31.40	36.87	34.07
Median	163.0	172.0	168.5
Minimum	101	80	108
Maximum	242	342	282
Month 6			
Number of patients:			
With values	54	70	80
With values above reference range	1 (1.9%)	1 (1.4%)	4 (5.0%)
With values below reference range	0	0	0
With values within reference range	53 (98.1%)	69 (98.6%)	76 (95.0%)
Summary statistics:			
Number of patients with values	54	70	80
Mean	170.6	173.3	170.9
SD	35.44	32.68	38.44
Median	167.0	169.5	160.5
Minimum	91	86	108
Maximum	296	295	305

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	55	67	74
With values above reference range	0	2 (3.0%)	2 (2.7%)
With values below reference range	0	0	0
With values within reference range	55 (100.0%)	65 (97.0%)	72 (97.3%)
Summary statistics:			
Number of patients with values	55	67	74
Mean	171.4	176.1	164.3
SD	31.43	39.30	36.47
Median	164.0	171.0	161.0
Minimum	106	75	104
Maximum	253	335	313
Month 12			
Number of patients:			
With values	51	58	67
With values above reference range	0	1 (1.7%)	4 (6.0%)
With values below reference range	0	0	0
With values within reference range	51 (100.0%)	57 (98.3%)	63 (94.0%)
Summary statistics:			
Number of patients with values	51	58	67
Mean	168.0	173.9	169.0
SD	31.83	41.51	51.70
Median	166.0	163.0	163.0
Minimum	88	73	99
Maximum	257	291	450

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	47	54	66
With values above reference range	2 (4.3%)	0	0
With values below reference range	0	0	0
With values within reference range	45 (95.7%)	54 (100.0%)	66 (100.0%)
Summary statistics:			
Number of patients with values	47	54	66
Mean	174.3	164.4	160.3
SD	46.39	34.58	30.43
Median	166.0	159.5	158.5
Minimum	106	86	106
Maximum	368	243	247
Month 18			
Number of patients:			
With values	45	51	60
With values above reference range	0	1 (2.0%)	0
With values below reference range	0	0	0
With values within reference range	45 (100.0%)	50 (98.0%)	60 (100.0%)
Summary statistics:			
Number of patients with values	45	51	60
Mean	163.2	166.6	162.2
SD	30.11	38.09	25.41
Median	163.0	167.0	161.0
Minimum	106	95	107
Maximum	266	292	217

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	43	50	55
With values above reference range	1 (2.3%)	2 (4.0%)	0
With values below reference range	0	0	0
With values within reference range	42 (97.7%)	48 (96.0%)	55 (100.0%)
Summary statistics:			
Number of patients with values	43	50	55
Mean	167.3	166.6	153.7
SD	42.76	54.37	25.48
Median	161.0	152.0	155.0
Minimum	95	69	105
Maximum	326	428	216
Month 24			
Number of patients:			
With values	36	41	52
With values above reference range	1 (2.8%)	0	0
With values below reference range	0	0	0
With values within reference range	35 (97.2%)	41 (100.0%)	52 (100.0%)
Summary statistics:			
Number of patients with values	36	41	52
Mean	168.3	161.1	160.2
SD	47.59	30.19	29.47
Median	161.0	158.0	159.0
Minimum	114	79	108
Maximum	379	253	235

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	36	40	44
With values above reference range	2 (5.6%)	1 (2.5%)	0
With values below reference range	0	0	0
With values within reference range	34 (94.4%)	39 (97.5%)	44 (100.0%)
Summary statistics:			
Number of patients with values	36	40	44
Mean	166.7	167.9	158.3
SD	47.39	35.78	30.83
Median	161.5	164.0	157.5
Minimum	80	61	112
Maximum	340	300	263
Month 30			
Number of patients:			
With values	29	35	42
With values above reference range	1 (3.4%)	0	0
With values below reference range	0	0	0
With values within reference range	28 (96.6%)	35 (100.0%)	42 (100.0%)
Summary statistics:			
Number of patients with values	29	35	42
Mean	176.0	165.6	159.3
SD	57.17	28.43	23.42
Median	161.0	167.0	159.0
Minimum	91	70	111
Maximum	419	215	212

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	26	33	34
With values above reference range	1 (3.8%)	0	0
With values below reference range	0	0	0
With values within reference range	25 (96.2%)	33 (100.0%)	34 (100.0%)
Summary statistics:			
Number of patients with values	26	33	34
Mean	173.2	162.5	161.4
SD	44.34	30.47	33.42
Median	166.5	164.0	155.5
Minimum	108	64	103
Maximum	328	234	246
Month 36			
Number of patients:			
With values	27	26	31
With values above reference range	1 (3.7%)	1 (3.8%)	0
With values below reference range	0	0	0
With values within reference range	26 (96.3%)	25 (96.2%)	31 (100.0%)
Summary statistics:			
Number of patients with values	27	26	31
Mean	173.6	175.2	161.6
SD	44.22	34.58	27.53
Median	172.0	165.5	151.0
Minimum	99	126	121
Maximum	304	276	227

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	14	14	20
With values above reference range	1 (7.1%)	0	0
With values below reference range	0	0	0
With values within reference range	13 (92.9%)	14 (100.0%)	20 (100.0%)
Summary statistics:			
Number of patients with values	14	14	20
Mean	165.5	169.9	157.3
SD	48.69	29.12	33.85
Median	156.0	164.5	150.5
Minimum	110	125	113
Maximum	290	226	227
Month 42			
Number of patients:			
With values	8	15	9
With values above reference range	0	1 (6.7%)	0
With values below reference range	0	0	0
With values within reference range	8 (100.0%)	14 (93.3%)	9 (100.0%)
Summary statistics:			
Number of patients with values	8	15	9
Mean	154.0	172.7	155.0
SD	10.25	41.53	23.91
Median	153.0	170.0	162.0
Minimum	141	131	120
Maximum	169	305	190

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	7	5	7
With values above reference range	1 (14.3%)	0	0
With values below reference range	0	0	0
With values within reference range	6 (85.7%)	5 (100.0%)	7 (100.0%)
Summary statistics:			
Number of patients with values	7	5	7
Mean	185.6	161.8	140.7
SD	88.12	60.63	28.36
Median	158.0	132.0	137.0
Minimum	96	124	109
Maximum	360	268	185

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 0			
Number of patients:			
With values	6	7	8
With values above reference range	2 (33.3%)	5 (71.4%)	2 (25.0%)
With values below reference range	0	0	0
With values within reference range	4 (66.7%)	2 (28.6%)	6 (75.0%)
Summary statistics:			
Number of patients with values	6	7	8
Mean	173.7	296.7	189.3
SD	83.74	178.95	103.67
Median	167.0	212.0	181.5
Minimum	89	127	79
Maximum	310	558	389
Open Label Baseline			
Number of patients:			
With values	61	78	90
With values above reference range	17 (27.9%)	30 (38.5%)	31 (34.4%)
With values below reference range	0	0	0
With values within reference range	44 (72.1%)	48 (61.5%)	59 (65.6%)
Summary statistics:			
Number of patients with values	61	78	90
Mean	179.3	210.8	187.8
SD	127.15	132.03	99.58
Median	145.0	169.5	159.0
Minimum	37	42	35
Maximum	813	558	478

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 1			
Number of patients:			
With values	2	1	0
With values above reference range	1 (50.0%)	0	
With values below reference range	0	0	
With values within reference range	1 (50.0%)	1 (100.0%)	
Summary statistics:			
Number of patients with values	2	1	0
Mean	154.0	180.0	
SD	121.62		
Median	154.0	180.0	
Minimum	68	180	
Maximum	240	180	
Month 2			
Number of patients:			
With values	1	2	3
With values above reference range	0	1 (50.0%)	1 (33.3%)
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	1 (50.0%)	2 (66.7%)
Summary statistics:			
Number of patients with values	1	2	3
Mean	112.0	203.5	192.7
SD		44.55	105.36
Median	112.0	203.5	148.0
Minimum	112	172	117
Maximum	112	235	313

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 3			
Number of patients:			
With values	6	2	5
With values above reference range	2 (33.3%)	1 (50.0%)	2 (40.0%)
With values below reference range	0	0	0
With values within reference range	4 (66.7%)	1 (50.0%)	3 (60.0%)
Summary statistics:			
Number of patients with values	6	2	5
Mean	140.8	179.5	171.2
SD	53.69	94.05	49.25
Median	137.0	179.5	194.0
Minimum	73	113	95
Maximum	204	246	217
Month 6			
Number of patients:			
With values	51	70	77
With values above reference range	18 (35.3%)	25 (35.7%)	27 (35.1%)
With values below reference range	0	0	0
With values within reference range	33 (64.7%)	45 (64.3%)	50 (64.9%)
Summary statistics:			
Number of patients with values	51	70	77
Mean	185.2	205.6	188.6
SD	106.46	131.92	99.36
Median	163.0	161.5	169.0
Minimum	55	50	38
Maximum	526	584	545

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 9			
Number of patients:			
With values	1	4	4
With values above reference range	0	0	3 (75.0%)
With values below reference range	0	0	0
With values within reference range	1 (100.0%)	4 (100.0%)	1 (25.0%)
Summary statistics:			
Number of patients with values	1	4	4
Mean	162.0	172.0	202.5
SD		12.44	79.43
Median	162.0	172.0	215.5
Minimum	162	158	94
Maximum	162	186	285
Month 12			
Number of patients:			
With values	49	60	67
With values above reference range	15 (30.6%)	25 (41.7%)	25 (37.3%)
With values below reference range	0	0	0
With values within reference range	34 (69.4%)	35 (58.3%)	42 (62.7%)
Summary statistics:			
Number of patients with values	49	60	67
Mean	186.3	205.4	192.0
SD	99.29	131.11	98.48
Median	153.0	155.0	181.0
Minimum	62	51	49
Maximum	440	598	534

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 15			
Number of patients:			
With values	6	8	8
With values above reference range	2 (33.3%)	2 (25.0%)	1 (12.5%)
With values below reference range	0	0	0
With values within reference range	4 (66.7%)	6 (75.0%)	7 (87.5%)
Summary statistics:			
Number of patients with values	6	8	8
Mean	184.8	163.9	181.9
SD	53.32	139.80	133.63
Median	178.0	114.0	140.0
Minimum	112	56	82
Maximum	250	481	495
Month 18			
Number of patients:			
With values	42	50	58
With values above reference range	11 (26.2%)	22 (44.0%)	17 (29.3%)
With values below reference range	0	0	0
With values within reference range	31 (73.8%)	28 (56.0%)	41 (70.7%)
Summary statistics:			
Number of patients with values	42	50	58
Mean	169.1	192.3	186.7
SD	82.73	116.26	101.07
Median	164.0	142.5	157.0
Minimum	37	55	64
Maximum	356	514	558

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 21			
Number of patients:			
With values	4	4	5
With values above reference range	2 (50.0%)	0	2 (40.0%)
With values below reference range	0	0	0
With values within reference range	2 (50.0%)	4 (100.0%)	3 (60.0%)
Summary statistics:			
Number of patients with values	4	4	5
Mean	210.8	143.0	170.4
SD	41.29	46.08	53.61
Median	212.5	150.5	196.0
Minimum	168	82	103
Maximum	250	189	221
Month 24			
Number of patients:			
With values	35	40	47
With values above reference range	11 (31.4%)	12 (30.0%)	20 (42.6%)
With values below reference range	0	0	0
With values within reference range	24 (68.6%)	28 (70.0%)	27 (57.4%)
Summary statistics:			
Number of patients with values	35	40	47
Mean	161.0	193.1	194.3
SD	83.73	148.38	91.19
Median	145.0	145.0	185.0
Minimum	61	54	73
Maximum	431	622	461

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 27			
Number of patients:			
With values	9	4	5
With values above reference range	6 (66.7%)	1 (25.0%)	3 (60.0%)
With values below reference range	0	0	0
With values within reference range	3 (33.3%)	3 (75.0%)	2 (40.0%)
Summary statistics:			
Number of patients with values	9	4	5
Mean	222.8	175.5	261.2
SD	130.85	52.22	158.07
Median	218.0	182.5	218.0
Minimum	63	107	75
Maximum	517	230	482
Month 30			
Number of patients:			
With values	25	33	41
With values above reference range	9 (36.0%)	13 (39.4%)	13 (31.7%)
With values below reference range	0	0	0
With values within reference range	16 (64.0%)	20 (60.6%)	28 (68.3%)
Summary statistics:			
Number of patients with values	25	33	41
Mean	173.6	194.7	214.8
SD	103.30	113.51	221.11
Median	160.0	174.0	140.0
Minimum	50	49	72
Maximum	432	513	1301

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 33			
Number of patients:			
With values	1	5	6
With values above reference range	1 (100.0%)	2 (40.0%)	2 (33.3%)
With values below reference range	0	0	0
With values within reference range	0	3 (60.0%)	4 (66.7%)
Summary statistics:			
Number of patients with values	1	5	6
Mean	274.0	231.6	156.7
SD		172.37	54.94
Median	274.0	130.0	165.0
Minimum	274	118	90
Maximum	274	517	222
Month 36			
Number of patients:			
With values	20	23	28
With values above reference range	4 (20.0%)	6 (26.1%)	13 (46.4%)
With values below reference range	0	0	0
With values within reference range	16 (80.0%)	17 (73.9%)	15 (53.6%)
Summary statistics:			
Number of patients with values	20	23	28
Mean	154.3	166.5	215.1
SD	66.93	93.00	148.37
Median	137.0	135.0	187.0
Minimum	55	48	93
Maximum	297	494	882

BRL 49653C/009

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 39			
Number of patients:			
With values	4	4	9
With values above reference range	1 (25.0%)	3 (75.0%)	3 (33.3%)
With values below reference range	0	0	0
With values within reference range	3 (75.0%)	1 (25.0%)	6 (66.7%)
Summary statistics:			
Number of patients with values	4	4	9
Mean	152.3	227.5	165.7
SD	58.71	115.18	72.27
Median	152.5	220.5	166.0
Minimum	94	95	73
Maximum	210	374	265
Month 42			
Number of patients:			
With values	8	12	8
With values above reference range	2 (25.0%)	3 (25.0%)	2 (25.0%)
With values below reference range	0	0	0
With values within reference range	6 (75.0%)	9 (75.0%)	6 (75.0%)
Summary statistics:			
Number of patients with values	8	12	8
Mean	169.6	160.4	153.5
SD	72.82	71.89	69.44
Median	146.0	141.0	147.0
Minimum	89	72	70
Maximum	282	286	273

Data Source Table 15.7.1b

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	015:S/2bd	2bd Comb Total 015:1bd+S/2bd	015:2bd+S/2bd
Month 45			
Number of patients:			
With values	5	3	6
With values above reference range	0	0	1 (16.7%)
With values below reference range	0	0	0
With values within reference range	5 (100.0%)	3 (100.0%)	5 (83.3%)
Summary statistics:			
Number of patients with values	5	3	6
Mean	147.4	118.0	168.7
SD	36.78	47.82	115.91
Median	144.0	101.0	123.0
Minimum	94	81	101
Maximum	182	172	403

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	1 (25.0%)	2 (18.2%)	0	0
With values within reference range	3 (75.0%)	9 (81.8%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	13.48	13.91	14.57	14.20
SD	2.034	1.178	1.046	
Median	14.15	13.90	14.65	14.20
Minimum	10.5	11.6	13.0	14.2
Maximum	15.1	15.9	15.9	14.2
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	1 (0.8%)	1 (0.7%)	5 (3.6%)	0
With values below reference range	17 (13.7%)	12 (8.8%)	6 (4.3%)	3 (11.1%)
With values within reference range	106 (85.5%)	123 (90.4%)	128 (92.1%)	24 (88.9%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	13.48	14.16	14.65	14.11
SD	1.502	1.234	1.295	1.451
Median	13.65	14.20	14.90	14.40
Minimum	6.0	11.6	11.1	11.1
Maximum	16.9	19.6	17.6	16.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	1 (9.1%)	0	
With values below reference range	1 (33.3%)	1 (9.1%)	0	
With values within reference range	2 (66.7%)	9 (81.8%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	13.53	14.02	13.60	
SD	1.150	1.897	1.515	
Median	13.50	14.50	13.60	
Minimum	12.4	10.7	12.1	
Maximum	14.7	17.6	15.4	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	3 (42.9%)	
With values within reference range	1 (100.0%)	1 (100.0%)	4 (57.1%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	14.30	12.20	13.06	
SD			1.443	
Median	14.30	12.20	13.10	
Minimum	14.3	12.2	11.6	
Maximum	14.3	12.2	14.9	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	2 (1.8%)	0	0	0
With values below reference range	20 (17.7%)	18 (14.3%)	25 (20.0%)	4 (20.0%)
With values within reference range	91 (80.5%)	108 (85.7%)	100 (80.0%)	16 (80.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	13.30	13.74	13.59	13.57
SD	1.437	1.093	1.205	1.412
Median	13.60	13.75	13.70	13.55
Minimum	8.5	11.3	10.1	11.0
Maximum	17.5	16.2	16.4	15.9
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	1 (0.9%)	0	1 (0.8%)	0
With values below reference range	18 (15.9%)	14 (11.3%)	20 (16.5%)	5 (33.3%)
With values within reference range	94 (83.2%)	110 (88.7%)	100 (82.6%)	10 (66.7%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	13.29	13.79	13.76	13.18
SD	1.456	1.167	1.284	1.664
Median	13.40	13.80	13.80	13.60
Minimum	6.9	10.6	10.2	10.4
Maximum	16.5	16.8	16.4	15.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	1 (0.9%)	0	1 (0.9%)	0
With values below reference range	14 (12.5%)	13 (10.6%)	17 (14.5%)	6 (33.3%)
With values within reference range	97 (86.6%)	110 (89.4%)	99 (84.6%)	12 (66.7%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	13.39	13.82	13.78	13.22
SD	1.438	1.243	1.333	1.661
Median	13.50	13.80	13.90	13.30
Minimum	7.3	9.1	9.6	10.0
Maximum	16.9	16.5	16.9	15.4
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	1 (1.0%)	0	1 (1.0%)	0
With values below reference range	14 (13.7%)	16 (14.5%)	14 (13.5%)	4 (25.0%)
With values within reference range	87 (85.3%)	94 (85.5%)	89 (85.6%)	12 (75.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	13.46	13.82	13.80	13.61
SD	1.298	1.276	1.365	1.694
Median	13.60	13.80	13.90	13.90
Minimum	9.4	8.5	10.3	9.5
Maximum	15.9	16.4	17.4	16.5

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	1 (1.0%)	0	2 (2.0%)	0
With values below reference range	14 (14.1%)	17 (15.7%)	16 (16.3%)	2 (22.2%)
With values within reference range	84 (84.8%)	91 (84.3%)	80 (81.6%)	7 (77.8%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	13.33	13.75	13.62	13.37
SD	1.456	1.067	1.518	1.184
Median	13.30	13.80	13.70	13.60
Minimum	8.8	10.5	8.7	11.6
Maximum	16.5	16.5	16.9	14.7
Month 18				
Number of patients:				
With values	95	96	89	10
With values above reference range	1 (1.1%)	0	1 (1.1%)	0
With values below reference range	13 (13.7%)	12 (12.5%)	11 (12.4%)	2 (20.0%)
With values within reference range	81 (85.3%)	84 (87.5%)	77 (86.5%)	8 (80.0%)
Summary statistics:				
Number of patients with values	95	96	89	10
Mean	13.36	13.74	13.78	13.56
SD	1.400	1.091	1.447	1.357
Median	13.60	13.70	13.80	13.35
Minimum	8.7	11.1	10.2	11.3
Maximum	16.5	16.4	16.8	16.5

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	0	2 (2.2%)	1 (1.2%)	0
With values below reference range	14 (15.4%)	9 (9.8%)	14 (16.9%)	1 (12.5%)
With values within reference range	77 (84.6%)	81 (88.0%)	68 (81.9%)	7 (87.5%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	13.36	13.82	13.62	13.56
SD	1.300	1.138	1.487	1.263
Median	13.50	13.80	13.80	14.00
Minimum	9.8	10.3	10.4	11.4
Maximum	16.0	17.8	16.9	14.9
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	0	0	0	0
With values below reference range	12 (14.5%)	14 (16.9%)	11 (14.1%)	0
With values within reference range	71 (85.5%)	69 (83.1%)	67 (85.9%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	13.47	13.64	13.57	13.40
SD	1.329	1.325	1.361	0.849
Median	13.50	13.80	13.45	13.40
Minimum	10.8	9.1	10.6	12.2
Maximum	15.8	16.5	16.8	14.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	0	0	2 (2.8%)	0
With values below reference range	10 (13.7%)	9 (11.7%)	8 (11.3%)	1 (16.7%)
With values within reference range	63 (86.3%)	68 (88.3%)	61 (85.9%)	5 (83.3%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	13.48	13.70	13.59	13.22
SD	1.258	1.146	1.481	1.486
Median	13.60	13.80	13.60	13.60
Minimum	10.0	10.4	10.0	11.4
Maximum	15.9	16.6	16.9	14.9
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	0	0	0	0
With values below reference range	7 (13.0%)	13 (18.8%)	6 (11.8%)	1 (20.0%)
With values within reference range	47 (87.0%)	56 (81.2%)	45 (88.2%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	13.53	13.51	13.64	13.26
SD	1.412	1.216	1.390	1.379
Median	13.65	13.50	13.80	13.50
Minimum	9.9	9.3	9.0	10.9
Maximum	15.7	16.3	17.0	14.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	0	0	0	0
With values below reference range	10 (20.0%)	6 (13.0%)	9 (16.7%)	1 (33.3%)
With values within reference range	40 (80.0%)	40 (87.0%)	45 (83.3%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	13.46	13.78	13.35	13.07
SD	1.529	1.182	1.370	2.050
Median	13.60	13.70	13.40	14.20
Minimum	9.1	11.3	9.5	10.7
Maximum	16.1	17.1	15.8	14.3
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	0	0	0	0
With values below reference range	3 (13.6%)	2 (7.7%)	5 (17.9%)	0
With values within reference range	19 (86.4%)	24 (92.3%)	23 (82.1%)	1 (100.0%)
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	13.47	13.69	13.21	11.10
SD	1.243	1.194	1.652	
Median	13.50	13.55	13.20	11.10
Minimum	11.2	11.1	8.9	11.1
Maximum	15.8	15.8	15.6	11.1

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	12.95	13.18	13.63	15.20
SD	1.061	0.783	1.279	
Median	12.95	13.45	13.45	15.20
Minimum	12.2	12.1	12.3	15.2
Maximum	13.7	14.2	15.6	15.2
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Hemoglobin (g/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	1 (25.0%)	3 (27.3%)	1 (16.7%)	0
With values within reference range	3 (75.0%)	8 (72.7%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	40.05	41.07	42.95	42.20
SD	5.606	3.608	2.828	
Median	41.10	40.50	43.35	42.20
Minimum	32.3	34.5	39.3	42.2
Maximum	45.7	47.0	45.7	42.2
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	1 (0.8%)	1 (0.7%)	3 (2.2%)	0
With values below reference range	22 (17.7%)	18 (13.2%)	9 (6.5%)	5 (18.5%)
With values within reference range	101 (81.5%)	117 (86.0%)	127 (91.4%)	22 (81.5%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	39.36	41.19	42.53	41.51
SD	4.192	3.553	3.637	4.274
Median	39.50	41.40	42.80	42.20
Minimum	19.6	34.5	32.1	32.7
Maximum	49.1	60.2	52.9	48.8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	1 (9.1%)	0	
With values below reference range	1 (33.3%)	2 (18.2%)	0	
With values within reference range	2 (66.7%)	8 (72.7%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	40.13	41.53	40.06	
SD	4.552	5.579	3.663	
Median	40.30	42.20	39.60	
Minimum	35.5	31.6	36.7	
Maximum	44.6	53.7	45.4	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	2 (28.6%)	
With values within reference range	1 (100.0%)	1 (100.0%)	5 (71.4%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	42.20	37.50	38.90	
SD			3.635	
Median	42.20	37.50	38.50	
Minimum	42.2	37.5	35.5	
Maximum	42.2	37.5	43.9	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	2 (1.8%)	0	1 (0.8%)	0
With values below reference range	19 (16.8%)	16 (12.7%)	19 (15.2%)	2 (10.0%)
With values within reference range	92 (81.4%)	110 (87.3%)	105 (84.0%)	18 (90.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	39.66	40.71	40.52	40.67
SD	4.070	3.203	3.469	3.801
Median	40.30	40.85	40.80	41.15
Minimum	25.6	34.2	29.6	33.5
Maximum	51.3	48.8	49.2	48.4
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	1 (0.9%)	1 (0.8%)	1 (0.8%)	0
With values below reference range	18 (15.9%)	20 (16.1%)	14 (11.6%)	5 (33.3%)
With values within reference range	94 (83.2%)	103 (83.1%)	106 (87.6%)	10 (66.7%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	39.83	41.10	41.00	39.53
SD	4.256	3.447	3.674	4.701
Median	40.00	40.85	41.50	40.30
Minimum	20.6	31.5	30.5	30.1
Maximum	50.1	50.4	48.5	45.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	124	117	18
With values above reference range	2 (1.8%)	0	1 (0.9%)	0
With values below reference range	11 (9.8%)	16 (12.9%)	18 (15.4%)	5 (27.8%)
With values within reference range	99 (88.4%)	108 (87.1%)	98 (83.8%)	13 (72.2%)
Summary statistics:				
Number of patients with values	112	124	117	18
Mean	39.97	41.06	40.82	39.75
SD	4.211	3.608	3.738	4.650
Median	40.60	41.25	41.20	39.90
Minimum	22.0	27.4	28.3	30.1
Maximum	50.5	48.7	48.9	46.0
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	3 (2.9%)	2 (1.8%)	3 (2.9%)	0
With values below reference range	14 (13.7%)	17 (15.5%)	18 (17.3%)	4 (25.0%)
With values within reference range	85 (83.3%)	91 (82.7%)	83 (79.8%)	12 (75.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	40.30	41.18	41.13	40.73
SD	3.909	3.742	3.990	4.360
Median	40.55	41.10	41.50	41.35
Minimum	30.3	27.3	31.9	29.9
Maximum	47.7	49.3	51.1	46.9

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	108	98	9
With values above reference range	1 (1.0%)	2 (1.9%)	3 (3.1%)	0
With values below reference range	16 (16.0%)	16 (14.8%)	14 (14.3%)	1 (11.1%)
With values within reference range	83 (83.0%)	90 (83.3%)	81 (82.7%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	108	98	9
Mean	40.06	41.25	41.05	40.54
SD	4.258	3.319	4.439	2.725
Median	40.05	41.20	41.15	41.00
Minimum	27.8	31.6	26.8	36.7
Maximum	49.7	50.2	51.0	44.5
Month 18				
Number of patients:				
With values	95	96	90	10
With values above reference range	1 (1.1%)	1 (1.0%)	4 (4.4%)	0
With values below reference range	10 (10.5%)	13 (13.5%)	9 (10.0%)	0
With values within reference range	84 (88.4%)	82 (85.4%)	77 (85.6%)	10 (100.0%)
Summary statistics:				
Number of patients with values	95	96	90	10
Mean	40.39	41.30	41.47	41.26
SD	4.124	3.347	4.222	3.596
Median	40.50	41.30	41.25	40.45
Minimum	27.8	33.8	31.7	35.8
Maximum	48.7	50.7	50.4	49.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	2 (2.2%)	3 (3.3%)	3 (3.6%)	0
With values below reference range	9 (9.9%)	7 (7.6%)	11 (13.3%)	0
With values within reference range	80 (87.9%)	82 (89.1%)	69 (83.1%)	8 (100.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	40.68	41.92	41.30	41.28
SD	3.848	3.442	4.525	3.281
Median	40.70	41.85	41.70	42.10
Minimum	30.3	31.9	31.0	35.2
Maximum	50.3	55.3	50.7	44.6
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	1 (1.2%)	2 (2.4%)	1 (1.3%)	0
With values below reference range	6 (7.2%)	13 (15.7%)	5 (6.4%)	0
With values within reference range	76 (91.6%)	68 (81.9%)	72 (92.3%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	41.17	41.41	41.51	40.84
SD	4.011	4.046	4.039	2.690
Median	41.30	41.50	41.65	40.70
Minimum	32.9	27.8	33.1	37.4
Maximum	48.3	51.6	51.8	44.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	0	2 (2.6%)	2 (2.8%)	0
With values below reference range	6 (8.2%)	6 (7.8%)	2 (2.8%)	1 (16.7%)
With values within reference range	67 (91.8%)	69 (89.6%)	67 (94.4%)	5 (83.3%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	41.33	42.04	41.67	39.97
SD	3.756	3.633	4.400	3.923
Median	41.50	42.10	42.20	41.05
Minimum	30.8	31.5	29.5	34.7
Maximum	47.3	52.6	53.0	44.4
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	2 (3.7%)	1 (1.4%)	0	0
With values below reference range	5 (9.3%)	11 (15.9%)	3 (5.9%)	0
With values within reference range	47 (87.0%)	57 (82.6%)	48 (94.1%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	41.39	41.01	41.87	40.82
SD	4.375	3.707	4.047	3.108
Median	41.85	40.90	42.10	41.30
Minimum	31.7	28.5	29.9	35.6
Maximum	50.9	50.3	49.8	43.7

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	1 (2.0%)	1 (2.2%)	1 (1.9%)	0
With values below reference range	7 (14.0%)	5 (10.9%)	5 (9.3%)	0
With values within reference range	42 (84.0%)	40 (87.0%)	48 (88.9%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	40.88	41.84	40.65	39.67
SD	4.451	3.728	3.973	4.738
Median	41.35	41.70	41.15	42.20
Minimum	29.0	35.3	30.4	34.2
Maximum	49.5	54.1	48.6	42.6
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	0	0	0	0
With values below reference range	2 (9.1%)	3 (11.5%)	4 (14.3%)	0
With values within reference range	20 (90.9%)	23 (88.5%)	24 (85.7%)	1 (100.0%)
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	40.50	41.25	39.96	35.90
SD	3.653	3.563	4.904	
Median	40.40	40.85	39.40	35.90
Minimum	34.2	33.1	26.6	35.9
Maximum	47.4	48.0	47.5	35.9

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	1 (16.7%)	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	39.05	39.10	40.83	45.40
SD	2.475	1.950	3.409	
Median	39.05	39.40	40.65	45.40
Minimum	37.3	36.3	37.4	45.4
Maximum	40.8	41.5	46.6	45.4
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Hematocrit (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	4.48	4.49	4.70	4.70
SD	0.695	0.359	0.210	
Median	4.50	4.40	4.65	4.70
Minimum	3.6	3.8	4.5	4.7
Maximum	5.3	5.2	5.1	4.7
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	0	2 (1.5%)	5 (3.6%)	1 (3.7%)
With values below reference range	14 (11.3%)	6 (4.4%)	4 (2.9%)	2 (7.4%)
With values within reference range	110 (88.7%)	128 (94.1%)	130 (93.5%)	24 (88.9%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	4.38	4.58	4.75	4.70
SD	0.501	0.425	0.435	0.508
Median	4.40	4.60	4.70	4.70
Minimum	1.9	3.5	3.5	3.4
Maximum	5.7	6.9	6.1	5.6

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	1 (9.1%)	0	
With values below reference range	1 (33.3%)	0	0	
With values within reference range	2 (66.7%)	10 (90.9%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	4.57	4.62	4.42	
SD	0.551	0.687	0.268	
Median	4.30	4.60	4.40	
Minimum	4.2	3.6	4.0	
Maximum	5.2	6.3	4.7	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	4.50	4.40	4.40	
SD			0.416	
Median	4.50	4.40	4.40	
Minimum	4.5	4.4	3.8	
Maximum	4.5	4.4	4.9	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	1 (0.9%)	1 (0.8%)	0	0
With values below reference range	15 (13.3%)	10 (7.9%)	14 (11.2%)	1 (5.0%)
With values within reference range	97 (85.8%)	115 (91.3%)	111 (88.8%)	19 (95.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	4.38	4.48	4.45	4.54
SD	0.455	0.376	0.379	0.477
Median	4.40	4.50	4.40	4.55
Minimum	2.8	3.3	3.3	3.3
Maximum	5.6	5.9	5.6	5.2
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	1 (0.9%)	1 (0.8%)	2 (1.7%)	0
With values below reference range	16 (14.2%)	12 (9.7%)	16 (13.2%)	2 (13.3%)
With values within reference range	96 (85.0%)	111 (89.5%)	103 (85.1%)	13 (86.7%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	4.35	4.47	4.46	4.39
SD	0.483	0.380	0.412	0.571
Median	4.40	4.50	4.50	4.40
Minimum	2.2	3.3	3.3	2.9
Maximum	5.3	6.0	5.6	5.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	0	1 (0.8%)	1 (0.9%)	0
With values below reference range	11 (9.8%)	13 (10.6%)	18 (15.4%)	2 (11.1%)
With values within reference range	101 (90.2%)	109 (88.6%)	98 (83.8%)	16 (88.9%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	4.38	4.47	4.44	4.39
SD	0.486	0.386	0.424	0.562
Median	4.40	4.50	4.40	4.50
Minimum	2.3	3.4	3.0	2.9
Maximum	5.8	5.9	5.6	5.0
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	1 (1.0%)	0	0	0
With values below reference range	10 (9.8%)	9 (8.2%)	16 (15.4%)	2 (12.5%)
With values within reference range	91 (89.2%)	101 (91.8%)	88 (84.6%)	14 (87.5%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	4.42	4.48	4.47	4.54
SD	0.456	0.391	0.438	0.497
Median	4.45	4.50	4.50	4.40
Minimum	3.4	3.4	3.4	3.9
Maximum	5.4	5.2	5.8	5.5

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	108	98	9
With values above reference range	1 (1.0%)	1 (0.9%)	1 (1.0%)	0
With values below reference range	15 (15.0%)	10 (9.3%)	13 (13.3%)	0
With values within reference range	84 (84.0%)	97 (89.8%)	84 (85.7%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	108	98	9
Mean	4.37	4.47	4.43	4.51
SD	0.488	0.388	0.458	0.298
Median	4.40	4.50	4.40	4.40
Minimum	3.3	3.4	3.2	4.2
Maximum	5.4	6.1	5.7	5.1
Month 18				
Number of patients:				
With values	95	96	90	10
With values above reference range	0	0	1 (1.1%)	0
With values below reference range	11 (11.6%)	7 (7.3%)	9 (10.0%)	2 (20.0%)
With values within reference range	84 (88.4%)	89 (92.7%)	80 (88.9%)	8 (80.0%)
Summary statistics:				
Number of patients with values	95	96	90	10
Mean	4.37	4.43	4.44	4.50
SD	0.462	0.338	0.444	0.437
Median	4.40	4.45	4.40	4.35
Minimum	3.1	3.4	3.4	4.1
Maximum	5.4	5.3	5.6	5.6

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	0	1 (1.1%)	0	0
With values below reference range	10 (11.0%)	7 (7.6%)	10 (12.0%)	0
With values within reference range	81 (89.0%)	84 (91.3%)	73 (88.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	4.36	4.48	4.40	4.50
SD	0.449	0.400	0.464	0.316
Median	4.40	4.50	4.40	4.45
Minimum	3.2	3.6	3.3	4.2
Maximum	5.3	6.7	5.7	5.0
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	0	0	1 (1.3%)	0
With values below reference range	9 (10.8%)	10 (12.0%)	9 (11.5%)	0
With values within reference range	74 (89.2%)	73 (88.0%)	68 (87.2%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	4.42	4.43	4.44	4.46
SD	0.482	0.402	0.473	0.456
Median	4.50	4.40	4.40	4.40
Minimum	3.3	3.3	3.4	4.0
Maximum	5.5	5.4	5.7	5.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	0	1 (1.3%)	1 (1.4%)	0
With values below reference range	6 (8.2%)	6 (7.8%)	6 (8.5%)	0
With values within reference range	67 (91.8%)	70 (90.9%)	64 (90.1%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	4.44	4.48	4.42	4.50
SD	0.437	0.396	0.477	0.283
Median	4.40	4.50	4.40	4.45
Minimum	3.2	3.4	3.3	4.2
Maximum	5.3	5.9	5.4	5.0
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	1 (1.9%)	0	0	0
With values below reference range	5 (9.3%)	9 (13.0%)	8 (15.7%)	0
With values within reference range	48 (88.9%)	60 (87.0%)	43 (84.3%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	4.44	4.38	4.37	4.44
SD	0.484	0.382	0.401	0.230
Median	4.50	4.40	4.40	4.40
Minimum	3.4	3.2	3.0	4.2
Maximum	5.7	5.3	5.1	4.8

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	0	1 (2.2%)	0	0
With values below reference range	9 (18.0%)	5 (10.9%)	9 (16.7%)	0
With values within reference range	41 (82.0%)	40 (87.0%)	45 (83.3%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	4.40	4.48	4.29	4.23
SD	0.536	0.443	0.449	0.231
Median	4.50	4.45	4.30	4.10
Minimum	3.0	3.8	3.1	4.1
Maximum	5.4	6.4	5.6	4.5
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	0	0	0	0
With values below reference range	3 (13.6%)	2 (7.7%)	2 (7.1%)	0
With values within reference range	19 (86.4%)	24 (92.3%)	26 (92.9%)	1 (100.0%)
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	4.42	4.43	4.25	4.20
SD	0.485	0.435	0.473	
Median	4.45	4.50	4.30	4.20
Minimum	3.7	3.5	2.9	4.2
Maximum	5.4	5.4	5.1	4.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	4.25	4.33	4.52	4.80
SD	0.495	0.151	0.319	
Median	4.25	4.40	4.55	4.80
Minimum	3.9	4.1	4.1	4.8
Maximum	4.6	4.5	4.9	4.8
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Red Blood Cell Count ($10^{12}/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	89.5	91.6	91.5	91.0
SD	2.65	3.20	5.24	
Median	90.0	91.0	90.0	91.0
Minimum	86	87	85	91
Maximum	92	97	100	91
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	2 (1.6%)	4 (2.9%)	2 (1.4%)	0
With values below reference range	5 (4.0%)	1 (0.7%)	3 (2.2%)	2 (7.4%)
With values within reference range	117 (94.4%)	131 (96.3%)	134 (96.4%)	25 (92.6%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	90.1	90.2	89.9	88.5
SD	4.51	5.09	5.59	5.57
Median	90.0	90.0	90.0	89.0
Minimum	74	60	63	74
Maximum	106	105	105	97

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCV (fL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	88.0	90.4	90.4	
SD	5.20	2.73	5.81	
Median	85.0	91.0	89.0	
Minimum	85	86	83	
Maximum	94	95	99	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	94.0	86.0	88.9	
SD			4.41	
Median	94.0	86.0	90.0	
Minimum	94	86	82	
Maximum	94	86	96	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (fL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	2 (1.8%)	3 (2.4%)	1 (0.8%)	0
With values below reference range	4 (3.5%)	2 (1.6%)	1 (0.8%)	2 (10.0%)
With values within reference range	107 (94.7%)	121 (96.0%)	123 (98.4%)	18 (90.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	90.8	91.2	91.3	90.0
SD	4.40	5.19	4.55	6.99
Median	91.0	91.0	91.0	91.5
Minimum	75	61	77	73
Maximum	105	109	107	100
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	3 (2.7%)	4 (3.2%)	3 (2.5%)	0
With values below reference range	3 (2.7%)	1 (0.8%)	3 (2.5%)	2 (13.3%)
With values within reference range	107 (94.7%)	119 (96.0%)	115 (95.0%)	13 (86.7%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	91.9	92.3	92.1	90.5
SD	4.78	5.57	6.12	7.53
Median	92.0	92.0	92.0	93.0
Minimum	77	61	64	74
Maximum	107	112	109	102

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	2 (1.8%)	4 (3.3%)	3 (2.6%)	1 (5.6%)
With values below reference range	2 (1.8%)	2 (1.6%)	3 (2.6%)	2 (11.1%)
With values within reference range	108 (96.4%)	117 (95.1%)	111 (94.9%)	15 (83.3%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	91.4	92.0	92.3	91.1
SD	4.74	5.46	5.86	8.07
Median	92.0	92.0	93.0	92.0
Minimum	74	62	65	74
Maximum	106	108	109	109
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	2 (2.0%)	4 (3.6%)	4 (3.8%)	0
With values below reference range	2 (2.0%)	2 (1.8%)	2 (1.9%)	2 (12.5%)
With values within reference range	98 (96.1%)	104 (94.5%)	98 (94.2%)	14 (87.5%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	91.6	92.1	92.4	90.1
SD	4.98	5.26	5.60	7.07
Median	92.0	92.0	93.0	92.0
Minimum	72	70	65	75
Maximum	106	108	108	100

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	2 (2.0%)	8 (7.4%)	4 (4.1%)	0
With values below reference range	2 (2.0%)	1 (0.9%)	3 (3.1%)	1 (11.1%)
With values within reference range	95 (96.0%)	99 (91.7%)	91 (92.9%)	8 (88.9%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	91.9	92.6	93.0	89.8
SD	4.96	5.93	6.33	6.98
Median	92.0	92.0	93.0	90.0
Minimum	70	62	65	76
Maximum	110	112	109	101
Month 18				
Number of patients:				
With values	95	96	89	10
With values above reference range	3 (3.2%)	4 (4.2%)	6 (6.7%)	0
With values below reference range	1 (1.1%)	0	3 (3.4%)	1 (10.0%)
With values within reference range	91 (95.8%)	92 (95.8%)	80 (89.9%)	9 (90.0%)
Summary statistics:				
Number of patients with values	95	96	89	10
Mean	92.9	93.7	93.8	91.7
SD	5.57	4.66	6.31	6.82
Median	94.0	93.0	94.0	93.5
Minimum	69	83	63	76
Maximum	109	109	108	101

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	4 (4.4%)	3 (3.3%)	5 (6.0%)	1 (12.5%)
With values below reference range	0	0	3 (3.6%)	1 (12.5%)
With values within reference range	87 (95.6%)	89 (96.7%)	75 (90.4%)	6 (75.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	93.5	93.7	94.2	91.8
SD	4.88	4.58	6.59	8.78
Median	94.0	94.0	95.0	92.5
Minimum	80	82	65	74
Maximum	109	107	111	105
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	4 (4.8%)	2 (2.4%)	4 (5.1%)	0
With values below reference range	1 (1.2%)	0	2 (2.6%)	0
With values within reference range	78 (94.0%)	81 (97.6%)	72 (92.3%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	93.5	93.8	94.0	92.0
SD	5.05	4.27	6.19	4.95
Median	94.0	93.0	95.0	93.0
Minimum	81	83	68	86
Maximum	109	110	106	98

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	3 (4.1%)	2 (2.6%)	4 (5.6%)	0
With values below reference range	0	0	2 (2.8%)	1 (16.7%)
With values within reference range	70 (95.9%)	75 (97.4%)	65 (91.5%)	5 (83.3%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	93.4	94.1	94.6	89.0
SD	4.44	4.58	6.24	9.25
Median	93.0	94.0	94.0	89.0
Minimum	84	82	68	75
Maximum	109	111	114	103
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	2 (3.7%)	3 (4.3%)	8 (15.7%)	0
With values below reference range	0	0	1 (2.0%)	0
With values within reference range	52 (96.3%)	66 (95.7%)	42 (82.4%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	93.6	93.9	95.9	92.6
SD	5.26	4.18	5.65	6.50
Median	93.0	93.0	96.0	93.0
Minimum	84	86	78	86
Maximum	116	108	111	102

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	3 (6.0%)	1 (2.2%)	6 (11.1%)	0
With values below reference range	1 (2.0%)	0	0	0
With values within reference range	46 (92.0%)	45 (97.8%)	48 (88.9%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	93.3	93.5	94.9	94.0
SD	6.23	4.53	5.51	9.54
Median	93.0	93.0	94.5	95.0
Minimum	81	84	80	84
Maximum	117	111	110	103
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	1 (4.5%)	1 (3.8%)	3 (10.7%)	0
With values below reference range	0	0	1 (3.6%)	0
With values within reference range	21 (95.5%)	25 (96.2%)	24 (85.7%)	1 (100.0%)
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	91.9	93.2	94.4	86.0
SD	4.87	5.11	6.42	
Median	92.5	92.5	95.0	86.0
Minimum	83	85	79	86
Maximum	102	112	109	86

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	1 (16.7%)	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	93.0	90.5	91.0	95.0
SD	4.24	3.45	6.60	
Median	93.0	91.0	92.5	95.0
Minimum	90	86	79	95
Maximum	96	95	97	95
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCV (FL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	30.00	31.04	31.13	30.60
SD	1.649	1.095	1.652	
Median	30.20	30.60	31.40	30.60
Minimum	28.2	29.8	28.2	30.6
Maximum	31.4	33.0	33.0	30.6
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	3 (2.4%)	6 (4.4%)	8 (5.8%)	0
With values below reference range	4 (3.2%)	1 (0.7%)	3 (2.2%)	3 (11.1%)
With values within reference range	117 (94.4%)	129 (94.9%)	128 (92.1%)	24 (88.9%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	30.76	30.97	30.97	29.98
SD	1.685	1.939	2.125	1.976
Median	30.60	30.60	31.40	29.80
Minimum	24.2	19.3	20.1	25.0
Maximum	36.3	36.3	37.9	33.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	29.80	30.53	30.60	
SD	1.600	1.578	2.332	
Median	29.80	30.60	30.60	
Minimum	28.2	28.2	27.4	
Maximum	31.4	33.0	33.8	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	1 (14.3%)	
With values within reference range	1 (100.0%)	1 (100.0%)	6 (85.7%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	32.20	28.20	29.80	
SD			1.532	
Median	32.20	28.20	29.80	
Minimum	32.2	28.2	26.6	
Maximum	32.2	28.2	31.4	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	1 (0.9%)	4 (3.2%)	3 (2.4%)	0
With values below reference range	5 (4.4%)	1 (0.8%)	2 (1.6%)	3 (15.0%)
With values within reference range	107 (94.7%)	121 (96.0%)	120 (96.0%)	17 (85.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	30.35	30.73	30.59	29.96
SD	1.667	1.935	1.654	2.603
Median	30.60	30.60	30.60	30.60
Minimum	23.4	19.3	25.8	23.4
Maximum	35.4	36.3	36.3	33.8
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	2 (1.8%)	4 (3.2%)	7 (5.8%)	1 (6.7%)
With values below reference range	5 (4.4%)	2 (1.6%)	4 (3.3%)	2 (13.3%)
With values within reference range	106 (93.8%)	118 (95.2%)	110 (90.9%)	12 (80.0%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	30.62	30.95	30.89	30.23
SD	1.759	1.913	2.230	2.945
Median	30.60	30.60	30.60	30.60
Minimum	24.2	19.3	20.1	24.2
Maximum	36.3	37.1	37.1	35.4

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	4 (3.6%)	5 (4.1%)	5 (4.3%)	1 (5.6%)
With values below reference range	1 (0.9%)	2 (1.6%)	4 (3.4%)	3 (16.7%)
With values within reference range	107 (95.5%)	116 (94.3%)	108 (92.3%)	14 (77.8%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	30.61	30.97	31.09	30.21
SD	1.733	1.937	2.202	3.046
Median	30.60	30.60	31.40	30.60
Minimum	24.2	20.1	20.9	24.2
Maximum	36.3	36.3	37.9	36.3
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	2 (2.0%)	6 (5.5%)	3 (2.9%)	0
With values below reference range	3 (2.9%)	1 (0.9%)	2 (1.9%)	2 (12.5%)
With values within reference range	97 (95.1%)	103 (93.6%)	99 (95.2%)	14 (87.5%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	30.54	30.84	30.93	29.90
SD	1.869	2.006	2.031	2.659
Median	30.60	30.60	30.60	31.00
Minimum	22.6	21.8	20.9	24.2
Maximum	36.3	37.9	37.1	33.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	2 (2.0%)	4 (3.7%)	4 (4.1%)	0
With values below reference range	3 (3.0%)	2 (1.9%)	5 (5.1%)	1 (11.1%)
With values within reference range	94 (94.9%)	102 (94.4%)	89 (90.8%)	8 (88.9%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	30.56	30.86	30.85	29.62
SD	1.900	2.077	2.329	2.794
Median	30.60	30.60	31.40	29.00
Minimum	21.8	19.3	20.1	24.2
Maximum	36.3	38.7	35.4	33.8
Month 18				
Number of patients:				
With values	95	96	89	10
With values above reference range	3 (3.2%)	3 (3.1%)	5 (5.6%)	0
With values below reference range	4 (4.2%)	0	3 (3.4%)	1 (10.0%)
With values within reference range	88 (92.6%)	93 (96.9%)	81 (91.0%)	9 (90.0%)
Summary statistics:				
Number of patients with values	95	96	89	10
Mean	30.67	31.08	31.15	30.12
SD	1.894	1.545	2.349	2.479
Median	30.60	30.60	31.40	30.60
Minimum	21.8	27.4	19.3	24.2
Maximum	36.3	36.3	36.3	33.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	2 (2.2%)	1 (1.1%)	4 (4.8%)	0
With values below reference range	1 (1.1%)	2 (2.2%)	4 (4.8%)	1 (12.5%)
With values within reference range	88 (96.7%)	89 (96.7%)	75 (90.4%)	7 (87.5%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	30.68	30.87	31.00	30.00
SD	1.777	1.728	2.259	3.016
Median	30.60	30.60	31.40	31.00
Minimum	25.8	26.6	20.1	24.2
Maximum	36.3	37.9	36.3	33.8
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	3 (3.6%)	3 (3.6%)	1 (1.3%)	0
With values below reference range	1 (1.2%)	0	3 (3.8%)	0
With values within reference range	79 (95.2%)	80 (96.4%)	74 (94.9%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	30.51	30.87	30.63	30.12
SD	1.823	1.516	2.199	2.161
Median	30.60	30.60	30.60	29.80
Minimum	26.6	27.4	20.9	27.4
Maximum	35.4	37.1	34.6	33.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	2 (2.7%)	1 (1.3%)	2 (2.8%)	0
With values below reference range	1 (1.4%)	1 (1.3%)	3 (4.2%)	1 (16.7%)
With values within reference range	70 (95.9%)	75 (97.4%)	66 (93.0%)	5 (83.3%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	30.43	30.65	30.81	29.40
SD	1.661	1.689	2.232	3.347
Median	30.60	30.60	30.60	29.00
Minimum	26.6	26.6	20.9	25.0
Maximum	36.3	37.1	37.1	34.6
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	3 (5.6%)	1 (1.4%)	1 (2.0%)	0
With values below reference range	1 (1.9%)	0	2 (3.9%)	1 (20.0%)
With values within reference range	50 (92.6%)	68 (98.6%)	48 (94.1%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	30.62	30.94	31.18	29.96
SD	1.790	1.523	1.860	2.677
Median	30.60	30.60	31.40	29.80
Minimum	26.6	28.2	25.8	26.6
Maximum	37.9	36.3	34.6	33.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	3 (6.0%)	1 (2.2%)	2 (3.7%)	0
With values below reference range	2 (4.0%)	1 (2.2%)	2 (3.7%)	1 (33.3%)
With values within reference range	45 (90.0%)	44 (95.7%)	50 (92.6%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	30.65	30.78	31.12	31.13
SD	2.092	1.809	1.903	4.105
Median	30.60	30.60	30.60	32.20
Minimum	25.8	26.6	26.6	26.6
Maximum	37.9	37.9	36.3	34.6
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	1 (4.5%)	2 (7.7%)	1 (3.6%)	0
With values below reference range	0	0	1 (3.6%)	1 (100.0%)
With values within reference range	21 (95.5%)	24 (92.3%)	26 (92.9%)	0
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	30.45	31.00	31.11	26.60
SD	1.574	2.028	2.180	
Median	30.60	30.60	31.40	26.60
Minimum	28.2	28.2	24.2	26.6
Maximum	34.6	37.9	35.4	26.6

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	1 (16.7%)	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	30.60	30.33	30.33	32.20
SD	1.131	1.093	2.513	
Median	30.60	30.20	31.00	32.20
Minimum	29.8	29.0	25.8	32.2
Maximum	31.4	32.2	32.2	32.2
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCH (PG)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	33.5	34.0	34.2	34.0
SD	1.00	0.00	0.41	
Median	34.0	34.0	34.0	34.0
Minimum	32	34	34	34
Maximum	34	34	35	34
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	0	0	0	0
With values below reference range	1 (0.8%)	0	0	0
With values within reference range	123 (99.2%)	136 (100.0%)	139 (100.0%)	27 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	34.1	34.3	34.3	34.0
SD	0.76	0.59	0.69	0.48
Median	34.0	34.0	34.0	34.0
Minimum	31	32	32	32
Maximum	35	35	35	35

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	33.7	33.5	33.4	
SD	1.53	1.04	1.34	
Median	34.0	34.0	34.0	
Minimum	32	32	32	
Maximum	35	35	35	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	34.0	32.0	33.3	
SD			1.25	
Median	34.0	32.0	34.0	
Minimum	34	32	32	
Maximum	34	32	35	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	0	0	0	0
With values below reference range	0	1 (0.8%)	0	0
With values within reference range	113 (100.0%)	125 (99.2%)	125 (100.0%)	20 (100.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	33.6	33.7	33.6	33.2
SD	0.88	0.92	0.88	1.15
Median	34.0	34.0	34.0	34.0
Minimum	32	31	32	32
Maximum	35	35	35	35
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	0	0	0	0
With values below reference range	1 (0.9%)	1 (0.8%)	3 (2.5%)	0
With values within reference range	112 (99.1%)	123 (99.2%)	118 (97.5%)	15 (100.0%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	33.4	33.6	33.5	33.4
SD	1.05	0.98	1.02	1.06
Median	34.0	34.0	34.0	34.0
Minimum	31	31	31	32
Maximum	35	35	35	35

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	112 (100.0%)	123 (100.0%)	117 (100.0%)	18 (100.0%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	33.6	33.7	33.7	33.1
SD	0.85	0.87	0.82	1.02
Median	34.0	34.0	34.0	34.0
Minimum	32	32	32	32
Maximum	35	35	35	34
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	0	0	0	0
With values below reference range	1 (1.0%)	1 (0.9%)	0	0
With values within reference range	101 (99.0%)	109 (99.1%)	104 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	33.4	33.7	33.5	33.1
SD	0.99	0.86	0.96	1.12
Median	34.0	34.0	34.0	33.0
Minimum	31	31	32	32
Maximum	35	35	35	35

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	0	0	0	0
With values below reference range	3 (3.0%)	5 (4.6%)	5 (5.1%)	0
With values within reference range	96 (97.0%)	103 (95.4%)	93 (94.9%)	9 (100.0%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	33.3	33.4	33.2	33.1
SD	1.09	1.03	1.16	1.05
Median	34.0	34.0	34.0	34.0
Minimum	31	31	29	32
Maximum	35	35	35	34
Month 18				
Number of patients:				
With values	95	96	89	10
With values above reference range	0	0	0	0
With values below reference range	4 (4.2%)	0	3 (3.4%)	0
With values within reference range	91 (95.8%)	96 (100.0%)	86 (96.6%)	10 (100.0%)
Summary statistics:				
Number of patients with values	95	96	89	10
Mean	33.0	33.3	33.3	32.8
SD	1.08	1.01	1.07	1.03
Median	34.0	34.0	34.0	32.0
Minimum	31	32	31	32
Maximum	35	35	35	34

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	0	0	0	0
With values below reference range	6 (6.6%)	3 (3.3%)	1 (1.2%)	0
With values within reference range	85 (93.4%)	89 (96.7%)	82 (98.8%)	8 (100.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	32.8	32.8	32.9	32.5
SD	1.11	1.08	1.02	0.93
Median	32.0	32.0	32.0	32.0
Minimum	31	31	31	32
Maximum	35	35	34	34
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	0	0	0	0
With values below reference range	2 (2.4%)	0	4 (5.1%)	0
With values within reference range	81 (97.6%)	83 (100.0%)	74 (94.9%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	32.5	32.8	32.6	32.8
SD	0.93	0.99	1.01	1.10
Median	32.0	32.0	32.0	32.0
Minimum	31	32	31	32
Maximum	34	34	35	34

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	0	0	0	0
With values below reference range	2 (2.7%)	5 (6.5%)	2 (2.8%)	0
With values within reference range	71 (97.3%)	72 (93.5%)	69 (97.2%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	32.4	32.4	32.5	33.0
SD	0.84	0.94	0.92	1.10
Median	32.0	32.0	32.0	33.0
Minimum	31	31	31	32
Maximum	34	34	34	34
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	0	0	0	0
With values below reference range	2 (3.7%)	3 (4.3%)	4 (7.8%)	1 (20.0%)
With values within reference range	52 (96.3%)	66 (95.7%)	47 (92.2%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	32.6	32.9	32.5	32.2
SD	0.98	1.06	1.01	1.10
Median	32.0	32.0	32.0	32.0
Minimum	31	31	31	31
Maximum	34	34	34	34

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	0	0	0	0
With values below reference range	1 (2.0%)	2 (4.3%)	1 (1.9%)	1 (33.3%)
With values within reference range	49 (98.0%)	44 (95.7%)	53 (98.1%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	32.8	32.8	32.7	33.0
SD	1.04	1.08	1.04	1.73
Median	32.0	32.0	32.0	34.0
Minimum	31	31	31	31
Maximum	35	35	35	34
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	1 (3.6%)	1 (100.0%)
With values within reference range	22 (100.0%)	26 (100.0%)	27 (96.4%)	0
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	33.3	33.1	32.9	31.0
SD	0.98	1.13	1.07	
Median	34.0	33.0	32.0	31.0
Minimum	32	32	31	31
Maximum	34	35	34	31

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	33.0	33.8	33.3	34.0
SD	1.41	0.98	1.03	
Median	33.0	34.0	34.0	34.0
Minimum	32	32	32	34
Maximum	34	35	34	34
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: MCHC (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	1 (9.1%)	0	0
With values below reference range	0	1 (9.1%)	0	0
With values within reference range	4 (100.0%)	9 (81.8%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	5.90	6.12	7.43	5.90
SD	0.913	2.585	1.219	
Median	5.90	5.50	6.80	5.90
Minimum	4.8	3.5	6.4	5.9
Maximum	7.0	12.2	9.4	5.9
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	1 (0.8%)	2 (1.5%)	5 (3.6%)	0
With values below reference range	7 (5.6%)	6 (4.4%)	2 (1.4%)	2 (7.4%)
With values within reference range	116 (93.5%)	128 (94.1%)	132 (95.0%)	25 (92.6%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	6.02	6.21	6.99	5.33
SD	2.160	1.719	1.827	1.175
Median	5.60	5.95	6.80	5.20
Minimum	3.2	3.2	3.0	3.2
Maximum	23.9	12.3	15.2	7.6

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	6.77	5.26	6.84	
SD	0.987	1.042	2.506	
Median	6.30	4.90	6.50	
Minimum	6.1	4.2	4.9	
Maximum	7.9	7.0	11.1	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	6.40	6.20	5.46	
SD			1.170	
Median	6.40	6.20	4.90	
Minimum	6.4	6.2	4.2	
Maximum	6.4	6.2	7.7	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	2 (1.8%)	2 (1.6%)	2 (1.6%)	0
With values below reference range	7 (6.2%)	6 (4.8%)	2 (1.6%)	5 (25.0%)
With values within reference range	104 (92.0%)	118 (93.7%)	121 (96.8%)	15 (75.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	5.81	5.92	6.10	5.12
SD	2.238	1.743	1.545	1.808
Median	5.40	5.60	6.00	4.70
Minimum	3.2	2.8	2.9	3.0
Maximum	23.5	13.6	12.0	9.8
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	2 (1.8%)	2 (1.6%)	3 (2.5%)	0
With values below reference range	7 (6.2%)	12 (9.7%)	6 (5.0%)	1 (6.7%)
With values within reference range	104 (92.0%)	110 (88.7%)	112 (92.6%)	14 (93.3%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	5.78	5.77	5.97	5.06
SD	2.218	1.821	1.621	1.017
Median	5.50	5.60	5.70	5.20
Minimum	3.1	2.6	2.9	3.4
Maximum	22.8	13.7	12.7	7.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	1 (0.9%)	1 (0.8%)	2 (1.7%)	0
With values below reference range	4 (3.6%)	8 (6.5%)	5 (4.3%)	3 (16.7%)
With values within reference range	107 (95.5%)	114 (92.7%)	110 (94.0%)	15 (83.3%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	5.88	5.82	6.10	4.99
SD	2.145	1.688	1.966	1.153
Median	5.55	5.50	5.70	4.95
Minimum	3.1	3.1	3.1	3.1
Maximum	22.7	10.9	18.1	7.5
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	2 (2.0%)	0	1 (1.0%)	0
With values below reference range	7 (6.9%)	10 (9.1%)	4 (3.8%)	2 (12.5%)
With values within reference range	93 (91.2%)	100 (90.9%)	99 (95.2%)	14 (87.5%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	5.77	5.57	6.05	4.81
SD	2.004	1.558	1.812	0.855
Median	5.50	5.50	5.85	4.90
Minimum	3.1	2.7	2.7	3.7
Maximum	19.5	10.2	15.2	6.4

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	108	98	9
With values above reference range	2 (2.0%)	1 (0.9%)	2 (2.0%)	0
With values below reference range	9 (9.0%)	10 (9.3%)	4 (4.1%)	2 (22.2%)
With values within reference range	89 (89.0%)	97 (89.8%)	92 (93.9%)	7 (77.8%)
Summary statistics:				
Number of patients with values	100	108	98	9
Mean	5.63	5.80	6.09	4.57
SD	2.260	1.805	1.828	0.784
Median	5.25	5.50	5.90	4.60
Minimum	3.1	2.9	2.6	3.6
Maximum	22.1	14.0	13.5	5.9
Month 18				
Number of patients:				
With values	95	96	90	10
With values above reference range	1 (1.1%)	2 (2.1%)	1 (1.1%)	0
With values below reference range	6 (6.3%)	6 (6.3%)	5 (5.6%)	3 (30.0%)
With values within reference range	88 (92.6%)	88 (91.7%)	84 (93.3%)	7 (70.0%)
Summary statistics:				
Number of patients with values	95	96	90	10
Mean	5.54	5.63	5.75	4.66
SD	1.888	1.871	1.592	1.218
Median	5.30	5.20	5.60	4.70
Minimum	3.0	2.8	3.1	2.5
Maximum	19.8	16.4	13.3	6.8

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	1 (1.1%)	0	2 (2.4%)	0
With values below reference range	10 (11.0%)	12 (13.0%)	2 (2.4%)	2 (25.0%)
With values within reference range	80 (87.9%)	80 (87.0%)	79 (95.2%)	6 (75.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	5.46	5.43	5.99	4.85
SD	1.797	1.599	1.709	1.282
Median	5.20	5.15	5.90	4.95
Minimum	2.3	2.7	3.0	2.8
Maximum	17.1	10.2	12.0	6.7
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	1 (1.2%)	0	0	0
With values below reference range	6 (7.2%)	9 (10.8%)	2 (2.6%)	1 (20.0%)
With values within reference range	76 (91.6%)	74 (89.2%)	76 (97.4%)	4 (80.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	5.54	5.20	5.69	4.56
SD	1.474	1.326	1.265	0.594
Median	5.30	5.00	5.50	4.60
Minimum	3.0	2.5	3.1	3.6
Maximum	11.9	8.6	9.6	5.1

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	2 (2.7%)	0	1 (1.4%)	0
With values below reference range	8 (11.0%)	8 (10.4%)	4 (5.6%)	3 (50.0%)
With values within reference range	63 (86.3%)	69 (89.6%)	66 (93.0%)	3 (50.0%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	5.69	5.38	5.87	4.07
SD	2.631	1.553	1.701	1.078
Median	5.30	5.00	5.80	3.95
Minimum	3.0	2.8	2.9	2.9
Maximum	22.2	9.8	12.3	5.9
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	1 (1.9%)	2 (2.9%)	0	0
With values below reference range	3 (5.6%)	8 (11.6%)	2 (3.9%)	1 (20.0%)
With values within reference range	50 (92.6%)	59 (85.5%)	49 (96.1%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	5.75	5.48	5.71	4.58
SD	2.216	1.863	1.185	0.661
Median	5.40	5.10	5.60	4.70
Minimum	2.6	2.7	3.6	3.6
Maximum	19.1	12.3	9.6	5.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	1 (2.0%)	0	1 (1.9%)	0
With values below reference range	2 (4.0%)	6 (13.0%)	3 (5.6%)	1 (33.3%)
With values within reference range	47 (94.0%)	40 (87.0%)	50 (92.6%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	5.61	5.44	5.89	3.90
SD	2.510	1.545	1.514	0.173
Median	5.15	5.20	5.75	4.00
Minimum	3.1	2.7	2.9	3.7
Maximum	20.7	10.4	11.5	4.0
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	1 (4.5%)	0	0	0
With values below reference range	3 (13.6%)	5 (19.2%)	1 (3.6%)	1 (100.0%)
With values within reference range	18 (81.8%)	21 (80.8%)	27 (96.4%)	0
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	6.30	4.57	5.92	3.20
SD	4.591	1.015	1.345	
Median	5.10	4.55	5.60	3.20
Minimum	2.9	2.6	3.6	3.2
Maximum	25.9	6.6	8.8	3.2

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Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	4.90	5.93	5.65	4.50
SD	0.990	0.816	0.862	
Median	4.90	5.90	5.70	4.50
Minimum	4.2	4.7	4.1	4.5
Maximum	5.6	7.2	6.7	4.5
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: White Blood Cell Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	1 (9.1%)	1 (16.7%)	0
With values within reference range	4 (100.0%)	10 (90.9%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	57.50	49.72	64.88	66.10
SD	5.999	10.456	12.712	
Median	59.00	47.00	69.50	66.10
Minimum	49.2	29.0	39.2	66.1
Maximum	62.8	70.2	72.1	66.1
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	0	2 (1.5%)	6 (4.3%)	0
With values below reference range	5 (4.0%)	7 (5.1%)	4 (2.9%)	1 (3.7%)
With values within reference range	119 (96.0%)	127 (93.4%)	129 (92.8%)	26 (96.3%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	55.47	56.25	59.32	55.06
SD	9.201	9.432	8.952	8.475
Median	55.80	57.05	59.90	55.30
Minimum	19.4	29.0	25.1	36.9
Maximum	74.9	78.9	78.6	68.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	0	
With values below reference range	0	1 (9.1%)	1 (20.0%)	
With values within reference range	3 (100.0%)	10 (90.9%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	52.80	56.01	49.82	
SD	10.768	7.544	21.496	
Median	54.20	56.00	52.50	
Minimum	41.4	36.4	13.5	
Maximum	62.8	64.1	69.3	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	1 (14.3%)	
With values within reference range	1 (100.0%)	1 (100.0%)	6 (85.7%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	53.60	49.70	51.96	
SD			11.747	
Median	53.60	49.70	56.80	
Minimum	53.6	49.7	30.7	
Maximum	53.6	49.7	64.1	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	112	125	124	20
With values above reference range	1 (0.9%)	2 (1.6%)	2 (1.6%)	0
With values below reference range	7 (6.3%)	7 (5.6%)	5 (4.0%)	0
With values within reference range	104 (92.9%)	116 (92.8%)	117 (94.4%)	20 (100.0%)
Summary statistics:				
Number of patients with values	112	125	124	20
Mean	54.51	54.70	55.95	57.15
SD	10.743	9.638	8.909	9.339
Median	54.70	53.90	55.70	58.65
Minimum	12.1	19.3	23.7	43.4
Maximum	77.1	80.9	87.7	73.5
Month 6				
Number of patients:				
With values	113	123	119	15
With values above reference range	2 (1.8%)	3 (2.4%)	2 (1.7%)	0
With values below reference range	6 (5.3%)	5 (4.1%)	7 (5.9%)	1 (6.7%)
With values within reference range	105 (92.9%)	115 (93.5%)	110 (92.4%)	14 (93.3%)
Summary statistics:				
Number of patients with values	113	123	119	15
Mean	55.21	56.08	57.03	57.99
SD	9.838	9.163	9.046	9.846
Median	55.40	55.10	56.90	57.20
Minimum	19.2	30.8	21.2	35.7
Maximum	78.2	81.0	80.3	74.5

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	121	117	18
With values above reference range	2 (1.8%)	1 (0.8%)	0	0
With values below reference range	2 (1.8%)	4 (3.3%)	10 (8.5%)	0
With values within reference range	105 (96.3%)	116 (95.9%)	107 (91.5%)	18 (100.0%)
Summary statistics:				
Number of patients with values	109	121	117	18
Mean	55.77	55.07	55.52	57.74
SD	8.633	8.240	9.431	7.206
Median	54.50	54.70	57.00	59.20
Minimum	34.7	32.8	25.1	43.1
Maximum	77.5	79.8	74.5	68.6
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	1 (1.0%)	0	3 (2.9%)	0
With values below reference range	6 (5.9%)	8 (7.3%)	4 (3.8%)	0
With values within reference range	95 (93.1%)	102 (92.7%)	97 (93.3%)	16 (100.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	54.24	54.30	57.04	55.88
SD	9.769	9.143	9.450	6.909
Median	56.35	54.25	57.70	56.05
Minimum	25.3	28.9	24.1	44.7
Maximum	75.4	75.0	90.5	68.9

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	106	97	9
With values above reference range	0	3 (2.8%)	1 (1.0%)	1 (11.1%)
With values below reference range	8 (8.0%)	6 (5.7%)	5 (5.2%)	0
With values within reference range	92 (92.0%)	97 (91.5%)	91 (93.8%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	106	97	9
Mean	54.02	55.94	56.29	62.37
SD	10.204	9.475	9.688	6.271
Median	54.90	56.80	57.00	62.50
Minimum	5.0	27.3	20.0	55.8
Maximum	73.9	76.8	81.4	77.1
Month 18				
Number of patients:				
With values	94	95	89	10
With values above reference range	1 (1.1%)	1 (1.1%)	0	0
With values below reference range	8 (8.5%)	3 (3.2%)	5 (5.6%)	0
With values within reference range	85 (90.4%)	91 (95.8%)	84 (94.4%)	10 (100.0%)
Summary statistics:				
Number of patients with values	94	95	89	10
Mean	55.35	56.82	56.28	57.07
SD	10.168	8.530	9.914	5.604
Median	56.40	57.10	56.90	57.60
Minimum	20.2	29.5	13.6	49.0
Maximum	79.6	80.0	70.8	65.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	91	83	8
With values above reference range	1 (1.1%)	0	1 (1.2%)	0
With values below reference range	3 (3.4%)	2 (2.2%)	5 (6.0%)	0
With values within reference range	85 (95.5%)	89 (97.8%)	77 (92.8%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	91	83	8
Mean	56.71	55.16	56.93	62.20
SD	8.728	8.359	10.082	8.733
Median	57.80	54.20	57.40	62.90
Minimum	28.5	30.5	23.0	46.0
Maximum	75.7	73.4	77.9	73.8
Month 24				
Number of patients:				
With values	82	83	77	5
With values above reference range	2 (2.4%)	1 (1.2%)	4 (5.2%)	0
With values below reference range	2 (2.4%)	2 (2.4%)	2 (2.6%)	0
With values within reference range	78 (95.1%)	80 (96.4%)	71 (92.2%)	5 (100.0%)
Summary statistics:				
Number of patients with values	82	83	77	5
Mean	58.57	56.14	58.24	62.70
SD	8.680	8.418	9.703	3.155
Median	59.55	55.70	57.90	61.20
Minimum	37.9	30.0	30.6	60.1
Maximum	83.1	75.7	82.7	67.6

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	76	70	6
With values above reference range	1 (1.4%)	0	3 (4.3%)	0
With values below reference range	3 (4.1%)	5 (6.6%)	5 (7.1%)	0
With values within reference range	69 (94.5%)	71 (93.4%)	62 (88.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	76	70	6
Mean	56.27	55.94	56.67	59.00
SD	8.988	10.195	10.051	7.054
Median	55.40	57.85	55.85	60.90
Minimum	31.2	10.9	28.4	45.5
Maximum	79.1	73.5	75.4	66.2
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	2 (3.7%)	0	1 (2.0%)	1 (20.0%)
With values below reference range	3 (5.6%)	3 (4.3%)	1 (2.0%)	0
With values within reference range	49 (90.7%)	66 (95.7%)	49 (96.1%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	56.78	57.55	56.85	66.08
SD	9.892	8.912	8.927	8.571
Median	57.00	58.00	56.90	63.20
Minimum	32.3	34.7	36.7	57.8
Maximum	86.6	75.0	75.1	75.7

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	0	0	1 (1.9%)	0
With values below reference range	4 (8.0%)	1 (2.2%)	3 (5.6%)	0
With values within reference range	46 (92.0%)	45 (97.8%)	50 (92.6%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	55.82	57.10	55.68	62.87
SD	10.348	7.395	8.600	3.547
Median	57.75	57.05	54.80	62.20
Minimum	19.5	37.3	37.2	59.7
Maximum	71.5	71.5	76.6	66.7
Month 36				
Number of patients:				
With values	21	26	28	1
With values above reference range	0	1 (3.8%)	3 (10.7%)	0
With values below reference range	2 (9.5%)	0	1 (3.6%)	0
With values within reference range	19 (90.5%)	25 (96.2%)	24 (85.7%)	1 (100.0%)
Summary statistics:				
Number of patients with values	21	26	28	1
Mean	55.65	56.05	58.77	61.50
SD	10.423	8.424	10.577	
Median	58.10	55.90	58.30	61.50
Minimum	37.6	43.2	35.0	61.5
Maximum	70.1	75.2	81.7	61.5

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	56.05	56.83	56.37	60.10
SD	14.496	9.638	11.466	
Median	56.05	59.10	58.65	60.10
Minimum	45.8	41.0	41.0	60.1
Maximum	66.3	67.8	72.9	60.1
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Neutrophils (Segs) (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	1 (9.1%)	1 (16.7%)	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	10 (90.9%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	32.18	37.77	27.65	25.80
SD	6.678	8.639	12.762	
Median	31.15	37.20	22.70	25.80
Minimum	25.6	19.7	21.2	25.8
Maximum	40.8	54.5	53.6	25.8
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	10 (8.1%)	5 (3.7%)	6 (4.3%)	3 (11.1%)
With values below reference range	2 (1.6%)	3 (2.2%)	4 (2.9%)	0
With values within reference range	112 (90.3%)	128 (94.1%)	129 (92.8%)	24 (88.9%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	34.04	32.44	30.28	33.27
SD	9.010	7.951	8.355	8.701
Median	33.50	31.20	29.40	30.80
Minimum	15.1	13.3	13.9	21.9
Maximum	76.1	54.6	69.9	54.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	1 (33.3%)	1 (9.1%)	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	2 (66.7%)	10 (90.9%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	37.70	32.88	35.40	
SD	14.742	7.774	16.776	
Median	35.80	31.80	28.90	
Minimum	24.0	23.9	20.2	
Maximum	53.3	51.4	63.5	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	1 (14.3%)	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	6 (85.7%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	29.40	36.80	35.47	
SD			9.905	
Median	29.40	36.80	32.00	
Minimum	29.4	36.8	23.9	
Maximum	29.4	36.8	53.1	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	112	125	124	20
With values above reference range	13 (11.6%)	6 (4.8%)	7 (5.6%)	0
With values below reference range	2 (1.8%)	2 (1.6%)	2 (1.6%)	1 (5.0%)
With values within reference range	97 (86.6%)	117 (93.6%)	115 (92.7%)	19 (95.0%)
Summary statistics:				
Number of patients with values	112	125	124	20
Mean	34.81	34.22	32.93	31.76
SD	10.357	8.051	8.855	9.729
Median	33.70	35.70	32.60	31.70
Minimum	13.6	12.8	5.1	15.9
Maximum	77.8	59.2	73.5	46.0
Month 6				
Number of patients:				
With values	113	123	119	15
With values above reference range	10 (8.8%)	6 (4.9%)	9 (7.6%)	1 (6.7%)
With values below reference range	3 (2.7%)	3 (2.4%)	1 (0.8%)	1 (6.7%)
With values within reference range	100 (88.5%)	114 (92.7%)	109 (91.6%)	13 (86.7%)
Summary statistics:				
Number of patients with values	113	123	119	15
Mean	34.41	33.04	32.45	30.41
SD	9.483	8.309	8.982	10.094
Median	33.60	33.10	32.80	29.10
Minimum	13.4	11.8	15.3	15.4
Maximum	76.4	52.5	75.3	51.9

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	121	117	18
With values above reference range	8 (7.3%)	6 (5.0%)	9 (7.7%)	0
With values below reference range	2 (1.8%)	1 (0.8%)	2 (1.7%)	0
With values within reference range	99 (90.8%)	114 (94.2%)	106 (90.6%)	18 (100.0%)
Summary statistics:				
Number of patients with values	109	121	117	18
Mean	33.81	33.81	33.27	30.31
SD	8.422	7.763	9.393	7.829
Median	33.50	33.20	31.80	30.40
Minimum	12.9	12.7	13.5	18.4
Maximum	54.1	54.8	71.2	44.6
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	13 (12.7%)	8 (7.3%)	6 (5.8%)	0
With values below reference range	1 (1.0%)	1 (0.9%)	2 (1.9%)	0
With values within reference range	88 (86.3%)	101 (91.8%)	96 (92.3%)	16 (100.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	34.69	33.66	32.16	32.06
SD	9.203	7.758	9.267	7.907
Median	33.15	33.50	30.65	30.85
Minimum	14.2	14.1	3.9	18.9
Maximum	69.6	55.1	71.9	44.7

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	106	97	9
With values above reference range	12 (12.0%)	8 (7.5%)	6 (6.2%)	0
With values below reference range	1 (1.0%)	2 (1.9%)	2 (2.1%)	1 (11.1%)
With values within reference range	87 (87.0%)	96 (90.6%)	89 (91.8%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	106	97	9
Mean	35.29	32.94	32.92	26.71
SD	8.839	8.360	9.859	7.166
Median	35.35	33.05	31.80	26.90
Minimum	14.9	15.0	13.8	10.3
Maximum	65.3	53.4	75.8	34.6
Month 18				
Number of patients:				
With values	94	95	89	10
With values above reference range	7 (7.4%)	2 (2.1%)	6 (6.7%)	0
With values below reference range	2 (2.1%)	1 (1.1%)	1 (1.1%)	0
With values within reference range	85 (90.4%)	92 (96.8%)	82 (92.1%)	10 (100.0%)
Summary statistics:				
Number of patients with values	94	95	89	10
Mean	34.25	32.54	33.15	32.15
SD	9.562	7.608	9.369	7.305
Median	33.55	32.50	32.50	30.85
Minimum	15.0	11.6	15.8	21.8
Maximum	74.4	57.1	75.1	43.5

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	91	83	8
With values above reference range	8 (9.0%)	3 (3.3%)	5 (6.0%)	0
With values below reference range	1 (1.1%)	1 (1.1%)	1 (1.2%)	0
With values within reference range	80 (89.9%)	87 (95.6%)	77 (92.8%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	91	83	8
Mean	33.12	33.72	31.84	26.78
SD	7.940	7.585	8.684	7.189
Median	32.40	34.60	31.70	25.20
Minimum	15.0	14.3	15.3	19.0
Maximum	52.0	51.3	54.3	41.4
Month 24				
Number of patients:				
With values	82	83	77	5
With values above reference range	3 (3.7%)	2 (2.4%)	6 (7.8%)	0
With values below reference range	2 (2.4%)	2 (2.4%)	3 (3.9%)	0
With values within reference range	77 (93.9%)	79 (95.2%)	68 (88.3%)	5 (100.0%)
Summary statistics:				
Number of patients with values	82	83	77	5
Mean	31.45	32.14	30.85	27.02
SD	8.242	7.612	9.002	4.059
Median	30.50	32.30	29.40	27.70
Minimum	8.3	11.7	12.1	20.5
Maximum	53.2	53.5	61.3	31.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	76	70	6
With values above reference range	7 (9.6%)	5 (6.6%)	5 (7.1%)	0
With values below reference range	1 (1.4%)	0	2 (2.9%)	0
With values within reference range	65 (89.0%)	71 (93.4%)	63 (90.0%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	76	70	6
Mean	33.08	32.29	32.28	30.25
SD	9.429	8.058	9.925	7.713
Median	33.00	31.10	32.70	29.50
Minimum	11.2	16.2	14.0	20.9
Maximum	65.5	50.6	61.0	43.6
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	5 (9.3%)	3 (4.3%)	5 (9.8%)	0
With values below reference range	2 (3.7%)	0	1 (2.0%)	1 (20.0%)
With values within reference range	47 (87.0%)	66 (95.7%)	45 (88.2%)	4 (80.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	33.47	31.85	32.57	25.70
SD	9.365	7.839	8.902	9.373
Median	33.55	31.20	32.00	26.00
Minimum	9.4	16.1	13.2	15.5
Maximum	57.2	53.8	55.1	37.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	5 (10.0%)	0	4 (7.4%)	0
With values below reference range	1 (2.0%)	0	3 (5.6%)	0
With values within reference range	44 (88.0%)	46 (100.0%)	47 (87.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	33.10	32.20	32.79	26.50
SD	11.654	7.400	9.163	4.258
Median	32.10	31.30	33.10	26.20
Minimum	5.0	17.6	12.5	22.4
Maximum	76.5	45.2	58.7	30.9
Month 36				
Number of patients:				
With values	21	26	28	1
With values above reference range	3 (14.3%)	0	2 (7.1%)	0
With values below reference range	1 (4.8%)	0	3 (10.7%)	0
With values within reference range	17 (81.0%)	26 (100.0%)	23 (82.1%)	1 (100.0%)
Summary statistics:				
Number of patients with values	21	26	28	1
Mean	33.88	32.61	30.19	29.80
SD	11.223	7.551	9.790	
Median	31.90	32.85	31.00	29.80
Minimum	15.5	17.6	12.4	29.8
Maximum	52.2	45.3	51.5	29.8

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100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	1 (16.7%)	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (83.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	32.00	32.68	33.65	30.80
SD	10.041	7.796	11.091	
Median	32.00	31.20	32.00	30.80
Minimum	24.9	24.1	17.6	30.8
Maximum	39.1	45.4	50.8	30.8
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Lymphocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	1 (9.1%)	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	10 (90.9%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	7.78	8.28	5.55	4.90
SD	0.974	2.201	1.167	
Median	7.45	7.20	5.65	4.90
Minimum	7.0	5.7	3.9	4.9
Maximum	9.2	12.5	6.9	4.9
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	4 (3.2%)	7 (5.1%)	0	0
With values below reference range	0	0	0	0
With values within reference range	120 (96.8%)	129 (94.9%)	139 (100.0%)	27 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	7.38	7.77	7.02	6.89
SD	2.202	2.958	1.926	1.835
Median	7.00	7.30	6.90	6.40
Minimum	3.2	2.1	2.5	4.4
Maximum	19.3	30.6	12.0	11.4

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	2 (40.0%)	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	3 (60.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	7.30	7.51	9.88	
SD	3.400	2.104	4.275	
Median	7.30	7.90	7.40	
Minimum	3.9	4.4	6.6	
Maximum	10.7	11.0	16.1	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	1 (100.0%)	0	1 (14.3%)	
With values below reference range	0	0	0	
With values within reference range	0	1 (100.0%)	6 (85.7%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	13.30	4.60	8.04	
SD			2.501	
Median	13.30	4.60	7.40	
Minimum	13.3	4.6	5.7	
Maximum	13.3	4.6	13.0	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	112	125	124	20
With values above reference range	2 (1.8%)	2 (1.6%)	2 (1.6%)	1 (5.0%)
With values below reference range	0	0	0	0
With values within reference range	110 (98.2%)	123 (98.4%)	122 (98.4%)	19 (95.0%)
Summary statistics:				
Number of patients with values	112	125	124	20
Mean	7.09	7.16	7.12	6.88
SD	2.079	3.942	2.007	1.873
Median	6.80	6.80	7.00	6.30
Minimum	2.9	0.1	2.1	5.0
Maximum	13.6	42.9	12.5	12.4
Month 6				
Number of patients:				
With values	113	123	119	15
With values above reference range	1 (0.9%)	2 (1.6%)	2 (1.7%)	1 (6.7%)
With values below reference range	0	0	0	0
With values within reference range	112 (99.1%)	121 (98.4%)	117 (98.3%)	14 (93.3%)
Summary statistics:				
Number of patients with values	113	123	119	15
Mean	6.72	6.77	6.72	7.46
SD	2.856	2.168	2.130	3.457
Median	6.30	6.60	6.50	6.60
Minimum	2.9	1.9	2.0	1.9
Maximum	29.2	15.0	14.8	17.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	121	117	18
With values above reference range	2 (1.8%)	1 (0.8%)	7 (6.0%)	0
With values below reference range	0	0	0	0
With values within reference range	107 (98.2%)	120 (99.2%)	110 (94.0%)	18 (100.0%)
Summary statistics:				
Number of patients with values	109	121	117	18
Mean	7.20	7.17	7.48	6.78
SD	1.920	2.176	2.398	1.867
Median	7.10	7.10	7.40	7.00
Minimum	3.8	1.1	2.5	3.7
Maximum	12.2	16.4	15.8	9.5
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	2 (2.0%)	6 (5.5%)	3 (2.9%)	0
With values below reference range	0	0	0	0
With values within reference range	100 (98.0%)	104 (94.5%)	101 (97.1%)	16 (100.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	7.56	7.97	7.14	6.83
SD	3.657	2.721	2.412	1.805
Median	7.10	7.40	6.90	6.90
Minimum	3.8	4.3	0.1	3.7
Maximum	36.9	25.2	14.0	11.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	106	97	9
With values above reference range	2 (2.0%)	2 (1.9%)	2 (2.1%)	1 (11.1%)
With values below reference range	0	0	0	0
With values within reference range	98 (98.0%)	104 (98.1%)	95 (97.9%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	106	97	9
Mean	6.83	7.20	6.90	7.54
SD	2.277	3.143	2.075	2.195
Median	6.70	6.95	6.70	7.70
Minimum	1.0	2.2	2.4	5.2
Maximum	16.0	31.9	12.9	12.2
Month 18				
Number of patients:				
With values	94	95	89	10
With values above reference range	4 (4.3%)	4 (4.2%)	1 (1.1%)	0
With values below reference range	0	0	0	0
With values within reference range	90 (95.7%)	91 (95.8%)	88 (98.9%)	10 (100.0%)
Summary statistics:				
Number of patients with values	94	95	89	10
Mean	6.61	6.99	6.65	6.25
SD	2.374	3.039	2.640	1.895
Median	6.20	6.90	6.50	6.25
Minimum	3.1	1.1	1.7	2.9
Maximum	17.3	26.7	24.0	8.7

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	91	83	8
With values above reference range	2 (2.2%)	5 (5.5%)	2 (2.4%)	0
With values below reference range	0	0	0	0
With values within reference range	87 (97.8%)	86 (94.5%)	81 (97.6%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	91	83	8
Mean	6.64	7.26	7.31	7.25
SD	2.631	2.334	2.626	1.626
Median	6.10	7.00	6.80	6.95
Minimum	2.7	2.9	2.5	4.8
Maximum	24.5	16.0	18.9	9.8
Month 24				
Number of patients:				
With values	82	83	77	5
With values above reference range	0	5 (6.0%)	3 (3.9%)	0
With values below reference range	0	0	0	0
With values within reference range	82 (100.0%)	78 (94.0%)	74 (96.1%)	5 (100.0%)
Summary statistics:				
Number of patients with values	82	83	77	5
Mean	6.77	7.95	7.28	7.52
SD	1.830	3.117	2.523	1.869
Median	6.50	7.40	7.10	7.70
Minimum	3.2	4.4	2.6	5.3
Maximum	11.7	28.4	19.3	10.1

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	76	70	6
With values above reference range	2 (2.7%)	2 (2.6%)	3 (4.3%)	0
With values below reference range	0	0	0	0
With values within reference range	71 (97.3%)	74 (97.4%)	67 (95.7%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	76	70	6
Mean	7.08	7.80	7.39	8.08
SD	2.357	5.933	2.615	1.653
Median	6.60	6.90	7.00	7.30
Minimum	3.1	3.1	3.0	6.8
Maximum	15.3	55.1	20.3	11.0
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	1 (1.9%)	1 (1.4%)	0	0
With values below reference range	0	0	0	0
With values within reference range	53 (98.1%)	68 (98.6%)	51 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	6.55	6.73	6.98	6.38
SD	2.129	2.218	1.980	3.075
Median	6.35	6.40	6.80	7.60
Minimum	2.0	0.5	2.2	1.0
Maximum	12.6	16.2	11.3	8.7

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	1 (2.0%)	1 (2.2%)	0	0
With values below reference range	0	0	0	0
With values within reference range	49 (98.0%)	45 (97.8%)	54 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	7.67	6.86	7.47	7.37
SD	3.368	1.935	2.148	1.079
Median	7.15	6.70	7.70	6.90
Minimum	3.4	2.6	2.3	6.6
Maximum	28.1	12.1	12.0	8.6
Month 36				
Number of patients:				
With values	21	26	28	1
With values above reference range	1 (4.8%)	1 (3.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	20 (95.2%)	25 (96.2%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	21	26	28	1
Mean	7.61	7.78	7.46	8.10
SD	2.475	1.955	1.515	
Median	7.50	7.30	7.25	8.10
Minimum	4.0	4.8	4.8	8.1
Maximum	13.0	12.7	10.0	8.1

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	7.60	6.77	7.32	5.30
SD	3.111	1.457	2.121	
Median	7.60	7.15	6.70	5.30
Minimum	5.4	4.6	5.8	5.3
Maximum	9.8	8.7	11.5	5.3
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Monocytes (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	2.25	3.77	1.48	2.40
SD	0.695	1.645	1.248	
Median	2.40	3.10	1.05	2.40
Minimum	1.3	1.6	0.4	2.4
Maximum	2.9	6.1	3.9	2.4
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	4 (3.2%)	6 (4.4%)	4 (2.9%)	5 (18.5%)
With values below reference range	0	0	0	0
With values within reference range	120 (96.8%)	130 (95.6%)	135 (97.1%)	22 (81.5%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	2.70	3.15	2.97	4.39
SD	1.802	1.970	1.908	2.812
Median	2.40	2.80	2.50	3.60
Minimum	0.2	0.0	0.0	0.9
Maximum	13.6	13.7	13.8	10.8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	1.83	3.24	4.32	
SD	0.666	1.130	2.860	
Median	2.00	3.00	3.60	
Minimum	1.1	1.5	2.2	
Maximum	2.4	5.2	9.3	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	1 (100.0%)	1 (14.3%)	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	0	6 (85.7%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	3.40	8.40	4.20	
SD			2.223	
Median	3.40	8.40	3.60	
Minimum	3.4	8.4	2.2	
Maximum	3.4	8.4	8.9	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	112	125	124	20
With values above reference range	6 (5.4%)	5 (4.0%)	4 (3.2%)	2 (10.0%)
With values below reference range	0	0	0	0
With values within reference range	106 (94.6%)	120 (96.0%)	120 (96.8%)	18 (90.0%)
Summary statistics:				
Number of patients with values	112	125	124	20
Mean	3.19	3.52	3.58	3.84
SD	2.369	1.888	1.971	2.565
Median	2.80	3.10	3.25	2.75
Minimum	0.3	0.0	0.4	0.3
Maximum	14.8	11.8	12.2	11.0
Month 6				
Number of patients:				
With values	113	123	119	15
With values above reference range	6 (5.3%)	9 (7.3%)	6 (5.0%)	1 (6.7%)
With values below reference range	0	0	0	0
With values within reference range	107 (94.7%)	114 (92.7%)	113 (95.0%)	14 (93.3%)
Summary statistics:				
Number of patients with values	113	123	119	15
Mean	3.27	3.70	3.41	3.72
SD	1.988	1.994	2.032	2.348
Median	2.90	3.50	3.00	4.00
Minimum	0.4	0.0	0.2	0.3
Maximum	12.9	9.4	13.8	8.5

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	121	117	18
With values above reference range	4 (3.7%)	9 (7.4%)	4 (3.4%)	4 (22.2%)
With values below reference range	0	0	0	0
With values within reference range	105 (96.3%)	112 (92.6%)	113 (96.6%)	14 (77.8%)
Summary statistics:				
Number of patients with values	109	121	117	18
Mean	2.86	3.57	3.36	4.74
SD	1.648	2.126	1.895	2.266
Median	2.60	3.20	3.00	4.60
Minimum	0.1	0.2	0.2	0.5
Maximum	8.8	12.4	11.0	9.0
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	7 (6.9%)	8 (7.3%)	6 (5.8%)	4 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	95 (93.1%)	102 (92.7%)	98 (94.2%)	12 (75.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	3.15	3.71	3.32	4.79
SD	2.497	2.391	2.052	2.575
Median	2.55	3.15	2.80	4.55
Minimum	0.4	0.0	0.5	0.3
Maximum	15.6	14.5	13.0	10.2

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	106	97	9
With values above reference range	6 (6.0%)	7 (6.6%)	5 (5.2%)	0
With values below reference range	0	0	0	0
With values within reference range	94 (94.0%)	99 (93.4%)	92 (94.8%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	106	97	9
Mean	3.43	3.58	3.54	3.04
SD	2.948	2.085	2.123	2.099
Median	2.90	3.20	3.30	2.90
Minimum	0.0	0.0	0.1	0.3
Maximum	19.0	11.1	14.6	6.8
Month 18				
Number of patients:				
With values	94	95	89	10
With values above reference range	7 (7.4%)	4 (4.2%)	6 (6.7%)	2 (20.0%)
With values below reference range	0	0	0	0
With values within reference range	87 (92.6%)	91 (95.8%)	83 (93.3%)	8 (80.0%)
Summary statistics:				
Number of patients with values	94	95	89	10
Mean	3.43	3.19	3.55	4.13
SD	2.629	2.222	2.332	3.044
Median	2.80	3.00	2.90	3.80
Minimum	0.7	0.0	0.4	0.3
Maximum	14.7	18.0	13.7	9.8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	91	83	8
With values above reference range	5 (5.6%)	7 (7.7%)	3 (3.6%)	0
With values below reference range	0	0	0	0
With values within reference range	84 (94.4%)	84 (92.3%)	80 (96.4%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	91	83	8
Mean	3.19	3.51	3.58	3.30
SD	2.687	2.217	2.645	2.295
Median	2.80	3.20	3.20	2.65
Minimum	0.2	0.3	0.1	0.7
Maximum	17.5	13.4	21.8	6.9
Month 24				
Number of patients:				
With values	82	83	77	5
With values above reference range	2 (2.4%)	5 (6.0%)	4 (5.2%)	0
With values below reference range	0	0	0	0
With values within reference range	80 (97.6%)	78 (94.0%)	73 (94.8%)	5 (100.0%)
Summary statistics:				
Number of patients with values	82	83	77	5
Mean	2.85	3.40	3.29	2.38
SD	2.023	1.896	2.776	2.009
Median	2.50	3.00	2.80	1.50
Minimum	0.2	0.1	0.1	0.6
Maximum	15.8	11.7	22.2	5.3

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	76	70	6
With values above reference range	5 (6.8%)	6 (7.9%)	3 (4.3%)	0
With values below reference range	0	0	0	0
With values within reference range	68 (93.2%)	70 (92.1%)	67 (95.7%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	76	70	6
Mean	3.20	3.56	3.29	2.30
SD	2.977	2.040	1.829	1.716
Median	2.50	3.15	2.95	1.90
Minimum	0.2	0.1	0.1	0.5
Maximum	20.7	11.4	9.6	5.3
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	1 (1.9%)	4 (5.8%)	2 (3.9%)	0
With values below reference range	0	0	0	0
With values within reference range	53 (98.1%)	65 (94.2%)	49 (96.1%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	2.82	3.48	3.23	1.24
SD	1.519	1.899	1.790	0.820
Median	2.50	3.00	3.10	0.90
Minimum	0.4	0.2	0.2	0.3
Maximum	7.5	11.8	8.1	2.2

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	2 (4.0%)	1 (2.2%)	2 (3.7%)	1 (33.3%)
With values below reference range	0	0	0	0
With values within reference range	48 (96.0%)	45 (97.8%)	52 (96.3%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	3.02	3.50	3.66	2.93
SD	2.669	1.638	1.845	4.389
Median	2.70	3.35	3.30	0.50
Minimum	0.1	0.6	0.2	0.3
Maximum	18.6	8.7	9.9	8.0
Month 36				
Number of patients:				
With values	21	26	28	1
With values above reference range	0	1 (3.8%)	2 (7.1%)	0
With values below reference range	0	0	0	0
With values within reference range	21 (100.0%)	25 (96.2%)	26 (92.9%)	1 (100.0%)
Summary statistics:				
Number of patients with values	21	26	28	1
Mean	2.49	3.18	3.28	0.40
SD	1.013	1.791	2.212	
Median	2.50	2.85	2.90	0.40
Minimum	0.3	0.2	0.5	0.4
Maximum	5.0	8.3	9.0	0.4

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	3.95	3.45	2.37	3.30
SD	1.344	1.636	0.582	
Median	3.95	2.95	2.30	3.30
Minimum	3.0	1.9	1.6	3.3
Maximum	4.9	6.0	3.2	3.3
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Eosinophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	0.30	0.45	0.43	0.80
SD	0.082	0.294	0.175	
Median	0.30	0.30	0.35	0.80
Minimum	0.2	0.1	0.3	0.8
Maximum	0.4	1.0	0.7	0.8
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	0	0	2 (1.4%)	0
With values below reference range	0	0	0	0
With values within reference range	124 (100.0%)	136 (100.0%)	137 (98.6%)	27 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	0.40	0.39	0.41	0.39
SD	0.233	0.231	0.293	0.176
Median	0.30	0.40	0.40	0.40
Minimum	0.0	0.0	0.0	0.1
Maximum	1.6	1.8	2.4	0.8

- 1910 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	11 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	0.37	0.36	0.58	
SD	0.115	0.196	0.311	
Median	0.30	0.40	0.50	
Minimum	0.3	0.1	0.3	
Maximum	0.5	0.7	1.1	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	0.30	0.50	0.33	
SD			0.160	
Median	0.30	0.50	0.30	
Minimum	0.3	0.5	0.1	
Maximum	0.3	0.5	0.6	

- 1911 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	112	125	124	20
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	112 (100.0%)	125 (100.0%)	124 (100.0%)	20 (100.0%)
Summary statistics:				
Number of patients with values	112	125	124	20
Mean	0.40	0.40	0.42	0.38
SD	0.180	0.186	0.219	0.161
Median	0.40	0.40	0.40	0.40
Minimum	0.1	0.1	0.1	0.2
Maximum	1.4	1.2	1.8	0.7
Month 6				
Number of patients:				
With values	113	123	119	15
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	113 (100.0%)	123 (100.0%)	119 (100.0%)	15 (100.0%)
Summary statistics:				
Number of patients with values	113	123	119	15
Mean	0.39	0.40	0.38	0.43
SD	0.173	0.250	0.181	0.219
Median	0.40	0.40	0.40	0.40
Minimum	0.0	0.0	0.0	0.0
Maximum	0.8	1.8	1.0	0.9

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	121	117	18
With values above reference range	0	1 (0.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	109 (100.0%)	120 (99.2%)	117 (100.0%)	18 (100.0%)
Summary statistics:				
Number of patients with values	109	121	117	18
Mean	0.36	0.39	0.36	0.43
SD	0.152	0.265	0.224	0.193
Median	0.30	0.30	0.30	0.40
Minimum	0.1	0.0	0.0	0.1
Maximum	0.9	2.1	1.5	0.8
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	102 (100.0%)	110 (100.0%)	104 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	0.36	0.37	0.34	0.44
SD	0.178	0.214	0.164	0.203
Median	0.30	0.30	0.30	0.40
Minimum	0.0	0.0	0.0	0.1
Maximum	1.0	1.2	1.0	0.9

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	106	97	9
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	100 (100.0%)	106 (100.0%)	97 (100.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	106	97	9
Mean	0.35	0.34	0.35	0.33
SD	0.174	0.191	0.182	0.180
Median	0.30	0.30	0.40	0.30
Minimum	0.0	0.0	0.0	0.1
Maximum	0.8	1.0	0.8	0.7
Month 18				
Number of patients:				
With values	94	95	89	10
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	94 (100.0%)	95 (100.0%)	89 (100.0%)	10 (100.0%)
Summary statistics:				
Number of patients with values	94	95	89	10
Mean	0.35	0.37	0.37	0.40
SD	0.143	0.182	0.197	0.163
Median	0.40	0.30	0.30	0.40
Minimum	0.0	0.0	0.0	0.2
Maximum	0.7	1.1	1.3	0.6

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	91	83	8
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	89 (100.0%)	91 (100.0%)	83 (100.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	91	83	8
Mean	0.33	0.34	0.35	0.48
SD	0.179	0.166	0.241	0.358
Median	0.30	0.30	0.30	0.40
Minimum	0.1	0.0	0.0	0.2
Maximum	1.0	1.0	1.7	1.3
Month 24				
Number of patients:				
With values	82	83	77	5
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	82 (100.0%)	83 (100.0%)	77 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	82	83	77	5
Mean	0.37	0.37	0.35	0.38
SD	0.220	0.242	0.223	0.164
Median	0.35	0.30	0.30	0.30
Minimum	0.1	0.0	0.0	0.2
Maximum	1.2	1.6	1.2	0.6

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	76	70	6
With values above reference range	1 (1.4%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	72 (98.6%)	76 (100.0%)	70 (100.0%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	76	70	6
Mean	0.38	0.42	0.37	0.37
SD	0.296	0.214	0.158	0.137
Median	0.30	0.40	0.35	0.35
Minimum	0.0	0.1	0.1	0.2
Maximum	2.3	1.5	0.8	0.6
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	54 (100.0%)	69 (100.0%)	51 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	0.39	0.38	0.37	0.60
SD	0.215	0.180	0.210	0.332
Median	0.35	0.40	0.30	0.50
Minimum	0.0	0.0	0.0	0.3
Maximum	1.4	0.8	1.0	1.0

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	50 (100.0%)	46 (100.0%)	54 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	0.39	0.34	0.41	0.33
SD	0.186	0.166	0.210	0.153
Median	0.40	0.30	0.40	0.30
Minimum	0.0	0.0	0.0	0.2
Maximum	0.9	0.9	1.1	0.5
Month 36				
Number of patients:				
With values	21	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	21 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	21	26	28	1
Mean	0.37	0.38	0.31	0.20
SD	0.171	0.205	0.142	
Median	0.30	0.40	0.30	0.20
Minimum	0.0	0.0	0.0	0.2
Maximum	0.7	0.9	0.7	0.2

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	0.40	0.27	0.30	0.50
SD	0.000	0.082	0.141	
Median	0.40	0.25	0.30	0.50
Minimum	0.4	0.2	0.1	0.5
Maximum	0.4	0.4	0.5	0.5
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Basophils (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	11 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	229.8	221.1	227.5	273.0
SD	25.67	45.85	33.68	
Median	218.5	219.0	217.5	273.0
Minimum	214	131	187	273
Maximum	268	288	271	273
Open Label Baseline				
Number of patients:				
With values	124	136	139	27
With values above reference range	2 (1.6%)	0	0	0
With values below reference range	3 (2.4%)	8 (5.9%)	5 (3.6%)	0
With values within reference range	119 (96.0%)	128 (94.1%)	134 (96.4%)	27 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	27
Mean	214.8	209.6	213.0	213.7
SD	55.82	49.56	51.92	45.16
Median	214.0	206.5	212.0	202.0
Minimum	118	111	116	140
Maximum	512	373	392	314

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	11	5	0
With values above reference range	0	1 (9.1%)	0	
With values below reference range	0	1 (9.1%)	0	
With values within reference range	3 (100.0%)	9 (81.8%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	3	11	5	0
Mean	212.7	227.5	212.6	
SD	82.65	92.31	17.50	
Median	178.0	213.0	214.0	
Minimum	153	126	187	
Maximum	307	480	230	
Month 2				
Number of patients:				
With values	1	1	7	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (100.0%)	1 (100.0%)	7 (100.0%)	
Summary statistics:				
Number of patients with values	1	1	7	0
Mean	198.0	230.0	214.0	
SD			56.04	
Median	198.0	230.0	208.0	
Minimum	198	230	145	
Maximum	198	230	294	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	113	126	125	20
With values above reference range	0	1 (0.8%)	0	0
With values below reference range	8 (7.1%)	7 (5.6%)	4 (3.2%)	0
With values within reference range	105 (92.9%)	118 (93.7%)	121 (96.8%)	20 (100.0%)
Summary statistics:				
Number of patients with values	113	126	125	20
Mean	212.0	208.3	208.3	213.5
SD	54.17	56.83	48.04	48.97
Median	210.0	206.5	210.0	208.5
Minimum	108	101	113	140
Maximum	350	567	348	327
Month 6				
Number of patients:				
With values	113	124	121	15
With values above reference range	0	1 (0.8%)	0	0
With values below reference range	4 (3.5%)	6 (4.8%)	5 (4.1%)	0
With values within reference range	109 (96.5%)	117 (94.4%)	116 (95.9%)	15 (100.0%)
Summary statistics:				
Number of patients with values	113	124	121	15
Mean	211.4	207.7	196.8	220.9
SD	51.58	57.83	42.33	41.46
Median	208.0	198.0	194.0	210.0
Minimum	122	96	114	165
Maximum	353	511	319	298

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	112	123	117	18
With values above reference range	0	2 (1.6%)	0	0
With values below reference range	4 (3.6%)	7 (5.7%)	7 (6.0%)	1 (5.6%)
With values within reference range	108 (96.4%)	114 (92.7%)	110 (94.0%)	17 (94.4%)
Summary statistics:				
Number of patients with values	112	123	117	18
Mean	212.0	207.4	206.0	209.1
SD	49.15	60.97	52.14	52.64
Median	213.0	204.0	211.0	209.5
Minimum	108	78	69	124
Maximum	354	510	380	338
Month 12				
Number of patients:				
With values	102	110	104	16
With values above reference range	0	1 (0.9%)	0	0
With values below reference range	3 (2.9%)	7 (6.4%)	5 (4.8%)	1 (6.3%)
With values within reference range	99 (97.1%)	102 (92.7%)	99 (95.2%)	15 (93.8%)
Summary statistics:				
Number of patients with values	102	110	104	16
Mean	220.0	212.8	217.2	216.3
SD	54.61	60.97	53.05	42.94
Median	213.5	213.5	219.0	219.0
Minimum	103	76	102	129
Maximum	356	539	382	303

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Platelet Count (10⁹/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	108	98	9
With values above reference range	1 (1.0%)	2 (1.9%)	1 (1.0%)	0
With values below reference range	2 (2.0%)	4 (3.7%)	0	0
With values within reference range	97 (97.0%)	102 (94.4%)	97 (99.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	108	98	9
Mean	223.1	221.2	220.8	215.0
SD	59.63	60.66	53.87	52.51
Median	224.0	209.0	221.0	213.0
Minimum	119	101	140	141
Maximum	406	529	412	337
Month 18				
Number of patients:				
With values	95	96	90	10
With values above reference range	1 (1.1%)	2 (2.1%)	0	0
With values below reference range	2 (2.1%)	6 (6.3%)	4 (4.4%)	0
With values within reference range	92 (96.8%)	88 (91.7%)	86 (95.6%)	10 (100.0%)
Summary statistics:				
Number of patients with values	95	96	90	10
Mean	224.8	222.9	218.1	218.8
SD	53.97	66.63	54.96	49.32
Median	227.0	219.5	222.5	212.0
Minimum	122	99	119	139
Maximum	471	560	385	310

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	91	92	83	8
With values above reference range	1 (1.1%)	2 (2.2%)	0	0
With values below reference range	2 (2.2%)	6 (6.5%)	2 (2.4%)	0
With values within reference range	88 (96.7%)	84 (91.3%)	81 (97.6%)	8 (100.0%)
Summary statistics:				
Number of patients with values	91	92	83	8
Mean	230.3	227.3	226.0	208.5
SD	60.91	72.82	52.65	45.35
Median	224.0	214.0	232.0	197.5
Minimum	108	49	113	137
Maximum	401	582	379	283
Month 24				
Number of patients:				
With values	83	83	78	5
With values above reference range	1 (1.2%)	2 (2.4%)	0	0
With values below reference range	0	3 (3.6%)	0	0
With values within reference range	82 (98.8%)	78 (94.0%)	78 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	83	83	78	5
Mean	230.8	232.5	224.5	215.6
SD	54.97	68.01	52.27	25.98
Median	236.0	218.0	229.0	210.0
Minimum	133	100	133	178
Maximum	413	545	381	244

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	73	77	71	6
With values above reference range	1 (1.4%)	2 (2.6%)	0	0
With values below reference range	2 (2.7%)	2 (2.6%)	1 (1.4%)	0
With values within reference range	70 (95.9%)	73 (94.8%)	70 (98.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	73	77	71	6
Mean	222.6	228.8	229.7	204.7
SD	58.97	61.27	54.82	52.80
Median	219.0	225.0	236.0	205.0
Minimum	127	105	121	133
Maximum	416	466	376	292
Month 30				
Number of patients:				
With values	54	69	51	5
With values above reference range	0	0	0	0
With values below reference range	3 (5.6%)	3 (4.3%)	0	0
With values within reference range	51 (94.4%)	66 (95.7%)	51 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	54	69	51	5
Mean	221.7	220.7	227.3	189.4
SD	59.84	55.23	55.86	30.47
Median	217.0	220.0	230.0	195.0
Minimum	90	108	130	138
Maximum	390	375	356	215

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	50	46	54	3
With values above reference range	1 (2.0%)	1 (2.2%)	0	0
With values below reference range	1 (2.0%)	1 (2.2%)	2 (3.7%)	1 (33.3%)
With values within reference range	48 (96.0%)	44 (95.7%)	52 (96.3%)	2 (66.7%)
Summary statistics:				
Number of patients with values	50	46	54	3
Mean	217.9	231.5	230.5	193.7
SD	54.31	65.73	58.77	57.74
Median	220.0	221.5	237.0	226.0
Minimum	120	125	125	127
Maximum	418	463	341	228
Month 36				
Number of patients:				
With values	22	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	22 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	22	26	28	1
Mean	226.7	227.4	237.8	189.0
SD	62.43	56.12	56.87	
Median	231.5	213.5	233.0	189.0
Minimum	136	153	141	189
Maximum	378	389	363	189

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Platelet Count ($10^9/L$)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	6	1
Mean	274.0	255.5	249.3	248.0
SD	32.53	51.32	73.73	
Median	274.0	276.0	261.0	248.0
Minimum	251	183	161	248
Maximum	297	315	339	248
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Platelet Count (10⁹/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	10	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	10 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	10	6	1
Mean	1.43	1.11	1.22	1.80
SD	0.150	0.443	0.232	
Median	1.40	1.10	1.10	1.80
Minimum	1.3	0.6	1.0	1.8
Maximum	1.6	2.1	1.6	1.8
Open Label Baseline				
Number of patients:				
With values	4	10	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	4 (100.0%)	10 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	10	6	1
Mean	1.43	1.11	1.22	1.80
SD	0.150	0.443	0.232	
Median	1.40	1.10	1.10	1.80
Minimum	1.3	0.6	1.0	1.8
Maximum	1.6	2.1	1.6	1.8

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	3	7	1	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	3 (100.0%)	7 (100.0%)	1 (100.0%)	
Summary statistics:				
Number of patients with values	3	7	1	0
Mean	1.20	1.16	0.50	
SD	0.361	0.321		
Median	1.10	1.20	0.50	
Minimum	0.9	0.6	0.5	
Maximum	1.6	1.5	0.5	
Month 2				
Number of patients:				
With values	0	1	4	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		1 (100.0%)	4 (100.0%)	
Summary statistics:				
Number of patients with values	0	1	4	0
Mean		0.90	0.98	
SD			0.275	
Median		0.90	0.95	
Minimum		0.9	0.7	
Maximum		0.9	1.3	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	108	120	17
With values above reference range	3 (2.8%)	1 (0.9%)	2 (1.7%)	0
With values below reference range	0	1 (0.9%)	0	0
With values within reference range	104 (97.2%)	106 (98.1%)	118 (98.3%)	17 (100.0%)
Summary statistics:				
Number of patients with values	107	108	120	17
Mean	1.17	1.16	1.22	1.15
SD	0.447	0.436	0.480	0.322
Median	1.10	1.10	1.15	1.10
Minimum	0.6	0.3	0.5	0.7
Maximum	2.8	3.0	4.0	1.7
Month 6				
Number of patients:				
With values	114	125	119	15
With values above reference range	7 (6.1%)	4 (3.2%)	2 (1.7%)	0
With values below reference range	0	0	1 (0.8%)	0
With values within reference range	107 (93.9%)	121 (96.8%)	116 (97.5%)	15 (100.0%)
Summary statistics:				
Number of patients with values	114	125	119	15
Mean	1.35	1.27	1.20	1.24
SD	0.726	0.468	0.409	0.481
Median	1.20	1.20	1.10	1.30
Minimum	0.6	0.6	0.4	0.6
Maximum	6.2	2.9	2.5	2.3

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	108	123	113	17
With values above reference range	4 (3.7%)	5 (4.1%)	4 (3.5%)	0
With values below reference range	0	0	0	1 (5.9%)
With values within reference range	104 (96.3%)	118 (95.9%)	109 (96.5%)	16 (94.1%)
Summary statistics:				
Number of patients with values	108	123	113	17
Mean	1.26	1.22	1.25	1.05
SD	0.595	0.464	0.462	0.312
Median	1.10	1.10	1.20	1.00
Minimum	0.6	0.5	0.6	0.4
Maximum	5.2	2.7	2.8	1.6
Month 12				
Number of patients:				
With values	104	110	106	16
With values above reference range	0	1 (0.9%)	2 (1.9%)	0
With values below reference range	0	2 (1.8%)	0	0
With values within reference range	104 (100.0%)	107 (97.3%)	104 (98.1%)	16 (100.0%)
Summary statistics:				
Number of patients with values	104	110	106	16
Mean	1.16	1.15	1.23	1.21
SD	0.371	0.375	0.424	0.338
Median	1.10	1.10	1.20	1.10
Minimum	0.5	0.4	0.5	0.8
Maximum	2.3	2.5	2.6	2.1

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	97	108	94	9
With values above reference range	0	0	2 (2.1%)	0
With values below reference range	0	0	0	0
With values within reference range	97 (100.0%)	108 (100.0%)	92 (97.9%)	9 (100.0%)
Summary statistics:				
Number of patients with values	97	108	94	9
Mean	1.14	1.13	1.18	1.19
SD	0.356	0.336	0.422	0.267
Median	1.00	1.10	1.10	1.20
Minimum	0.6	0.5	0.5	0.8
Maximum	2.3	2.1	2.5	1.7
Month 18				
Number of patients:				
With values	92	94	83	10
With values above reference range	1 (1.1%)	1 (1.1%)	2 (2.4%)	0
With values below reference range	0	0	0	0
With values within reference range	91 (98.9%)	93 (98.9%)	81 (97.6%)	10 (100.0%)
Summary statistics:				
Number of patients with values	92	94	83	10
Mean	1.13	1.16	1.23	1.11
SD	0.345	0.348	0.445	0.321
Median	1.10	1.10	1.10	1.10
Minimum	0.5	0.5	0.6	0.6
Maximum	2.6	2.5	2.9	1.8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	89	89	78	7
With values above reference range	2 (2.2%)	1 (1.1%)	1 (1.3%)	0
With values below reference range	0	0	0	0
With values within reference range	87 (97.8%)	88 (98.9%)	77 (98.7%)	7 (100.0%)
Summary statistics:				
Number of patients with values	89	89	78	7
Mean	1.24	1.09	1.22	1.04
SD	0.469	0.343	0.442	0.151
Median	1.10	1.00	1.20	1.00
Minimum	0.5	0.5	0.5	0.9
Maximum	3.0	2.6	3.1	1.3
Month 24				
Number of patients:				
With values	78	79	71	4
With values above reference range	2 (2.6%)	0	2 (2.8%)	0
With values below reference range	1 (1.3%)	0	0	0
With values within reference range	75 (96.2%)	79 (100.0%)	69 (97.2%)	4 (100.0%)
Summary statistics:				
Number of patients with values	78	79	71	4
Mean	1.21	1.17	1.22	1.28
SD	0.640	0.411	0.429	0.050
Median	1.10	1.10	1.10	1.30
Minimum	0.4	0.5	0.5	1.2
Maximum	5.6	2.2	2.6	1.3

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	77	68	5
With values above reference range	0	0	3 (4.4%)	0
With values below reference range	0	0	0	0
With values within reference range	71 (100.0%)	77 (100.0%)	65 (95.6%)	5 (100.0%)
Summary statistics:				
Number of patients with values	71	77	68	5
Mean	1.05	1.11	1.21	1.24
SD	0.340	0.369	0.571	0.270
Median	1.00	1.10	1.10	1.30
Minimum	0.5	0.5	0.5	0.8
Maximum	2.0	2.3	3.6	1.5
Month 30				
Number of patients:				
With values	48	62	49	5
With values above reference range	0	2 (3.2%)	0	0
With values below reference range	0	1 (1.6%)	0	0
With values within reference range	48 (100.0%)	59 (95.2%)	49 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	48	62	49	5
Mean	1.05	1.09	1.09	1.14
SD	0.312	0.450	0.338	0.270
Median	1.00	1.10	1.10	1.10
Minimum	0.6	0.4	0.5	0.8
Maximum	1.8	2.8	2.2	1.5

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	49	45	52	2
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	49 (100.0%)	45 (100.0%)	52 (100.0%)	2 (100.0%)
Summary statistics:				
Number of patients with values	49	45	52	2
Mean	1.15	1.06	1.10	1.20
SD	0.348	0.281	0.382	0.424
Median	1.10	1.00	1.00	1.20
Minimum	0.5	0.6	0.5	0.9
Maximum	2.0	2.0	2.1	1.5
Month 36				
Number of patients:				
With values	24	26	26	1
With values above reference range	0	0	1 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	25 (96.2%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	26	1
Mean	1.21	1.14	1.40	1.20
SD	0.451	0.315	0.400	
Median	1.15	1.10	1.35	1.20
Minimum	0.6	0.7	0.8	1.2
Maximum	2.1	1.8	2.8	1.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	5	6	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	5 (100.0%)	6 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	5	6	1
Mean	1.00	1.10	1.07	0.80
SD	0.000	0.212	0.225	
Median	1.00	1.10	1.10	0.80
Minimum	1.0	0.8	0.8	0.8
Maximum	1.0	1.3	1.3	0.8
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Reticulocyte Count (%)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	10.0	12.2	11.0	14.0
SD	2.83	3.58	2.83	
Median	10.0	11.5	10.0	14.0
Minimum	8	9	8	14
Maximum	12	19	14	14
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	0	4 (2.9%)	5 (3.6%)	1 (3.6%)
With values below reference range	0	0	0	0
With values within reference range	124 (100.0%)	132 (97.1%)	134 (96.4%)	27 (96.4%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	11.0	12.7	13.6	12.7
SD	2.76	4.44	4.16	3.71
Median	11.0	12.0	13.0	12.0
Minimum	7	6	6	7
Maximum	22	36	30	23

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	1 (12.5%)	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	7 (87.5%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	7.5	13.9	13.4	
SD	0.71	7.77	3.21	
Median	7.5	12.0	13.0	
Minimum	7	6	9	
Maximum	8	30	17	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		8.0	11.3	
SD		1.41	1.15	
Median		8.0	12.0	
Minimum		7	10	
Maximum		9	12	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	125	121	18
With values above reference range	1 (0.9%)	1 (0.8%)	1 (0.8%)	0
With values below reference range	0	0	0	0
With values within reference range	105 (99.1%)	124 (99.2%)	120 (99.2%)	18 (100.0%)
Summary statistics:				
Number of patients with values	106	125	121	18
Mean	10.9	11.6	12.0	11.4
SD	3.14	3.39	3.03	3.85
Median	10.0	11.0	11.0	12.0
Minimum	3	3	7	6
Maximum	27	23	23	22
Month 6				
Number of patients:				
With values	113	122	117	16
With values above reference range	0	1 (0.8%)	1 (0.9%)	0
With values below reference range	0	0	0	0
With values within reference range	113 (100.0%)	121 (99.2%)	116 (99.1%)	16 (100.0%)
Summary statistics:				
Number of patients with values	113	122	117	16
Mean	10.7	11.2	11.1	11.4
SD	2.90	3.26	3.26	3.18
Median	10.0	10.0	11.0	10.5
Minimum	6	5	5	8
Maximum	21	24	27	18

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	2 (1.8%)	1 (0.8%)	2 (1.8%)	0
With values below reference range	0	0	0	0
With values within reference range	108 (98.2%)	120 (99.2%)	108 (98.2%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	10.8	11.5	11.7	11.5
SD	2.91	3.36	3.24	2.79
Median	10.0	11.0	11.0	11.0
Minimum	7	7	8	7
Maximum	24	27	27	17
Month 12				
Number of patients:				
With values	98	109	101	17
With values above reference range	0	2 (1.8%)	2 (2.0%)	0
With values below reference range	0	0	0	0
With values within reference range	98 (100.0%)	107 (98.2%)	99 (98.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	98	109	101	17
Mean	10.6	10.9	10.8	10.5
SD	3.07	3.86	3.84	2.87
Median	10.0	10.0	10.0	11.0
Minimum	5	5	4	6
Maximum	20	31	26	15

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	0	2 (1.8%)	2 (2.0%)	0
With values below reference range	0	0	0	0
With values within reference range	100 (100.0%)	107 (98.2%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	9.6	10.3	10.6	10.2
SD	3.47	3.84	4.16	1.92
Median	9.0	10.0	10.0	9.0
Minimum	2	1	4	8
Maximum	21	23	25	14
Month 18				
Number of patients:				
With values	96	97	87	10
With values above reference range	0	0	1 (1.1%)	0
With values below reference range	0	0	0	0
With values within reference range	96 (100.0%)	97 (100.0%)	86 (98.9%)	10 (100.0%)
Summary statistics:				
Number of patients with values	96	97	87	10
Mean	9.4	10.0	10.2	11.5
SD	3.40	3.71	4.09	2.51
Median	8.5	10.0	10.0	12.0
Minimum	5	5	3	8
Maximum	21	20	26	15

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	2 (2.1%)	1 (1.1%)	1 (1.3%)	0
With values below reference range	0	0	0	0
With values within reference range	92 (97.9%)	91 (98.9%)	79 (98.8%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	9.6	10.0	9.8	12.0
SD	4.01	3.49	3.70	3.63
Median	8.5	9.0	9.0	13.0
Minimum	4	5	2	7
Maximum	27	25	23	16
Month 24				
Number of patients:				
With values	84	81	78	4
With values above reference range	4 (4.8%)	0	1 (1.3%)	0
With values below reference range	0	0	0	0
With values within reference range	80 (95.2%)	81 (100.0%)	77 (98.7%)	4 (100.0%)
Summary statistics:				
Number of patients with values	84	81	78	4
Mean	10.2	10.3	10.5	9.8
SD	5.18	3.49	4.76	1.50
Median	9.0	9.0	9.0	10.0
Minimum	4	5	1	8
Maximum	33	21	30	11

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	78	71	6
With values above reference range	2 (2.9%)	1 (1.3%)	1 (1.4%)	0
With values below reference range	0	0	0	0
With values within reference range	68 (97.1%)	77 (98.7%)	70 (98.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	78	71	6
Mean	10.5	10.3	10.6	10.3
SD	4.44	3.61	3.91	3.61
Median	9.0	9.5	9.0	10.0
Minimum	5	4	6	6
Maximum	27	24	25	15
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	1 (1.8%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	54 (98.2%)	69 (100.0%)	52 (100.0%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	9.5	10.3	10.4	10.8
SD	4.29	3.27	3.98	4.86
Median	9.0	10.0	10.0	8.5
Minimum	4	3	3	8
Maximum	35	18	20	18

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	1 (1.9%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	52 (98.1%)	47 (100.0%)	52 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	9.5	10.0	9.4	11.0
SD	3.51	3.77	3.41	3.61
Median	8.0	9.0	9.0	12.0
Minimum	5	5	4	7
Maximum	23	21	19	14
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	8.5	9.9	9.3	8.0
SD	2.19	3.22	2.99	
Median	8.0	10.0	9.0	8.0
Minimum	5	6	5	8
Maximum	15	19	18	8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	1 (20.0%)	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	4 (80.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	8.5	7.7	11.2	13.0
SD	2.12	3.67	7.66	
Median	8.5	6.5	9.0	13.0
Minimum	7	3	5	13
Maximum	10	13	24	13
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Bilirubin (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	9	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	9 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	9	5	1
Mean	72.5	71.7	73.6	70.0
SD	3.54	3.35	5.77	
Median	72.5	71.0	76.0	70.0
Minimum	70	67	65	70
Maximum	75	77	80	70
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	0	2 (1.5%)	0	3 (10.7%)
With values below reference range	0	0	0	0
With values within reference range	124 (100.0%)	134 (98.5%)	139 (100.0%)	25 (89.3%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	71.1	71.1	71.7	74.8
SD	4.40	4.84	3.92	6.36
Median	71.0	70.0	72.0	72.5
Minimum	58	58	60	65
Maximum	81	88	81	93

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	76.0	72.9	71.8	
SD	1.41	2.53	1.92	
Median	76.0	72.0	72.0	
Minimum	75	69	69	
Maximum	77	76	74	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		70.5	69.3	
SD		0.71	8.50	
Median		70.5	69.0	
Minimum		70	61	
Maximum		71	78	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	126	122	18
With values above reference range	1 (0.9%)	0	0	1 (5.6%)
With values below reference range	0	1 (0.8%)	0	0
With values within reference range	105 (99.1%)	125 (99.2%)	122 (100.0%)	17 (94.4%)
Summary statistics:				
Number of patients with values	106	126	122	18
Mean	69.8	69.7	69.4	76.0
SD	4.26	4.94	4.10	4.67
Median	69.0	70.0	69.0	75.5
Minimum	60	53	60	69
Maximum	82	85	81	85
Month 6				
Number of patients:				
With values	111	122	113	16
With values above reference range	0	2 (1.6%)	0	1 (6.3%)
With values below reference range	1 (0.9%)	0	1 (0.9%)	0
With values within reference range	110 (99.1%)	120 (98.4%)	112 (99.1%)	15 (93.8%)
Summary statistics:				
Number of patients with values	111	122	113	16
Mean	69.6	69.3	69.3	74.9
SD	4.03	4.67	4.52	3.22
Median	69.0	69.0	69.0	74.0
Minimum	59	60	56	70
Maximum	80	91	83	82

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	0	1 (0.8%)	1 (0.9%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	111 (100.0%)	120 (99.2%)	110 (99.1%)	16 (94.1%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	69.8	68.5	69.7	74.2
SD	4.33	4.16	4.72	3.94
Median	69.0	68.0	69.0	74.0
Minimum	62	59	60	68
Maximum	82	82	87	84
Month 12				
Number of patients:				
With values	96	109	102	17
With values above reference range	2 (2.1%)	0	2 (2.0%)	1 (5.9%)
With values below reference range	0	0	1 (1.0%)	0
With values within reference range	94 (97.9%)	109 (100.0%)	99 (97.1%)	16 (94.1%)
Summary statistics:				
Number of patients with values	96	109	102	17
Mean	70.9	70.0	70.7	74.2
SD	4.30	4.20	4.89	3.78
Median	70.0	70.0	70.0	74.0
Minimum	61	60	56	69
Maximum	87	81	88	82

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	1 (1.0%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	99 (99.0%)	109 (100.0%)	98 (100.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	71.0	70.5	70.9	75.1
SD	4.51	3.99	4.19	2.20
Median	71.0	71.0	70.0	75.0
Minimum	60	61	60	70
Maximum	82	80	80	77
Month 18				
Number of patients:				
With values	96	97	87	10
With values above reference range	1 (1.0%)	2 (2.1%)	1 (1.1%)	1 (10.0%)
With values below reference range	0	0	0	0
With values within reference range	95 (99.0%)	95 (97.9%)	86 (98.9%)	9 (90.0%)
Summary statistics:				
Number of patients with values	96	97	87	10
Mean	71.7	71.3	72.0	74.1
SD	4.62	4.14	4.76	3.96
Median	71.0	71.0	72.0	73.5
Minimum	59	62	58	69
Maximum	82	82	82	82

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	2 (2.1%)	1 (1.1%)	0	1 (12.5%)
With values below reference range	0	0	0	0
With values within reference range	92 (97.9%)	92 (98.9%)	81 (100.0%)	7 (87.5%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	72.0	71.6	71.6	76.4
SD	4.17	4.29	4.39	4.37
Median	72.0	71.0	71.0	75.5
Minimum	61	63	60	72
Maximum	86	85	81	86
Month 24				
Number of patients:				
With values	84	81	78	5
With values above reference range	3 (3.6%)	2 (2.5%)	2 (2.6%)	0
With values below reference range	0	0	0	0
With values within reference range	81 (96.4%)	79 (97.5%)	76 (97.4%)	5 (100.0%)
Summary statistics:				
Number of patients with values	84	81	78	5
Mean	72.6	71.8	72.4	75.0
SD	4.56	4.87	4.66	3.81
Median	72.0	71.0	73.0	77.0
Minimum	61	62	60	70
Maximum	84	89	83	79

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	78	71	6
With values above reference range	0	3 (3.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	70 (100.0%)	75 (96.2%)	71 (100.0%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	78	71	6
Mean	71.6	72.0	72.2	74.7
SD	3.90	4.69	4.22	3.01
Median	71.0	71.0	72.0	76.0
Minimum	64	64	61	70
Maximum	81	86	84	78
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	2 (3.6%)	0	0	0
With values below reference range	0	0	1 (1.9%)	0
With values within reference range	53 (96.4%)	69 (100.0%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	71.7	71.1	72.1	72.0
SD	4.75	3.92	4.86	2.94
Median	71.0	71.0	73.0	72.0
Minimum	63	62	58	69
Maximum	82	83	81	75

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	0	0	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	53 (100.0%)	47 (100.0%)	51 (98.1%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	70.7	71.5	71.3	72.7
SD	4.19	4.14	4.66	3.21
Median	70.0	72.0	71.0	74.0
Minimum	61	61	62	69
Maximum	82	81	84	75
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	71.7	70.2	71.2	76.0
SD	3.91	2.65	4.49	
Median	71.5	71.0	71.0	76.0
Minimum	65	65	60	76
Maximum	79	74	79	76

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	66.5	71.7	71.0	76.0
SD	2.12	4.84	3.74	
Median	66.5	72.5	70.0	76.0
Minimum	65	66	68	76
Maximum	68	78	77	76
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Total Protein (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	9	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	9 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	9	5	1
Mean	41.5	42.1	42.6	42.0
SD	2.12	1.54	2.30	
Median	41.5	43.0	43.0	42.0
Minimum	40	39	39	42
Maximum	43	44	45	42
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	0	0	0	1 (3.6%)
With values below reference range	0	0	0	0
With values within reference range	124 (100.0%)	136 (100.0%)	139 (100.0%)	27 (96.4%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	42.3	42.7	42.9	43.4
SD	2.13	2.07	1.74	2.85
Median	42.0	43.0	43.0	43.0
Minimum	36	35	38	39
Maximum	48	49	47	51

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	45.0	42.6	42.2	
SD	1.41	1.06	1.48	
Median	45.0	43.0	42.0	
Minimum	44	41	40	
Maximum	46	44	44	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		42.0	42.0	
SD		1.41	3.61	
Median		42.0	43.0	
Minimum		41	38	
Maximum		43	45	

- 1961 -

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	126	122	18
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	107 (100.0%)	126 (100.0%)	122 (100.0%)	18 (100.0%)
Summary statistics:				
Number of patients with values	107	126	122	18
Mean	41.4	41.6	41.5	43.0
SD	1.93	2.03	1.76	1.78
Median	42.0	42.0	41.5	43.0
Minimum	35	34	37	40
Maximum	46	47	46	46
Month 6				
Number of patients:				
With values	111	122	114	16
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	111 (100.0%)	122 (100.0%)	114 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	111	122	114	16
Mean	41.4	41.4	41.4	42.7
SD	2.03	1.76	1.78	1.49
Median	42.0	42.0	41.0	42.5
Minimum	34	36	37	40
Maximum	46	46	46	46

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	111 (100.0%)	121 (100.0%)	111 (100.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	41.3	40.9	41.2	42.1
SD	1.89	1.79	1.82	1.92
Median	41.0	41.0	41.0	43.0
Minimum	37	36	37	39
Maximum	46	46	46	45
Month 12				
Number of patients:				
With values	96	109	102	17
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	96 (100.0%)	109 (100.0%)	102 (100.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	96	109	102	17
Mean	41.6	41.6	41.7	42.0
SD	1.92	1.81	1.79	1.27
Median	41.5	42.0	41.5	42.0
Minimum	36	38	38	39
Maximum	46	47	47	45

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	100 (100.0%)	109 (100.0%)	98 (100.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	41.6	41.8	41.7	43.1
SD	2.48	2.00	2.15	1.05
Median	42.0	41.0	42.0	43.0
Minimum	33	34	35	41
Maximum	47	46	46	44
Month 18				
Number of patients:				
With values	96	97	87	10
With values above reference range	0	0	0	0
With values below reference range	1 (1.0%)	0	0	0
With values within reference range	95 (99.0%)	97 (100.0%)	87 (100.0%)	10 (100.0%)
Summary statistics:				
Number of patients with values	96	97	87	10
Mean	42.0	42.0	42.1	41.8
SD	2.38	1.86	2.11	1.81
Median	42.0	42.0	42.0	41.5
Minimum	31	37	37	39
Maximum	48	46	47	46

- 1964 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	94 (100.0%)	93 (100.0%)	81 (100.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	42.0	42.0	41.8	43.3
SD	2.02	1.93	1.80	1.49
Median	42.0	42.0	42.0	44.0
Minimum	37	37	38	41
Maximum	46	46	46	45
Month 24				
Number of patients:				
With values	84	81	78	5
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	84 (100.0%)	81 (100.0%)	78 (100.0%)	5 (100.0%)
Summary statistics:				
Number of patients with values	84	81	78	5
Mean	41.8	41.5	41.7	41.6
SD	2.34	1.97	2.11	1.34
Median	42.0	41.0	41.5	41.0
Minimum	36	36	38	40
Maximum	48	48	47	43

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	78	71	6
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	70 (100.0%)	78 (100.0%)	71 (100.0%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	78	71	6
Mean	41.4	41.7	41.3	41.3
SD	1.92	1.81	2.12	1.75
Median	41.0	41.0	41.0	41.5
Minimum	37	38	34	39
Maximum	46	47	47	44
Month 30				
Number of patients:				
With values	54	69	52	4
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	54 (100.0%)	69 (100.0%)	52 (100.0%)	4 (100.0%)
Summary statistics:				
Number of patients with values	54	69	52	4
Mean	41.5	41.4	41.4	41.3
SD	2.23	1.74	2.14	1.26
Median	42.0	41.0	41.0	41.0
Minimum	35	37	37	40
Maximum	46	45	47	43

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	53 (100.0%)	47 (100.0%)	52 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	41.8	42.0	41.8	41.0
SD	1.95	1.69	1.80	2.65
Median	42.0	42.0	42.0	40.0
Minimum	37	38	39	39
Maximum	48	46	46	44
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	42.5	42.3	41.9	42.0
SD	2.00	1.72	2.14	
Median	43.0	42.5	41.5	42.0
Minimum	39	40	38	42
Maximum	46	47	47	42

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	41.5	42.0	44.0	43.0
SD	2.12	1.41	1.73	
Median	41.5	42.0	43.0	43.0
Minimum	40	40	43	43
Maximum	43	44	47	43
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Albumin (g/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	20.0	21.0	16.8	15.0
SD	1.41	4.85	3.83	
Median	20.0	21.0	16.0	15.0
Minimum	19	14	12	15
Maximum	21	29	22	15
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	2 (1.6%)	3 (2.2%)	7 (5.0%)	0
With values below reference range	0	0	0	0
With values within reference range	122 (98.4%)	133 (97.8%)	132 (95.0%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	19.0	20.7	22.7	20.5
SD	8.04	8.95	11.78	6.51
Median	18.0	18.0	20.0	19.5
Minimum	10	9	10	14
Maximum	82	69	90	48

- 1970 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open		4bd Mono Total		
Label Medication	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	17.0	19.6	31.0	
SD	0.00	6.97	14.12	
Median	17.0	19.5	34.0	
Minimum	17	8	17	
Maximum	17	31	50	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		16.0	17.3	
SD		8.49	4.62	
Median		16.0	20.0	
Minimum		10	12	
Maximum		22	20	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	105	125	121	17
With values above reference range	1 (1.0%)	2 (1.6%)	2 (1.7%)	0
With values below reference range	0	0	0	0
With values within reference range	104 (99.0%)	123 (98.4%)	119 (98.3%)	17 (100.0%)
Summary statistics:				
Number of patients with values	105	125	121	17
Mean	19.5	20.8	19.7	21.3
SD	6.30	8.78	8.21	6.17
Median	18.0	18.0	17.0	19.0
Minimum	11	10	10	14
Maximum	47	86	61	38
Month 6				
Number of patients:				
With values	113	122	117	16
With values above reference range	1 (0.9%)	1 (0.8%)	1 (0.9%)	0
With values below reference range	0	0	0	0
With values within reference range	112 (99.1%)	121 (99.2%)	116 (99.1%)	16 (100.0%)
Summary statistics:				
Number of patients with values	113	122	117	16
Mean	19.4	21.0	19.8	22.1
SD	6.01	9.39	7.79	7.05
Median	18.0	19.0	18.0	20.0
Minimum	10	11	9	15
Maximum	43	88	63	40

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	2 (1.8%)	1 (0.8%)	1 (0.9%)	0
With values below reference range	0	0	0	0
With values within reference range	108 (98.2%)	120 (99.2%)	109 (99.1%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	19.5	19.7	19.9	23.5
SD	8.61	7.19	8.50	7.98
Median	17.5	18.0	17.0	21.0
Minimum	10	11	10	15
Maximum	72	74	68	46
Month 12				
Number of patients:				
With values	100	110	101	17
With values above reference range	1 (1.0%)	1 (0.9%)	4 (4.0%)	0
With values below reference range	0	0	0	0
With values within reference range	99 (99.0%)	109 (99.1%)	97 (96.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	100	110	101	17
Mean	19.5	20.3	23.0	22.6
SD	9.12	8.23	23.96	6.88
Median	18.0	19.0	18.0	21.0
Minimum	10	9	10	14
Maximum	90	85	232	40

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	2 (2.0%)	0	1 (1.0%)	0
With values below reference range	0	0	0	0
With values within reference range	98 (98.0%)	109 (100.0%)	97 (99.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	20.3	19.6	20.6	22.4
SD	9.54	5.49	8.60	7.06
Median	18.0	19.0	18.0	21.0
Minimum	10	8	11	14
Maximum	76	41	75	38
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	0	2 (2.1%)	2 (2.2%)	0
With values below reference range	0	0	0	0
With values within reference range	97 (100.0%)	95 (97.9%)	88 (97.8%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	18.9	21.1	21.0	22.1
SD	5.78	9.36	9.14	5.02
Median	18.0	19.0	19.0	21.5
Minimum	9	9	11	16
Maximum	41	67	72	33

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	1 (1.1%)	1 (1.1%)	2 (2.5%)	0
With values below reference range	0	0	0	0
With values within reference range	93 (98.9%)	91 (98.9%)	78 (97.5%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	19.5	20.1	21.5	22.3
SD	6.66	6.68	9.07	5.06
Median	18.0	19.0	19.0	21.0
Minimum	10	11	10	16
Maximum	53	44	60	30
Month 24				
Number of patients:				
With values	84	81	80	4
With values above reference range	0	1 (1.2%)	1 (1.3%)	0
With values below reference range	0	0	0	0
With values within reference range	84 (100.0%)	80 (98.8%)	79 (98.8%)	4 (100.0%)
Summary statistics:				
Number of patients with values	84	81	80	4
Mean	18.6	20.1	20.9	22.8
SD	5.54	6.30	9.91	3.77
Median	17.0	18.0	19.0	23.0
Minimum	11	11	11	19
Maximum	41	43	88	26

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	1 (1.4%)	0	3 (4.2%)	0
With values below reference range	0	0	0	0
With values within reference range	70 (98.6%)	78 (100.0%)	68 (95.8%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	19.0	20.0	22.7	22.3
SD	6.15	4.99	9.81	5.54
Median	18.0	19.0	20.0	21.0
Minimum	11	10	11	16
Maximum	50	35	60	29
Month 30				
Number of patients:				
With values	55	70	52	4
With values above reference range	2 (3.6%)	0	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	53 (96.4%)	70 (100.0%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	70	52	4
Mean	20.5	20.3	22.3	19.5
SD	8.86	5.92	8.28	1.29
Median	19.0	19.0	20.5	19.5
Minimum	12	9	12	18
Maximum	64	39	53	21

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	1 (1.9%)	0	2 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	52 (98.1%)	47 (100.0%)	50 (96.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	19.5	19.8	21.6	23.7
SD	6.70	5.29	13.22	9.07
Median	18.0	19.0	19.0	25.0
Minimum	9	12	12	14
Maximum	47	37	92	32
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	1 (3.6%)	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	27 (96.4%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	19.4	19.6	22.0	18.0
SD	6.41	7.45	18.07	
Median	17.5	18.0	18.5	18.0
Minimum	12	13	9	18
Maximum	41	51	111	18

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	16.5	17.2	22.2	21.0
SD	2.12	3.37	5.89	
Median	16.5	17.0	20.0	21.0
Minimum	15	13	16	21
Maximum	18	23	31	21
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGOT/ASAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	13.0	21.6	23.4	16.0
SD	0.00	11.36	12.38	
Median	13.0	15.5	21.0	16.0
Minimum	13	10	11	16
Maximum	13	38	44	16
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	3 (2.4%)	7 (5.1%)	14 (10.1%)	0
With values below reference range	0	0	0	0
With values within reference range	121 (97.6%)	129 (94.9%)	125 (89.9%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	18.1	21.2	28.0	21.1
SD	12.10	11.74	15.93	7.91
Median	15.0	16.5	24.0	19.0
Minimum	7	7	8	10
Maximum	119	70	90	39

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open		4bd Mono Total		
Label Medication	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	12.5	18.8	34.2	
SD	2.12	8.10	16.65	
Median	12.5	17.5	35.0	
Minimum	11	5	17	
Maximum	14	29	59	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		11.5	16.7	
SD		4.95	3.21	
Median		11.5	18.0	
Minimum		8	13	
Maximum		15	19	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	105	125	121	17
With values above reference range	1 (1.0%)	0	4 (3.3%)	0
With values below reference range	0	0	0	0
With values within reference range	104 (99.0%)	125 (100.0%)	117 (96.7%)	17 (100.0%)
Summary statistics:				
Number of patients with values	105	125	121	17
Mean	18.3	19.8	20.0	18.6
SD	8.66	8.95	9.86	6.74
Median	16.0	18.0	17.0	18.0
Minimum	8	6	8	9
Maximum	70	48	60	36
Month 6				
Number of patients:				
With values	113	122	117	16
With values above reference range	0	1 (0.8%)	4 (3.4%)	0
With values below reference range	0	0	0	0
With values within reference range	113 (100.0%)	121 (99.2%)	113 (96.6%)	16 (100.0%)
Summary statistics:				
Number of patients with values	113	122	117	16
Mean	18.1	20.0	19.6	18.2
SD	6.99	10.13	10.81	5.71
Median	17.0	17.0	17.0	18.0
Minimum	7	6	7	9
Maximum	45	65	77	34

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	3 (2.7%)	2 (1.7%)	2 (1.8%)	0
With values below reference range	0	0	0	0
With values within reference range	107 (97.3%)	119 (98.3%)	108 (98.2%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	18.5	18.6	18.9	17.8
SD	10.17	8.70	9.37	6.28
Median	16.0	16.0	16.0	17.0
Minimum	8	5	8	10
Maximum	78	51	60	36
Month 12				
Number of patients:				
With values	100	110	101	17
With values above reference range	1 (1.0%)	1 (0.9%)	5 (5.0%)	0
With values below reference range	0	0	0	0
With values within reference range	99 (99.0%)	109 (99.1%)	96 (95.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	100	110	101	17
Mean	17.0	18.4	21.4	18.9
SD	8.49	8.01	24.81	5.45
Median	15.0	16.5	16.0	19.0
Minimum	6	6	6	10
Maximum	69	50	240	33

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	2 (2.0%)	0	3 (3.1%)	0
With values below reference range	0	0	0	0
With values within reference range	98 (98.0%)	109 (100.0%)	95 (96.9%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	18.2	18.4	18.8	19.1
SD	10.91	8.40	10.20	5.84
Median	15.5	16.0	16.0	19.0
Minimum	4	4	7	10
Maximum	88	45	63	29
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	1 (1.0%)	3 (3.1%)	3 (3.3%)	0
With values below reference range	0	0	0	0
With values within reference range	96 (99.0%)	94 (96.9%)	87 (96.7%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	16.7	19.6	19.4	17.1
SD	7.50	12.73	12.00	5.07
Median	15.0	16.0	16.0	17.0
Minimum	6	6	7	9
Maximum	53	92	84	28

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	1 (1.1%)	1 (1.1%)	3 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	93 (98.9%)	91 (98.9%)	77 (96.3%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	17.2	17.8	18.8	17.8
SD	7.25	8.16	11.14	4.59
Median	16.0	15.0	15.0	18.5
Minimum	6	7	7	12
Maximum	50	49	61	25
Month 24				
Number of patients:				
With values	84	81	80	4
With values above reference range	0	2 (2.5%)	3 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	84 (100.0%)	79 (97.5%)	77 (96.3%)	4 (100.0%)
Summary statistics:				
Number of patients with values	84	81	80	4
Mean	15.8	18.9	18.9	21.5
SD	5.47	9.76	12.03	11.79
Median	15.0	16.0	15.5	22.0
Minimum	5	7	7	9
Maximum	31	66	82	33

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	77	67	6
With values above reference range	1 (1.4%)	0	4 (6.0%)	0
With values below reference range	0	0	0	0
With values within reference range	69 (98.6%)	77 (100.0%)	63 (94.0%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	77	67	6
Mean	17.0	17.4	20.3	18.7
SD	8.38	6.63	13.82	6.22
Median	15.0	16.0	16.0	18.0
Minimum	7	6	7	11
Maximum	65	39	84	26
Month 30				
Number of patients:				
With values	47	54	38	4
With values above reference range	1 (2.1%)	1 (1.9%)	1 (2.6%)	0
With values below reference range	0	0	0	0
With values within reference range	46 (97.9%)	53 (98.1%)	37 (97.4%)	4 (100.0%)
Summary statistics:				
Number of patients with values	47	54	38	4
Mean	17.7	19.4	21.7	14.8
SD	8.71	10.42	13.05	5.44
Median	16.0	15.5	17.0	14.0
Minimum	6	8	8	9
Maximum	51	58	77	22

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	35	25	26	3
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	35 (100.0%)	25 (100.0%)	26 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	35	25	26	3
Mean	16.4	18.5	15.1	16.7
SD	6.87	8.78	5.05	8.39
Median	15.0	16.0	14.0	21.0
Minimum	4	8	7	7
Maximum	34	40	28	22
Month 36				
Number of patients:				
With values	10	10	14	1
With values above reference range	0	0	1 (7.1%)	0
With values below reference range	0	0	0	0
With values within reference range	10 (100.0%)	10 (100.0%)	13 (92.9%)	1 (100.0%)
Summary statistics:				
Number of patients with values	10	10	14	1
Mean	16.4	19.9	24.4	8.0
SD	8.55	10.50	19.75	
Median	13.5	17.0	20.5	8.0
Minimum	10	10	7	8
Maximum	35	46	82	8

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	1	2	1	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	1 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	1	2	1	1
Mean	10.0	18.5	18.0	18.0
SD		2.12		
Median	10.0	18.5	18.0	18.0
Minimum	10	17	18	18
Maximum	10	20	18	18
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: SGPT/ALAT (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	37.5	28.8	27.4	18.0
SD	41.72	14.73	8.44	
Median	37.5	32.0	30.0	18.0
Minimum	8	5	13	18
Maximum	67	50	35	18
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	6 (4.8%)	10 (7.4%)	30 (21.6%)	2 (7.1%)
With values below reference range	0	0	0	0
With values within reference range	118 (95.2%)	126 (92.6%)	109 (78.4%)	26 (92.9%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	27.3	32.8	53.7	31.6
SD	20.60	25.88	66.69	21.71
Median	21.0	24.5	35.0	24.5
Minimum	7	3	10	8
Maximum	150	157	460	93

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	2 (40.0%)	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	3 (60.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	31.0	17.4	100.0	
SD	14.14	8.63	127.22	
Median	31.0	16.0	58.0	
Minimum	21	9	23	
Maximum	41	34	325	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		11.0	28.3	
SD		1.41	12.42	
Median		11.0	35.0	
Minimum		10	14	
Maximum		12	36	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	125	121	17
With values above reference range	4 (3.8%)	10 (8.0%)	9 (7.4%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	102 (96.2%)	115 (92.0%)	112 (92.6%)	16 (94.1%)
Summary statistics:				
Number of patients with values	106	125	121	17
Mean	28.2	34.6	30.7	30.4
SD	30.73	31.24	22.18	27.98
Median	21.0	25.0	22.0	18.0
Minimum	6	5	7	7
Maximum	257	218	121	113
Month 6				
Number of patients:				
With values	112	122	117	16
With values above reference range	5 (4.5%)	12 (9.8%)	12 (10.3%)	0
With values below reference range	0	0	0	0
With values within reference range	107 (95.5%)	110 (90.2%)	105 (89.7%)	16 (100.0%)
Summary statistics:				
Number of patients with values	112	122	117	16
Mean	27.0	38.2	33.7	26.1
SD	20.74	61.05	36.98	18.49
Median	21.0	25.0	23.0	17.5
Minimum	6	2	7	7
Maximum	141	627	299	62

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	5 (4.5%)	14 (11.6%)	11 (10.0%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	105 (95.5%)	107 (88.4%)	99 (90.0%)	16 (94.1%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	28.1	38.5	36.6	27.2
SD	19.29	55.11	37.69	20.34
Median	21.5	25.0	24.5	22.0
Minimum	7	4	8	2
Maximum	120	519	225	77
Month 12				
Number of patients:				
With values	99	109	101	17
With values above reference range	4 (4.0%)	12 (11.0%)	12 (11.9%)	0
With values below reference range	0	0	0	0
With values within reference range	95 (96.0%)	97 (89.0%)	89 (88.1%)	17 (100.0%)
Summary statistics:				
Number of patients with values	99	109	101	17
Mean	30.1	43.7	41.3	28.1
SD	23.68	73.90	45.56	22.25
Median	25.0	26.0	25.0	21.0
Minimum	6	9	6	5
Maximum	175	675	256	73

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	7 (7.0%)	12 (11.0%)	12 (12.2%)	0
With values below reference range	0	0	0	0
With values within reference range	93 (93.0%)	97 (89.0%)	86 (87.8%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	33.5	37.5	44.8	25.6
SD	40.52	31.73	64.86	17.74
Median	23.0	28.0	27.0	21.0
Minimum	6	10	9	9
Maximum	357	187	552	65
Month 18				
Number of patients:				
With values	97	97	89	10
With values above reference range	4 (4.1%)	14 (14.4%)	10 (11.2%)	0
With values below reference range	0	0	0	0
With values within reference range	93 (95.9%)	83 (85.6%)	79 (88.8%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	89	10
Mean	30.4	39.4	42.7	23.7
SD	25.30	36.22	49.10	16.91
Median	23.0	27.0	28.0	19.5
Minimum	7	10	10	8
Maximum	167	250	312	64

- 1994 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	6 (6.4%)	10 (10.9%)	13 (16.3%)	0
With values below reference range	0	0	0	0
With values within reference range	88 (93.6%)	82 (89.1%)	67 (83.8%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	31.6	34.7	45.5	25.8
SD	27.87	26.40	52.70	17.44
Median	25.0	27.0	30.0	22.0
Minimum	7	10	9	8
Maximum	201	170	280	63
Month 24				
Number of patients:				
With values	84	81	80	4
With values above reference range	7 (8.3%)	9 (11.1%)	10 (12.5%)	1 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	77 (91.7%)	72 (88.9%)	70 (87.5%)	3 (75.0%)
Summary statistics:				
Number of patients with values	84	81	80	4
Mean	31.6	37.1	41.9	29.0
SD	26.32	28.55	46.79	34.27
Median	22.0	26.0	29.0	14.0
Minimum	7	12	9	8
Maximum	171	147	269	80

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	5 (7.0%)	7 (9.0%)	8 (11.3%)	0
With values below reference range	0	0	0	0
With values within reference range	66 (93.0%)	71 (91.0%)	63 (88.7%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	34.2	32.8	47.8	24.8
SD	36.06	22.54	72.10	16.73
Median	24.0	25.5	30.0	22.5
Minimum	9	11	9	9
Maximum	202	110	531	56
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	6 (10.9%)	5 (7.2%)	8 (15.4%)	0
With values below reference range	0	0	0	0
With values within reference range	49 (89.1%)	64 (92.8%)	44 (84.6%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	35.6	35.0	47.7	15.3
SD	40.12	26.29	62.58	7.50
Median	25.0	25.0	26.0	14.0
Minimum	7	10	11	9
Maximum	232	143	358	24

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	6 (11.3%)	3 (6.4%)	8 (15.4%)	0
With values below reference range	0	0	0	0
With values within reference range	47 (88.7%)	44 (93.6%)	44 (84.6%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	35.0	31.0	46.5	28.7
SD	27.81	22.06	53.61	27.43
Median	25.0	24.0	29.0	17.0
Minimum	10	9	9	9
Maximum	174	120	282	60
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	2 (7.7%)	2 (7.1%)	0
With values below reference range	0	0	0	0
With values within reference range	23 (95.8%)	24 (92.3%)	26 (92.9%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	27.7	30.5	37.6	8.0
SD	15.18	22.34	41.97	
Median	23.0	25.0	27.0	8.0
Minimum	10	12	13	8
Maximum	70	114	235	8

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	2 (33.3%)	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	4 (66.7%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	23.0	36.8	25.8	21.0
SD	8.49	38.39	9.31	
Median	23.0	14.5	29.0	21.0
Minimum	17	10	15	21
Maximum	29	99	38	21
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Gamma Glutamyl Transferase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	51.0	61.0	70.2	55.0
SD	11.31	18.23	17.73	
Median	51.0	54.5	79.0	55.0
Minimum	43	39	44	55
Maximum	59	86	86	55
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	0	1 (0.7%)	3 (2.2%)	0
With values below reference range	1 (0.8%)	0	0	0
With values within reference range	123 (99.2%)	135 (99.3%)	136 (97.8%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	56.3	61.3	70.3	69.0
SD	16.88	58.63	28.62	19.91
Median	53.5	53.5	66.0	65.5
Minimum	19	21	37	41
Maximum	121	712	324	115

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	1 (20.0%)	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	4 (80.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	49.0	48.1	90.4	
SD	4.24	8.25	77.59	
Median	49.0	46.5	60.0	
Minimum	46	38	39	
Maximum	52	65	228	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		59.0	60.3	
SD		14.14	10.41	
Median		59.0	57.0	
Minimum		49	52	
Maximum		69	72	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	125	121	16
With values above reference range	0	1 (0.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	106 (100.0%)	124 (99.2%)	121 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	106	125	121	16
Mean	55.9	54.8	56.4	62.3
SD	16.21	16.19	14.94	12.97
Median	53.0	53.0	54.0	56.5
Minimum	24	22	25	46
Maximum	121	141	99	85
Month 6				
Number of patients:				
With values	112	122	117	16
With values above reference range	0	1 (0.8%)	1 (0.9%)	0
With values below reference range	0	2 (1.6%)	0	0
With values within reference range	112 (100.0%)	119 (97.5%)	116 (99.1%)	16 (100.0%)
Summary statistics:				
Number of patients with values	112	122	117	16
Mean	56.7	55.2	56.9	61.3
SD	17.89	16.35	20.47	10.42
Median	52.0	54.0	54.0	60.5
Minimum	25	18	28	47
Maximum	117	130	217	80

- 2002 -

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BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	1 (0.9%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	109 (99.1%)	121 (100.0%)	110 (100.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	58.3	57.2	58.6	63.5
SD	19.21	17.23	16.76	17.90
Median	56.0	55.0	57.0	59.0
Minimum	24	21	28	46
Maximum	147	111	120	106
Month 12				
Number of patients:				
With values	97	109	101	17
With values above reference range	2 (2.1%)	2 (1.8%)	2 (2.0%)	0
With values below reference range	0	0	0	0
With values within reference range	95 (97.9%)	107 (98.2%)	99 (98.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	97	109	101	17
Mean	61.6	61.2	62.2	65.1
SD	20.72	20.88	22.79	15.88
Median	58.0	59.0	57.0	61.0
Minimum	26	21	31	46
Maximum	157	181	205	103

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	1 (1.0%)	0	2 (2.0%)	0
With values below reference range	0	0	0	0
With values within reference range	98 (99.0%)	108 (100.0%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	61.9	61.9	70.6	64.3
SD	21.04	16.39	66.24	13.90
Median	57.0	58.0	61.0	63.0
Minimum	22	23	32	49
Maximum	156	100	670	86
Month 18				
Number of patients:				
With values	95	95	88	10
With values above reference range	1 (1.1%)	0	3 (3.4%)	0
With values below reference range	0	0	0	0
With values within reference range	94 (98.9%)	95 (100.0%)	85 (96.6%)	10 (100.0%)
Summary statistics:				
Number of patients with values	95	95	88	10
Mean	62.1	61.1	65.8	65.7
SD	23.30	18.57	34.33	15.04
Median	58.0	60.0	59.0	65.5
Minimum	27	22	30	46
Maximum	185	119	256	88

- 2004 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	92	91	80	8
With values above reference range	2 (2.2%)	0	4 (5.0%)	0
With values below reference range	0	0	0	0
With values within reference range	90 (97.8%)	91 (100.0%)	76 (95.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	92	91	80	8
Mean	60.0	60.7	66.3	64.5
SD	21.80	16.96	29.62	16.66
Median	55.0	59.0	60.0	61.5
Minimum	21	29	32	48
Maximum	154	108	243	94
Month 24				
Number of patients:				
With values	83	79	79	4
With values above reference range	1 (1.2%)	1 (1.3%)	1 (1.3%)	0
With values below reference range	0	0	0	0
With values within reference range	82 (98.8%)	78 (98.7%)	78 (98.7%)	4 (100.0%)
Summary statistics:				
Number of patients with values	83	79	79	4
Mean	61.6	64.4	65.2	70.5
SD	27.07	19.51	28.05	13.10
Median	56.0	62.0	60.0	68.0
Minimum	22	30	32	59
Maximum	244	152	229	87

- 2005 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	77	71	6
With values above reference range	2 (2.8%)	0	2 (2.8%)	0
With values below reference range	0	0	0	0
With values within reference range	69 (97.2%)	77 (100.0%)	69 (97.2%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	77	71	6
Mean	62.3	59.7	66.0	66.3
SD	35.22	16.04	31.85	18.05
Median	55.0	58.0	58.0	61.0
Minimum	23	24	33	50
Maximum	290	99	233	89
Month 30				
Number of patients:				
With values	54	67	52	4
With values above reference range	0	0	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	54 (100.0%)	67 (100.0%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	54	67	52	4
Mean	55.9	62.1	64.6	67.8
SD	17.38	18.11	36.78	21.99
Median	52.5	62.0	57.0	68.5
Minimum	27	26	27	45
Maximum	116	118	291	89

- 2006 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	45	52	3
With values above reference range	1 (1.9%)	0	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	52 (98.1%)	45 (100.0%)	51 (98.1%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	45	52	3
Mean	62.6	61.5	64.1	61.7
SD	42.95	20.64	35.86	21.94
Median	54.0	59.0	58.5	49.0
Minimum	24	34	28	49
Maximum	344	109	279	87
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	50.1	55.1	58.4	79.0
SD	10.59	15.76	18.27	
Median	48.0	51.0	58.5	79.0
Minimum	30	29	29	79
Maximum	76	86	94	79

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	59.5	71.0	55.0	61.0
SD	0.71	23.22	9.11	
Median	59.5	72.5	52.0	61.0
Minimum	59	40	43	61
Maximum	60	101	66	61
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Alkaline Phosphatase (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

CONFIDENTIAL

BRL-049653/RSD-
 100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	1 (50.0%)	0	1 (20.0%)	0
With values below reference range	0	0	0	0
With values within reference range	1 (50.0%)	10 (100.0%)	4 (80.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	105.0	82.0	92.0	90.0
SD	35.36	13.98	23.87	
Median	105.0	80.0	80.0	90.0
Minimum	80	70	70	90
Maximum	130	110	130	90
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	3 (2.4%)	3 (2.2%)	2 (1.4%)	2 (7.1%)
With values below reference range	2 (1.6%)	7 (5.1%)	1 (0.7%)	0
With values within reference range	119 (96.0%)	126 (92.6%)	136 (97.8%)	26 (92.9%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	91.5	88.2	90.9	95.0
SD	44.87	19.76	15.42	19.91
Median	86.0	86.0	89.0	100.0
Minimum	49	48	55	60
Maximum	548	161	151	130

- 2010 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	1 (50.0%)	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (50.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	95.0	86.3	98.0	
SD	49.50	10.61	14.83	
Median	95.0	85.0	100.0	
Minimum	60	70	80	
Maximum	130	100	120	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		75.0	86.7	
SD		7.07	11.55	
Median		75.0	80.0	
Minimum		70	80	
Maximum		80	100	

- 2011 -

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	125	121	17
With values above reference range	2 (1.9%)	4 (3.2%)	1 (0.8%)	1 (5.9%)
With values below reference range	2 (1.9%)	3 (2.4%)	0	0
With values within reference range	102 (96.2%)	118 (94.4%)	120 (99.2%)	16 (94.1%)
Summary statistics:				
Number of patients with values	106	125	121	17
Mean	85.0	86.2	90.0	94.7
SD	16.40	17.82	14.43	18.07
Median	90.0	80.0	90.0	100.0
Minimum	50	40	60	70
Maximum	150	160	140	140
Month 6				
Number of patients:				
With values	111	122	117	16
With values above reference range	3 (2.7%)	5 (4.1%)	3 (2.6%)	0
With values below reference range	0	4 (3.3%)	0	0
With values within reference range	108 (97.3%)	113 (92.6%)	114 (97.4%)	16 (100.0%)
Summary statistics:				
Number of patients with values	111	122	117	16
Mean	86.4	88.5	91.1	92.5
SD	17.20	21.58	19.55	17.32
Median	90.0	90.0	90.0	95.0
Minimum	60	50	60	70
Maximum	140	220	230	120

- 2012 -

CONFIDENTIAL

BRL-049653/RSD-
100TV/9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	2 (1.8%)	4 (3.3%)	2 (1.8%)	1 (5.9%)
With values below reference range	0	2 (1.7%)	0	0
With values within reference range	108 (98.2%)	115 (95.0%)	108 (98.2%)	16 (94.1%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	86.7	87.8	88.8	92.9
SD	18.08	17.96	16.74	20.85
Median	85.0	90.0	90.0	90.0
Minimum	60	50	60	60
Maximum	190	140	140	130
Month 12				
Number of patients:				
With values	99	109	101	17
With values above reference range	3 (3.0%)	5 (4.6%)	3 (3.0%)	1 (5.9%)
With values below reference range	1 (1.0%)	3 (2.8%)	2 (2.0%)	0
With values within reference range	95 (96.0%)	101 (92.7%)	96 (95.0%)	16 (94.1%)
Summary statistics:				
Number of patients with values	99	109	101	17
Mean	84.5	88.2	89.9	90.6
SD	17.34	20.33	19.00	18.19
Median	80.0	90.0	90.0	90.0
Minimum	50	40	40	60
Maximum	160	160	190	130

- 2013 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	4 (4.0%)	5 (4.6%)	8 (8.2%)	0
With values below reference range	1 (1.0%)	3 (2.8%)	1 (1.0%)	0
With values within reference range	95 (95.0%)	101 (92.7%)	89 (90.8%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	88.2	88.7	93.1	86.7
SD	21.48	20.64	21.84	18.03
Median	90.0	90.0	90.0	90.0
Minimum	50	40	50	60
Maximum	220	150	190	120
Month 18				
Number of patients:				
With values	97	97	89	10
With values above reference range	7 (7.2%)	6 (6.2%)	6 (6.7%)	0
With values below reference range	1 (1.0%)	1 (1.0%)	0	0
With values within reference range	89 (91.8%)	90 (92.8%)	83 (93.3%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	89	10
Mean	91.6	93.1	94.8	84.0
SD	30.95	30.83	25.59	16.47
Median	90.0	90.0	90.0	80.0
Minimum	50	50	60	60
Maximum	290	330	260	110

- 2014 -

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	3 (3.2%)	5 (5.4%)	3 (3.8%)	0
With values below reference range	3 (3.2%)	3 (3.3%)	0	0
With values within reference range	88 (93.6%)	84 (91.3%)	77 (96.3%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	85.6	89.9	93.0	87.5
SD	19.38	21.76	22.75	16.69
Median	80.0	90.0	90.0	90.0
Minimum	50	40	60	60
Maximum	160	160	220	110
Month 24				
Number of patients:				
With values	84	81	80	4
With values above reference range	6 (7.1%)	3 (3.7%)	4 (5.0%)	0
With values below reference range	1 (1.2%)	2 (2.5%)	2 (2.5%)	2 (50.0%)
With values within reference range	77 (91.7%)	76 (93.8%)	74 (92.5%)	2 (50.0%)
Summary statistics:				
Number of patients with values	84	81	80	4
Mean	88.6	86.2	90.3	77.5
SD	21.06	19.53	19.74	32.02
Median	85.0	90.0	90.0	75.0
Minimum	50	40	50	50
Maximum	170	140	150	110

- 2015 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	3 (4.2%)	4 (5.1%)	3 (4.2%)	0
With values below reference range	1 (1.4%)	3 (3.8%)	1 (1.4%)	0
With values within reference range	67 (94.4%)	71 (91.0%)	67 (94.4%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	87.2	89.6	92.5	78.3
SD	19.43	21.29	22.21	18.35
Median	80.0	90.0	90.0	75.0
Minimum	50	50	50	60
Maximum	160	150	200	100
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	2 (3.6%)	6 (8.7%)	2 (3.8%)	0
With values below reference range	1 (1.8%)	2 (2.9%)	1 (1.9%)	0
With values within reference range	52 (94.5%)	61 (88.4%)	49 (94.2%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	85.8	87.8	91.2	77.5
SD	27.47	21.27	18.11	15.00
Median	90.0	90.0	90.0	80.0
Minimum	50	50	50	60
Maximum	240	140	140	90

- 2016 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	3 (5.7%)	3 (6.4%)	2 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	50 (94.3%)	44 (93.6%)	50 (96.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	89.8	88.5	89.6	80.0
SD	24.14	19.33	19.30	20.00
Median	90.0	90.0	80.0	80.0
Minimum	60	60	60	60
Maximum	200	140	160	100
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	3 (11.5%)	3 (10.7%)	0
With values below reference range	0	1 (3.8%)	0	0
With values within reference range	23 (95.8%)	22 (84.6%)	25 (89.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	89.2	93.8	97.5	60.0
SD	19.09	29.68	37.28	
Median	90.0	90.0	95.0	60.0
Minimum	60	50	60	60
Maximum	130	200	260	60

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

- 2017 -

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	100.0	78.3	78.0	100.0
SD	28.28	13.29	10.95	
Median	100.0	80.0	80.0	100.0
Minimum	80	60	60	100
Maximum	120	90	90	100
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

- 2018 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Creatinine (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

- 2019 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	1 (50.0%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	1 (50.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	8.55	5.44	5.18	4.00
SD	3.041	0.728	1.624	
Median	8.55	5.20	5.90	4.00
Minimum	6.4	4.5	3.3	4.0
Maximum	10.7	6.7	6.9	4.0
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	8 (6.5%)	2 (1.5%)	3 (2.2%)	0
With values below reference range	0	1 (0.7%)	0	0
With values within reference range	116 (93.5%)	133 (97.8%)	136 (97.8%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	6.52	6.12	5.75	6.13
SD	2.515	1.656	1.505	1.445
Median	6.15	6.00	5.60	6.15
Minimum	2.6	2.1	3.3	3.9
Maximum	24.4	14.7	12.0	8.8

- 2020 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	6.75	5.75	5.96	
SD	1.061	1.233	1.885	
Median	6.75	5.50	6.20	
Minimum	6.0	4.4	3.7	
Maximum	7.5	7.9	8.7	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	1 (33.3%)	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	2 (66.7%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		5.55	7.53	
SD		0.778	2.040	
Median		5.55	8.00	
Minimum		5.0	5.3	
Maximum		6.1	9.3	

- 2021 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	126	122	18
With values above reference range	6 (5.6%)	5 (4.0%)	3 (2.5%)	0
With values below reference range	0	0	0	0
With values within reference range	101 (94.4%)	121 (96.0%)	119 (97.5%)	18 (100.0%)
Summary statistics:				
Number of patients with values	107	126	122	18
Mean	6.63	6.62	6.22	5.92
SD	2.161	2.195	1.471	1.291
Median	6.30	6.50	6.20	5.70
Minimum	2.6	2.9	3.3	3.8
Maximum	15.8	23.8	11.9	8.9
Month 6				
Number of patients:				
With values	112	122	115	16
With values above reference range	5 (4.5%)	3 (2.5%)	4 (3.5%)	1 (6.3%)
With values below reference range	0	0	0	0
With values within reference range	107 (95.5%)	119 (97.5%)	111 (96.5%)	15 (93.8%)
Summary statistics:				
Number of patients with values	112	122	115	16
Mean	6.50	6.69	6.43	6.53
SD	1.770	2.683	1.704	1.570
Median	6.20	6.30	6.20	6.40
Minimum	2.7	3.0	3.4	4.5
Maximum	13.3	30.3	13.1	10.6

- 2022 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	8 (7.2%)	2 (1.7%)	3 (2.7%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	103 (92.8%)	119 (98.3%)	108 (97.3%)	16 (94.1%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	6.54	6.41	6.09	6.84
SD	2.250	1.450	1.474	1.608
Median	6.00	6.50	5.90	6.30
Minimum	2.7	3.5	3.3	4.7
Maximum	18.8	10.1	11.5	9.8
Month 12				
Number of patients:				
With values	96	109	102	17
With values above reference range	4 (4.2%)	4 (3.7%)	3 (2.9%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	92 (95.8%)	105 (96.3%)	99 (97.1%)	16 (94.1%)
Summary statistics:				
Number of patients with values	96	109	102	17
Mean	6.24	6.58	6.08	6.28
SD	1.882	1.982	1.602	1.782
Median	6.00	6.30	5.95	6.50
Minimum	2.6	3.0	3.5	3.3
Maximum	14.0	18.5	11.9	9.9

- 2023 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	6 (6.0%)	4 (3.7%)	5 (5.1%)	1 (11.1%)
With values below reference range	0	0	0	0
With values within reference range	94 (94.0%)	105 (96.3%)	93 (94.9%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	6.51	6.55	6.30	5.91
SD	2.335	1.565	1.799	1.939
Median	6.20	6.50	6.00	5.40
Minimum	2.6	3.2	3.6	3.7
Maximum	19.8	11.8	13.2	9.2
Month 18				
Number of patients:				
With values	96	97	87	10
With values above reference range	7 (7.3%)	4 (4.1%)	4 (4.6%)	0
With values below reference range	1 (1.0%)	0	0	0
With values within reference range	88 (91.7%)	93 (95.9%)	83 (95.4%)	10 (100.0%)
Summary statistics:				
Number of patients with values	96	97	87	10
Mean	6.78	6.61	6.46	5.24
SD	2.364	1.627	1.897	1.136
Median	6.55	6.50	6.20	5.25
Minimum	2.4	3.4	3.6	3.6
Maximum	18.1	12.5	15.2	7.3

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	6 (6.4%)	6 (6.5%)	4 (4.9%)	0
With values below reference range	0	0	0	0
With values within reference range	88 (93.6%)	87 (93.5%)	77 (95.1%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	6.51	6.72	6.38	6.09
SD	2.230	1.874	1.970	1.290
Median	6.00	6.50	6.00	5.90
Minimum	3.1	3.5	3.8	4.6
Maximum	18.5	12.1	14.0	8.8
Month 24				
Number of patients:				
With values	84	81	78	5
With values above reference range	3 (3.6%)	0	4 (5.1%)	0
With values below reference range	0	0	0	0
With values within reference range	81 (96.4%)	81 (100.0%)	74 (94.9%)	5 (100.0%)
Summary statistics:				
Number of patients with values	84	81	78	5
Mean	6.32	6.48	6.44	5.50
SD	1.810	1.431	2.698	1.179
Median	6.25	6.20	6.00	5.40
Minimum	2.8	3.5	3.4	3.8
Maximum	13.6	10.0	24.5	6.8

- 2025 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	78	71	6
With values above reference range	3 (4.3%)	3 (3.8%)	6 (8.5%)	0
With values below reference range	0	0	0	0
With values within reference range	67 (95.7%)	75 (96.2%)	65 (91.5%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	78	71	6
Mean	6.66	6.65	6.65	6.22
SD	2.238	1.599	3.170	1.270
Median	6.55	6.50	6.00	6.60
Minimum	3.5	2.9	3.2	4.2
Maximum	16.9	12.0	26.5	7.4
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	4 (7.3%)	3 (4.3%)	2 (3.8%)	0
With values below reference range	1 (1.8%)	0	0	0
With values within reference range	50 (90.9%)	66 (95.7%)	50 (96.2%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	6.37	6.80	6.32	6.28
SD	2.086	1.796	2.052	2.081
Median	6.10	6.60	6.00	6.30
Minimum	2.4	3.4	3.9	3.8
Maximum	11.9	12.3	17.2	8.7

- 2026 -

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BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	6 (11.3%)	3 (6.4%)	3 (5.8%)	0
With values below reference range	0	0	0	0
With values within reference range	47 (88.7%)	44 (93.6%)	49 (94.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	6.78	6.58	6.48	5.13
SD	2.360	1.718	2.039	1.834
Median	6.20	6.20	5.80	4.50
Minimum	2.8	3.3	3.9	3.7
Maximum	15.6	10.4	15.2	7.2
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	3 (12.5%)	1 (3.8%)	3 (10.7%)	0
With values below reference range	0	0	0	0
With values within reference range	21 (87.5%)	25 (96.2%)	25 (89.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	7.31	6.69	7.52	6.50
SD	3.071	1.715	5.628	
Median	6.80	6.40	6.25	6.50
Minimum	3.8	3.3	4.5	6.5
Maximum	18.9	10.8	34.3	6.5

- 2027 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	6.05	5.70	5.72	2.80
SD	0.495	1.624	1.165	
Median	6.05	5.45	5.90	2.80
Minimum	5.7	4.3	4.0	2.8
Maximum	6.4	8.8	7.2	2.8
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Blood Urea Nitrogen (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
 100TV9/1/CPMS-009

- 2029 -

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	1 (50.0%)	0	0	0
With values below reference range	0	3 (30.0%)	1 (20.0%)	0
With values within reference range	1 (50.0%)	7 (70.0%)	4 (80.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	426.0	264.6	324.6	242.0
SD	239.00	44.27	111.80	
Median	426.0	279.0	357.0	242.0
Minimum	257	189	188	242
Maximum	595	322	427	242
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	2 (1.6%)	3 (2.2%)	2 (1.4%)	3 (10.7%)
With values below reference range	18 (14.5%)	17 (12.5%)	34 (24.5%)	5 (17.9%)
With values within reference range	104 (83.9%)	116 (85.3%)	103 (74.1%)	20 (71.4%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	291.7	309.8	288.7	299.7
SD	90.47	91.80	85.37	104.68
Median	288.0	304.0	273.0	273.5
Minimum	83	104	101	166
Maximum	595	716	573	563

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Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	1 (50.0%)	0	1 (20.0%)	
With values below reference range	0	1 (12.5%)	2 (40.0%)	
With values within reference range	1 (50.0%)	7 (87.5%)	2 (40.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	385.5	264.1	297.6	
SD	116.67	46.91	136.70	
Median	385.5	264.0	250.0	
Minimum	303	195	202	
Maximum	468	324	537	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	2 (66.7%)	
With values within reference range		2 (100.0%)	1 (33.3%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		282.0	239.7	
SD		2.83	99.61	
Median		282.0	200.0	
Minimum		280	166	
Maximum		284	353	

- 2031 -

CONFIDENTIAL

BRL-049653/RSD-
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BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	126	122	18
With values above reference range	2 (1.9%)	5 (4.0%)	0	1 (5.6%)
With values below reference range	17 (15.9%)	16 (12.7%)	38 (31.1%)	4 (22.2%)
With values within reference range	88 (82.2%)	105 (83.3%)	84 (68.9%)	13 (72.2%)
Summary statistics:				
Number of patients with values	107	126	122	18
Mean	278.5	293.1	253.7	300.3
SD	103.71	87.57	78.94	110.89
Median	259.0	292.0	247.0	267.5
Minimum	67	137	82	163
Maximum	789	557	485	592
Month 6				
Number of patients:				
With values	112	122	115	16
With values above reference range	3 (2.7%)	3 (2.5%)	1 (0.9%)	1 (6.3%)
With values below reference range	16 (14.3%)	11 (9.0%)	30 (26.1%)	3 (18.8%)
With values within reference range	93 (83.0%)	108 (88.5%)	84 (73.0%)	12 (75.0%)
Summary statistics:				
Number of patients with values	112	122	115	16
Mean	288.8	304.3	266.6	306.4
SD	89.57	80.38	78.99	99.86
Median	286.5	299.0	259.0	281.5
Minimum	75	134	109	141
Maximum	687	585	491	537

- 2032 -

CONFIDENTIAL

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BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	2 (1.8%)	1 (0.8%)	0	3 (17.6%)
With values below reference range	16 (14.4%)	16 (13.2%)	31 (27.9%)	1 (5.9%)
With values within reference range	93 (83.8%)	104 (86.0%)	80 (72.1%)	13 (76.5%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	281.0	292.6	269.3	321.1
SD	88.89	78.38	82.24	114.72
Median	272.0	290.0	260.0	306.0
Minimum	112	97	131	151
Maximum	797	472	502	552
Month 12				
Number of patients:				
With values	99	110	102	17
With values above reference range	2 (2.0%)	1 (0.9%)	2 (2.0%)	2 (11.8%)
With values below reference range	13 (13.1%)	10 (9.1%)	25 (24.5%)	4 (23.5%)
With values within reference range	84 (84.8%)	99 (90.0%)	75 (73.5%)	11 (64.7%)
Summary statistics:				
Number of patients with values	99	110	102	17
Mean	290.7	299.8	286.3	310.8
SD	87.00	88.11	95.18	111.51
Median	285.0	287.0	271.5	289.0
Minimum	83	99	92	180
Maximum	590	557	527	559

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	1 (1.0%)	5 (4.6%)	4 (4.1%)	0
With values below reference range	8 (8.0%)	8 (7.3%)	22 (22.4%)	2 (22.2%)
With values within reference range	91 (91.0%)	96 (88.1%)	72 (73.5%)	7 (77.8%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	302.3	315.6	299.0	273.7
SD	87.40	90.48	99.26	71.32
Median	288.0	306.0	298.0	256.0
Minimum	116	135	101	182
Maximum	666	589	541	404
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	0	5 (5.2%)	6 (6.7%)	0
With values below reference range	9 (9.3%)	5 (5.2%)	14 (15.6%)	0
With values within reference range	88 (90.7%)	87 (89.7%)	70 (77.8%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	305.5	325.6	319.6	290.6
SD	78.08	83.33	98.65	73.10
Median	308.0	315.0	308.0	287.5
Minimum	85	111	117	171
Maximum	508	555	569	418

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	0	2 (2.2%)	9 (11.1%)	0
With values below reference range	11 (11.7%)	11 (11.8%)	12 (14.8%)	0
With values within reference range	83 (88.3%)	80 (86.0%)	60 (74.1%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	302.2	316.0	326.9	282.1
SD	81.27	86.34	108.20	75.83
Median	301.5	307.0	317.0	267.5
Minimum	61	126	126	189
Maximum	493	576	592	393
Month 24				
Number of patients:				
With values	84	81	80	5
With values above reference range	1 (1.2%)	3 (3.7%)	2 (2.5%)	0
With values below reference range	9 (10.7%)	8 (9.9%)	11 (13.8%)	1 (20.0%)
With values within reference range	74 (88.1%)	70 (86.4%)	67 (83.8%)	4 (80.0%)
Summary statistics:				
Number of patients with values	84	81	80	5
Mean	304.3	303.0	313.6	263.2
SD	77.83	77.52	104.17	129.92
Median	297.0	297.0	303.0	195.0
Minimum	86	132	127	168
Maximum	519	534	650	473

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	2 (2.8%)	6 (7.7%)	4 (5.6%)	0
With values below reference range	4 (5.6%)	5 (6.4%)	6 (8.5%)	1 (16.7%)
With values within reference range	65 (91.5%)	67 (85.9%)	61 (85.9%)	5 (83.3%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	325.5	316.6	327.5	262.2
SD	87.36	91.49	108.43	92.29
Median	321.0	304.0	313.0	261.0
Minimum	119	104	158	162
Maximum	607	575	833	407
Month 30				
Number of patients:				
With values	55	70	52	4
With values above reference range	1 (1.8%)	4 (5.7%)	3 (5.8%)	0
With values below reference range	4 (7.3%)	8 (11.4%)	6 (11.5%)	0
With values within reference range	50 (90.9%)	58 (82.9%)	43 (82.7%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	70	52	4
Mean	325.7	314.7	322.1	241.3
SD	81.64	80.63	104.81	32.91
Median	324.0	313.0	304.0	235.0
Minimum	112	161	128	209
Maximum	543	528	589	286

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	1 (1.9%)	1 (2.1%)	2 (3.8%)	0
With values below reference range	5 (9.4%)	5 (10.6%)	6 (11.5%)	0
With values within reference range	47 (88.7%)	41 (87.2%)	44 (84.6%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	326.8	312.8	315.0	272.0
SD	83.36	76.15	100.39	96.32
Median	305.0	313.0	316.5	241.0
Minimum	170	128	146	195
Maximum	507	522	534	380
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	0	2 (7.1%)	0
With values below reference range	2 (8.3%)	1 (3.8%)	5 (17.9%)	0
With values within reference range	21 (87.5%)	25 (96.2%)	21 (75.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	337.4	283.3	323.1	190.0
SD	104.70	45.31	151.93	
Median	343.0	276.0	292.5	190.0
Minimum	171	206	145	190
Maximum	621	412	885	190

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	1 (16.7%)	0	0
With values below reference range	0	1 (16.7%)	0	0
With values within reference range	2 (100.0%)	4 (66.7%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	286.0	300.3	271.2	260.0
SD	41.01	116.94	110.69	
Median	286.0	295.5	232.0	260.0
Minimum	257	121	158	260
Maximum	315	477	437	260
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Uric Acid (umol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	140.0	140.0	139.8	140.0
SD	0.00	2.49	1.64	
Median	140.0	140.0	139.0	140.0
Minimum	140	137	138	140
Maximum	140	145	142	140
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	2 (1.6%)	3 (2.2%)	3 (2.2%)	0
With values below reference range	0	3 (2.2%)	3 (2.2%)	0
With values within reference range	122 (98.4%)	133 (95.6%)	133 (95.7%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	139.9	140.0	139.8	139.0
SD	2.31	3.17	2.72	2.10
Median	140.0	140.0	140.0	138.5
Minimum	135	120	132	136
Maximum	149	150	149	144

- 2040 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	1 (12.5%)	0	
With values within reference range	2 (100.0%)	7 (87.5%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	142.0	140.0	137.2	
SD	5.66	4.11	1.79	
Median	142.0	141.0	137.0	
Minimum	138	134	135	
Maximum	146	145	139	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		138.5	142.0	
SD		4.95	3.46	
Median		138.5	140.0	
Minimum		135	140	
Maximum		142	146	

- 2041 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	126	122	18
With values above reference range	3 (2.8%)	2 (1.6%)	3 (2.5%)	0
With values below reference range	3 (2.8%)	2 (1.6%)	1 (0.8%)	1 (5.6%)
With values within reference range	100 (94.3%)	122 (96.8%)	118 (96.7%)	17 (94.4%)
Summary statistics:				
Number of patients with values	106	126	122	18
Mean	139.8	139.7	139.3	138.7
SD	4.04	2.57	2.74	2.24
Median	140.0	140.0	139.0	139.0
Minimum	131	130	130	134
Maximum	167	149	148	141
Month 6				
Number of patients:				
With values	113	122	118	16
With values above reference range	1 (0.9%)	2 (1.6%)	1 (0.8%)	0
With values below reference range	2 (1.8%)	2 (1.6%)	1 (0.8%)	0
With values within reference range	110 (97.3%)	118 (96.7%)	116 (98.3%)	16 (100.0%)
Summary statistics:				
Number of patients with values	113	122	118	16
Mean	139.8	139.9	139.7	139.4
SD	2.49	2.56	2.45	2.80
Median	139.0	139.5	140.0	139.0
Minimum	133	131	134	135
Maximum	147	148	147	144

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	0	1 (0.8%)	0	0
With values below reference range	2 (1.8%)	2 (1.7%)	3 (2.7%)	0
With values within reference range	109 (98.2%)	118 (97.5%)	108 (97.3%)	17 (100.0%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	139.8	140.3	139.4	139.1
SD	2.60	2.43	2.94	2.06
Median	139.0	140.0	140.0	139.0
Minimum	129	133	123	136
Maximum	145	147	146	143
Month 12				
Number of patients:				
With values	99	110	102	17
With values above reference range	1 (1.0%)	3 (2.7%)	1 (1.0%)	0
With values below reference range	4 (4.0%)	1 (0.9%)	3 (2.9%)	0
With values within reference range	94 (94.9%)	106 (96.4%)	98 (96.1%)	17 (100.0%)
Summary statistics:				
Number of patients with values	99	110	102	17
Mean	139.7	140.4	139.9	139.8
SD	2.82	2.62	2.54	2.17
Median	140.0	140.0	140.0	140.0
Minimum	132	132	133	137
Maximum	147	152	147	144

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	2 (2.0%)	3 (2.8%)	0	0
With values below reference range	2 (2.0%)	1 (0.9%)	1 (1.0%)	0
With values within reference range	96 (96.0%)	105 (96.3%)	97 (99.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	140.1	140.6	140.2	139.4
SD	2.54	2.61	2.39	2.79
Median	140.0	141.0	140.0	140.0
Minimum	134	134	134	136
Maximum	147	150	145	144
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	3 (3.1%)	3 (3.1%)	2 (2.2%)	0
With values below reference range	2 (2.1%)	3 (3.1%)	0	1 (10.0%)
With values within reference range	92 (94.8%)	91 (93.8%)	88 (97.8%)	9 (90.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	140.6	140.5	140.7	139.0
SD	2.94	3.03	2.59	2.98
Median	140.0	141.0	141.0	139.0
Minimum	132	130	135	134
Maximum	150	150	148	143

- 2044 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	4 (4.3%)	3 (3.2%)	2 (2.5%)	0
With values below reference range	3 (3.2%)	1 (1.1%)	2 (2.5%)	0
With values within reference range	87 (92.6%)	89 (95.7%)	77 (95.1%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	140.6	140.9	140.9	140.5
SD	2.97	3.01	2.80	2.51
Median	140.0	141.0	140.0	141.0
Minimum	130	133	134	136
Maximum	148	150	151	143
Month 24				
Number of patients:				
With values	84	81	81	5
With values above reference range	2 (2.4%)	3 (3.7%)	2 (2.5%)	0
With values below reference range	0	0	1 (1.2%)	0
With values within reference range	82 (97.6%)	78 (96.3%)	78 (96.3%)	5 (100.0%)
Summary statistics:				
Number of patients with values	84	81	81	5
Mean	140.7	140.8	140.9	140.2
SD	2.56	2.96	2.92	2.49
Median	140.0	141.0	141.0	141.0
Minimum	135	135	132	136
Maximum	149	148	147	142

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	1 (1.4%)	2 (2.6%)	3 (4.2%)	0
With values below reference range	2 (2.8%)	0	1 (1.4%)	0
With values within reference range	68 (95.8%)	76 (97.4%)	67 (94.4%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	140.2	140.6	140.4	139.5
SD	2.76	2.42	3.19	2.26
Median	140.0	140.0	140.0	140.0
Minimum	134	136	134	136
Maximum	147	147	154	142
Month 30				
Number of patients:				
With values	56	70	52	4
With values above reference range	0	1 (1.4%)	2 (3.8%)	0
With values below reference range	0	1 (1.4%)	2 (3.8%)	0
With values within reference range	56 (100.0%)	68 (97.1%)	48 (92.3%)	4 (100.0%)
Summary statistics:				
Number of patients with values	56	70	52	4
Mean	139.8	139.9	139.4	141.3
SD	2.59	2.73	3.11	1.71
Median	140.0	140.0	139.0	141.5
Minimum	135	131	134	139
Maximum	146	150	151	143

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	0	1 (2.1%)	1 (1.9%)	0
With values below reference range	2 (3.8%)	1 (2.1%)	1 (1.9%)	0
With values within reference range	51 (96.2%)	45 (95.7%)	50 (96.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	140.0	140.3	140.1	140.0
SD	2.56	2.68	2.48	1.00
Median	140.0	141.0	140.0	140.0
Minimum	133	134	134	139
Maximum	145	148	148	141
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	0	0
With values below reference range	1 (4.2%)	0	0	0
With values within reference range	23 (95.8%)	26 (100.0%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	140.0	141.2	141.3	142.0
SD	2.94	2.27	2.13	
Median	140.0	141.5	141.0	142.0
Minimum	132	135	137	142
Maximum	146	145	146	142

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	143.0	141.5	141.2	140.0
SD	1.41	1.38	1.64	
Median	143.0	142.0	142.0	140.0
Minimum	142	139	139	140
Maximum	144	143	143	140
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Sodium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	4.10	4.51	4.32	4.40
SD	0.283	0.296	0.303	
Median	4.10	4.40	4.50	4.40
Minimum	3.9	4.2	3.9	4.4
Maximum	4.3	5.2	4.6	4.4
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	3 (2.4%)	1 (0.7%)	1 (0.7%)	0
With values below reference range	0	1 (0.7%)	0	0
With values within reference range	121 (97.6%)	134 (98.5%)	138 (99.3%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	4.43	4.47	4.47	4.30
SD	0.397	0.367	0.334	0.312
Median	4.40	4.40	4.40	4.30
Minimum	3.6	3.4	3.8	3.7
Maximum	6.4	5.8	5.4	5.1

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BRL-049653/RSD-
 100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	1 (12.5%)	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	7 (87.5%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	4.40	4.61	4.26	
SD	0.849	0.582	0.313	
Median	4.40	4.60	4.20	
Minimum	3.8	3.9	3.8	
Maximum	5.0	5.8	4.6	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		4.85	4.33	
SD		0.212	0.252	
Median		4.85	4.30	
Minimum		4.7	4.1	
Maximum		5.0	4.6	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	105	123	120	16
With values above reference range	2 (1.9%)	3 (2.4%)	2 (1.7%)	0
With values below reference range	0	0	0	0
With values within reference range	103 (98.1%)	120 (97.6%)	118 (98.3%)	16 (100.0%)
Summary statistics:				
Number of patients with values	105	123	120	16
Mean	4.44	4.45	4.45	4.38
SD	0.365	0.373	0.368	0.312
Median	4.40	4.40	4.40	4.35
Minimum	3.7	3.8	3.6	3.6
Maximum	5.7	6.3	5.7	5.0
Month 6				
Number of patients:				
With values	111	120	117	16
With values above reference range	2 (1.8%)	4 (3.3%)	0	0
With values below reference range	1 (0.9%)	0	0	0
With values within reference range	108 (97.3%)	116 (96.7%)	117 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	111	120	117	16
Mean	4.45	4.46	4.41	4.39
SD	0.348	0.374	0.310	0.307
Median	4.40	4.40	4.40	4.40
Minimum	3.4	3.5	3.7	3.8
Maximum	5.6	5.8	5.3	4.9

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	109	119	109	17
With values above reference range	3 (2.8%)	3 (2.5%)	1 (0.9%)	0
With values below reference range	0	0	0	0
With values within reference range	106 (97.2%)	116 (97.5%)	108 (99.1%)	17 (100.0%)
Summary statistics:				
Number of patients with values	109	119	109	17
Mean	4.44	4.48	4.40	4.39
SD	0.357	0.378	0.350	0.295
Median	4.40	4.50	4.30	4.40
Minimum	3.6	3.7	3.5	3.8
Maximum	5.6	6.0	5.5	5.0
Month 12				
Number of patients:				
With values	98	109	99	16
With values above reference range	4 (4.1%)	2 (1.8%)	0	0
With values below reference range	2 (2.0%)	0	1 (1.0%)	0
With values within reference range	92 (93.9%)	107 (98.2%)	98 (99.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	98	109	99	16
Mean	4.44	4.52	4.43	4.43
SD	0.422	0.400	0.327	0.332
Median	4.40	4.50	4.50	4.45
Minimum	2.7	3.6	3.4	3.9
Maximum	5.8	5.8	5.2	5.1

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	8
With values above reference range	2 (2.0%)	3 (2.8%)	1 (1.0%)	0
With values below reference range	0	0	0	0
With values within reference range	97 (98.0%)	105 (97.2%)	97 (99.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	99	108	98	8
Mean	4.44	4.50	4.43	4.30
SD	0.398	0.403	0.357	0.396
Median	4.40	4.40	4.40	4.30
Minimum	3.6	3.7	3.5	3.7
Maximum	5.8	6.3	5.4	4.8
Month 18				
Number of patients:				
With values	95	94	88	10
With values above reference range	2 (2.1%)	2 (2.1%)	1 (1.1%)	1 (10.0%)
With values below reference range	0	2 (2.1%)	0	0
With values within reference range	93 (97.9%)	90 (95.7%)	87 (98.9%)	9 (90.0%)
Summary statistics:				
Number of patients with values	95	94	88	10
Mean	4.49	4.39	4.47	4.58
SD	0.401	0.372	0.350	0.432
Median	4.40	4.30	4.50	4.55
Minimum	3.7	3.3	3.7	4.0
Maximum	6.1	5.4	5.8	5.5

- 2054 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	92	91	79	8
With values above reference range	1 (1.1%)	3 (3.3%)	2 (2.5%)	0
With values below reference range	0	0	1 (1.3%)	0
With values within reference range	91 (98.9%)	88 (96.7%)	76 (96.2%)	8 (100.0%)
Summary statistics:				
Number of patients with values	92	91	79	8
Mean	4.46	4.50	4.40	4.54
SD	0.346	0.393	0.403	0.447
Median	4.40	4.50	4.40	4.55
Minimum	3.7	3.8	3.2	3.8
Maximum	5.8	5.6	5.4	5.3
Month 24				
Number of patients:				
With values	83	79	80	4
With values above reference range	2 (2.4%)	2 (2.5%)	1 (1.3%)	0
With values below reference range	1 (1.2%)	0	0	0
With values within reference range	80 (96.4%)	77 (97.5%)	79 (98.8%)	4 (100.0%)
Summary statistics:				
Number of patients with values	83	79	80	4
Mean	4.53	4.47	4.48	4.53
SD	0.423	0.377	0.352	0.506
Median	4.50	4.40	4.40	4.45
Minimum	3.4	3.8	3.8	4.1
Maximum	5.5	5.6	5.4	5.1

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	76	71	6
With values above reference range	0	6 (7.9%)	1 (1.4%)	0
With values below reference range	0	0	0	0
With values within reference range	71 (100.0%)	70 (92.1%)	70 (98.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	76	71	6
Mean	4.51	4.53	4.40	4.33
SD	0.368	0.443	0.405	0.273
Median	4.50	4.40	4.40	4.35
Minimum	3.5	3.7	3.6	3.9
Maximum	5.3	5.9	5.8	4.7
Month 30				
Number of patients:				
With values	55	68	52	4
With values above reference range	3 (5.5%)	2 (2.9%)	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	52 (94.5%)	66 (97.1%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	68	52	4
Mean	4.49	4.41	4.39	4.30
SD	0.421	0.478	0.437	0.529
Median	4.40	4.40	4.40	4.40
Minimum	3.9	3.6	3.5	3.6
Maximum	5.6	6.8	6.5	4.8

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	46	52	3
With values above reference range	4 (7.5%)	1 (2.2%)	0	0
With values below reference range	0	0	0	0
With values within reference range	49 (92.5%)	45 (97.8%)	52 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	46	52	3
Mean	4.64	4.47	4.43	4.57
SD	0.902	0.400	0.349	0.651
Median	4.40	4.40	4.50	4.60
Minimum	3.7	3.8	3.7	3.9
Maximum	9.0	5.6	5.2	5.2
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	1 (3.8%)	1 (3.6%)	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	25 (96.2%)	27 (96.4%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	4.58	4.57	4.57	4.10
SD	0.275	0.386	0.353	
Median	4.50	4.55	4.45	4.10
Minimum	4.2	4.1	4.1	4.1
Maximum	5.1	5.5	5.4	4.1

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BRL-049653/RSD-
 100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	4.40	4.55	4.56	4.70
SD	0.141	0.423	0.195	
Median	4.40	4.50	4.70	4.70
Minimum	4.3	4.1	4.3	4.7
Maximum	4.5	5.2	4.7	4.7
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Potassium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	1 (10.0%)	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	9 (90.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	101.5	105.1	102.8	106.0
SD	2.12	1.91	4.02	
Median	101.5	105.0	102.0	106.0
Minimum	100	102	99	106
Maximum	103	109	107	106
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	6 (4.8%)	8 (5.9%)	2 (1.4%)	1 (3.6%)
With values below reference range	0	1 (0.7%)	0	0
With values within reference range	118 (95.2%)	127 (93.4%)	137 (98.6%)	27 (96.4%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	103.6	103.7	103.6	103.1
SD	2.69	3.46	2.59	2.56
Median	103.0	104.0	104.0	103.5
Minimum	96	82	96	98
Maximum	112	112	111	109

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	1 (50.0%)	1 (12.5%)	0	
With values below reference range	0	0	0	
With values within reference range	1 (50.0%)	7 (87.5%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	104.5	103.4	100.4	
SD	6.36	4.07	0.55	
Median	104.5	101.5	100.0	
Minimum	100	100	100	
Maximum	109	111	101	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		102.5	104.0	
SD		0.71	4.58	
Median		102.5	105.0	
Minimum		102	99	
Maximum		103	108	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	126	122	18
With values above reference range	3 (2.8%)	6 (4.8%)	4 (3.3%)	0
With values below reference range	0	0	1 (0.8%)	0
With values within reference range	104 (97.2%)	120 (95.2%)	117 (95.9%)	18 (100.0%)
Summary statistics:				
Number of patients with values	107	126	122	18
Mean	103.5	103.8	103.4	101.9
SD	3.08	2.74	2.80	2.90
Median	103.0	104.0	103.0	102.5
Minimum	96	96	94	95
Maximum	113	111	110	107
Month 6				
Number of patients:				
With values	113	122	118	16
With values above reference range	5 (4.4%)	6 (4.9%)	3 (2.5%)	0
With values below reference range	0	0	0	0
With values within reference range	108 (95.6%)	116 (95.1%)	115 (97.5%)	16 (100.0%)
Summary statistics:				
Number of patients with values	113	122	118	16
Mean	104.1	103.7	103.5	102.9
SD	2.63	2.80	2.71	2.63
Median	104.0	104.0	104.0	102.0
Minimum	96	96	98	100
Maximum	110	112	110	108

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	111	17
With values above reference range	6 (5.4%)	6 (5.0%)	2 (1.8%)	1 (5.9%)
With values below reference range	0	0	1 (0.9%)	0
With values within reference range	105 (94.6%)	115 (95.0%)	108 (97.3%)	16 (94.1%)
Summary statistics:				
Number of patients with values	111	121	111	17
Mean	103.6	104.1	103.2	103.8
SD	2.91	2.71	3.23	2.40
Median	104.0	104.0	103.0	104.0
Minimum	95	95	83	100
Maximum	110	110	110	109
Month 12				
Number of patients:				
With values	100	110	102	17
With values above reference range	6 (6.0%)	4 (3.6%)	5 (4.9%)	1 (5.9%)
With values below reference range	1 (1.0%)	0	0	0
With values within reference range	93 (93.0%)	106 (96.4%)	97 (95.1%)	16 (94.1%)
Summary statistics:				
Number of patients with values	100	110	102	17
Mean	103.3	104.1	103.7	103.0
SD	3.35	2.77	2.93	3.37
Median	103.5	104.5	104.0	103.0
Minimum	92	96	95	98
Maximum	110	109	112	109

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	12 (12.0%)	5 (4.6%)	2 (2.0%)	0
With values below reference range	0	0	0	0
With values within reference range	88 (88.0%)	104 (95.4%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	104.0	104.5	103.5	103.4
SD	3.05	2.64	2.73	2.70
Median	104.0	105.0	104.0	103.0
Minimum	99	96	95	99
Maximum	113	110	112	107
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	5 (5.2%)	6 (6.2%)	5 (5.6%)	1 (10.0%)
With values below reference range	1 (1.0%)	1 (1.0%)	1 (1.1%)	0
With values within reference range	91 (93.8%)	90 (92.8%)	84 (93.3%)	9 (90.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	103.3	103.6	103.4	104.4
SD	3.25	3.45	3.21	3.20
Median	104.0	104.0	104.0	105.0
Minimum	93	92	94	99
Maximum	110	114	112	109

- 2064 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	5 (5.3%)	3 (3.2%)	6 (7.4%)	0
With values below reference range	3 (3.2%)	0	1 (1.2%)	0
With values within reference range	86 (91.5%)	90 (96.8%)	74 (91.4%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	103.0	103.8	103.8	103.1
SD	3.36	2.87	3.35	1.81
Median	103.0	104.0	104.0	103.0
Minimum	93	98	92	100
Maximum	109	111	112	106
Month 24				
Number of patients:				
With values	84	81	81	5
With values above reference range	4 (4.8%)	4 (4.9%)	0	1 (20.0%)
With values below reference range	0	0	0	0
With values within reference range	80 (95.2%)	77 (95.1%)	81 (100.0%)	4 (80.0%)
Summary statistics:				
Number of patients with values	84	81	81	5
Mean	103.6	103.7	103.0	104.2
SD	2.95	2.95	2.56	3.35
Median	104.0	103.0	103.0	105.0
Minimum	95	95	95	101
Maximum	111	112	107	109

- 2065 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	1 (1.4%)	0	2 (2.8%)	0
With values below reference range	0	0	0	0
With values within reference range	70 (98.6%)	78 (100.0%)	69 (97.2%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	103.4	103.6	103.5	104.0
SD	2.86	2.62	3.04	2.37
Median	104.0	104.0	103.0	104.0
Minimum	95	97	96	101
Maximum	110	108	111	107
Month 30				
Number of patients:				
With values	56	70	52	4
With values above reference range	1 (1.8%)	2 (2.9%)	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	55 (98.2%)	68 (97.1%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	56	70	52	4
Mean	103.5	103.9	103.0	104.3
SD	2.88	3.05	3.01	1.89
Median	104.0	104.0	103.0	103.5
Minimum	97	95	95	103
Maximum	109	111	109	107

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	1 (1.9%)	1 (2.1%)	1 (1.9%)	0
With values below reference range	0	0	0	0
With values within reference range	52 (98.1%)	46 (97.9%)	51 (98.1%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	103.1	103.7	103.4	104.3
SD	2.90	2.95	2.39	1.53
Median	103.0	104.0	103.0	104.0
Minimum	97	95	99	103
Maximum	109	110	109	106
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	0	1 (3.6%)	0
With values below reference range	0	1 (3.8%)	0	0
With values within reference range	23 (95.8%)	25 (96.2%)	27 (96.4%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	102.4	104.1	103.6	102.0
SD	3.15	3.02	2.16	
Median	101.5	104.0	104.0	102.0
Minimum	95	94	100	102
Maximum	109	108	109	102

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	105.5	103.8	103.8	103.0
SD	2.12	3.13	1.64	
Median	105.5	104.0	103.0	103.0
Minimum	104	99	102	103
Maximum	107	107	106	103
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Chloride (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	1 (50.0%)	0	0	0
With values below reference range	1 (50.0%)	0	0	0
With values within reference range	0	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	26.0	24.7	24.6	27.0
SD	9.90	2.26	2.07	
Median	26.0	24.0	25.0	27.0
Minimum	19	22	22	27
Maximum	33	29	27	27
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	3 (2.4%)	1 (0.7%)	5 (3.6%)	0
With values below reference range	3 (2.4%)	1 (0.7%)	4 (2.9%)	2 (7.1%)
With values within reference range	118 (95.2%)	134 (98.5%)	130 (93.5%)	26 (92.9%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	26.2	26.0	25.9	24.0
SD	3.12	2.48	3.28	3.40
Median	26.0	26.0	26.0	24.5
Minimum	19	19	18	17
Maximum	36	33	39	31

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	25.5	24.5	26.2	
SD	2.12	3.12	3.27	
Median	25.5	24.0	27.0	
Minimum	24	21	21	
Maximum	27	29	30	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		25.5	26.3	
SD		2.12	2.08	
Median		25.5	27.0	
Minimum		24	24	
Maximum		27	28	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	126	122	17
With values above reference range	2 (1.9%)	5 (4.0%)	8 (6.6%)	0
With values below reference range	2 (1.9%)	1 (0.8%)	1 (0.8%)	0
With values within reference range	102 (96.2%)	120 (95.2%)	113 (92.6%)	17 (100.0%)
Summary statistics:				
Number of patients with values	106	126	122	17
Mean	26.5	26.5	27.2	26.4
SD	3.05	3.32	3.27	2.71
Median	26.5	26.5	27.0	26.0
Minimum	16	12	18	21
Maximum	35	39	39	30
Month 6				
Number of patients:				
With values	113	122	118	16
With values above reference range	2 (1.8%)	1 (0.8%)	5 (4.2%)	1 (6.3%)
With values below reference range	5 (4.4%)	2 (1.6%)	6 (5.1%)	1 (6.3%)
With values within reference range	106 (93.8%)	119 (97.5%)	107 (90.7%)	14 (87.5%)
Summary statistics:				
Number of patients with values	113	122	118	16
Mean	24.8	25.2	25.3	24.3
SD	3.14	3.33	3.50	4.16
Median	25.0	25.0	25.0	25.0
Minimum	16	12	17	15
Maximum	33	35	39	33

- 2072 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	110	17
With values above reference range	4 (3.6%)	5 (4.1%)	3 (2.7%)	0
With values below reference range	1 (0.9%)	1 (0.8%)	1 (0.9%)	0
With values within reference range	106 (95.5%)	115 (95.0%)	106 (96.4%)	17 (100.0%)
Summary statistics:				
Number of patients with values	111	121	110	17
Mean	27.1	26.5	26.7	25.4
SD	3.01	3.12	3.36	3.00
Median	27.0	27.0	27.0	26.0
Minimum	18	19	5	20
Maximum	33	36	35	31
Month 12				
Number of patients:				
With values	99	110	102	17
With values above reference range	3 (3.0%)	2 (1.8%)	2 (2.0%)	1 (5.9%)
With values below reference range	4 (4.0%)	0	0	0
With values within reference range	92 (92.9%)	108 (98.2%)	100 (98.0%)	16 (94.1%)
Summary statistics:				
Number of patients with values	99	110	102	17
Mean	25.8	26.1	26.0	25.5
SD	3.44	2.89	3.18	3.18
Median	26.0	26.0	26.0	25.0
Minimum	16	20	20	21
Maximum	38	33	36	33

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	0	2 (1.8%)	1 (1.0%)	0
With values below reference range	0	2 (1.8%)	1 (1.0%)	0
With values within reference range	100 (100.0%)	105 (96.3%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	26.3	25.8	26.2	26.3
SD	2.59	3.13	2.86	1.58
Median	26.0	26.0	26.0	26.0
Minimum	20	18	18	24
Maximum	32	36	33	29
Month 18				
Number of patients:				
With values	97	97	90	10
With values above reference range	5 (5.2%)	2 (2.1%)	0	0
With values below reference range	0	3 (3.1%)	3 (3.3%)	0
With values within reference range	92 (94.8%)	92 (94.8%)	87 (96.7%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	90	10
Mean	26.4	25.0	25.7	25.4
SD	3.15	3.37	3.16	2.22
Median	26.0	25.0	26.0	26.0
Minimum	20	12	17	20
Maximum	34	35	32	28

- 2074 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	93	81	8
With values above reference range	5 (5.3%)	2 (2.2%)	1 (1.2%)	1 (12.5%)
With values below reference range	1 (1.1%)	2 (2.2%)	1 (1.2%)	0
With values within reference range	88 (93.6%)	89 (95.7%)	79 (97.5%)	7 (87.5%)
Summary statistics:				
Number of patients with values	94	93	81	8
Mean	26.1	26.3	26.2	27.1
SD	3.07	3.22	2.89	2.85
Median	26.0	26.0	27.0	27.0
Minimum	17	19	18	24
Maximum	33	35	33	33
Month 24				
Number of patients:				
With values	84	81	80	5
With values above reference range	0	2 (2.5%)	1 (1.3%)	1 (20.0%)
With values below reference range	0	2 (2.5%)	3 (3.8%)	0
With values within reference range	84 (100.0%)	77 (95.1%)	76 (95.0%)	4 (80.0%)
Summary statistics:				
Number of patients with values	84	81	80	5
Mean	25.8	25.7	25.5	27.6
SD	2.70	2.95	3.28	4.04
Median	26.0	25.0	26.0	27.0
Minimum	20	19	18	23
Maximum	32	35	36	34

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	1 (1.4%)	0	1 (1.4%)	0
With values below reference range	1 (1.4%)	0	2 (2.8%)	0
With values within reference range	69 (97.2%)	78 (100.0%)	68 (95.8%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	26.4	25.5	26.1	25.7
SD	3.25	2.95	3.18	3.88
Median	27.0	25.0	26.0	25.0
Minimum	16	21	19	20
Maximum	33	32	33	32
Month 30				
Number of patients:				
With values	55	70	52	4
With values above reference range	2 (3.6%)	5 (7.1%)	0	0
With values below reference range	0	3 (4.3%)	4 (7.7%)	0
With values within reference range	53 (96.4%)	62 (88.6%)	48 (92.3%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	70	52	4
Mean	26.0	25.6	25.4	26.8
SD	3.28	3.60	3.45	3.10
Median	26.0	25.0	25.5	26.0
Minimum	20	18	18	24
Maximum	34	35	32	31

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	48	52	3
With values above reference range	1 (1.9%)	2 (4.2%)	2 (3.8%)	0
With values below reference range	0	1 (2.1%)	0	0
With values within reference range	52 (98.1%)	45 (93.8%)	50 (96.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	48	52	3
Mean	27.0	27.0	27.7	23.7
SD	2.39	3.29	2.78	2.08
Median	27.0	27.5	28.0	23.0
Minimum	21	19	21	22
Maximum	33	34	33	26
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	1 (3.8%)	1 (3.6%)	0
With values below reference range	0	0	0	0
With values within reference range	23 (95.8%)	25 (96.2%)	27 (96.4%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	26.7	26.3	27.5	27.0
SD	3.14	2.96	3.20	
Median	27.0	26.5	27.0	27.0
Minimum	21	21	23	27
Maximum	34	34	37	27

- 2077 -

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	1 (16.7%)	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	5 (83.3%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	27.5	27.2	26.6	25.0
SD	0.71	4.79	3.51	
Median	27.5	26.5	26.0	25.0
Minimum	27	22	22	25
Maximum	28	33	31	25
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Bicarbonate (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
 100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	0
With values above reference range	3 (75.0%)	6 (54.5%)	6 (100.0%)	
With values below reference range	0	0	0	
With values within reference range	1 (25.0%)	5 (45.5%)	0	
Summary statistics:				
Number of patients with values	4	11	6	0
Mean	152.0	143.5	171.2	
SD	57.10	49.62	30.84	
Median	144.0	132.0	172.5	
Minimum	91	89	136	
Maximum	229	252	211	
Open Label Baseline				
Number of patients:				
With values	124	136	139	0
With values above reference range	82 (66.1%)	103 (75.7%)	110 (79.1%)	
With values below reference range	1 (0.8%)	0	1 (0.7%)	
With values within reference range	41 (33.1%)	33 (24.3%)	28 (20.1%)	
Summary statistics:				
Number of patients with values	124	136	139	0
Mean	144.1	153.2	155.2	
SD	40.68	39.56	37.23	
Median	136.0	148.0	152.0	
Minimum	61	86	75	
Maximum	280	266	286	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	120	132	133	25
With values above reference range	74 (61.7%)	95 (72.0%)	117 (88.0%)	21 (84.0%)
With values below reference range	0	0	0	0
With values within reference range	46 (38.3%)	37 (28.0%)	16 (12.0%)	4 (16.0%)
Summary statistics:				
Number of patients with values	120	132	133	25
Mean	144.9	147.7	175.9	166.1
SD	49.82	37.61	49.02	50.93
Median	136.5	143.0	164.0	148.0
Minimum	89	80	105	105
Maximum	521	284	366	273
Month 2				
Number of patients:				
With values	113	131	134	23
With values above reference range	64 (56.6%)	90 (68.7%)	115 (85.8%)	17 (73.9%)
With values below reference range	0	1 (0.8%)	0	0
With values within reference range	49 (43.4%)	40 (30.5%)	19 (14.2%)	6 (26.1%)
Summary statistics:				
Number of patients with values	113	131	134	23
Mean	139.9	142.9	164.9	147.8
SD	37.19	33.66	40.96	35.47
Median	130.0	136.0	155.0	139.0
Minimum	82	73	86	98
Maximum	255	246	284	223

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100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	117	127	130	22
With values above reference range	73 (62.4%)	84 (66.1%)	111 (85.4%)	17 (77.3%)
With values below reference range	0	0	0	0
With values within reference range	44 (37.6%)	43 (33.9%)	19 (14.6%)	5 (22.7%)
Summary statistics:				
Number of patients with values	117	127	130	22
Mean	139.5	141.8	162.8	149.3
SD	34.55	35.43	43.17	45.67
Median	130.0	134.0	154.0	142.0
Minimum	79	82	86	80
Maximum	250	266	298	259
Month 6				
Number of patients:				
With values	114	127	122	17
With values above reference range	64 (56.1%)	74 (58.3%)	85 (69.7%)	11 (64.7%)
With values below reference range	0	0	0	0
With values within reference range	50 (43.9%)	53 (41.7%)	37 (30.3%)	6 (35.3%)
Summary statistics:				
Number of patients with values	114	127	122	17
Mean	136.9	137.8	149.7	139.3
SD	34.31	35.66	39.69	29.62
Median	129.0	130.0	141.0	125.0
Minimum	84	91	80	102
Maximum	239	312	286	204

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	114	125	116	18
With values above reference range	71 (62.3%)	76 (60.8%)	87 (75.0%)	11 (61.1%)
With values below reference range	1 (0.9%)	0	0	1 (5.6%)
With values within reference range	42 (36.8%)	49 (39.2%)	29 (25.0%)	6 (33.3%)
Summary statistics:				
Number of patients with values	114	125	116	18
Mean	138.1	136.6	148.1	131.2
SD	36.37	29.16	35.01	29.86
Median	133.0	134.0	141.0	130.5
Minimum	75	84	87	64
Maximum	246	220	268	191
Month 12				
Number of patients:				
With values	104	114	108	17
With values above reference range	63 (60.6%)	79 (69.3%)	71 (65.7%)	9 (52.9%)
With values below reference range	0	0	0	0
With values within reference range	41 (39.4%)	35 (30.7%)	37 (34.3%)	8 (47.1%)
Summary statistics:				
Number of patients with values	104	114	108	17
Mean	139.0	140.6	147.5	132.3
SD	35.47	31.47	39.60	28.67
Median	132.0	135.0	141.0	125.0
Minimum	82	79	89	98
Maximum	237	243	304	182

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	104	110	98	8
With values above reference range	60 (57.7%)	64 (58.2%)	68 (69.4%)	4 (50.0%)
With values below reference range	2 (1.9%)	0	0	0
With values within reference range	42 (40.4%)	46 (41.8%)	30 (30.6%)	4 (50.0%)
Summary statistics:				
Number of patients with values	104	110	98	8
Mean	137.2	138.4	145.5	130.8
SD	39.50	33.42	35.83	24.26
Median	129.5	130.0	136.5	118.0
Minimum	30	87	89	109
Maximum	248	246	277	175
Month 18				
Number of patients:				
With values	99	98	89	9
With values above reference range	63 (63.6%)	60 (61.2%)	58 (65.2%)	3 (33.3%)
With values below reference range	1 (1.0%)	0	0	0
With values within reference range	35 (35.4%)	38 (38.8%)	31 (34.8%)	6 (66.7%)
Summary statistics:				
Number of patients with values	99	98	89	9
Mean	141.5	139.2	148.1	121.6
SD	41.92	32.83	42.79	24.42
Median	136.0	132.0	134.0	109.0
Minimum	61	86	89	98
Maximum	257	266	280	162

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	95	82	8
With values above reference range	61 (64.9%)	64 (67.4%)	59 (72.0%)	4 (50.0%)
With values below reference range	2 (2.1%)	1 (1.1%)	0	0
With values within reference range	31 (33.0%)	30 (31.6%)	23 (28.0%)	4 (50.0%)
Summary statistics:				
Number of patients with values	94	95	82	8
Mean	139.8	141.0	145.5	120.8
SD	40.45	38.50	35.07	15.48
Median	130.0	136.0	139.0	118.0
Minimum	71	68	87	102
Maximum	241	318	257	143
Month 24				
Number of patients:				
With values	84	83	78	5
With values above reference range	54 (64.3%)	50 (60.2%)	54 (69.2%)	2 (40.0%)
With values below reference range	1 (1.2%)	1 (1.2%)	0	0
With values within reference range	29 (34.5%)	32 (38.6%)	24 (30.8%)	3 (60.0%)
Summary statistics:				
Number of patients with values	84	83	78	5
Mean	140.2	140.5	146.4	122.6
SD	41.70	36.87	35.60	14.54
Median	133.0	132.0	138.0	120.0
Minimum	75	70	96	107
Maximum	284	279	291	145

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BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	74	77	72	6
With values above reference range	44 (59.5%)	53 (68.8%)	45 (62.5%)	2 (33.3%)
With values below reference range	0	1 (1.3%)	0	0
With values within reference range	30 (40.5%)	23 (29.9%)	27 (37.5%)	4 (66.7%)
Summary statistics:				
Number of patients with values	74	77	72	6
Mean	142.0	137.3	140.3	126.2
SD	42.89	31.95	32.44	34.58
Median	133.0	130.0	129.5	121.5
Minimum	79	61	95	91
Maximum	295	221	237	189
Month 30				
Number of patients:				
With values	56	69	51	4
With values above reference range	35 (62.5%)	46 (66.7%)	30 (58.8%)	1 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	21 (37.5%)	23 (33.3%)	21 (41.2%)	3 (75.0%)
Summary statistics:				
Number of patients with values	56	69	51	4
Mean	137.6	141.7	138.9	121.8
SD	35.26	37.44	29.15	18.01
Median	131.0	132.0	134.0	116.0
Minimum	82	86	96	107
Maximum	227	282	204	148

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	52	48	54	3
With values above reference range	29 (55.8%)	24 (50.0%)	36 (66.7%)	1 (33.3%)
With values below reference range	1 (1.9%)	0	0	0
With values within reference range	22 (42.3%)	24 (50.0%)	18 (33.3%)	2 (66.7%)
Summary statistics:				
Number of patients with values	52	48	54	3
Mean	145.3	134.0	138.7	119.7
SD	44.18	31.57	32.78	18.58
Median	133.0	124.0	131.0	111.0
Minimum	71	84	80	107
Maximum	250	230	248	141
Month 36				
Number of patients:				
With values	23	26	27	1
With values above reference range	11 (47.8%)	17 (65.4%)	16 (59.3%)	0
With values below reference range	0	0	0	0
With values within reference range	12 (52.2%)	9 (34.6%)	11 (40.7%)	1 (100.0%)
Summary statistics:				
Number of patients with values	23	26	27	1
Mean	141.4	133.7	139.1	123.0
SD	55.17	25.27	33.19	
Median	123.0	136.5	129.0	123.0
Minimum	82	96	87	123
Maximum	320	200	204	123

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	7	1
With values above reference range	0	2 (33.3%)	6 (85.7%)	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	4 (66.7%)	1 (14.3%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	7	1
Mean	119.5	131.0	135.7	112.0
SD	2.12	32.83	21.70	
Median	119.5	118.0	132.0	112.0
Minimum	118	95	102	112
Maximum	121	179	173	112
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Fasting Plasma Glucose (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	1 (20.0%)	0
With values within reference range	2 (100.0%)	10 (100.0%)	4 (80.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	1.10	1.08	0.92	1.20
SD	0.141	0.140	0.164	
Median	1.10	1.10	1.00	1.20
Minimum	1.0	0.9	0.7	1.2
Maximum	1.2	1.3	1.1	1.2
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	1 (0.8%)	2 (1.5%)	0	0
With values below reference range	2 (1.6%)	3 (2.2%)	3 (2.2%)	0
With values within reference range	121 (97.6%)	131 (96.3%)	136 (97.8%)	28 (100.0%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	1.11	1.10	1.07	1.11
SD	0.165	0.155	0.165	0.104
Median	1.10	1.10	1.10	1.10
Minimum	0.6	0.7	0.7	0.9
Maximum	1.9	1.5	1.5	1.3

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	1 (50.0%)	0	0	
With values below reference range	0	0	0	
With values within reference range	1 (50.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	1.40	1.03	1.04	
SD	0.141	0.158	0.167	
Median	1.40	1.00	1.00	
Minimum	1.3	0.8	0.9	
Maximum	1.5	1.2	1.3	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		1.15	1.07	
SD		0.071	0.208	
Median		1.15	1.00	
Minimum		1.1	0.9	
Maximum		1.2	1.3	

- 2091 -

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	125	121	17
With values above reference range	0	4 (3.2%)	1 (0.8%)	0
With values below reference range	2 (1.9%)	1 (0.8%)	3 (2.5%)	0
With values within reference range	105 (98.1%)	120 (96.0%)	117 (96.7%)	17 (100.0%)
Summary statistics:				
Number of patients with values	107	125	121	17
Mean	1.08	1.12	1.06	1.12
SD	0.149	0.164	0.161	0.163
Median	1.10	1.10	1.10	1.10
Minimum	0.6	0.8	0.6	0.9
Maximum	1.4	1.5	1.5	1.4
Month 6				
Number of patients:				
With values	112	122	117	16
With values above reference range	0	2 (1.6%)	2 (1.7%)	0
With values below reference range	2 (1.8%)	2 (1.6%)	3 (2.6%)	0
With values within reference range	110 (98.2%)	118 (96.7%)	112 (95.7%)	16 (100.0%)
Summary statistics:				
Number of patients with values	112	122	117	16
Mean	1.09	1.10	1.07	1.06
SD	0.160	0.179	0.158	0.150
Median	1.10	1.10	1.10	1.00
Minimum	0.6	0.7	0.7	0.9
Maximum	1.5	1.8	1.5	1.3

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	1 (0.9%)	1 (0.8%)	0	0
With values below reference range	2 (1.8%)	4 (3.3%)	0	0
With values within reference range	107 (97.3%)	116 (95.9%)	110 (100.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	1.08	1.10	1.07	1.12
SD	0.149	0.157	0.144	0.148
Median	1.10	1.10	1.10	1.10
Minimum	0.6	0.7	0.8	0.9
Maximum	1.5	1.5	1.4	1.4
Month 12				
Number of patients:				
With values	99	109	101	17
With values above reference range	0	2 (1.8%)	0	0
With values below reference range	1 (1.0%)	3 (2.8%)	2 (2.0%)	0
With values within reference range	98 (99.0%)	104 (95.4%)	99 (98.0%)	17 (100.0%)
Summary statistics:				
Number of patients with values	99	109	101	17
Mean	1.08	1.08	1.06	1.08
SD	0.147	0.162	0.136	0.159
Median	1.10	1.10	1.10	1.10
Minimum	0.7	0.7	0.7	0.8
Maximum	1.4	1.5	1.4	1.4

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	1 (1.0%)	4 (3.7%)	0	0
With values below reference range	0	0	2 (2.0%)	0
With values within reference range	99 (99.0%)	105 (96.3%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	1.10	1.11	1.06	1.08
SD	0.140	0.144	0.134	0.148
Median	1.10	1.10	1.10	1.10
Minimum	0.8	0.8	0.8	0.9
Maximum	1.4	1.5	1.3	1.3
Month 18				
Number of patients:				
With values	97	97	89	10
With values above reference range	1 (1.0%)	3 (3.1%)	2 (2.2%)	0
With values below reference range	1 (1.0%)	1 (1.0%)	2 (2.2%)	0
With values within reference range	95 (97.9%)	93 (95.9%)	85 (95.5%)	10 (100.0%)
Summary statistics:				
Number of patients with values	97	97	89	10
Mean	1.11	1.10	1.08	1.08
SD	0.156	0.157	0.156	0.140
Median	1.10	1.10	1.10	1.10
Minimum	0.8	0.7	0.7	0.9
Maximum	1.6	1.5	1.5	1.3

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 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	2 (2.1%)	3 (3.3%)	0	0
With values below reference range	0	1 (1.1%)	3 (3.8%)	0
With values within reference range	92 (97.9%)	88 (95.7%)	77 (96.3%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	1.11	1.12	1.07	1.01
SD	0.152	0.158	0.153	0.146
Median	1.10	1.10	1.10	1.00
Minimum	0.8	0.8	0.7	0.8
Maximum	1.5	1.5	1.4	1.3
Month 24				
Number of patients:				
With values	84	81	80	4
With values above reference range	0	1 (1.2%)	2 (2.5%)	0
With values below reference range	0	1 (1.2%)	3 (3.8%)	0
With values within reference range	84 (100.0%)	79 (97.5%)	75 (93.8%)	4 (100.0%)
Summary statistics:				
Number of patients with values	84	81	80	4
Mean	1.08	1.08	1.07	1.03
SD	0.121	0.151	0.158	0.096
Median	1.10	1.10	1.10	1.05
Minimum	0.9	0.7	0.6	0.9
Maximum	1.4	1.4	1.5	1.1

- 2095 -

CONFIDENTIAL

 BRL-049653/RSD-
 100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	71	78	71	6
With values above reference range	2 (2.8%)	3 (3.8%)	0	0
With values below reference range	0	0	1 (1.4%)	0
With values within reference range	69 (97.2%)	75 (96.2%)	70 (98.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	71	78	71	6
Mean	1.10	1.12	1.07	1.07
SD	0.165	0.161	0.136	0.175
Median	1.10	1.10	1.10	1.00
Minimum	0.8	0.8	0.7	0.9
Maximum	1.7	1.5	1.4	1.4
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	1 (1.8%)	1 (1.4%)	1 (1.9%)	0
With values below reference range	0	1 (1.4%)	0	0
With values within reference range	54 (98.2%)	67 (97.1%)	51 (98.1%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	1.11	1.11	1.09	1.00
SD	0.151	0.160	0.153	0.082
Median	1.10	1.10	1.10	1.00
Minimum	0.8	0.7	0.8	0.9
Maximum	1.4	1.5	1.6	1.1

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	2 (3.8%)	0	0	0
With values below reference range	0	0	0	0
With values within reference range	51 (96.2%)	47 (100.0%)	52 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	1.09	1.09	1.07	1.03
SD	0.148	0.124	0.155	0.153
Median	1.10	1.10	1.10	1.00
Minimum	0.9	0.8	0.8	0.9
Maximum	1.5	1.4	1.4	1.2
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	0	1 (3.6%)	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	26 (100.0%)	27 (96.4%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	1.09	1.09	1.07	1.00
SD	0.115	0.151	0.174	
Median	1.10	1.10	1.00	1.00
Minimum	0.9	0.9	0.8	1.0
Maximum	1.3	1.4	1.5	1.0

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	1.15	1.20	1.04	1.20
SD	0.071	0.179	0.152	
Median	1.15	1.15	1.10	1.20
Minimum	1.1	1.0	0.8	1.2
Maximum	1.2	1.5	1.2	1.2
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Phosphorus (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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BRL-049653/RSD-
100TV9/1/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	9	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	9 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	9	5	1
Mean	2.45	2.41	2.46	2.40
SD	0.071	0.060	0.114	
Median	2.45	2.40	2.50	2.40
Minimum	2.4	2.3	2.3	2.4
Maximum	2.5	2.5	2.6	2.4
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	5 (4.0%)	6 (4.4%)	7 (5.0%)	3 (10.7%)
With values below reference range	0	2 (1.5%)	0	0
With values within reference range	119 (96.0%)	128 (94.1%)	132 (95.0%)	25 (89.3%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	2.40	2.41	2.41	2.44
SD	0.102	0.105	0.096	0.169
Median	2.40	2.40	2.40	2.40
Minimum	2.1	1.8	2.2	2.3
Maximum	2.7	2.7	2.7	3.1

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	2.45	2.38	2.40	
SD	0.071	0.071	0.100	
Median	2.45	2.40	2.40	
Minimum	2.4	2.2	2.3	
Maximum	2.5	2.4	2.5	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	1 (33.3%)	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	2 (66.7%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		2.40	2.50	
SD		0.141	0.100	
Median		2.40	2.50	
Minimum		2.3	2.4	
Maximum		2.5	2.6	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	107	126	122	16
With values above reference range	4 (3.7%)	1 (0.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	103 (96.3%)	125 (99.2%)	122 (100.0%)	16 (100.0%)
Summary statistics:				
Number of patients with values	107	126	122	16
Mean	2.37	2.37	2.37	2.39
SD	0.091	0.085	0.084	0.089
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.2	2.2	2.3
Maximum	2.7	2.7	2.6	2.5
Month 6				
Number of patients:				
With values	110	122	114	16
With values above reference range	3 (2.7%)	6 (4.9%)	3 (2.6%)	0
With values below reference range	0	0	0	0
With values within reference range	107 (97.3%)	116 (95.1%)	111 (97.4%)	16 (100.0%)
Summary statistics:				
Number of patients with values	110	122	114	16
Mean	2.39	2.39	2.39	2.36
SD	0.095	0.092	0.089	0.081
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.2	2.2	2.2
Maximum	2.7	2.7	2.6	2.5

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	111	121	110	17
With values above reference range	3 (2.7%)	5 (4.1%)	2 (1.8%)	1 (5.9%)
With values below reference range	0	1 (0.8%)	0	0
With values within reference range	108 (97.3%)	115 (95.0%)	108 (98.2%)	16 (94.1%)
Summary statistics:				
Number of patients with values	111	121	110	17
Mean	2.37	2.37	2.38	2.38
SD	0.093	0.113	0.090	0.109
Median	2.40	2.40	2.40	2.40
Minimum	2.2	1.6	2.2	2.2
Maximum	2.7	2.6	2.7	2.7
Month 12				
Number of patients:				
With values	95	109	102	17
With values above reference range	3 (3.2%)	4 (3.7%)	4 (3.9%)	0
With values below reference range	0	0	0	0
With values within reference range	92 (96.8%)	105 (96.3%)	98 (96.1%)	17 (100.0%)
Summary statistics:				
Number of patients with values	95	109	102	17
Mean	2.40	2.40	2.40	2.38
SD	0.100	0.091	0.100	0.075
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.3	2.1	2.3
Maximum	2.6	2.7	2.6	2.5

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	99	108	98	9
With values above reference range	2 (2.0%)	2 (1.9%)	2 (2.0%)	0
With values below reference range	0	1 (0.9%)	0	0
With values within reference range	97 (98.0%)	105 (97.2%)	96 (98.0%)	9 (100.0%)
Summary statistics:				
Number of patients with values	99	108	98	9
Mean	2.36	2.38	2.38	2.41
SD	0.093	0.092	0.090	0.078
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.1	2.2	2.3
Maximum	2.6	2.7	2.7	2.5
Month 18				
Number of patients:				
With values	94	95	86	10
With values above reference range	0	4 (4.2%)	4 (4.7%)	0
With values below reference range	0	1 (1.1%)	0	0
With values within reference range	94 (100.0%)	90 (94.7%)	82 (95.3%)	10 (100.0%)
Summary statistics:				
Number of patients with values	94	95	86	10
Mean	2.37	2.38	2.39	2.35
SD	0.099	0.092	0.090	0.071
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.1	2.2	2.2
Maximum	2.6	2.6	2.6	2.4

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	92	92	81	8
With values above reference range	1 (1.1%)	1 (1.1%)	0	0
With values below reference range	0	1 (1.1%)	0	0
With values within reference range	91 (98.9%)	90 (97.8%)	81 (100.0%)	8 (100.0%)
Summary statistics:				
Number of patients with values	92	92	81	8
Mean	2.36	2.36	2.37	2.34
SD	0.096	0.100	0.083	0.052
Median	2.40	2.30	2.40	2.30
Minimum	2.2	2.1	2.1	2.3
Maximum	2.6	2.7	2.5	2.4
Month 24				
Number of patients:				
With values	83	79	77	5
With values above reference range	3 (3.6%)	2 (2.5%)	1 (1.3%)	1 (20.0%)
With values below reference range	0	0	0	0
With values within reference range	80 (96.4%)	77 (97.5%)	76 (98.7%)	4 (80.0%)
Summary statistics:				
Number of patients with values	83	79	77	5
Mean	2.38	2.37	2.38	2.42
SD	0.096	0.088	0.094	0.110
Median	2.40	2.40	2.40	2.40
Minimum	2.2	2.2	2.2	2.3
Maximum	2.7	2.6	2.6	2.6

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	77	71	6
With values above reference range	2 (2.9%)	1 (1.3%)	1 (1.4%)	0
With values below reference range	0	0	0	0
With values within reference range	68 (97.1%)	76 (98.7%)	70 (98.6%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	77	71	6
Mean	2.36	2.38	2.38	2.32
SD	0.092	0.091	0.094	0.117
Median	2.40	2.40	2.40	2.30
Minimum	2.2	2.2	2.2	2.2
Maximum	2.6	2.6	2.6	2.5
Month 30				
Number of patients:				
With values	53	67	52	4
With values above reference range	0	2 (3.0%)	2 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	53 (100.0%)	65 (97.0%)	50 (96.2%)	4 (100.0%)
Summary statistics:				
Number of patients with values	53	67	52	4
Mean	2.36	2.37	2.37	2.33
SD	0.093	0.104	0.108	0.050
Median	2.40	2.40	2.35	2.30
Minimum	2.2	2.2	2.2	2.3
Maximum	2.6	2.6	2.7	2.4

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	45	52	3
With values above reference range	0	2 (4.4%)	3 (5.8%)	0
With values below reference range	0	1 (2.2%)	0	0
With values within reference range	53 (100.0%)	42 (93.3%)	49 (94.2%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	45	52	3
Mean	2.35	2.37	2.35	2.33
SD	0.082	0.110	0.100	0.058
Median	2.30	2.40	2.30	2.30
Minimum	2.2	2.1	2.2	2.3
Maximum	2.5	2.6	2.6	2.4
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	1 (4.2%)	1 (3.8%)	2 (7.1%)	0
With values below reference range	0	0	0	0
With values within reference range	23 (95.8%)	25 (96.2%)	26 (92.9%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	2.35	2.36	2.40	2.20
SD	0.088	0.081	0.110	
Median	2.40	2.40	2.40	2.20
Minimum	2.2	2.2	2.2	2.2
Maximum	2.6	2.6	2.7	2.2

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	2.45	2.38	2.38	2.40
SD	0.071	0.098	0.084	
Median	2.45	2.40	2.40	2.40
Minimum	2.4	2.2	2.3	2.4
Maximum	2.5	2.5	2.5	2.4
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Calcium (mmol/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	2	10	5	1
With values above reference range	0	0	0	0
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	10 (100.0%)	5 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	2	10	5	1
Mean	193.0	162.7	146.8	186.0
SD	21.21	31.14	18.90	
Median	193.0	165.5	148.0	186.0
Minimum	178	133	128	186
Maximum	208	235	174	186
Open Label Baseline				
Number of patients:				
With values	124	136	139	28
With values above reference range	1 (0.8%)	2 (1.5%)	1 (0.7%)	1 (3.6%)
With values below reference range	0	0	0	0
With values within reference range	123 (99.2%)	134 (98.5%)	138 (99.3%)	27 (96.4%)
Summary statistics:				
Number of patients with values	124	136	139	28
Mean	177.0	164.6	158.0	176.2
SD	36.04	31.68	29.36	81.82
Median	174.5	164.0	156.0	162.0
Minimum	91	82	87	104
Maximum	312	313	265	546

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1				
Number of patients:				
With values	2	8	5	0
With values above reference range	0	0	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	8 (100.0%)	5 (100.0%)	
Summary statistics:				
Number of patients with values	2	8	5	0
Mean	170.5	151.3	170.0	
SD	2.12	38.29	22.83	
Median	170.5	151.0	175.0	
Minimum	169	91	142	
Maximum	172	207	195	
Month 2				
Number of patients:				
With values	0	2	3	0
With values above reference range		0	0	
With values below reference range		0	0	
With values within reference range		2 (100.0%)	3 (100.0%)	
Summary statistics:				
Number of patients with values	0	2	3	0
Mean		168.0	150.3	
SD		7.07	50.86	
Median		168.0	168.0	
Minimum		163	93	
Maximum		173	190	

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	106	125	121	17
With values above reference range	3 (2.8%)	5 (4.0%)	3 (2.5%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	103 (97.2%)	120 (96.0%)	118 (97.5%)	16 (94.1%)
Summary statistics:				
Number of patients with values	106	125	121	17
Mean	181.9	180.5	172.5	188.7
SD	47.83	44.47	34.34	43.01
Median	174.0	173.0	167.0	177.0
Minimum	81	92	92	130
Maximum	452	416	292	275
Month 6				
Number of patients:				
With values	112	122	114	16
With values above reference range	4 (3.6%)	5 (4.1%)	1 (0.9%)	2 (12.5%)
With values below reference range	0	0	0	0
With values within reference range	108 (96.4%)	117 (95.9%)	113 (99.1%)	14 (87.5%)
Summary statistics:				
Number of patients with values	112	122	114	16
Mean	181.2	178.3	173.1	202.4
SD	38.81	36.97	34.67	55.38
Median	176.0	175.0	170.5	192.0
Minimum	82	82	99	120
Maximum	304	327	262	326

- 2112 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	110	121	110	17
With values above reference range	2 (1.8%)	1 (0.8%)	2 (1.8%)	0
With values below reference range	0	0	0	0
With values within reference range	108 (98.2%)	120 (99.2%)	108 (98.2%)	17 (100.0%)
Summary statistics:				
Number of patients with values	110	121	110	17
Mean	173.8	171.0	172.6	200.9
SD	37.99	32.42	35.15	29.22
Median	168.5	169.0	170.5	208.0
Minimum	82	81	102	153
Maximum	299	258	278	248
Month 12				
Number of patients:				
With values	97	109	101	17
With values above reference range	1 (1.0%)	0	4 (4.0%)	1 (5.9%)
With values below reference range	0	0	0	0
With values within reference range	96 (99.0%)	109 (100.0%)	97 (96.0%)	16 (94.1%)
Summary statistics:				
Number of patients with values	97	109	101	17
Mean	166.6	166.5	168.2	191.8
SD	33.10	31.91	46.96	46.54
Median	162.0	167.0	156.0	180.0
Minimum	78	67	96	128
Maximum	272	260	422	282

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	100	109	98	9
With values above reference range	0	2 (1.8%)	1 (1.0%)	1 (11.1%)
With values below reference range	0	0	0	0
With values within reference range	100 (100.0%)	107 (98.2%)	97 (99.0%)	8 (88.9%)
Summary statistics:				
Number of patients with values	100	109	98	9
Mean	168.5	167.9	166.9	195.9
SD	33.39	27.96	33.10	40.66
Median	161.0	167.0	164.0	186.0
Minimum	79	110	103	140
Maximum	252	258	286	273
Month 18				
Number of patients:				
With values	96	97	87	10
With values above reference range	2 (2.1%)	2 (2.1%)	0	1 (10.0%)
With values below reference range	0	0	0	0
With values within reference range	94 (97.9%)	95 (97.9%)	87 (100.0%)	9 (90.0%)
Summary statistics:				
Number of patients with values	96	97	87	10
Mean	172.0	171.6	168.2	203.6
SD	37.06	31.67	33.17	44.36
Median	166.0	167.0	164.0	205.0
Minimum	71	111	95	129
Maximum	289	315	253	274

- 2114 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	94	92	80	8
With values above reference range	2 (2.1%)	0	2 (2.5%)	0
With values below reference range	0	0	0	0
With values within reference range	92 (97.9%)	92 (100.0%)	78 (97.5%)	8 (100.0%)
Summary statistics:				
Number of patients with values	94	92	80	8
Mean	170.9	171.1	172.3	206.8
SD	37.88	29.06	36.75	31.99
Median	165.0	171.0	169.5	218.0
Minimum	71	107	103	139
Maximum	276	249	290	245
Month 24				
Number of patients:				
With values	84	81	78	4
With values above reference range	1 (1.2%)	0	2 (2.6%)	0
With values below reference range	0	0	0	0
With values within reference range	83 (98.8%)	81 (100.0%)	76 (97.4%)	4 (100.0%)
Summary statistics:				
Number of patients with values	84	81	78	4
Mean	170.4	170.5	172.0	235.3
SD	37.35	30.50	38.64	8.50
Median	169.5	173.0	170.0	235.0
Minimum	67	106	104	227
Maximum	283	255	306	244

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	70	78	71	6
With values above reference range	0	0	3 (4.2%)	0
With values below reference range	0	0	0	0
With values within reference range	70 (100.0%)	78 (100.0%)	68 (95.8%)	6 (100.0%)
Summary statistics:				
Number of patients with values	70	78	71	6
Mean	167.5	173.2	182.0	194.8
SD	34.78	29.90	53.34	29.01
Median	167.5	173.5	175.0	202.5
Minimum	78	115	108	145
Maximum	257	252	478	223
Month 30				
Number of patients:				
With values	55	69	52	4
With values above reference range	0	3 (4.3%)	2 (3.8%)	0
With values below reference range	0	0	0	0
With values within reference range	55 (100.0%)	66 (95.7%)	50 (96.2%)	4 (100.0%)
Summary statistics:				
Number of patients with values	55	69	52	4
Mean	171.9	179.0	181.7	204.5
SD	29.72	35.86	40.47	33.67
Median	173.0	174.0	175.5	206.5
Minimum	87	124	111	164
Maximum	243	317	315	241

- 2116 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	53	47	52	3
With values above reference range	0	1 (2.1%)	0	0
With values below reference range	0	0	0	0
With values within reference range	53 (100.0%)	46 (97.9%)	52 (100.0%)	3 (100.0%)
Summary statistics:				
Number of patients with values	53	47	52	3
Mean	171.5	173.6	175.0	230.3
SD	34.66	28.33	36.76	39.55
Median	169.0	167.0	172.5	243.0
Minimum	91	131	113	186
Maximum	268	270	270	262
Month 36				
Number of patients:				
With values	24	26	28	1
With values above reference range	0	1 (3.8%)	0	0
With values below reference range	0	0	0	0
With values within reference range	24 (100.0%)	25 (96.2%)	28 (100.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	24	26	28	1
Mean	170.0	169.7	176.5	214.0
SD	31.50	33.25	35.21	
Median	173.0	161.5	170.5	214.0
Minimum	126	131	111	214
Maximum	247	265	253	214

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	6	5	1
With values above reference range	0	0	0	1 (100.0%)
With values below reference range	0	0	0	0
With values within reference range	2 (100.0%)	6 (100.0%)	5 (100.0%)	0
Summary statistics:				
Number of patients with values	2	6	5	1
Mean	160.0	167.5	164.6	263.0
SD	56.57	33.55	34.54	
Median	160.0	170.0	176.0	263.0
Minimum	120	117	114	263
Maximum	200	219	205	263
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: LDH (U/L)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 0				
Number of patients:				
With values	4	11	6	1
With values above reference range	2 (50.0%)	4 (36.4%)	3 (50.0%)	0
With values below reference range	0	0	0	0
With values within reference range	2 (50.0%)	7 (63.6%)	3 (50.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	4	11	6	1
Mean	231.0	174.8	220.5	82.0
SD	180.10	95.34	126.13	
Median	185.0	180.0	206.0	82.0
Minimum	67	70	96	82
Maximum	487	355	385	82
Open Label Baseline				
Number of patients:				
With values	124	136	139	26
With values above reference range	35 (28.2%)	45 (33.1%)	37 (26.6%)	5 (19.2%)
With values below reference range	0	0	0	0
With values within reference range	89 (71.8%)	91 (66.9%)	102 (73.4%)	21 (80.8%)
Summary statistics:				
Number of patients with values	124	136	139	26
Mean	175.8	180.3	168.4	159.0
SD	124.56	110.24	98.09	74.41
Median	142.5	156.0	144.0	137.0
Minimum	52	42	45	75
Maximum	911	837	576	364

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open		4bd Mono Total			
Label	Medication	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 1					
Number of patients:					
With values		3	6	2	0
With values above reference range		1 (33.3%)	2 (33.3%)	1 (50.0%)	
With values below reference range		0	0	0	
With values within reference range		2 (66.7%)	4 (66.7%)	1 (50.0%)	
Summary statistics:					
Number of patients with values		3	6	2	0
Mean		183.7	188.3	185.0	
SD		168.42	130.11	124.45	
Median		93.0	142.5	185.0	
Minimum		80	98	97	
Maximum		378	440	273	
Month 2					
Number of patients:					
With values		0	1	4	0
With values above reference range			0	1 (25.0%)	
With values below reference range			0	0	
With values within reference range			1 (100.0%)	3 (75.0%)	
Summary statistics:					
Number of patients with values		0	1	4	0
Mean			115.0	137.5	
SD				67.00	
Median			115.0	131.5	
Minimum			115	64	
Maximum			115	223	

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 3				
Number of patients:				
With values	4	11	11	0
With values above reference range	2 (50.0%)	3 (27.3%)	4 (36.4%)	
With values below reference range	0	0	0	
With values within reference range	2 (50.0%)	8 (72.7%)	7 (63.6%)	
Summary statistics:				
Number of patients with values	4	11	11	0
Mean	213.5	168.5	164.6	
SD	124.76	98.76	73.88	
Median	213.5	146.0	135.0	
Minimum	79	58	88	
Maximum	348	388	289	
Month 6				
Number of patients:				
With values	111	120	113	15
With values above reference range	34 (30.6%)	39 (32.5%)	41 (36.3%)	4 (26.7%)
With values below reference range	0	0	0	0
With values within reference range	77 (69.4%)	81 (67.5%)	72 (63.7%)	11 (73.3%)
Summary statistics:				
Number of patients with values	111	120	113	15
Mean	175.0	183.3	193.8	160.0
SD	124.72	118.44	131.34	88.60
Median	142.0	151.0	143.0	128.0
Minimum	37	42	50	47
Maximum	801	728	700	363

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 9				
Number of patients:				
With values	6	10	9	4
With values above reference range	2 (33.3%)	3 (30.0%)	8 (88.9%)	1 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	4 (66.7%)	7 (70.0%)	1 (11.1%)	3 (75.0%)
Summary statistics:				
Number of patients with values	6	10	9	4
Mean	156.0	172.7	360.3	149.0
SD	95.90	128.91	166.01	93.45
Median	124.0	113.0	278.0	154.0
Minimum	69	70	148	33
Maximum	292	480	638	255
Month 12				
Number of patients:				
With values	96	107	102	16
With values above reference range	26 (27.1%)	30 (28.0%)	34 (33.3%)	4 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	70 (72.9%)	77 (72.0%)	68 (66.7%)	12 (75.0%)
Summary statistics:				
Number of patients with values	96	107	102	16
Mean	178.9	163.8	190.4	146.1
SD	178.84	87.89	125.84	97.47
Median	137.0	143.0	151.5	98.5
Minimum	46	48	40	66
Maximum	1612	534	719	397

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 15				
Number of patients:				
With values	7	14	8	1
With values above reference range	1 (14.3%)	5 (35.7%)	4 (50.0%)	0
With values below reference range	0	0	0	0
With values within reference range	6 (85.7%)	9 (64.3%)	4 (50.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	7	14	8	1
Mean	179.7	188.3	177.1	148.0
SD	189.56	92.12	105.98	
Median	125.0	167.0	186.0	148.0
Minimum	65	58	51	148
Maximum	604	390	308	148
Month 18				
Number of patients:				
With values	89	94	83	8
With values above reference range	21 (23.6%)	25 (26.6%)	25 (30.1%)	0
With values below reference range	0	0	0	0
With values within reference range	68 (76.4%)	69 (73.4%)	58 (69.9%)	8 (100.0%)
Summary statistics:				
Number of patients with values	89	94	83	8
Mean	163.0	166.7	198.1	104.5
SD	111.26	98.03	149.39	53.89
Median	129.0	140.5	149.0	99.0
Minimum	50	56	42	39
Maximum	687	624	897	188

- 2124 -

CONFIDENTIAL

BRL-049653/RSD-
100TV9/L/CPMS-009

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 21				
Number of patients:				
With values	4	4	5	0
With values above reference range	1 (25.0%)	1 (25.0%)	2 (40.0%)	
With values below reference range	0	0	0	
With values within reference range	3 (75.0%)	3 (75.0%)	3 (60.0%)	
Summary statistics:				
Number of patients with values	4	4	5	0
Mean	182.0	146.3	246.4	
SD	108.47	66.97	248.45	
Median	173.0	125.5	129.0	
Minimum	59	91	88	
Maximum	323	243	684	
Month 24				
Number of patients:				
With values	76	74	68	4
With values above reference range	15 (19.7%)	16 (21.6%)	18 (26.5%)	1 (25.0%)
With values below reference range	0	0	0	0
With values within reference range	61 (80.3%)	58 (78.4%)	50 (73.5%)	3 (75.0%)
Summary statistics:				
Number of patients with values	76	74	68	4
Mean	155.5	153.8	163.3	132.8
SD	116.49	93.22	96.05	62.79
Median	126.5	133.0	134.5	110.0
Minimum	54	53	54	86
Maximum	972	702	487	225

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 27				
Number of patients:				
With values	8	8	5	1
With values above reference range	2 (25.0%)	3 (37.5%)	2 (40.0%)	0
With values below reference range	0	0	0	0
With values within reference range	6 (75.0%)	5 (62.5%)	3 (60.0%)	1 (100.0%)
Summary statistics:				
Number of patients with values	8	8	5	1
Mean	221.8	168.1	173.6	43.0
SD	195.25	95.09	77.85	
Median	133.5	138.0	125.0	43.0
Minimum	90	60	111	43
Maximum	658	365	266	43
Month 30				
Number of patients:				
With values	47	61	46	3
With values above reference range	7 (14.9%)	15 (24.6%)	13 (28.3%)	0
With values below reference range	0	0	0	0
With values within reference range	40 (85.1%)	46 (75.4%)	33 (71.7%)	3 (100.0%)
Summary statistics:				
Number of patients with values	47	61	46	3
Mean	137.0	170.6	172.8	80.3
SD	53.93	132.99	123.64	20.50
Median	127.0	134.0	134.0	80.0
Minimum	49	50	42	60
Maximum	281	900	705	101

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 33				
Number of patients:				
With values	22	14	18	0
With values above reference range	7 (31.8%)	4 (28.6%)	6 (33.3%)	
With values below reference range	0	0	0	
With values within reference range	15 (68.2%)	10 (71.4%)	12 (66.7%)	
Summary statistics:				
Number of patients with values	22	14	18	0
Mean	181.3	160.7	205.6	
SD	70.72	60.39	141.00	
Median	173.0	152.5	165.5	
Minimum	51	72	40	
Maximum	308	276	619	
Month 36				
Number of patients:				
With values	17	22	21	1
With values above reference range	5 (29.4%)	1 (4.5%)	1 (4.8%)	0
With values below reference range	0	0	0	0
With values within reference range	12 (70.6%)	21 (95.5%)	20 (95.2%)	1 (100.0%)
Summary statistics:				
Number of patients with values	17	22	21	1
Mean	165.6	122.9	130.7	108.0
SD	130.33	53.96	56.64	
Median	141.0	121.5	127.0	108.0
Minimum	50	57	47	108
Maximum	596	296	310	108

BRL 49653C/009

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
 Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 39				
Number of patients:				
With values	2	5	4	0
With values above reference range	0	2 (40.0%)	0	
With values below reference range	0	0	0	
With values within reference range	2 (100.0%)	3 (60.0%)	4 (100.0%)	
Summary statistics:				
Number of patients with values	2	5	4	0
Mean	97.0	203.4	65.0	
SD	18.38	83.25	23.68	
Median	97.0	179.0	67.5	
Minimum	84	96	35	
Maximum	110	312	90	
Month 42				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

Data Source Table 15.7.1c

Summary of Laboratory Data (Safety) at Each Visit
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension
Parameter: Triglycerides (mg/dL)

Time Relative to Start of Open Label Medication	4bd Mono Total			
	020:4bd/4bd	020:2bd/4bd	020:G/4bd	025:Total
Month 45				
Number of patients:				
With values	0	0	0	0
With values above reference range				
With values below reference range				
With values within reference range				
Summary statistics:				
Number of patients with values	0	0	0	0
Mean				
SD				
Median				
Minimum				
Maximum				

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Data Source Table 15.7.4a
 Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
 at Any Time During the On-Therapy (During the Open Label Study) Period
 All Patients Who Entered Study 009

Laboratory Test	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Hemoglobin		
Number of patients with values	224	402
With value above range	2 (0.9%)	2 (0.5%)
With value below range	3 (1.3%)	15 (3.7%)
Hematocrit		
Number of patients with values	224	402
With value above range	3 (1.3%)	4 (1.0%)
With value below range	5 (2.2%)	17 (4.2%)
White Blood Cell Count		
Number of patients with values	224	402
With value above range	0	4 (1.0%)
With value below range	2 (0.9%)	11 (2.7%)
Neutrophils (Segs)		
Number of patients with values	224	401
With value above range	0	0
With value below range	3 (1.3%)	7 (1.7%)
Lymphocytes		
Number of patients with values	224	401
With value above range	0	0
With value below range	3 (1.3%)	3 (0.7%)
Platelet Count		
Number of patients with values	224	402
With value above range	1 (0.4%)	2 (0.5%)
With value below range	2 (0.9%)	4 (1.0%)
Total Bilirubin		
Number of patients with values	224	403
With value above range	5 (2.2%)	1 (0.2%)
With value below range	0	0
Total Protein		
Number of patients with values	224	403
With value above range	0	0
With value below range	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4a
Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
at Any Time During the On-Therapy (During the Open Label Study) Period
All Patients Who Entered Study 009

Laboratory Test	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Albumin		
Number of patients with values	224	403
With value above range	0	0
With value below range	0	0
SGOT/ASAT		
Number of patients with values	224	403
With value above range	1 (0.4%)	1 (0.2%)
With value below range	0	0
SGPT/ALAT		
Number of patients with values	224	403
With value above range	1 (0.4%)	1 (0.2%)
With value below range	0	0
Gamma Glutamyl Transferase		
Number of patients with values	224	403
With value above range	9 (4.0%)	12 (3.0%)
With value below range	0	0
Alkaline Phosphatase		
Number of patients with values	224	403
With value above range	0	1 (0.2%)
With value below range	0	0
Creatinine		
Number of patients with values	224	403
With value above range	13 (5.8%)	19 (4.7%)
With value below range	0	0
Blood Urea Nitrogen		
Number of patients with values	224	403
With value above range	1 (0.4%)	4 (1.0%)
With value below range	0	0
Uric Acid		
Number of patients with values	224	403
With value above range	0	4 (1.0%)
With value below range	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4a
 Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
 at Any Time During the On-Therapy (During the Open Label Study) Period
 All Patients Who Entered Study 009

Laboratory Test	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Sodium		
Number of patients with values	224	403
With value above range	0	4 (1.0%)
With value below range	2 (0.9%)	3 (0.7%)
Potassium		
Number of patients with values	224	403
With value above range	3 (1.3%)	5 (1.2%)
With value below range	0	1 (0.2%)
Bicarbonate		
Number of patients with values	224	403
With value above range	1 (0.4%)	0
With value below range	5 (2.2%)	4 (1.0%)
Fasting Plasma Glucose		
Number of patients with values	226	423
With value above range	0	1 (0.2%)
With value below range	1 (0.4%)	1 (0.2%)
Phosphorus		
Number of patients with values	224	403
With value above range	2 (0.9%)	1 (0.2%)
With value below range	0	0
Calcium		
Number of patients with values	224	403
With value above range	1 (0.4%)	0
With value below range	0	1 (0.2%)
LDH		
Number of patients with values	224	403
With value above range	0	0
With value below range	0	0
Triglycerides		
Number of patients with values	213	392
With value above range	2 (0.9%)	3 (0.8%)
With value below range	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4b
 Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
 at Any Time During the On-Therapy (During the Open Label Study) Period
 All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Laboratory Test	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Hemoglobin			
Number of patients with values	60	76	88
With value above range	0	1 (1.3%)	1 (1.1%)
With value below range	1 (1.7%)	1 (1.3%)	1 (1.1%)
Hematocrit			
Number of patients with values	60	76	88
With value above range	1 (1.7%)	1 (1.3%)	1 (1.1%)
With value below range	0	2 (2.6%)	3 (3.4%)
White Blood Cell Count			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	2 (3.3%)	0	0
Neutrophils (Segs)			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	2 (3.3%)	1 (1.3%)	0
Lymphocytes			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	2 (2.6%)	1 (1.1%)
Platelet Count			
Number of patients with values	60	76	88
With value above range	0	0	1 (1.1%)
With value below range	0	1 (1.3%)	1 (1.1%)
Total Bilirubin			
Number of patients with values	60	76	88
With value above range	2 (3.3%)	3 (3.9%)	0
With value below range	0	0	0
Total Protein			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4b
Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
at Any Time During the On-Therapy (During the Open Label Study) Period
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Laboratory Test	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Albumin			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	0	0
SGOT/ASAT			
Number of patients with values	60	76	88
With value above range	0	1 (1.3%)	0
With value below range	0	0	0
SGPT/ALAT			
Number of patients with values	60	76	88
With value above range	0	1 (1.3%)	0
With value below range	0	0	0
Gamma Glutamyl Transferase			
Number of patients with values	60	76	88
With value above range	1 (1.7%)	3 (3.9%)	5 (5.7%)
With value below range	0	0	0
Alkaline Phosphatase			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	0	0
Creatinine			
Number of patients with values	60	76	88
With value above range	2 (3.3%)	2 (2.6%)	9 (10.2%)
With value below range	0	0	0
Blood Urea Nitrogen			
Number of patients with values	60	76	88
With value above range	0	1 (1.3%)	0
With value below range	0	0	0
Uric Acid			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4b
Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
at Any Time During the On-Therapy (During the Open Label Study) Period
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Laboratory Test	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Sodium			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	1 (1.3%)	1 (1.1%)
Potassium			
Number of patients with values	60	76	88
With value above range	0	1 (1.3%)	2 (2.3%)
With value below range	0	0	0
Bicarbonate			
Number of patients with values	60	76	88
With value above range	1 (1.7%)	0	0
With value below range	0	2 (2.6%)	3 (3.4%)
Fasting Plasma Glucose			
Number of patients with values	60	77	89
With value above range	0	0	0
With value below range	0	0	1 (1.1%)
Phosphorus			
Number of patients with values	60	76	88
With value above range	0	0	2 (2.3%)
With value below range	0	0	0
Calcium			
Number of patients with values	60	76	88
With value above range	0	0	1 (1.1%)
With value below range	0	0	0
LDH			
Number of patients with values	60	76	88
With value above range	0	0	0
With value below range	0	0	0
Triglycerides			
Number of patients with values	58	74	81
With value above range	0	0	2 (2.5%)
With value below range	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4c
 Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
 at Any Time During the On-Therapy (During the Open Label Study) Period
 All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Laboratory Test	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Hemoglobin				
Number of patients with values	117	133	131	20
With value above range	1 (0.9%)	0	1 (0.8%)	0
With value below range	5 (4.3%)	5 (3.8%)	5 (3.8%)	0
Hematocrit				
Number of patients with values	117	133	131	20
With value above range	1 (0.9%)	2 (1.5%)	1 (0.8%)	0
With value below range	5 (4.3%)	5 (3.8%)	6 (4.6%)	1 (5.0%)
White Blood Cell Count				
Number of patients with values	117	133	131	20
With value above range	2 (1.7%)	1 (0.8%)	1 (0.8%)	0
With value below range	3 (2.6%)	5 (3.8%)	2 (1.5%)	1 (5.0%)
Neutrophils (Segs)				
Number of patients with values	117	132	131	20
With value above range	0	0	0	0
With value below range	4 (3.4%)	1 (0.8%)	2 (1.5%)	0
Lymphocytes				
Number of patients with values	117	132	131	20
With value above range	0	0	0	0
With value below range	1 (0.9%)	0	2 (1.5%)	0
Platelet Count				
Number of patients with values	117	133	131	20
With value above range	0	2 (1.5%)	0	0
With value below range	0	3 (2.3%)	1 (0.8%)	0
Total Bilirubin				
Number of patients with values	117	133	132	20
With value above range	1 (0.9%)	0	0	0
With value below range	0	0	0	0
Total Protein				
Number of patients with values	117	133	132	20
With value above range	0	0	0	0
With value below range	0	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4c
Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
at Any Time During the On-Therapy (During the Open Label Study) Period
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Laboratory Test	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Albumin				
Number of patients with values	117	133	132	20
With value above range	0	0	0	0
With value below range	0	0	0	0
SGOT/ASAT				
Number of patients with values	117	133	132	20
With value above range	0	0	1 (0.8%)	0
With value below range	0	0	0	0
SGPT/ALAT				
Number of patients with values	117	133	132	20
With value above range	0	0	1 (0.8%)	0
With value below range	0	0	0	0
Gamma Glutamyl Transferase				
Number of patients with values	117	133	132	20
With value above range	3 (2.6%)	4 (3.0%)	5 (3.8%)	0
With value below range	0	0	0	0
Alkaline Phosphatase				
Number of patients with values	117	133	132	20
With value above range	0	0	1 (0.8%)	0
With value below range	0	0	0	0
Creatinine				
Number of patients with values	117	133	132	20
With value above range	8 (6.8%)	3 (2.3%)	8 (6.1%)	0
With value below range	0	0	0	0
Blood Urea Nitrogen				
Number of patients with values	117	133	132	20
With value above range	1 (0.9%)	1 (0.8%)	2 (1.5%)	0
With value below range	0	0	0	0
Uric Acid				
Number of patients with values	117	133	132	20
With value above range	3 (2.6%)	0	1 (0.8%)	0
With value below range	0	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.7.4c
Summary of Laboratory Data Values (Safety) of Potential Clinical Concern
at Any Time During the On-Therapy (During the Open Label Study) Period
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Laboratory Test	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Sodium				
Number of patients with values	117	133	132	20
With value above range	2 (1.7%)	1 (0.8%)	1 (0.8%)	0
With value below range	1 (0.9%)	0	2 (1.5%)	0
Potassium				
Number of patients with values	117	133	132	20
With value above range	3 (2.6%)	1 (0.8%)	1 (0.8%)	0
With value below range	1 (0.9%)	0	0	0
Bicarbonate				
Number of patients with values	117	133	132	20
With value above range	0	0	0	0
With value below range	0	2 (1.5%)	1 (0.8%)	1 (5.0%)
Fasting Plasma Glucose				
Number of patients with values	121	135	136	30
With value above range	1 (0.8%)	0	0	0
With value below range	1 (0.8%)	0	0	0
Phosphorus				
Number of patients with values	117	133	132	20
With value above range	0	1 (0.8%)	0	0
With value below range	0	0	0	0
Calcium				
Number of patients with values	117	133	132	20
With value above range	0	0	0	0
With value below range	0	1 (0.8%)	0	0
LDH				
Number of patients with values	117	133	132	20
With value above range	0	0	0	0
With value below range	0	0	0	0
Triglycerides				
Number of patients with values	117	131	124	19
With value above range	1 (0.9%)	1 (0.8%)	1 (0.8%)	0
With value below range	0	0	0	0

Note: A patient may be represented only once per parameter/category combination

Data Source Table 15.8.3Ba

Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline
All Patients Who Entered Study 009

	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Ventricular Rate (bpm)		
< 50	8 (3.5%)	21 (4.9%)
> 120	0	1 (0.2%)
PR Interval (msec)		
> 300	1 (0.4%)	2 (0.5%)
Increase of > 25% when baseline PR > 200	2 (0.9%)	4 (0.9%)
Increase of > 50% when baseline PR <= 200	3 (1.3%)	6 (1.4%)
QRS Interval (msec)		
> 200	2 (0.9%)	10 (2.3%)
Increase of > 25% when baseline QRS > 100	2 (0.9%)	4 (0.9%)
Increase of > 50% when baseline QRS <= 100	9 (3.9%)	24 (5.6%)
QTc Interval (msec)		
> 500	11 (4.8%)	23 (5.3%)
Increase of > 15% when baseline QTc > 440	2 (0.9%)	1 (0.2%)
Increase of > 30% when baseline QTc <= 440	4 (1.7%)	7 (1.6%)

Data Source Table 15.8.3Bb

Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

	015:S/2bd (N=61)	2bd Comb Total 015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Ventricular Rate (bpm)			
< 50	3 (4.9%)	2 (2.6%)	3 (3.3%)
> 120	0	0	0
PR Interval (msec)			
> 300	0	0	1 (1.1%)
Increase of > 25% when baseline PR > 200	0	1 (1.3%)	1 (1.1%)
Increase of > 50% when baseline PR <= 200	1 (1.6%)	1 (1.3%)	1 (1.1%)
QRS Interval (msec)			
> 200	1 (1.6%)	1 (1.3%)	0
Increase of > 25% when baseline QRS > 100	1 (1.6%)	1 (1.3%)	0
Increase of > 50% when baseline QRS <= 100	3 (4.9%)	1 (1.3%)	5 (5.6%)
QTc Interval (msec)			
> 500	5 (8.2%)	4 (5.1%)	2 (2.2%)
Increase of > 15% when baseline QTc > 440	1 (1.6%)	1 (1.3%)	0
Increase of > 30% when baseline QTc <= 440	0	3 (3.8%)	1 (1.1%)

Data Source Table 15.8.3Bc

Summary of On-Therapy (During the Open Label Study) ECG Values of Potential Clinical Concern Based on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

	020:4bd/4bd (N=124)	4bd Mono 020:2bd/4bd (N=136)	Total 020:G/4bd (N=139)	025:Total (N=30)
Ventricular Rate (bpm)				
< 50	10 (8.1%)	7 (5.1%)	4 (2.9%)	0
> 120	0	0	1 (0.7%)	0
PR Interval (msec)				
> 300	0	2 (1.5%)	0	0
Increase of > 25% when baseline PR > 200	1 (0.8%)	2 (1.5%)	1 (0.7%)	0
Increase of > 50% when baseline PR <= 200	1 (0.8%)	4 (2.9%)	1 (0.7%)	0
QRS Interval (msec)				
> 200	3 (2.4%)	3 (2.2%)	4 (2.9%)	0
Increase of > 25% when baseline QRS > 100	0	0	4 (2.9%)	0
Increase of > 50% when baseline QRS <= 100	8 (6.5%)	7 (5.1%)	9 (6.5%)	0
QTc Interval (msec)				
> 500	9 (7.3%)	8 (5.9%)	6 (4.3%)	0
Increase of > 15% when baseline QTc > 440	0	0	1 (0.7%)	0
Increase of > 30% when baseline QTc <= 440	1 (0.8%)	4 (2.9%)	2 (1.4%)	0

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Blank		
Not Present at Baseline	229	430
New Onset	3 (1.3%)	3 (0.7%)
Supraventricular tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Ectopic Rhythm Nos		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Pacemaker rhythm		
Not Present at Baseline	227	428
New Onset	0 (0.0%)	2 (0.5%)
Sinus bradycardia		
Not Present at Baseline	191	362
New Onset	36 (18.8%)	83 (22.9%)
Sick sinus syndrome		
Not Present at Baseline	228	430
New Onset	0 (0.0%)	0 (0.0%)
Sinus arrhythmia		
Not Present at Baseline	229	428
New Onset	2 (0.9%)	9 (2.1%)
Sinus tachycardia		
Not Present at Baseline	227	428
New Onset	2 (0.9%)	5 (1.2%)
Wandering atrial pacemaker		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Premature atrial contractions		
Not Present at Baseline	228	426
New Onset	4 (1.8%)	7 (1.6%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Paroxysmal atrial tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Chronic ectopic atrial tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Multifocal atrial tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Atrial flutter		
Not Present at Baseline	229	429
New Onset	1 (0.4%)	2 (0.5%)
Atrial fibrillation		
Not Present at Baseline	226	426
New Onset	2 (0.9%)	9 (2.1%)
Junctional (AV nodal) premature contractions		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
AV Junctional Rhythm		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	0 (0.0%)
Junctional (Av nodal) tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Premature Ventricular Contractions (NOS)		
Not Present at Baseline	226	427
New Onset	5 (2.2%)	12 (2.8%)
Ventricular couplets		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	2 (0.5%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Unifocal PVC's		
Not Present at Baseline	228	428
New Onset	3 (1.3%)	7 (1.6%)
Multifocal PVC's		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Bigeminy		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Accelerated idioventricular rhythm		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Ventricular tachycardia		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Ventricular fibrillation		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
First degree AV block		
Not Present at Baseline	216	417
New Onset	8 (3.7%)	22 (5.3%)
Second degree AV block, Type I		
Not Present at Baseline	229	429
New Onset	1 (0.4%)	1 (0.2%)
Second degree Av block, Type II		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	0 (0.0%)
Third degree AV block		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Intraventricular conduction delay		
Not Present at Baseline	229	426
New Onset	2 (0.9%)	11 (2.6%)
Right bundle branch block		
Not Present at Baseline	220	419
New Onset	7 (3.2%)	13 (3.1%)
Left bundle branch block		
Not Present at Baseline	226	426
New Onset	3 (1.3%)	5 (1.2%)
Left anterior hemiblock		
Not Present at Baseline	217	418
New Onset	6 (2.8%)	10 (2.4%)
Left posterior hemiblock		
Not Present at Baseline	229	430
New Onset	2 (0.9%)	1 (0.2%)
Pre-excitation Syndrome Nos		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	1 (0.2%)
Wolff-Parkinson-White syndrome		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	0 (0.0%)
EKG Axis Finding Nos		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	0 (0.0%)
Right Axis deviation		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	1 (0.2%)
Left Axis deviation		
Not Present at Baseline	209	417
New Onset	6 (2.9%)	17 (4.1%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Right ventricular hypertrophy		
Not Present at Baseline	228	430
New Onset	0 (0.0%)	1 (0.2%)
Left ventricular hypertrophy		
Not Present at Baseline	225	425
New Onset	5 (2.2%)	5 (1.2%)
Right atrial hypertrophy, P pulmonale		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	0 (0.0%)
Left atrial hypertrophy, P mitrale		
Not Present at Baseline	224	424
New Onset	5 (2.2%)	10 (2.4%)
Normal Voltage EKG		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	0 (0.0%)
Increased Ventricular Voltage Nos		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	2 (0.5%)
Low Ventricular Voltage Nos		
Not Present at Baseline	229	430
New Onset	2 (0.9%)	2 (0.5%)
Myocardial ischemia (non-specific)		
Not Present at Baseline	225	429
New Onset	3 (1.3%)	0 (0.0%)
Myocardial ischemia Anterior		
Not Present at Baseline	227	430
New Onset	6 (2.6%)	3 (0.7%)
Myocardial ischemia Lateral		
Not Present at Baseline	225	423
New Onset	8 (3.6%)	8 (1.9%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Myocardial ischemia Posterior		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	1 (0.2%)
Myocardial ischemia Inferior		
Not Present at Baseline	221	426
New Onset	3 (1.4%)	5 (1.2%)
Myocardial ischemia Septal		
Not Present at Baseline	228	429
New Onset	2 (0.9%)	1 (0.2%)
Nonspecific ST-T changes		
Not Present at Baseline	219	410
New Onset	22 (10.0%)	41 (10.0%)
S-T Changes Strain		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
ST segment depression > 1mm		
Not Present at Baseline	229	425
New Onset	1 (0.4%)	2 (0.5%)
ST segment elevation > 1mm		
Not Present at Baseline	228	429
New Onset	0 (0.0%)	3 (0.7%)
Q-wave > 0.04 sec		
Not Present at Baseline	227	430
New Onset	4 (1.8%)	6 (1.4%)
Prolonged QT-interval		
Not Present at Baseline	226	429
New Onset	4 (1.8%)	6 (1.4%)
Poor R-wave progression		
Not Present at Baseline	225	430
New Onset	7 (3.1%)	5 (1.2%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
U-wave		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
T-wave flat		
Not Present at Baseline	225	422
New Onset	11 (4.9%)	4 (0.9%)
T-wave inversion		
Not Present at Baseline	214	422
New Onset	12 (5.6%)	10 (2.4%)
T-wave peaked		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	0 (0.0%)
T Wave Abnormal,Nos		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	0 (0.0%)
Digitalis effect		
Not Present at Baseline	229	429
New Onset	0 (0.0%)	4 (0.9%)
Myocardial infarction, acute (non-specific)		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Anterior		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	2 (0.5%)
Myocardial infarction, acute Lateral		
Not Present at Baseline	228	430
New Onset	0 (0.0%)	1 (0.2%)
Myocardial infarction, acute Posterior		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Ba

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Entered Study 009

Parameter	2bd Comb Total (N=229)	4bd Mono Total (N=430)
Myocardial infarction, acute Inferior		
Not Present at Baseline	229	430
New Onset	3 (1.3%)	1 (0.2%)
Myocardial infarction, acute Septal		
Not Present at Baseline	229	430
New Onset	1 (0.4%)	1 (0.2%)
Myocardial infarction, old (non-specific)		
Not Present at Baseline	229	428
New Onset	0 (0.0%)	2 (0.5%)
Myocardial infarction, old Anterior		
Not Present at Baseline	224	427
New Onset	5 (2.2%)	2 (0.5%)
Myocardial infarction, old Lateral		
Not Present at Baseline	226	430
New Onset	0 (0.0%)	1 (0.2%)
Myocardial infarction, old Posterior		
Not Present at Baseline	229	430
New Onset	0 (0.0%)	1 (0.2%)
Myocardial infarction, old Inferior		
Not Present at Baseline	226	426
New Onset	7 (3.1%)	6 (1.4%)
Myocardial infarction, old Septal		
Not Present at Baseline	228	429
New Onset	2 (0.9%)	2 (0.5%)
Total Number of Patients with Normal ECG at Baseline	148	321

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Blank			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	1 (1.3%)	1 (1.1%)
Supraventricular tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ectopic Rhythm Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pacemaker rhythm			
Not Present at Baseline	60	77	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus bradycardia			
Not Present at Baseline	53	64	74
New Onset	14 (26.4%)	10 (15.6%)	12 (16.2%)
Sick sinus syndrome			
Not Present at Baseline	61	78	89
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus arrhythmia			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	0 (0.0%)	1 (1.1%)
Sinus tachycardia			
Not Present at Baseline	61	78	88
New Onset	1 (1.6%)	1 (1.3%)	0 (0.0%)
Wandering atrial pacemaker			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Premature atrial contractions			
Not Present at Baseline	61	77	90
New Onset	0 (0.0%)	2 (2.6%)	2 (2.2%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Paroxysmal atrial tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic ectopic atrial tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Multifocal atrial tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Atrial flutter			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Atrial fibrillation			
Not Present at Baseline	61	77	88
New Onset	0 (0.0%)	0 (0.0%)	2 (2.3%)
Junctional (AV nodal) premature contractions			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
AV Junctional Rhythm			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Junctional (Av nodal) tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Premature Ventricular Contractions (NOS)			
Not Present at Baseline	61	76	89
New Onset	1 (1.6%)	0 (0.0%)	4 (4.5%)
Ventricular couplets			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	1 (1.3%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Unifocal PVC's			
Not Present at Baseline	61	78	89
New Onset	1 (1.6%)	0 (0.0%)	2 (2.2%)
Multifocal PVC's			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bigeminy			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Accelerated idioventricular rhythm			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular tachycardia			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular fibrillation			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
First degree AV block			
Not Present at Baseline	58	72	86
New Onset	3 (5.2%)	2 (2.8%)	3 (3.5%)
Second degree AV block, Type I			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Second degree Av block, Type II			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Third degree AV block			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Intraventricular conduction delay			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	0 (0.0%)	1 (1.1%)
Right bundle branch block			
Not Present at Baseline	58	74	88
New Onset	3 (5.2%)	1 (1.4%)	3 (3.4%)
Left bundle branch block			
Not Present at Baseline	60	76	90
New Onset	1 (1.7%)	0 (0.0%)	2 (2.2%)
Left anterior hemiblock			
Not Present at Baseline	57	75	85
New Onset	1 (1.8%)	2 (2.7%)	3 (3.5%)
Left posterior hemiblock			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	2 (2.2%)
Pre-excitation Syndrome Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Wolff-Parkinson-White syndrome			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
EKG Axis Finding Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Right Axis deviation			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Left Axis deviation			
Not Present at Baseline	55	74	80
New Onset	2 (3.6%)	3 (4.1%)	1 (1.3%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Right ventricular hypertrophy			
Not Present at Baseline	61	78	89
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Left ventricular hypertrophy			
Not Present at Baseline	60	75	90
New Onset	2 (3.3%)	2 (2.7%)	1 (1.1%)
Right atrial hypertrophy, P pulmonale			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Left atrial hypertrophy, P mitrale			
Not Present at Baseline	61	75	88
New Onset	1 (1.6%)	0 (0.0%)	4 (4.5%)
Normal Voltage EKG			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increased Ventricular Voltage Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low Ventricular Voltage Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	2 (2.2%)
Myocardial ischemia (non-specific)			
Not Present at Baseline	61	76	88
New Onset	2 (3.3%)	0 (0.0%)	1 (1.1%)
Myocardial ischemia Anterior			
Not Present at Baseline	60	77	90
New Onset	1 (1.7%)	1 (1.3%)	4 (4.4%)
Myocardial ischemia Lateral			
Not Present at Baseline	60	76	89
New Onset	4 (6.7%)	0 (0.0%)	4 (4.5%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Myocardial ischemia Posterior			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	0 (0.0%)	0 (0.0%)
Myocardial ischemia Inferior			
Not Present at Baseline	59	76	86
New Onset	1 (1.7%)	1 (1.3%)	1 (1.2%)
Myocardial ischemia Septal			
Not Present at Baseline	60	78	90
New Onset	0 (0.0%)	0 (0.0%)	2 (2.2%)
Nonspecific ST-T changes			
Not Present at Baseline	59	74	86
New Onset	6 (10.2%)	11 (14.9%)	5 (5.8%)
S-T Changes Strain			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
ST segment depression > 1mm			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	0 (0.0%)	0 (0.0%)
ST segment elevation > 1mm			
Not Present at Baseline	61	77	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Q-wave > 0.04 sec			
Not Present at Baseline	61	77	89
New Onset	0 (0.0%)	1 (1.3%)	3 (3.4%)
Prolonged QT-interval			
Not Present at Baseline	61	76	89
New Onset	0 (0.0%)	4 (5.3%)	0 (0.0%)
Poor R-wave progression			
Not Present at Baseline	59	77	89
New Onset	1 (1.7%)	2 (2.6%)	4 (4.5%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
U-wave			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
T-wave flat			
Not Present at Baseline	59	78	88
New Onset	3 (5.1%)	4 (5.1%)	4 (4.5%)
T-wave inversion			
Not Present at Baseline	56	72	86
New Onset	3 (5.4%)	2 (2.8%)	7 (8.1%)
T-wave peaked			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	1 (1.3%)	0 (0.0%)
T Wave Abnormal,Nos			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Digitalis effect			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute (non-specific)			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Anterior			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	1 (1.1%)
Myocardial infarction, acute Lateral			
Not Present at Baseline	61	78	89
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Posterior			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bb

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 2mg bd in the Open Label Extension

Parameter	2bd Comb Total		
	015:S/2bd (N=61)	015:1bd+S/2bd (N=78)	015:2bd+S/2bd (N=90)
Myocardial infarction, acute Inferior			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	1 (1.3%)	1 (1.1%)
Myocardial infarction, acute Septal			
Not Present at Baseline	61	78	90
New Onset	1 (1.6%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old (non-specific)			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old Anterior			
Not Present at Baseline	59	77	88
New Onset	1 (1.7%)	1 (1.3%)	3 (3.4%)
Myocardial infarction, old Lateral			
Not Present at Baseline	60	77	89
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old Posterior			
Not Present at Baseline	61	78	90
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old Inferior			
Not Present at Baseline	61	76	89
New Onset	1 (1.6%)	2 (2.6%)	4 (4.5%)
Myocardial infarction, old Septal			
Not Present at Baseline	61	78	89
New Onset	0 (0.0%)	1 (1.3%)	1 (1.1%)
Total Number of Patients with Normal ECG at Baseline	40	49	59

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Blank				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	1 (0.7%)	1 (0.7%)	0 (0.0%)
Supraventricular tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ectopic Rhythm Nos				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pacemaker rhythm				
Not Present at Baseline	124	136	137	30
New Onset	0 (0.0%)	2 (1.5%)	0 (0.0%)	0 (0.0%)
Sinus bradycardia				
Not Present at Baseline	105	112	114	30
New Onset	20 (19.0%)	27 (24.1%)	30 (26.3%)	6 (20.0%)
Sick sinus syndrome				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus arrhythmia				
Not Present at Baseline	123	136	138	30
New Onset	2 (1.6%)	3 (2.2%)	2 (1.4%)	2 (6.7%)
Sinus tachycardia				
Not Present at Baseline	124	135	138	30
New Onset	3 (2.4%)	2 (1.5%)	0 (0.0%)	0 (0.0%)
Wandering atrial pacemaker				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Premature atrial contractions				
Not Present at Baseline	123	136	137	29
New Onset	4 (3.3%)	1 (0.7%)	1 (0.7%)	1 (3.4%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Paroxysmal atrial tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic ectopic atrial tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Multifocal atrial tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Atrial flutter				
Not Present at Baseline	124	135	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	1 (3.3%)
Atrial fibrillation				
Not Present at Baseline	122	134	139	30
New Onset	1 (0.8%)	3 (2.2%)	5 (3.6%)	0 (0.0%)
Junctional (AV nodal) premature contractions				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AV Junctional Rhythm				
Not Present at Baseline	124	136	138	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Junctional (Av nodal) tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Premature Ventricular Contractions (NOS)				
Not Present at Baseline	123	134	139	30
New Onset	5 (4.1%)	2 (1.5%)	4 (2.9%)	1 (3.3%)
Ventricular couplets				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	1 (3.3%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Unifocal PVC's				
Not Present at Baseline	123	135	139	30
New Onset	4 (3.3%)	1 (0.7%)	2 (1.4%)	0 (0.0%)
Multifocal PVC's				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Bigeminy				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Accelerated idioventricular rhythm				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular tachycardia				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular fibrillation				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
First degree AV block				
Not Present at Baseline	122	130	135	29
New Onset	9 (7.4%)	4 (3.1%)	8 (5.9%)	1 (3.4%)
Second degree AV block, Type I				
Not Present at Baseline	124	135	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Second degree Av block, Type II				
Not Present at Baseline	124	135	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Third degree AV block				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Intraventricular conduction delay				
Not Present at Baseline	122	135	138	30
New Onset	4 (3.3%)	3 (2.2%)	4 (2.9%)	0 (0.0%)
Right bundle branch block				
Not Present at Baseline	120	133	135	30
New Onset	2 (1.7%)	4 (3.0%)	4 (3.0%)	3 (10.0%)
Left bundle branch block				
Not Present at Baseline	124	135	136	30
New Onset	1 (0.8%)	0 (0.0%)	3 (2.2%)	1 (3.3%)
Left anterior hemiblock				
Not Present at Baseline	120	134	133	30
New Onset	3 (2.5%)	2 (1.5%)	5 (3.8%)	0 (0.0%)
Left posterior hemiblock				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pre-excitation Syndrome Nos				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Wolff-Parkinson-White syndrome				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
EKG Axis Finding Nos				
Not Present at Baseline	124	136	138	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Right Axis deviation				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Left Axis deviation				
Not Present at Baseline	118	131	137	30
New Onset	3 (2.5%)	7 (5.3%)	6 (4.4%)	1 (3.3%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Right ventricular hypertrophy				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.3%)
Left ventricular hypertrophy				
Not Present at Baseline	123	134	137	30
New Onset	2 (1.6%)	0 (0.0%)	2 (1.5%)	1 (3.3%)
Right atrial hypertrophy, P pulmonale				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Left atrial hypertrophy, P mitrale				
Not Present at Baseline	121	134	138	30
New Onset	3 (2.5%)	5 (3.7%)	2 (1.4%)	0 (0.0%)
Normal Voltage EKG				
Not Present at Baseline	124	136	138	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increased Ventricular Voltage Nos				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Low Ventricular Voltage Nos				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Myocardial ischemia (non-specific)				
Not Present at Baseline	123	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial ischemia Anterior				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	2 (1.4%)	0 (0.0%)
Myocardial ischemia Lateral				
Not Present at Baseline	122	135	135	30
New Onset	1 (0.8%)	2 (1.5%)	4 (3.0%)	1 (3.3%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Myocardial ischemia Posterior				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Myocardial ischemia Inferior				
Not Present at Baseline	122	136	137	30
New Onset	1 (0.8%)	2 (1.5%)	0 (0.0%)	2 (6.7%)
Myocardial ischemia Septal				
Not Present at Baseline	123	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Nonspecific ST-T changes				
Not Present at Baseline	116	127	136	30
New Onset	13 (11.2%)	10 (7.9%)	12 (8.8%)	6 (20.0%)
S-T Changes Strain				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ST segment depression > 1mm				
Not Present at Baseline	122	135	137	30
New Onset	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
ST segment elevation > 1mm				
Not Present at Baseline	123	136	139	30
New Onset	0 (0.0%)	2 (1.5%)	1 (0.7%)	0 (0.0%)
Q-wave > 0.04 sec				
Not Present at Baseline	124	136	139	30
New Onset	2 (1.6%)	3 (2.2%)	1 (0.7%)	0 (0.0%)
Prolonged QT-interval				
Not Present at Baseline	124	136	138	30
New Onset	3 (2.4%)	1 (0.7%)	2 (1.4%)	0 (0.0%)
Poor R-wave progression				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	1 (0.7%)	3 (2.2%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
U-wave				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T-wave flat				
Not Present at Baseline	121	134	136	30
New Onset	2 (1.7%)	2 (1.5%)	0 (0.0%)	0 (0.0%)
T-wave inversion				
Not Present at Baseline	123	132	136	30
New Onset	2 (1.6%)	3 (2.3%)	4 (2.9%)	1 (3.3%)
T-wave peaked				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T Wave Abnormal,Nos				
Not Present at Baseline	124	135	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Digitalis effect				
Not Present at Baseline	123	136	139	30
New Onset	0 (0.0%)	3 (2.2%)	0 (0.0%)	1 (3.3%)
Myocardial infarction, acute (non-specific)				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Anterior				
Not Present at Baseline	124	136	139	30
New Onset	2 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Lateral				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Myocardial infarction, acute Posterior				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

- 2164 -

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Data Source Table 15.8.5Bc

Summary of Abnormal ECG Observations On-Therapy (During the Open Label Study) That Were Not Present on Open Label Baseline
All Patients Who Received Rosiglitazone 4mg bd in the Open Label Extension

Parameter	4bd Mono Total			
	020:4bd/4bd (N=124)	020:2bd/4bd (N=136)	020:G/4bd (N=139)	025:Total (N=30)
Myocardial infarction, acute Inferior				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, acute Septal				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old (non-specific)				
Not Present at Baseline	124	135	138	30
New Onset	1 (0.8%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old Anterior				
Not Present at Baseline	123	134	139	30
New Onset	0 (0.0%)	0 (0.0%)	2 (1.4%)	0 (0.0%)
Myocardial infarction, old Lateral				
Not Present at Baseline	124	136	139	30
New Onset	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Myocardial infarction, old Posterior				
Not Present at Baseline	124	136	139	30
New Onset	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction, old Inferior				
Not Present at Baseline	122	135	138	30
New Onset	1 (0.8%)	3 (2.2%)	2 (1.4%)	0 (0.0%)
Myocardial infarction, old Septal				
Not Present at Baseline	124	135	139	30
New Onset	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Total Number of Patients with Normal ECG at Baseline	92	93	106	29

Note: Denominator is total number of patients without each specific abnormal ECG codes at baseline

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Table 15.9.1

**Event Rates of On-therapy Reports of Cardiovascular AEs and Edema –
Rosiglitazone Monotherapy**

SB Document Number: BRL-049653/RSD-101VRD/1

**Table 15.9.1a: On-therapy Reports of Cardiovascular Events -
Rosiglitazone Monotherapy**

Preferred Term*	RSG Monotherapy			Placebo
	N = 3172			N = 601
	4095.7 Pt Yrs			169.5 Pt Yrs
	n	%	Rate/100 Pt Yrs	Rate/100 Pt Yrs
Angina pectoris	68	2.1	1.7	1.8
Dyspnea	57	1.8	1.4	1.8
Myocardial infarction	42	1.3	1.0	0.6
Cardiomegaly	39	1.2	1.0	4.1
Coronary artery disorder	37	1.2	0.9	1.2
Cerebrovascular disorder	34	1.1	0.8	2.4
Peripheral ischemia	28	0.9	0.7	0
Cardiac failure	28	0.9	0.7	0.6
Myocardial ischemia	15	0.5	0.4	0.6
Angina pectoris aggravated	13	0.4	0.3	0
Claudication intermittent	11	0.3	0.3	0
Thrombosis coronary	10	0.3	0.2	0
Pulmonary edema	5	0.2	0.1	0
Cardiac failure left	4	0.1	0.1	0
Cardiac arrest	2	<0.1	<0.1	
Cardiomyopathy	1	<0.1	<0.1	0
Circulatory failure	1	<0.1	<0.1	0
Cardiac failure right	1	<0.1	<0.1	0

**Table 15.9.1b: On-therapy Reports of Edema – Rosiglitazone
Monotherapy**

Preferred Term*	RSG Monotherapy			Placebo
	N = 3172			N = 601
	4095.7 Pt Yrs			169.5 Pt Yrs
	n	%	Rate/100 pt yrs	Rate/100 pt yrs
Total patients with Edema AEs**	338	10.7	9.1	4.8
Edema dependent	163	5.1	4.0	2.4
Edema legs	134	4.2	3.3	1.8
Edema peripheral	35	1.1	0.9	1.8
Edema generalized	31	1.0	0.8	0.6
Edema	14	0.4	0.3	0

* A patient may experience more than one event.

**Patients counted only once, regardless of number of preferred terms

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Table 15.9.2

**Events Rates of On-therapy Reports of Cardiovascular AEs and Edema –
Rosiglitazone with Metformin in Combination**

SB Document Number: BRL-049653/RSD-101VRF/1

**Table 15.9.2a: On-therapy Reports of Cardiovascular Events -
Rosiglitazone and Metformin Combination**

Preferred Term*	RSG + MET			MET
	N = 651			N = 276
	896.1 Pt Yrs			118.9 Pt Yrs
	n	%	Rate/100 Pt Yrs	Rate/100 Pt Yrs
Coronary artery disorder	16	2.5	1.8	0.8
Dyspnea	14	2.2	1.6	4.2
Peripheral ischemia	14	2.2	1.6	1.7
Myocardial infarction	10	1.5	1.1	0.8
Angina pectoris aggravated	9	1.4	1.0	0
Angina pectoris	8	1.2	0.9	0.8
Cerebrovascular disorder	6	0.9	0.7	0.8
Myocardial ischemia	6	0.9	0.7	0
Cardiac failure	5	0.8	0.6	0
Thrombosis coronary	5	0.8	0.6	0.8
Cardiomegaly	3	0.5	0.3	0.8
Claudication intermittent	3	0.5	0.3	0
Cardiac failure left	0	0	0	0
Cardiac arrest	0	0	0	0
Cardiomyopathy	0	0	0	0
Circulatory failure	0	0	0	0
Cardiac failure right	0	0	0	0
Pulmonary edema	0	0	0	0

* In any RSG group, sorted by Safety Update 2000 population.

**Table 15.9.2b: On-therapy Reports of Edema – Rosiglitazone with
Metformin in Combination**

Preferred Term*	RSG + MET			MET
	N = 651			N = 276
	896.1 Pt Yrs			118.9 Pt Yrs
	n	%	Rate/100 Pt Yrs	Rate/100 Pt Yrs
Total patients with Edema AEs**	96	14.8	12.2	4.3
Edema dependent	46	7.1	5.1	0.8
Edema legs	29	4.5	3.2	0.8
Edema peripheral	16	2.5	1.8	1.7
Edema generalized	14	2.2	1.6	0.8
Edema	6	0.9	0.7	0

* A patient may experience more than one event.

** Patients counted only once, regardless of number of preferred terms

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Table 15.9.3

**Events Rates of On-therapy Reports of Cardiovascular AEs and Edema –
Rosiglitazone with Sulfonylurea in Combination**

SB Document Number: BRL-049653/RSD-101VRG/1

**Table 15.9.3a: On-therapy Reports of Cardiovascular Events -
Rosiglitazone and Sulfonylurea Combination**

Preferred Term*	RSG + SU			SU
	N = 1076			N = 903
	1364.6 Pt Yrs			679.6 Pt Yrs
	n	%	Rate/100 Pt Yrs	Rate/100 Pt Yrs
Dyspnea	35	3.3	2.6	1.0
Angina pectoris	21	2.0	1.5	1.0
Myocardial infarction	19	1.8	1.4	1.0
Peripheral ischemia	16	1.5	1.2	1.3
Cardiac failure	15	1.4	1.1	0.4
Coronary artery disorder	13	1.2	1.0	0.2
Angina pectoris aggravated	10	0.9	0.7	0.2
Cerebrovascular disorder	7	0.7	0.5	0.7
Cardiomegaly	5	0.5	0.4	0.7
Myocardial ischemia	4	0.4	0.3	0.2
Thrombosis coronary	3	0.3	0.2	0
Cardiac failure left	3	0.3	0.2	0
Claudication intermittent	2	0.2	0.2	0.6
Cardiomyopathy	2	0.2	0.2	0
Cardiac arrest	1	0.1	0.1	0
Pulmonary edema	1	0.1	0.1	0
Circulatory failure	0	0	0	0
Cardiac failure right	0	0	0	0

**Table 15.9.3b: On-therapy Reports of Edema – Rosiglitazone with
Sulfonylurea in Combination**

Preferred Term*	RSG + SU			SU
	N = 1076			N = 903
	1364.6 Pt Yrs			679.6 Pt Yrs
	n	%	Rate/100 Pt Yrs	Rate/100 Pt Yrs
Total patients with Edema AEs**	105	9.8	8.3	2.2
Edema dependent	47	4.4	3.4	1.2
Edema legs	45	4.2	3.3	0.6
Edema peripheral	19	1.8	1.4	0
Edema generalized	10	0.9	0.7	0.2
Edema	5	0.5	0.4	0.3

* A patient may experience more than one event.

**Patients counted only once, regardless of number of preferred terms

Appendices

Appendix A

	Page
Protocols (including Amendments)	2174
Blank Case Report Form (CRF)	2315
Investigator CVs	2530
Certificates of Analysis	2718

Protocols (including Amendments)

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100TV9/1/CPMS-009

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Rosiglitazone

BRL 49653

**A multicentre, open label extension study to assess the long term safety,
tolerability and efficacy of BRL 49653C when administered to patients with
Non-insulin Dependent Diabetes Mellitus (NIDDM)**

Incorporating Amendment no. 4 (all countries except France)
009

Clinical Protocol



*Clinical R & D, Europe, **Biometrics

SB Document Number: BRL-049653/RSD-100J6W/6

Issue Date: 22nd November 1996
Amended: 11th December 1997, 15th October 1998, 02 December
1999, 14 January 2000

Endorsements



Clinical Unit: Cardiopulmonary Therapeutic Team

Document No.: BRL-049653/RSD-100J6W/6

Drug Name: Rosiglitazone

Compound No: BRL 49653

Protocol Title: A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-insulin Dependent Diabetes Mellitus (NIDDM)

CPMS Number: 049653/009

SB Site Monitor: [REDACTED]

Contact Information:

I, the undersigned, have reviewed this protocol, including Appendices, and I will conduct the clinical study as described and will adhere to the Ethical and Regulatory Considerations stated. I have read and understood the contents of the Investigator Brochure.

, Investigator

Date

Table of Contents

	Page
List of Appendices	5
Synopsis	6
1 Introduction	9
2 Objectives	10
2.1 Primary Objective(s)	10
2.2 Secondary Objective(s)	11
3 Study Design Overview	11
3.1 Study Design	11
3.2 Schedule of Assessments	12
4 Study Population	13
4.1 Planned Number of Subjects	13
4.2 Inclusion Criteria	14
4.3 Exclusion Criteria	14
5 Conduct of the Study	16
5.1 Ethical and Regulatory Considerations	16
5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)	16
5.1.2 Informed Consent	16
5.2 General Instructions	17
5.2.1 Concomitant Diabetes Medications	17
5.2.2 Study Visits	18
5.3 Outline of Study Procedures	19
5.4 Study Procedures	19
5.4.1 Visit 1 - Start of Study	19
5.4.2 Visits 2 to 18 - mid study visits (1 - 45 months)	20
5.4.3 Visit 19 - Final study visit (48 months)	22
5.4.4 Unscheduled Visits	22
5.5 Clinical Observations and Procedures	23
5.5.1 In-clinic dosing	23
5.5.2 Clinical laboratory testing for efficacy and safety	23
5.5.3 Measurement of blood pressure and heart rate	25
5.5.4 ECG measurements	25
5.5.5 Clinical laboratory blood and urine sampling and handling	26
5.5.6 Medical history and diet check	26
6 Study Medication and Administration	27
6.1 Study Medication	27
6.2 Dosage and Administration	27
6.3 Method of Blinding	27
6.4 Packaging	27

6.5	Labelling and Preparation	28
6.6	Storage	29
6.7	Drug Accountability	29
6.8	Assessment of Compliance	29
6.9	Treatment of Study Medication Overdose	30
6.10	Occupational Safety	30
6.11	Concomitant Medication/Treatment	30
7	Outcomes Research and Pharmacoeconomics	31
8	Adverse Experiences	31
8.1	Eliciting and Documenting Adverse Experiences	31
8.2	Assessment of Intensity	33
8.3	Assessment of Causality	33
8.4	Follow-up of Adverse Experiences	34
8.5	Serious Adverse Experiences	34
8.5.1	Definition of Serious Adverse Experiences	34
8.5.2	Reporting Serious Adverse Experiences	36
8.6	Reporting of Overdose	36
8.7	Pregnancy	36
9	Subject Completion and Withdrawal	37
9.1	Definitions	37
9.2	Procedures for Handling Withdrawals	37
9.3	Reasons for Withdrawal	37
10	Data Evaluation	39
10.1	Target Sample Size	39
10.2	Method of Randomization	39
10.3	Planned Efficacy Analysis	39
10.3.1	Primary Efficacy Variables	39
10.3.2	Secondary Efficacy Variables	39
10.3.3	Pharmacodynamic Evaluations	40
10.3.4	Comparison of Interest	40
10.3.5	Methods of Analysis	40
10.3.6	Subject Populations/Dataset to be Analysed	41
10.4	Planned Safety Evaluation	41
10.5	Interim Analysis	42
11	Administrative Matters	42
12	References	43
13	Appendices	44

List of Appendices

	Page
Appendix A Declaration of Helsinki	45
Appendix B Administrative Matters.	50
Appendix C Sample Informed Consent Statement and Patient Information Leaflet	55
Appendix D Outline of Study Procedures.	65
Appendix E Echocardiography Results Table - 49653/006	67
Appendix F1 Definition of NIDDM.	68
Appendix F2 Calculation of Daily Calorific Requirement for Weight Maintenance	69

Synopsis

Compound/Protocol No.

BRL 49653/009

Protocol Title

A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM).

Rationale

The pathophysiology of NIDDM is characterised by aberrant insulin secretion from pancreatic β -cells and/or resistance to the action of insulin in peripheral tissues. Owing to the increased demands it places on insulin secretion, insulin resistance may be responsible for the progression of NIDDM by causing β -cell exhaustion. Insulin resistance is also commonly associated with the cardiovascular risk factors of hyperinsulinaemia, dyslipidaemia and hypertension.

BRL 49653 is a novel, orally active member of the thiazolidinedione class of antidiabetic agents. In animal models it lowers resistance to insulin in peripheral tissues, reducing hyperglycaemia and hyperinsulinaemia, with a concomitant improvement in lipid profile. Its activity in improving glycaemic status and reducing circulating levels of insulin has been confirmed in a large phase II study of NIDDM patients (for more details see [1.0 Introduction](#)).

BRL 49653C does not appear to increase secretion of insulin and hence its use would be expected to avoid the risk of exhausting pancreatic function. Furthermore, it would be predicted not to cause hypoglycaemia (a potential complication of treatment with insulin secretagogues).

BRL 49653 is being evaluated in a number of controlled clinical trials in which the duration of treatment ranges from a matter of weeks to 12 months. NIDDM is a condition requiring treatment over many years and it is necessary to assess the long term safety of the compound.

Objective(s)**Primary**

To evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM.

Secondary

To evaluate the long term efficacy of BRL 49653 in terms of glycaemia. A pharmacodynamic evaluation of lipidaemia will also be performed.

Study Population

Patients who have completed a previous BRL 49653 study and who meet the entry criteria for this study will be invited to participate in this extension study. Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate. It is estimated that between 400 and 1000 patients will enter the study. Approximately 100 centers in Europe will participate.

Safety Parameters

Physical examination
Adverse experiences
Laboratory safety data
ECG parameters
Vital signs (systolic and diastolic blood pressure and heart rate)
Body weight

Efficacy Parameters

Fasting plasma glucose
HbA_{1c}
Fasting plasma insulin (specific)
Urinary albumin (measured as a random sample in clinic at Visits 1, 5 and 7)

Pharmacodynamic Parameters

Fasting lipid levels : (i.e. total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids).

Dosing Schedule

Patients on monotherapy in the previous study will receive BRL 49653 4 mg bd. Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy in the previous study will receive BRL 49653 2 mg bd, in addition to their other hypoglycaemic therapy. For patients on combination therapy the dose of their other hypoglycaemic therapy may be altered during the study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it would improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

1 Introduction

Non-insulin dependent diabetes mellitus (NIDDM) occurs in 5% of 50-year-old-adults and 20% of the 80-year-old population[1] [2]. Aberrant insulin secretion from pancreatic β -cells, insulin resistance in peripheral tissues with reduced glucose uptake (particularly in muscle and liver), and excess hepatic glucose production are the primary pathogenic mechanisms believed to be responsible for the associated metabolic abnormalities[3] [4] [5] [6].

Currently available therapies for NIDDM include insulin and oral hypoglycemic agents (e.g. sulphonylureas, biguanides, and alpha-glucosidase inhibitors). BRL 49653C is a highly potent and orally active anti-diabetic thiazolidinedione compound. The thiazolidinediones represent a novel class of compounds that act as "insulin sensitizers" in target tissues. Unlike sulphonylureas, BRL 49653C has been shown to reduce elevated blood glucose without a concomitant increase in insulin levels.

In animal testing, repeat oral administration of BRL 49653C has been effective in reducing hyperglycemia, hyperinsulinemia, hypertriglyceridemia, and free fatty acids associated with insulin-resistant models of NIDDM. In the genetically obese mouse, the potency of BRL 49653C as an antihyperglycemic agent, was compared with other insulin sensitizers, and BRL 49653C was proven to be at least 100 times more potent than CS-045 (troglitazone) and at least 30 times more potent than pioglitazone. More detailed pre-clinical information is summarised in the Investigational Brochure[7].

As of January 1996, BRL 49653C had been administered to 140 subjects in seven Phase I and Clinical Pharmacology studies. Of these 140 subjects, 91 received one or more single doses of BRL 49653C up to 20 mg. This includes 10 healthy elderly males (≥ 65 years of age). Additionally, 36 obese, non-diabetic males and females received doses of up to 5 mg/day for 10 consecutive days, and 13 NIDDM patients received doses of up to 2 mg/day for seven consecutive days. In general, BRL 49653C was well tolerated when administered as single doses from 0.2 to 20 mg and in doses up to 5 mg when given daily for 10 days. More detailed information is summarised in the Investigational Brochure.

The safety, efficacy, and tolerability of BRL 49653C has been assessed in 379 NIDDM patients in a Phase II, double-blind, placebo controlled dose response study. Of the 379 randomised patients, 75, 73, 72, 79, and 80 patients received twice daily doses of placebo, 0.05 mg, 0.25 mg, 1 mg, and 2 mg, respectively.

Analysis of covariance showed highly significant ($p < 0.001$) treatment effects on lowering fasting plasma glucose (FPG) at twice daily doses of 1 mg and 2 mg. At the higher dose of 2 mg bid, the fasting plasma glucose was reduced by approximately 20% compared to placebo at week 12. The onset of effect was evident by week 1 and the rate of decline continued steadily through week 6. Doses of 0.05 mg bid and 0.25 mg bid were not effective in lowering blood glucose[8]. The decrease in FPG at the higher doses was reflected in lowered serum fructosamine and HgbA_{1C} values at week 12 compared to placebo.

Overall, treatment with BRL 49653C was safe and well tolerated at the twice daily doses of 0.5 mg to 2 mg when compared to placebo. The percentage of patients reporting adverse events in each of the treatment groups (64.6% to 68.4%) was similar to the placebo group (64%). Echocardiography (2D M-Mode) showed no difference in left ventricular mass between the BRL 49653C treatment groups and the placebo group ([Appendix E](#)). A small trend showing reduction in hemoglobin (from 14.5 to 14.3 g/100 ml) and hematocrit was observed at higher doses. The absolute reductions ($< 2\%$ from baseline) were not considered to be of clinical significance.

During the 12-week treatment period, a total of nine serious adverse experiences (SAEs) were reported: There were three SAEs in each of the placebo and 2.0 mg groups and one in each of the 0.05, 0.25 and 1.0 mg groups. Two deaths were reported during the study, both of which were attributed to an acute myocardial infarction. One case, a 52 year old male (2.0 mg group) was designated as possibly related to study medication by the investigator, and the other case, a 71 year old male (0.25 mg group), was considered unrelated to study medication by the investigator. All other SAEs were specified by the investigators as being unrelated to trial medication, apart from 1 case of exercise induced non-sustained ventricular tachycardia in a 56 year old male receiving placebo. Causal relationship was given as possibly related in this case.

Please refer to the Investigator Brochure for a review of the pre-clinical and clinical studies of BRL 49653C.

2 Objectives

2.1 Primary Objective(s)

To evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral

hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM.

2.2 Secondary Objective(s)

To evaluate the long term efficacy of BRL 49653 in terms of glycaemia. A pharmacodynamic evaluation of lipidaemia will also be performed.

3 Study Design Overview

3.1 Study Design

This is a phase IIIA, multicentre, open label, study of BRL 49653C administered to patients with Non-insulin Dependent Diabetes Mellitus. Patients will receive study medication for up to 48 months.

Patients that satisfy the eligibility criteria, ([sections 4.2](#) and [4.3](#)) may enter the study. Each patient will have 15 visits during the study.

Patients on monotherapy in the previous study will receive BRL 49653 4 mg bd. Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy in the previous study will receive BRL 49653 2 mg bd, in addition to their other hypoglycaemic therapy. For patients on combination therapy the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it would improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen. The use of insulin is prohibited during the study.

Doses of BRL 49653C tablets are to be taken one before breakfast (am) and one before their evening meal (pm). Timing of the doses of other hypoglycaemic agents (for patients on combination therapy) will be as per the investigator's normal clinical practice.

Patients will be assessed according to the schedule detailed in Outline of Study Procedures (on the next page), and [section 5.3](#) of the protocol.

3.2 Schedule of Assessments

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 4a#	Visit 5	Visit 5a #	Visit 6	Visit 6a#
	1 mo	2 mo	3 mo	4 mo	6 mo	8 mo	9 mo	10 mo	
Demography	X								
Medical History	X								
Physical examination	X	X	X	X		X		X	
AE check	X ¹	X	X	X		X		X	
BP & HR	X ²	X	X	X		X		X	
ECG	X ²					X			
Weight	X ²			X		X		X	
Compliance		X	X	X		X		X	
Labs (blood & urine) - safety	X ²			X		X		X	
Labs (safety – LFTs)					X		X		X
Labs (blood) - efficacy (FPG, HbA1c)	X ²	X	X	X		X		X	
Labs (blood) - efficacy - (other) ³	X ²					X			
Urine Albumin	X					X			
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X		X		X	

	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
	12 mo	15 mo	18 mo	21 mo	24 mo	27 mo	30 mo	33 mo
Demography								
Medical History								
Physical examination	X	X	X	X	X	X	X	X
AE check	X	X	X	X	X	X	X	X
BP & HR	X	X	X	X	X	X	X	X
ECG	X		X		X		X	
Weight	X	X	X	X	X	X	X	X
Compliance	X	X	X	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X		X	
Urine Albumin	X		X		X		X	
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X	X

	Visit 15 36 mo	Visit 16 39 mo	Visit 17 42 mo	Visit 18 45 mo	Visit 19 48 mo
Demography					
Medical History					
Physical examination	X	X	X	X	X
AE check	X	X	X	X	X
BP & HR	X	X	X	X	X
ECG	X		X		X
Weight	X	X	X	X	X
Compliance	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X
Urine Albumin	X		X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X

If the patient withdraws early, then the Conclusion/Early Withdrawal assessment should be completed.

¹ Adverse events still ongoing at end of the previous study will be recorded at Visit 1 (in the Adverse Experience section).

¹ Concomitant Medication still ongoing at end of the previous study will be recorded at Visit 1 (in the Concomitant Medication section at the end of module 1).

² Where duplicated, Visit 1 assessments will be taken from the final visit for the preceding study.

³ Labs (efficacy - other) = Insulin, Lipids.

#visit 4a = visit 4 + 1 month

#visit 5a = visit 5 + 2 months

#visit 6a = visit 6 + 1 month

4 Study Population

4.1 Planned Number of Subjects

Patients who have completed a previous BRL 49653 study and who meet the entry criteria for this study will be invited to participate in this extension study.

Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate. It is estimated that between 400 and 1000 patients will enter the study.

Approximately 100 centers in Europe will participate.

4.2 Inclusion Criteria

Only patients who fulfil **all** the following criteria will be eligible for inclusion in the study.

- 1 Patients with NIDDM (as defined by the criteria of the National Diabetes Data Group [[Appendix F1](#)]) may enter the study if they have successfully completed a BRL 49653 protocol which specifies the availability of this open label extension study.
- 2 Patients must not have discontinued study medication in the preceding study for more than 10 days.
- 3 Study medication in the preceding study must have been found to be safe and well tolerated throughout its duration by both the investigator and the patient.
- 4 Female patients must be post menopausal, i.e. > 6 months without menstrual period, surgically sterile, or using hormonal contraceptives or intrauterine contraceptive devices. Female patients taking hormonal contraceptives must also use an additional barrier form or intrauterine form of birth control.
- 5 Subjects who have given written informed consent to participate.

4.3 Exclusion Criteria

Use of an investigational drug within 30 days or 5 half-lives (whichever is longer) preceding the first dose of study medication.

A patient will be excluded from the study if any of the following apply:

- 1 Patients who are pregnant or lactating, or who plan for pregnancy within the time frame of the study.
- 2 Patients who experienced any significant and/or serious Adverse Experience during the preceding protocol which, in the opinion of the investigator, could have been attributed to study medication.
- 3 A clinically significant laboratory abnormality was recorded during the preceding protocol which in the opinion of the investigator, would preclude long term treatment with BRL 49653.
- 4 The patient withdrew from the preceding study for any reason.

- 5 Any clinically significant abnormality identified in the end of study assessments for the preceding study (eg physical examination, electrocardiogram, etc. as appropriate) which in the judgement of the investigator would preclude safe completion of this study.
- 6 Symptomatic diabetic neuropathy of sufficient severity to require treatment for control of symptoms (e.g. painful peripheral neuropathy, symptomatic orthostatic hypotension, urinary retention, gastric stasis, pedal ulcers).
- 7 Diabetic retinopathy imminently requiring treatment for preserving or restoring vision.

5 Conduct of the Study

5.1 Ethical and Regulatory Considerations

The study will be conducted according to Good Clinical Practice guidelines and the Declaration of Helsinki, as amended (Protocol [Appendix A](#)).

5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)

ERCs/IRBs must be constituted according to the local laws/customs of each participating country.

This protocol will be submitted to an appropriate Committee or Board and their written unconditional approval obtained and submitted to the sponsor before commencement of the study. SB will supply relevant data for the investigator to submit to the hospital/university/independent ERC/IRB for the protocol's review and approval. Verification of the ERC/IRB's unconditional approval of the protocol and either the written informed consent statement or oral witnessed consent form with written information to be given to the subjects will be transmitted to the SB Study Monitor prior to shipment of drug supplies and CRFs to the site. This approval must refer to the study by exact protocol title and number, identify the documents reviewed and state the date of review.

The ERC/IRB must be informed by the investigator of all subsequent protocol amendments and of serious or unexpected adverse experiences occurring during the study which are likely to affect the safety of the subjects or the conduct of the study. Approval for such changes must be transmitted in writing to the SB Study Monitor via the investigator

5.1.2 Informed Consent

The principles of informed consent in the current edition of the Declaration of Helsinki (Protocol [Appendix A](#)) should be implemented in each clinical study before protocol-specified procedures are carried out.

Information should be given in both oral and written form whenever possible and deemed appropriate by the ERC/IRB. Subjects, their relatives, guardians or, if necessary, legal representatives must be given ample opportunity to enquire about details of the study.

The consent form generated by the investigator with the assistance of SB, must be approved (along with the protocol) by the ERC/IRB and be acceptable to SB. Consent forms must be in a language fully comprehensible to the prospective subject. Where appropriate, informed consent shall be documented by the use of a written consent form approved by the ERC/IRB and signed by the subject or the subject's legally authorised representative.

The written consent document will embody the elements of informed consent as described in the Declaration of Helsinki and will also comply with local regulations. This form may be read to the subject or the subject's legally authorised representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

Consent must be documented either by the subject's dated signature or by the signature of an independent witness who records the subject's assent. In either event, the signature confirms the consent is based on information that has been understood. Each subject's signed informed consent form must be kept on file by the investigator for possible inspection by Regulatory Authorities and/or SB professional and Regulatory Compliance persons.

A sample Informed Consent form is attached as [Appendix C](#).

5.2 General Instructions

5.2.1 Concomitant Diabetes Medications

The use of insulin is prohibited during the study.

Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

For patients on combination therapy, the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it is necessary in order to improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

5.2.2 Study Visits

Patient visits should be scheduled to occur in the morning. Patients are to be instructed to fast (i.e., refrain from eating and drinking) from 11:00 PM on the night before their visit until after blood specimen collection for clinical laboratory evaluation has been completed. Water consumption is permitted during the fasting period.

Laboratory assessments must be completed in the fasting condition. At any clinic visit, if the patient is not in a fasted condition, specimens for laboratory assessments are not to be collected. The patient should return to the clinic the following day in a fasted condition for laboratory specimen collection. Non-fasting blood samples should only be taken at scheduled visits if the patient is unable to return to the clinic the following day. The investigator must stress to the patient the importance of attending scheduled visits in a fasted state. Non-fasting blood samples will only be used in the analysis for parameters which are not affected by the fed/fasted state.

All laboratory samples will be sent by courier to a central laboratory (SmithKline Beecham Clinical Laboratories). Full guidance, training, and materials for storage and transportation of samples will be provided to all centres. Normal methods and quality control used for the tests will be provided for the sponsor by SmithKline Beecham Clinical Laboratories.

Any result which falls outside the laboratory normal range will be considered abnormal. The investigator will indicate if this value is clinically significant. All laboratory tests with clinically abnormal values (i.e., beyond those expected with patients with NIDDM of this age group) occurring during the study will be repeated until the values return to normal. If this does not occur within a reasonable time, then the etiology will be identified and the sponsor informed.

Patients should be instructed **not** to take their morning dose of study medication on all study visit days, since they will be given this dose after all fasting laboratory specimens have been collected. Patients are to be reminded to bring their remaining study medication with them on study visit days.

As indicated above, for patients on combination therapy the investigator may alter the dose of the non-BRL 49653 hypoglycaemic agent if it is deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment. In order to ensure patient safety, the investigator should follow his/her normal

practice when making such a dose adjustment with respect to when the patient is next reviewed, arranging additional, unscheduled visits if necessary.

If a patient withdraws from the study before visit 19 then the Conclusion/Early Withdrawal assessment and the Study Conclusion/Withdrawal section should be completed in the case report form (CRF).

5.3 Outline of Study Procedures

Please refer to [Appendix D](#).

5.4 Study Procedures

Liver function test monitoring

Visits 1, 4, 4a, 5, 5a, 6, 6a, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 (1, 3, 4, 6, 8, 9, 10, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42, 45 months of treatment)

Liver function tests (i.e ALT, AST, alkaline phosphatase and total bilirubin) should be reviewed at each of the above visits.

- If ALT is > 3 times the upper limit of normal range, an evaluation of viral hepatitis (A, B and C) should be performed and liver function tests should be re-assessed within 1 week. If ALT remains > 3 times the upper limit of normal range, the patient should be withdrawn.

Visit 19 (48 months of treatment)

If ALT is > 3 times the upper limit of normal range, an evaluation of viral hepatitis (A, B and C) should be performed and liver function tests should be re-assessed within 1 week.

5.4.1 Visit 1 - Start of Study

At Visit 1 the investigator should perform the following:

- Obtain patient's written informed consent.
- Confirm the patient's eligibility and complete the checklist of the inclusion and exclusion criteria.

- Physical examination including standardized measurement of blood pressure, heart rate (Refer to [section 5.5](#)) and a pregnancy test (non-post menopausal women only).
- Measure body weight (without shoes).
- Take fasting blood and urine laboratory specimens ([section 5.5](#)).
- Check the patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#)).
- Standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patients case report form).

Where the above assessments duplicate those being performed on the same day as part of the final visit of the previous study, the results can be transcribed into the CRF for this study without having to re-perform the assessment.

Patients should be dispensed 5 weeks of treatment with BRL 49653 and instructed how to take it.

Visit 2 should be scheduled for 1 month $\pm$ 7 days' time. Patients should be instructed to bring all remaining study medication with them to each study visit.

5.4.2 Visits 2 to 18 - mid study visits (1 - 45 months)

General Instructions

Visits 2, 3 and 4 should be scheduled after 1, 2 and 3 months $\pm$ 7 days of treatment, respectively. Visits 5 to 18 should be scheduled after 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42 and 45 months $\pm$ 14 days of treatment (see outline of study procedures - [Appendix D](#)).

At each visit :

- Check the patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#)).
- Take fasting blood laboratory specimens for efficacy assessment of FPG and HbA1c ([section 5.5](#)).
- Check FPG results from the previous visit to ensure that they are no greater than 15 mmol/L in the first 3 months and no greater than 12 mmol/L in the remainder of the study (see [9.3 Reasons for Withdrawal](#))

- Standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#))
- Check compliance
- Check concomitant medication.
- Check for any adverse experiences.
- Schedule the next visit and dispense BRL 49653 medication (5 weeks of medication at visits 2 and 3; 15 weeks of medication at visits 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18).

Patients should be instructed to bring all remaining study medication with them to **each** study visit.

Additional visits (visit 4a, 5a, 6a) should be scheduled after visit 4 (+1 month), visit 5 (+2 months) and visit 6 (+1month) $\pm$ 14 days of treatment. These additional visits will be scheduled to allow an extra safety blood sample to be taken for liver function testing. No further assessments will be performed at these visits.

Visit-Specific Instructions

Visits 4, 6, 8, 10, 12, 14, 16 and 18 (3, 9, 15, 21, 27, 33, 39 and 45 months' treatment)

At Visits 4, 6, 8, 10, 12, 14, 16 and 18 in addition to the assessments listed under 'General Instructions' above, the investigator will:

- Weigh the patient (without shoes).
- Take fasting blood and urine laboratory specimens for safety assessment ([section 5.5](#)).

Visits 5, 7, 9, 11, 13, 15 and 17 (6, 12, 18, 24, 30, 36 and 42 months' treatment)

At Visits 5, 7, 9, 11, 13, 15 and 17 in addition to the assessments listed under 'General Instructions' above, the investigator will:

- Weigh the patient (without shoes).

- Take fasting blood and urine laboratory specimens for safety assessment, for 'efficacy - other', i.e. insulin and lipids and for urinary albumin ([section 5.5](#)).
- Perform a standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patients case report form).

5.4.3 Visit 19 - Final study visit (48 months)

At the final visit, Visit 19, (48 months) the following procedures will be performed:

- Physical examination including standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#)).
- Body weight (without shoes).
- Fasting blood and urine laboratory specimens for safety assessment, for FPG and HbA1c, for 'efficacy - other', i.e. insulin and lipids and for urinary albumin ([section 5.5](#)).
- Diet check, since previous.
- Standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#)).
- Standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patients case report form).
- Concomitant medication check.
- Check compliance
- Adverse experience check.
- Study conclusion record.

Note: Protocol-specified birth control methods must be continued for a minimum of 30 days after the patient receives the last dose of study medication.

5.4.4 Unscheduled Visits

For patients on combination therapy, the investigator may alter the dose of the non-BRL 49653 hypoglycaemic agent if it is deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment.

In order to ensure patient safety, the investigator should follow his/her normal practice when making such a dose adjustment with respect to when the patient is next reviewed, arranging additional, unscheduled visits if necessary. All unscheduled visits will be recorded in the Unscheduled Visit section of the case report form.

5.5 Clinical Observations and Procedures

5.5.1 In-clinic dosing

Patients should be scheduled to attend study visit days in the morning (AM). Each patient should be fasting, (i.e. nothing to eat or drink since 11pm the night before), and should not have taken their morning dose of study medication. After all clinical laboratory tests are completed in the fasting condition, the patient will be dosed in the clinic from the supply of study medication.

5.5.2 Clinical laboratory testing for efficacy and safety

The following **fasting** laboratory tests will be performed at the times specified in the protocol:

SafetyBiochemistry

Total Protein	LDH	Uric Acid	Potassium	γ GT
Albumin	Total Bilirubin	Calcium	Chloride	
ALT (SGPT)	Urea Nitrogen	Phosphorus	Bicarbonate	
AST (SGOT)	Creatinine	Sodium	Alkaline Phosphatase	

Haematology

Platelet Count	<i>RBC Indices:</i>	<i>WBC Differential:</i>
RBC Count	MCV	Neutrophils
Haemoglobin	MCH	Lymphocytes
Haematocrit	MCHC	Monocytes
Reticulocyte count	WBC Count	Eosinophils
	Basophils	

Urinalysis

Appearance	Glucose	WBCs / HPF
Specific Gravity	Ketones	Squamous Epithelial Cells
pH	Occult Blood	
Protein	RBCs / HPF	

Hepatitis testing*

Hep A antibody total
Hep B antibody total
Hep C antibody

Efficacy

Plasma Glucose
Haemoglobin A1c
Specific insulin levels
Urinary albumin (spot sample)

Pharmacodynamic*Lipid levels:*

Total Cholesterol
HDL Cholesterol
LDL Cholesterol
Triglycerides
Free Fatty Acids

*to be performed if ALT > 3 times upper limit of normal range

A central laboratory will be used for the routine haematological and biochemical assessments. All centres within a country should send their samples to this designated laboratory. Samples must be **clearly labelled** with the patient's number, initials, protocol number, centre number, visit number and date. Full details for the preparation and shipment of samples will be provided by the central laboratory to the Investigator before the start of the study.

All laboratory tests with values that become significantly abnormal after study drug administration should be repeated until the values return to normal (or baseline). Abnormal laboratory values should only be recorded as an Adverse Experience if symptomatic or if potentially life threatening without symptoms or if deemed appropriate by the Investigator. If such values do not return to normal within a period judged reasonable by the Investigator, the etiology should be identified and the Sponsor notified.

5.5.3 Measurement of blood pressure and heart rate

The plethysmographic method (with a mercury column sphygmomanometer) must be used to measure blood pressure throughout the study. All measurements will be made on the patient's non-dominant arm supported at heart level, using the same cuff size. If the patient's arm circumference is > 32 cm, a large blood pressure cuff should be used. Diastolic blood pressure will be measured at the disappearance of Korotkoff sounds - phase V. If possible, measurement will be taken by the same staff member at each visit.

Blood pressure and heart rate will be measured after the patient sits quietly for at least 5 minutes.

5.5.4 ECG measurements

A 12-lead ECG will be recorded at Visits 1, 5, 7, 9, 11, 13, 15, 17 and 19 i.e. after 0, 6, 12, 18, 24, 30, 36, 42 and 48 months. Atrial and ventricular rate, PR, QRS and QT intervals, and axis deviation will be recorded in the CRF. A sample of each ECG recorded, clearly labelled with patient initials, patient number (if randomised), protocol number, centre number and date taken will be inserted into the appropriate plastic wallet in the CRF. All clinically significant abnormalities found at baseline should be documented, and any clinically significant ECG abnormalities occurring during the study should be documented on the adverse experience forms ([Section 8.0](#)).

5.5.5 Clinical laboratory blood and urine sampling and handling

At each study visit (visits 1 to 19), approximately 30 ml of blood will be obtained from an arm vein and collected into colour coded sample collection tubes. Samples will be obtained prior to dosing and the exact time of sample collection and the time of administration of the dose will be recorded on the CRF.

No more than one hour should elapse between blood withdrawal and freezing of the separated plasma. Blood samples will be centrifuged for approximately 15 minutes at approximately 4°C. If a refrigerated centrifuge is not available, the blood samples should be processed as quickly as possible and not left standing at room temperature. The plasma will be transferred to a plain polypropylene tube labelled with the following information: Study centre number, patient number, week of study, date, and time of sample. Plasma samples will be stored frozen at approximately -70°C to await assay. If -70°C facilities are not available, then samples must be stored at -20°C and collected arranged with SmithKline Beecham Clinical Laboratories (SBCL) as soon as possible. Urine specimens will be collected at visits 1, 4, 5, 6 and 7. Urine samples will be sent to SBCL for albumin analysis. SBCL will provide the handling and transportation of the drug specimens to the central laboratory. As appropriate, urine will also be tested at each visit to check for pregnancy (women only). The investigator must read the laboratory manual for specific sampling and handling procedures.

5.5.6 Medical history and diet check

All relevant previous medical history will not need to be recorded again at Visit 1. This information was recorded on the case record form from the previous study. However, any new medical history will be documented at subsequent visits (including Visit 1). Standard medical terminology will be used to record all current conditions by diagnosis. Following the diet check at visit 1, instruction should only be given/repeated for patients who demonstrate a lack of understanding of their diet. At each subsequent visit, the patient must be encouraged to comply with their weight maintenance diet.

6 Study Medication and Administration

6.1 Study Medication

BRL 49653C will be supplied by SmithKline Beecham in the form of 2 mg tablets. For patients for whom the BRL 49653 is being added to pre-existing oral hypoglycaemic agents (i.e. the patients on combination therapy) the non-BRL 49653C agent will continue to be supplied by individual study centres.

The BRL 49653C 2 mg will be supplied as white, bi-convex, film coated (7 mm) tablets.

6.2 Dosage and Administration

The investigator must complete the number of tablets in the blank spaces before dispensing the study medication. Dosing instructions will be as follows:

Take tablet(s) in the morning **BEFORE** breakfast and tablet(s) in the evening **BEFORE** a meal.

On the morning of a clinic visit do not take any medication.

Return all empty medication packs and remaining medication at the next clinic visit.

6.3 Method of Blinding

The study will not be blinded, study medication (BRL 49653) will be provided open label.

6.4 Packaging

Study medication will be presented in HDPE bottles which will contain an overage for each period of the study, to allow for some flexibility of the intervals between visits.

Medication for each patient will be packed in bottles containing: 70 x BRL 49653 2 mg tablets

The following number of containers will be dispensed to the patient at each visit:

Visit	Period of treatment	No of tablets to dispense - 2mg bd	No of tablets to dispense - 4mg bd
1	4wks $\pm$ 7 days	1 x 70	2 x 70
2	4wks $\pm$ 7 days	1 x 70	2 x 70
3	4wks $\pm$ 7 days	1 x 70	2 x 70
4	3months $\pm$ 2 weeks	3 x 70	6 x 70
5	3months $\pm$ 2 weeks	3 x 70	6 x 70
6	3months $\pm$ 2 weeks	3 x 70	6 x 70
7	3months $\pm$ 2 weeks	3 x 70	6 x 70
8	3months $\pm$ 2 weeks	3 x 70	6 x 70
9	3months $\pm$ 2 weeks	3 x 70	6 x 70
10	3months $\pm$ 2 weeks	3 x 70	6 x 70
11	3months $\pm$ 2 weeks	3 x 70	6 x 70
12	3months $\pm$ 2 weeks	3 x 70	6 x 70
13	3months $\pm$ 2 weeks	3 x 70	6 x 70
14	3months $\pm$ 2 weeks	3 x 70	6 x 70
15	3months $\pm$ 2 weeks	3 x 70	6 x 70
16	3months $\pm$ 2 weeks	3 x 70	6 x 70
17	3months $\pm$ 2 weeks	3 x 70	6 x 70
18	3months $\pm$ 2 weeks	3 x 70	6 x 70

For patients for whom the BRL 49653 is being added to pre-existing oral hypoglycaemic agents (i.e. the patients on combination therapy) the non-BRL 49653C agent will continue to be supplied by individual study centres.

6.5 Labelling and Preparation

A two-panel double-blind label consisting of a fixed portion and a tear-off portion will be attached to each study medication pack. The Investigator or his/her designate will remove the tear-off label from each pack at the time of dispensing and attach it to the appropriate page in the CRF.

Labels will contain:

- patient identification (to be added at time of dispensing)
- protocol number
- clinical trial supply job number
- dosage directions
- expiry date (*only if required by local regulations*)
- any locally required regulatory statements
- Keep out of reach of children

- For Clinical Trial Use Only
- SB address

6.6 Storage

Study medication will be stored between 15°C and 30°C in a secured, supervised location. A log for recording receipt of and use of study medications will be maintained by the designated personnel at the investigator site.

6.7 Drug Accountability

At the time of delivery of medication to the study site, the Investigator or his/her designate or pharmacist (where appropriate) will sign a Drug Receipt Form to confirm that the supplies for the study have been received. This will specify job or lot numbers, quantities shipped/delivered and the date of receipt. The form will also contain a statement confirming that the investigational products will be handled and stored safely and properly. The investigator/pharmacist must also ensure that the investigational products will only be dispensed to patients in accordance with the protocol, and that any unused products, including placebo, will be returned to SB.

The Investigator or his/her designate or pharmacist (where appropriate) will record all study medication dispensed on a Drug Accountability Form. At the end of the study, reconciliation must be made between the amount of medication supplied, dispensed and subsequently returned to SB. Any discrepancies must be accounted for. A certificate of return must be signed incorporating the assurance from the Investigator or Pharmacist that all used and unused investigational products have been returned. Supplies will in the majority of cases, be returned to the local SB site for subsequent destruction. In exceptional cases, supplies may be destroyed at the centre. Destruction should only be performed by authorised personnel who are aware of any possible hazardous effects and following receipt of written approval from the local SB office. The procedure should be documented in full, in writing.

6.8 Assessment of Compliance

The number of BRL 49653 tablets dispensed at each clinic visit will be recorded and patient will be instructed to return any unused drug at the next visit. Counts

of tablets returned will be made at the beginning of Visits 2 to 19. Compliance will be calculated for BRL 49653 tablets as follows:

$$\frac{\{\text{No. dispensed} - \text{No. returned}\}}{Y \times \{\text{No. days since the last visit}\}} \times 100$$

where Y = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)
where Y = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

6.9 Treatment of Study Medication Overdose

The dose of BRL 49653C considered to be an overdose has not been defined. Treatment of suspected or confirmed overdose should be symptomatic.

For reporting of overdosage, see [section 8.6](#).

6.10 Occupational Safety

Study drugs are not expected to pose significant occupational safety risks to investigational staff under normal conditions of use and administration. However, precautions should be taken to avoid direct skin contact, eye contact and generating aerosols or mists. In case of unintentional occupational exposure, treat as if the material contained the active pharmaceutical even though it is absent from placebo formulations. A Material Safety Data Sheet (MSDS) describing occupational hazards and recommended handling precautions for the active formulated pharmaceutical(s) as well as the placebo are available upon request by contacting [REDACTED]. In case of occupational exposure, contact the site monitor or medical monitor for the study.

6.11 Concomitant Medication/Treatment

The use of insulin is prohibited during the study.

Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

For patients on combination therapy, the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for

example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it is necessary in order to improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

The use of fibrates or statins will be allowed without restriction during the study. Dosage levels of all other concomitant medications should, if medically appropriate, remain unchanged while the patient is enrolled in the study. All concomitant medication taken during the study must be recorded in the case report form with indication, daily dose and dates of administration. If dosage change of concomitant medication is necessary, information pertaining to the change must also be documented on the patient's case report form (concomitant medication pages).

Rosiglitazone, like other thiazolidinediones, causes mild fluid retention in some patients which is generally responsive to loop diuretics. This should be taken into account when managing patients with fluid retention.

7 Outcomes Research and Pharmacoeconomics

Outcomes research and pharmacoeconomics will not be analysed in this study.

8 Adverse Experiences

The recording of adverse experiences is an important aspect of study documentation. Detailed guidelines are set out below.

8.1 Eliciting and Documenting Adverse Experiences

It is the responsibility of the investigator to document all adverse experiences which occur during the investigation.

An adverse experience includes any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical study whether associated with the study medication, active comparator or placebo and whether or not considered drug related. This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the

significant worsening of the disease under investigation that is not recorded elsewhere in the case record form under specific efficacy assessments. Anticipated day-to-day fluctuations of pre-existing conditions, including the disease under study, that do not represent a clinically significant exacerbation or worsening need not be considered adverse experiences. Discrete episodes of chronic conditions occurring during a study period should be reported as adverse experiences in order to assess changes in frequency or severity.

Adverse experiences should be documented in terms of a medical diagnosis(es). When this is not possible, the adverse experience should be documented in terms of signs and/or symptoms observed by the investigator or reported by the patient at each study visit.

Any pre-existing conditions or signs and/or symptoms present in a patient prior to the start of the study should be recorded on the Medical/Surgical history form within the patient's case report form (CRF).

Adverse experiences which occur after informed consent is obtained, but prior to starting active or randomised treatment will be documented on the 'Baseline signs and symptoms' report form as instructed by the SB clinical study monitor. All adverse experiences occurring after administration of the first dose of study medication (i.e., active drug, placebo, comparator drug) and on or before the final visit, must be reported on the Adverse Experience form in the subject's CRF. All subsequent adverse experiences, whether no drug (i.e. during reference 'run-in' or 'wash-out' period) or when active drug or placebo is being administered, must be reported **REGARDLESS OF WHETHER OR NOT THEY ARE CONSIDERED DRUG RELATED**.

Serious adverse experiences which occur during the clinical study or within 30 days or five half lives, whichever is the longer, of receiving the last dose of study medication, whether or nor related to study drug, must be reported.

Instances of death, cancer or congenital abnormality if brought to the attention of the Investigator **AT ANY TIME** after cessation of study medication **AND** considered by the Investigator to be possibly related to study medication, should be reported to the Study Monitor.

At each visit/assessment, adverse experiences will be evaluated by the Investigator. Adverse experiences not previously documented in the study will be recorded in the adverse experience record form within the patient's CRF. The nature of each experience, date and time (where appropriate) of onset, outcome, course (i.e. intermittent or constant), maximum intensity, action taken with respect

to dosage and relationship to treatment should be established. Details of changes to the dosage schedule or any corrective treatment should be recorded on the appropriate pages of the CRF.

Adverse experiences already documented in the CRF (i.e., at a previous assessment) and designated as 'ongoing' should be reviewed at subsequent visits as necessary. If these have resolved, the documentation in the CRF should be completed. If an adverse experience increases in frequency or severity during a study period, a new record of the experience will be started.

For studies in which there is a delay of greater than 30 days between dosing, and during this time no protocol specific procedures required (e.g. vaccine studies), adverse experiences will be recorded for a period of 30 days only after each dosage administration (See [section 8.5](#) for qualification with regard to serious AEs).

As a consistent method of soliciting AEs, ask the subject a non-leading questions such as:

"Have you felt different in any way since starting the new treatment/or since the last visit?"

8.2 Assessment of Intensity

Maximum intensity should be assigned to one of the following categories:

Mild: An adverse experience which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: An adverse experience which is sufficiently discomforting to interfere with normal everyday activities.

Severe: An adverse experience which prevents normal everyday activities.

8.3 Assessment of Causality

Every effort should be made by the investigator to explain each adverse experience and assess its relationship, if any, to study drug treatment. Causality should be assessed using the following categories: not related, unlikely, suspected (*reasonable possibility*), probable.

Not related: The adverse experience is definitely not related to the test drug.

Unlikely: There are other, more likely causes and the drug is not suspected as a cause.

Suspected (*reasonable possibility*): A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but *there is a reasonable possibility that the experience was caused by the drug*.

Probable: There *probably* is a direct cause and effect relationship between the adverse experience and the study drug.

The degree of certainty with which an adverse experience is attributed to drug treatment (or alternative causes, e.g. natural history of the underlying diseases, concomitant therapy, etc.) will be determined by how well the experience can be understood in terms of one or more of the following:

- Known pharmacology of the drug.
- Reaction of similar nature being previously observed with this drug or class of drug.
- The experience having often been reported in literature for similar drugs as drug related e.g. skin rashes, blood dyscrasia.
- The experience being related by time to drug ingestion terminating with drug withdrawal (dechallenge) or reproduced on rechallenge.

8.4 Follow-up of Adverse Experiences

Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilized. Reports relative to the subsequent course of an AE noted for any subject must be submitted to the clinical study monitor.

8.5 Serious Adverse Experiences

8.5.1 Definition of Serious Adverse Experiences

A serious adverse experience is any event which is fatal, life threatening, disabling/incapacitating or results in hospitalisation, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or

intentional). In addition any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug will be documented as a serious event.

Life threatening - definition:

An adverse experience is life threatening if the subject was at immediate risk of death from the event as it occurred (i.e., it does not include a reaction that if it had occurred in a more serious form might have caused death). For example, drug induced hepatitis that resolved without evidence of hepatic failure would not be considered life threatening even though drug induced hepatitis can be fatal.

Disability/incapacitating - definition:

An adverse experience is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the subject's ability to carry out normal life functions.

Hospitalisation - definition

AEs requiring hospitalisation should be considered serious. Hospitalisation for elective surgery or routine clinical procedures that are not the result of an AE (e.g., elective surgery for a pre-existing condition) need not be considered AEs and should be recorded on the medical/surgical procedures form. If anything untoward is reported during the procedure, that occurrence must be reported as an AE, either 'serious' or 'non-serious' according to the usual criteria.

In general, hospitalisation signifies that the subject has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out-patient setting. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE should be considered serious.

Routine Clinical Procedure - definition

One which is defined in the protocol as a procedure which may take place during the study period and should not interfere with the study drug administration or any of the ongoing protocol specific procedures.

8.5.2 Reporting Serious Adverse Experiences

Any serious adverse experiences which occur at any time during the clinical study or within 30 days or five half lives, whichever is the longer, of receiving the last dose of study medication, whether or not related to the study medication, must be reported by the investigator to the study monitor by telephone within 24 hours:

Investigators should not wait to receive additional information to fully document the event before notifying SmithKline Beecham of a serious adverse experience. The telephone report should be followed by a full written summary utilising the SB serious AE worksheet detailing relevant aspects of the adverse experiences in question. Where applicable, information from relevant hospital case records and autopsy reports should be obtained.

Instances of death, cancer or congenital abnormality if brought to the attention of the Investigator AT ANY TIME after cessation of study medication AND considered by the Investigator to a previous clinical trial, should be reported to the site monitor.

8.6 Reporting of Overdose

Any instance of overdosage (suspected or confirmed and irrespective of whether or not it involved study medication) must be communicated to SmithKline Beecham within 24 hours and be fully documented as a serious adverse experience. Details of any signs or symptoms and their management should be recorded including details of any antidote(s) administered.

8.7 Pregnancy

Subjects who become pregnant during the study should discontinue the study immediately, unless the protocol states otherwise. Subjects should be instructed to notify the investigator if it is determined after completion of the study that they become pregnant either during the treatment phase of the study or within 30 days (or five half-lives after the treatment period) whichever is longer. Whenever possible a pregnancy should be followed to term, any premature terminations reported, and the status of the mother and child should be reported to SmithKline Beecham after delivery.

9 Subject Completion and Withdrawal

9.1 Definitions

- All patients will be considered to have completed the current study upon completion of 48 months' treatment and of the assessments and procedures scheduled at Visit 19.
- Any patient who enters the study, (i.e. gives written informed consent) but does not, **for any reason** complete the study according to the definition given above, will be considered as a withdrawal, irrespective of whether they have received any study medication.

9.2 Procedures for Handling Withdrawals

Bottles of medication assigned to patient(s) who have been withdrawn, and which have been opened, will not be re-used.

Patients who terminate their participation in the study due to adverse experiences should be followed up as appropriate ([Section 8.4](#)) in order to determine the final outcome.

All patients who withdrew or are withdrawn from the study after receiving study medication should return for a follow-up visit wherever possible and the Conclusion/Early Withdrawal assessment and procedures should be completed in the CRF.

Case Report Forms of **all** patients entered into the study must be kept and the reasons for withdrawal will be noted on the Study Conclusion page for all enrolled patients who do not complete the study. In addition, the date of last dose of study medication must be recorded on the Study Conclusion page for all patients withdrawn from the study.

9.3 Reasons for Withdrawal

Every effort must be made by the Investigator to keep patients in the study. However, a patient may be discontinued prior to completion of the study for the following reasons:

- Adverse experience (see [Section 8.0](#)). NB a patient with clinical evidence of anaemia experiencing angina or exacerbation of pre-existing angina should be withdrawn from the study.
- Lack of efficacy (i.e. insufficient therapeutic effect), as defined below:
 - Patients with a fasting plasma glucose ≥ 15 mmol/L on 2 consecutive occasions at any time during the first 3 months of treatment (the second test to be performed within 7 days of recording a value of 15 mmol/L).
 - For months 3-48 of treatment, patients with a fasting plasma glucose ≥ 12 mmol/L on 2 consecutive occasions (the second test to be performed within 7 days of recording a value of 12 mmol/L).
 - Fasting blood glucose has increased to a level that is deemed by the investigator to be a safety risk to the patient.
 - Patients will be withdrawn if they require insulin.
 - Any other metabolic disorder deemed by the investigator to be a safety risk to the patient.
- A protocol violation, including lack of compliance visit schedule or treatment prohibited concomitant medications.
- Patient lost to follow-up.
- The patient requested an early discontinuation.
- Termination of the study by SmithKline Beecham.
- Other (reason to be documented in the CRF).

All adverse experiences leading to withdrawal of a patient must be fully documented and followed-up as appropriate (see [Section 8.0](#)). To ensure that all withdrawals due to Adverse Experiences are correctly identified, "Adverse Experience" should only be checked as the reason for withdrawal on the Study Conclusion page for those patients for whom an Adverse Experience was considered to be the direct cause of the patient withdrawing from the study. This is particularly important when Adverse Experiences are ongoing at the time of withdrawal but the reason for withdrawal is not related to the Adverse Experiences.

10 Data Evaluation

The primary objective is to evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM. The secondary objective is to evaluate the long term efficacy of BRL 49653 in terms of glycaemia and lipidaemia.

10.1 Target Sample Size

Patients who have completed a previous BRL 49653 study and who meet the eligibility criteria for this study will be invited to participate in this extension study. Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate, if eligible. It is estimated that between 400 and 1000 patients will enter the study. Approximately 100 centers in Europe will participate.

10.2 Method of Randomization

Treatment allocation is not randomised.

10.3 Planned Efficacy Analysis

10.3.1 Primary Efficacy Variables

The primary efficacy variable is change from baseline in HbA_{1c} at month 48. There are 2 baselines: open-label baseline and double-blind baseline. Double-blind baseline is defined as the baseline before the double-blind medication was issued in the previous study. Because all assessments should be performed before open-label medication is issued, open-label baseline will be defined as those results obtained on the first day of open-label medication but prior to the ingestion of medication. If test results are not available for the first day of open-label medication, then the values obtained on the nearest preceding date will be considered as open-label baseline.

10.3.2 Secondary Efficacy Variables

The secondary efficacy variables are analysed as change from baseline at month 48 (as defined in [10.3.1](#)) for:

fasting plasma glucose
fasting specific insulin levels
urinary albumin

10.3.3 Pharmacodynamic Evaluations

For all pharmacodynamic parameters (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids), summary statistics at each visit will be produced.

Summary statistics for percent change from baseline and change from baseline will be calculated for total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids; change from baseline will be calculated for total cholesterol/HDL ratio, LDL/HDL ratio.

For patients with triglycerides >400mg/dL at any scheduled visit, LDL-cholesterol (and related ratios) will be excluded from the summaries described above.

10.3.4 Comparison of Interest

Because this study consists of a non-randomised, pre-selected population of patients all receiving BRL 49653, hypothesis testing will not be performed. However, patients will be grouped according to whether they are receiving BRL 49653 4 mg bd as monotherapy or 2 mg bd in combination with another oral hypoglycaemic agent. In addition, these groups will be presented according to the treatment they received in the preceding protocols. See [table](#) below using protocol 49653/020 as an example of the previous protocol (in protocol 49653/020 patients are randomised to receive monotherapy BRL 49653 4 mg bd, 2 mg bd or glibenclamide).

Treatment Group	BRL49653 Dose rotocol 020	BRL 49653 Dose Protocol 009
020 2 mg/4 mg	020 2 mg bid	4 mg bid
020 4 mg/4 mg	020 4 mg bid	4 mg bid
020 glibenclamide/4 mg	020 glibenclamide	4 mg bid

10.3.5 Methods of Analysis

Descriptive statistics for each treatment group will be used to summarise the efficacy variables. For each time period, graphs will be constructed for mean change in efficacy variables from baseline (as defined in [10.3.1](#)). Time periods

will be defined as relative time from the double blind baseline in the previous study.

10.3.6 Subject Populations/Dataset to be Analysed

Data will be analysed with the patients who take at least one dose of study medication after entering the study. The interim analysis will be done for the same patient population. Missing values will be kept missing (last value will not be carried forward).

10.4 Planned Safety Evaluation

Evaluation of safety data will include all patients who received study medication. Clinical interpretation will be based upon review of displays of adverse events and laboratory values. Principal considerations in this evaluation will be time to onset, and investigator-reported relationship of either adverse events or laboratory abnormalities to study medication. Other safety parameters, such as patient withdrawals, ECGs, and laboratory values, will be summarised.

Adverse experiences documented in the previous protocols as 'continuing at end of study' will be transcribed onto the 49653/009 case report form. Because the onset of these experiences will have been prior to the start of open-label medication, these experiences will be considered as pre-therapy for reporting of 49653/009 data.

Body weight and vital signs (i.e. systolic, diastolic blood pressure and heart rate), and ECGs will be analysed as change from baseline at month 48.

Reports of hypoglycaemia will be grouped into:

- Adverse event reports of hypoglycaemia.
- Adverse event reports of hypoglycaemia plus a plasma glucose of < 50 mg/dL.
- Adverse event reports of hypoglycaemia with third party intervention/hospitalisation.

These will be summarised across the treatment groups as part of the safety assessment.

10.5 Interim Analysis

For administrative reasons, interim descriptions of the data will be required prior to the NDA/MAA filing.

However, there is no intention to stop the study based on these interim descriptions of the data.

The analyses for these interim descriptions will be performed as described above (10.0 - 10.4) using the data that has been collected at the time of the clinical cut-off.

11 Administrative Matters

To comply with Good Clinical Practice Guidelines, important administrative obligations relating to Investigator responsibilities, monitoring, archiving data, audits, confidentiality and publications must be fulfilled as given in [Appendix B](#).

12 References

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CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

CONFIDENTIAL

BRL-049653/RSD-
100J6W/6

13 Appendices

Appendix A Declaration of Helsinki

World Medical Association DECLARATION OF HELSINKI

Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects

Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964
and amended by the
29th World Medical Assembly
Tokyo, Japan, October 1975
35th World Medical Assembly
Venice, Italy, October 1983
41st World Medical Assembly
Hong Kong, September 1989
and the
48th General Assembly
Somerset West, Republic of South Africa, October 1996.

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human

subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In

that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity make it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replace that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the

experimental protocol for transmission the independent committee (see [1,2](#)).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers -- either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Appendix B Administrative Matters

I Responsibilities Of The Investigator

To ensure that he/she has sufficient time to conduct and complete the study, and has adequate staff and appropriate facilities which are available for the duration of the study, and to ensure that other studies do not divert essential subject/patients or facilities away from the study at hand.

To submit an up-to-date curriculum vitae and other credentials (e.g. medical license number in the United States) to the sponsor and - where required - to relevant authorities.

To acquire the normal ranges for laboratory tests performed locally and, if required by local regulations, obtain the Laboratory Licence or Certification.

To prepare and maintain adequate case histories designed to record observations and other data pertinent to the study.

II Protocol Amendments

No changes to the study protocol will be allowed unless discussed in detail with the SmithKline Beecham (SB) Medical Monitor and filed as an amendment/modification to this protocol.

Any amendment/modification to the protocol will be adhered to by the participating centre (or all participating centres) and will apply to all subjects following approval as appropriate by the Ethical Review Committee or Institutional Review Board.

III Sponsor's Termination Of Study

SB reserves the right to discontinue the clinical study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be tendered.

IV Case Report Form Instructions

Prior to screening the first potential participant, the investigator will provide a list showing the signature and handwritten initials of all individuals authorised to make or change entries on case report forms (CRFs). If the authorised individuals should change during the study, the investigator is to inform SB.

CRFs will be supplied by SB for recording all data. It is the responsibility of the investigator or co-investigator to ensure that CRFs are legible and completely filled in with a black ink ballpoint pen. The subject's identification (2-3 alphabetic letters representing initials or first letter of subject's name), the patient identification (PID) if not already pre-printed and the visit date, will be entered on the CRF Header Pages as required.

Errors must be corrected by drawing a single line through the incorrect entry and writing in the new value/data positioned as close to the original as possible. The correction must then be initialled, dated and justified by the authorised individual making the change. Do not obliterate, write over, or erase the original entry when making a correction.

When a subject completes a visit, it is anticipated that relevant sections of the CRF will be completed by the investigator (or designated staff) within 24 hours of the last data becoming available, but in no case later than 5 days. Similarly, when a subject completes a study, it is anticipated that all relevant CRF pages will be completed within 24 hours of the last data becoming available, but in no case later than 5 days. This also applies to forms for potential study participants who were not randomised to a treatment group.

As soon as the subject has completed/withdrawn from the study and the CRF is completed the principal investigator or designated physician(s) under his/her supervision will sign the adverse experience page(s) as well as study conclusion page of the CRF to confirm that they have reviewed the data and that the data are completed and accurate. If sections of a CRF are to be brought into SB prior to study conclusion, a section conclusion signature is required.

An original (top copy) CRF must be submitted for all subjects who have undergone protocol specific procedures, whether or not the subject completed the study.

While completed CRFs will be reviewed by an SB professional monitor at study site, errors detected by subsequent in-house CRF review may necessitate clarification or correction of errors and documentation and approval by the investigator.

Any questions or comments related to the CRF should be directed to the assigned study monitor.

V Monitoring By SmithKline Beecham (i.e. the Sponsor)

Monitoring visits by a professional representative of the sponsor will be scheduled to take place before entry of the first subject, during the study at appropriate intervals and after the last subject is completed.

These visits are for the purpose of verifying adherence to the protocol and the completeness and exactness of data entered on the CRF and Drug Inventory Forms. The monitor will verify CRF entries by comparing them with the hospital/clinic/office records which will be made available for this purpose. The monitor will retrieve completed CRF sections at each visit. Adequate time and space for these visits must be made available by the investigator.

Investigator must ensure provision of reasonable space and adequate qualified personnel for monitoring visits.

VI Archiving Of Data

The investigator must retain subject records and CRFs as well as drug disposition records in an easily retrievable form until disposal has been agreed in writing with SB. The investigator must have a 'key' linking the subject's study identification number (i.e. treatment number) to the subject's clinical file. If the investigator moves or retires, he/she must nominate someone in writing to be responsible for record keeping. Archived data may be held on microfiche or electronic record, provided that a back-up exists and a hard copy can be obtained from it if required.

SB agrees to retain a copy of the protocol, documentation, approvals and all other documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out.

VII Audits

For the purpose of compliance with Good Clinical Practice and Regulatory Agency Guidelines it may be necessary for SB or a Drug Regulatory Agency to conduct a site audit. This may occur at any time from start to after conclusion of the study.

When an investigator signs the protocol, he agrees to allow the Drug Regulatory Agency and SB auditors to inspect his/her study records. Furthermore, if an investigator refuses an inspection, his data will not be accepted in support of a New Drug Registration and/or Application.

SB has a substantial investment in clinical studies. Having the highest quality data and studies are essential aspects of drug development. SB has a Regulatory Compliance staff who audit investigational sites. Regulatory Compliance assesses the quality of data with regard to accuracy, adequacy and consistency. In addition, Regulatory Compliance assures that SB sponsored studies are in accordance with the relevant Good Clinical Practices regulations/guidelines are being followed.

To accomplish these functions, Regulatory Compliance selects investigational sites to audit. These audits usually take 1 to 2 days. The SB audits entail review of source documents supporting the adequacy and accuracy of CRFs, review of documentation required to be maintained, and checks on drug accountability. The SB audit therefore helps prepare an investigator for a possible regulatory agency inspection as well as assuring SB of the validity of the database across investigational sites.

The Inspector will be especially interested in the following items:

- Log of visits from the sponsor's representatives.
- ERC/IRB approval.
- Test article accountability.
- Approved study protocol and amendments.
- Informed consent of the subjects.
- Medical records supportive of CRF data.
- Reports to the ERC/IRB and the sponsor.
- Record retention.

SB will gladly help investigators prepare for an inspection.

VIII Confidentiality And Publication

You agree that all information communicated to you by SB is the exclusive property of SB and you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed by you or such person to any third party without the prior written consent of SB. You shall communicate the results of the work promptly to SB.

We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall so request you will delay publication for a maximum of six months to enable us to protect our rights in such information or material. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to a journal or scientific meeting, should be sent to the

study monitor prior to submission. SB will undertake to comment on such documents within four weeks.

All rights and interests worldwide in any inventions, know-how or other intellectual or industrial property rights which arise during the course of and/or as a result of the clinical study which is the subject of this Protocol or which otherwise arise from the information or materials supplied under this Agreement, shall be assigned to, vest in and remain the property of SmithKline Beecham plc.

Appendix C Sample Informed Consent Statement and Patient Information Leaflet

WRITTEN INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

INVESTIGATOR:

STUDY TITLE: A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM).

PROTOCOL NO.: 49653 / 009

SPONSOR: SmithKline Beecham Pharmaceuticals ("The Company").

INFORMATION

1. DESCRIPTION/PURPOSE OF THE STUDY

This is a medical research study.

Its purpose is to determine the long term safety and effectiveness of BRL 49653C ("the product"), an anti-diabetic drug, at two different doses, one dose as monotherapy and the other dose as combination therapy with other hypoglycaemic agents.

The study will last for less than 49 months.

Approximately 400 to 1000 other patients will take part in this study.

The study will involve a minimum of fifteen visits to the clinic and the following tests will be carried out:

A physical examination.

An electrocardiogram (ECG) will be performed seven times during the study. The ECG test will be performed at Visits 1, 5, 7, 9, 11, 13, 15, 17 and 19. The ECG test will be used to check your heart.

At each visit, approximately 30 ml of blood will be taken through a needle in your vein for laboratory tests; a urine sample will be collected at visit 1 and at visits 4 to 19.

The protocol has been reviewed and accepted by an independent ethics review committee.

2. RISKS ASSOCIATED WITH THE STUDY

All drugs may cause side-effects in some patients. The most common side-effect of BRL 49653C, "the product", known to "the Company" at this time is headache. It is possible that treatment with BRL 49653C could lower your blood sugar too much. This could make you feel tired, dizzy, sweaty, and or nauseated (sick). Also, it could cause your heart to feel that it is racing. These signs and symptoms are referred to as hypoglycaemia (low blood sugar). If such sugar changes persist, the study physician may remove you from the study so that you can be treated with medication chosen by your own doctor.

In a study of 380 patients, BRL 49653C was associated with other side effects. These side effects were seen in patients taking BRL 49653C and were also seen in patients taking a non-active drug (placebo). The side effects for both active drug and non-active drug (placebo) occurred in a similar number of cases and at a similar strength.

Certain procedures, including heart rate and blood pressure monitoring, form part of the clinical study. These investigations would normally be carried out by a physician in routine examination of your condition. In addition, electrocardiogram (ECG) recordings will be made and three blood samples (approximately 30 ml total) will be taken.

The drugs used in this study may involve other risks that are not known at the present-time.

Liver Monitoring

Another member of the same class of drugs, troglitazone, has been found to cause liver injury in some patients. However, we have not seen evidence of a pattern of liver injury with rosiglitazone.

In America, rosiglitazone is a marketed drug and to date approximately 250,000 patients have been treated with it. Amongst the 250,000 patients treated so far, a few liver-related events have been observed. These events have been reviewed by a panel of independent experts and they concluded that these cases do not suggest that rosiglitazone causes liver injury. So far, in clinical trials, more than 3300 people have taken rosiglitazone for at least 6 months and over 2000 people have taken it for at least 12 months. In these patients, there have been no reports of damage to the liver caused by treatment with this drug.

A few patients have had either small or moderate increases in their liver enzymes. However, most of these patients continued in the clinical trials without experiencing any further increase in their liver enzymes.

As a precaution, liver tests will be performed at least every two months during the first year of this study and at least every 6 months after that. However, they may be checked more frequently, if your doctor thinks it appropriate.

If you experience unexplained nausea, vomiting, abdominal pain, fatigue, loss of appetite and/or dark-colored urine, inform your doctor.

If this occurs in between scheduled study visits, telephone your doctor immediately. Your doctor may ask you to return to the clinic and/or to stop taking study medication.

Lipids, Anaemia and Oedema

A small number of patients taking rosiglitazone developed increases in cholesterol, decreases in red blood cell count (anaemia), or fluid accumulation (oedema). Most of these side effects were mild or moderate, and patients were rarely withdrawn from the study by the doctor for these side effects. During the study, you will be examined by the study doctor and your cholesterol and blood counts will be checked on a regular basis. If you experience shortness of breath, tightness or pain in the chest you should contact your study doctor immediately. If you currently suffer from angina and you feel the frequency of the angina is increasing, you should contact your study doctor immediately.

3. BENEFITS ASSOCIATED WITH THE STUDY

There is no guarantee that you will benefit by participating in this study; however, you and other patients in the future may benefit from this study and any future medical research. Such benefits include the possibility that your condition may improve and that this study may help develop a new therapy for others with similar conditions.

Visits, procedures (tests) related to the study, and study medications will be provided at no charge to you. If you complete the current study, you may have the option of continuing the study, if it is extended.

4. ALTERNATIVE THERAPY

There are alternative therapies for your diabetes. If you have questions about other therapies, ask your doctor for additional information.

5. CONFIDENTIALITY AND SOURCE DOCUMENT REVIEW

Your participation in the study will be treated as confidential and any records or results relating to the study shall not be disclosed to any third party other than representatives of "the Company" or its affiliated companies or regulatory bodies for medicines in the UK or elsewhere, for the purposes of effecting registration of "the product" or for the purposes of medical research, or as may otherwise be required in law.

Your identity will remain confidential.

"The Company" will ensure that it complies with any national data protection regulations.

6. RIGHT TO ASK QUESTIONS AND/OR WITHDRAW FROM THE STUDY

You have the right to ask questions concerning the potential and/or known hazards of this study at any time. You will be informed of any significant new information pertaining to your safety.

If you have any questions concerning this study, please contact:

Name Tel. No.

You have the right to withdraw from the study at any time and do not have to give a reason for so doing.

Should you wish to withdraw from the study at any time, your routine medical care will not be affected in any way.

Your doctor may withdraw you from the study at any time if it is felt to be in your best interest.

If you should withdraw voluntarily from the study or are asked by the doctor to leave the study, you must return all unused study medications. You will be asked

questions about your experience with the study drug. You also may be asked to co-operate in having whatever laboratory tests and physical examinations the doctor considers necessary.

7. COMPENSATION (MEDICAL/FINANCIAL) TO BE PROVIDED

If you become ill or injured as a result of participation in this clinical study, medical treatment will be provided, and the costs of such treatment will be paid by "the Company". If you have any questions concerning the availability of compensation/medical care, or if you think you have experienced a research-related illness or injury, contact:

Name: (Investigator) Tel. No.:

8. COSTS

The Company will reimburse you for any additional costs incurred as a participant in this study i.e. travel expenses to and from the clinic.

9. VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled.

You may discontinue your participation in the study at any time without loss of benefits to which you are otherwise entitled.

You are entitled to receive a signed copy of this form.

CONSENT

I, ..., have read and understand all the preceding information describing this medical research study and all my questions have been answered to my satisfaction. I have read the Patient Information Leaflet relating to this study. I voluntarily consent to participate in this study.

Dr. has explained to me this study in detail. I voluntarily consent to participate in this trial.

Signature of Patient
(Parent/Legal Representative)

Date: _____

SAMPLE PATIENT INFORMATION LEAFLET

Thank you for your interest in our study. The purpose of it is to find out whether a new drug, BRL 49653C (the drug code number), is useful in treating patients such as yourself, who have non-insulin dependant diabetes mellitus (NIDDM).

ABOUT THE INVESTIGATIONAL DRUG AND THE STUDY

BRL 49653C is an investigational drug. This means that it has not been approved by the regulatory authorities for sale, but it may be tested in medical research studies such as this one. BRL 49653C is a new type of drug called an "insulin sensitizer" which can help make the insulin your body produces work better and help to decrease your blood sugar levels.

It has been shown in other studies that BRL 49653C may be able to help control your diabetes. This medical research study is therefore being run to try and help your diabetes safely using BRL 49653C.

As many as 400 to 1000 patients at about 100 centres in Europe may take part in this study. The whole study, from first visit to last visit, is approximately 48 months long. If you agree to take part, you will be asked to take regular study medication.

The study is called "open" because you will receive active study medication. You (and all the other patients) will take BRL 49653C in the morning and then again in the evening. **IT IS IMPORTANT THAT YOU TAKE YOUR MEDICATION AS DIRECTED BY THE STUDY DOCTOR.** If you were taking two types of study medication for your diabetes in the previous study, for example, you were also taking a sulphonylurea, then you will be asked to continue to take this. If you were taking study medication on its own during the previous study, then you will not need to change your therapy.

During this study you may experience side effects of study medications. It is possible that treatment with BRL 49653C could lower your blood sugar too much. This could make you feel tired, dizzy, sweaty, and/or nauseated (sick). Also, it could cause your heart to feel as if it is racing. These signs and symptoms are referred to as hypoglycaemia (low blood sugar). If such blood sugar changes continue, the study doctor may remove you from the study so that you can be treated with medication chosen by your own doctor.

So far, BRL 49653C has been given to more than 4500 patients in controlled clinical trials and more than 250000 patients in the US. In the previous studies,

headache was the most common side effect; however, BRL 49653C may have other side effects, some of which are not yet known. The side effects which were seen in patients taking BRL 49653C, were also seen in patients taking a non-active drug (placebo). The side effects for both active drug and non-active drug (placebo) occurred in a similar number of cases and at a similar strength. To date, no studies have been reported to show how BRL 49653C interacts with other prescribed medications or over-the counter medications that you may be taking.

At this time, we do not know the effect of BRL 49653C on the developing foetus. Therefore, there is a risk that if you become pregnant, you could have a miscarriage, or your baby could be deformed. Pregnancy **must** be avoided during the study and for at least 30 days after you take the last dose of study medication. Women must agree not to become pregnant during the study, and only women who agree not to become pregnant will be allowed to participate. At any time, if you suspect that you are pregnant while participating in the study, you must call your doctor immediately and discontinue the study medication because of the unknown risk to the developing foetus. Your doctor will start alternative treatment for your diabetes following withdrawal from the study.

STUDY PROCEDURES

If you decide to take part in the study, then your last visit in the previous study will be the first visit in this new study, i.e. you will not need to attend an extra visit at the start. However, at this visit, all the aims of the new study and procedures involved will be explained to you in full by your doctor. Please feel free to ask your doctor any questions. You should only consent to participate when you are satisfied that everything about the study has been explained to you by the study doctor.

At the first visit, the study doctor or a member of the study staff will ask you how you felt since the last visit. All the procedures scheduled to take place for the previous study will be completed at the first visit. You will have a medical examination which will include an electrocardiogram (ECG). The ECG test (pictures of the heart) will be repeated four more times during the study.

After the first visit you will come to the clinic again for 19 more visits (in the morning). For approximately 9 hours prior to these visits (after 11:00 pm at night until your visit the next morning), you will be asked not to eat or drink (water is allowed). At each visit, blood will be taken through a needle in your vein for laboratory tests. In all, approximately one cup full of blood (possibly a little more if additional tests are needed) will be taken during the study but your body will

quickly make up for this small loss. A urine specimen will also be collected at visit 1, and at visits 4 to 19. If appropriate (women only), a small amount of urine will also be used at each study visit to test that you are not pregnant.

At the first visit you will receive your study medication and instructions on how to take it. You may also receive guidance on your diet if required from a qualified member of the study team. You should not change your previous diet habits unless told to do so.

If you were taking two types of study medication for your diabetes in the previous study, then you will be asked to take two tablets of BRL 49653C each day, together with your other medication. At the start of breakfast in the morning (am) you will take one tablet of BRL 49653C together with your other diabetes medication, and in the evening (pm) you will take one tablet of BRL 49653C before your meal.

If you were taking only one type of study medication for your diabetes in the previous study, then you will be asked to take four tablets of BRL 49653C each day. At the start of breakfast in the morning (am) you will take two tablets of BRL 49653C, and in the evening (pm) you will take two more tablets of BRL 49653C before your meal.

On the day of your visit you will not take your morning dose of study medication at home, but will be given it in the clinic after your tests have been completed. You must remember not to eat or drink (water is allowed) after 11:00 pm the night before your visit (this includes breakfast on the day of your visit). It is important to tell the study doctor if you have had anything to eat or drink (except water) within 9 hours of the visit or if you have taken your morning study medication by mistake. You must also remember to bring all your study medication to the clinic at each visit.

BENEFITS

There is no guarantee that you will benefit by participating in this study; however, you and other patients in the future may benefit from this study and any future medical research. Such benefits include the possibility that your condition may improve and that this study may help develop a new therapy for others with similar conditions.

Clinic visits, procedures related to the study, and study medications will be provided at no charge to you. If you complete the current study, you may have the option of continuing the study, if it is extended.

ALTERNATIVE TREATMENT

Other medications are available to treat diabetes. If you have questions about other treatments, ask your doctor for more information.

CONFIDENTIALITY OF INFORMATION

Your participation in the study will be treated as confidential, and any records or results relating to the study shall not be disclosed to any third party other than representatives of "the Company" or its affiliated companies or regulatory bodies. This means that your identity and your medical records will remain confidential.

We hope you will consider taking part in this study and we thank you for your interest even if you decide not to participate. Your doctor will be able to answer any questions about the study that you may have.

Appendix D Outline of Study Procedures

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 4a#	Visit 5	Visit 5a #	Visit 6	Visit 6a#
	1 mo	2 mo	3 mo	4 mo	6 mo	8 mo	9 mo	10 mo	
Demography	X								
Medical History	X								
Physical examination	X	X	X	X		X		X	
AE check	X ¹	X	X	X		X		X	
BP & HR	X ²	X	X	X		X		X	
ECG	X ²					X			
Weight	X ²			X		X		X	
Compliance		X	X	X		X		X	
Labs (blood & urine) - safety	X ²			X		X		X	
Labs (safety – LFTs)					X		X		X
Labs (blood) - efficacy (FPG, HbA1c)	X ²	X	X	X		X		X	
Labs (blood) - efficacy - (other) ³	X ²					X			
Urine Albumin	X					X			
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X		X		X	

	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
	12 mo	15 mo	18 mo	21 mo	24 mo	27 mo	30 mo	33 mo
Demography								
Medical History								
Physical examination	X	X	X	X	X	X	X	X
AE check	X	X	X	X	X	X	X	X
BP & HR	X	X	X	X	X	X	X	X
ECG	X		X		X		X	
Weight	X	X	X	X	X	X	X	X
Compliance	X	X	X	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X		X	
Urine Albumin	X		X		X		X	
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X	X

	Visit 15 36 mo	Visit 16 39 mo	Visit 17 42 mo	Visit 18 45 mo	Visit 19 48 mo
Demography					
Medical History					
Physical examination	X	X	X	X	X
AE check	X	X	X	X	X
BP & HR	X	X	X	X	X
ECG	X		X		X
Weight	X	X	X	X	X
Compliance	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X
Urine Albumin	X		X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X

If the patient withdraws early, then the Conclusion/Early Withdrawal assessment should be completed.

¹ Adverse events still ongoing at end of the previous study will be recorded at Visit 1 (in the Adverse Experience section).

¹ Concomitant Medication still ongoing at end of the previous study will be recorded at Visit 1 (in the Concomitant Medication section at the end of module 1).

² Where duplicated, Visit 1 assessments will be taken from the final visit for the preceding study.

³ Labs (efficacy - other) = Insulin, Lipids.

#visit 4a = visit 4 + 1 month

#visit 5a = visit 5 + 2 months

#visit 6a = visit 6 + 1 month

**Appendix E Echocardiography Results Table -
49653/006**

	Placebo	2mg bid
Baseline	159.73	154.64
week 6	158.04	153.74
week 12	157.86	151.64

Mean values for LV mass (g) at week 12

Appendix F1 Definition of NIDDM

Class: Non-insulin dependent types (NIDDM) Type II.

Former terminology: Adult-onset diabetes, maturity-onset diabetes, maturity-onset-type diabetes, MOD, ketosis-resistant diabetes stable diabetes.

Associated factors: There are probably multiple aetiologies for this class, the common outcome being derangement of carbohydrate metabolism. Evidence on familial aggregation of diabetes implies genetic factors, and this class includes diabetes presenting in children and adults in which autosomal dominant inheritance has been clearly established (formerly termed the MODY type, maturity-onset diabetes in the young). Environmental factors superimposed on genetic susceptibility are probably involved in the onset of the NIDDM types. Obesity is suspected as an etiologic factor and is recommended as a criterion for dividing NIDDM into two subclasses, according the presence or absence of obesity.

Clinical characteristics: Persons in this subclass are not insulin-dependent or ketosis-prone, although they may use insulin for correction of symptomatic or persistent hyperglycaemia and they can develop ketosis under special circumstances such as episodes of infection or stress. Serum insulin levels may be normal, elevated, or depressed. In the preponderance of cases, onset is after age 40, but NIDDM is known to occur at all ages. About 60-90% of NIDDM subjects are obese and constitute a subtype of NIDDM; in these patients, glucose tolerance is often improved by weight loss. Hyperinsulinaemia and insulin resistance characterize some patients in this subtype.

Diagnostic criteria: Diagnosis of diabetes in adults should be based on:

- 1 unequivocal elevation of plasma glucose concentration together with the classical symptoms of diabetes, or
- 2 elevated fasting plasma glucose concentration on more than one occasion, or
- 3 elevated plasma glucose concentration after an oral glucose challenge on more than one occasion.

Appendix F2 Calculation of Daily Calorific Requirement for Weight Maintenance

Patients may be instructed by a Registered Dietician, a qualified nutrition professional, or suitably qualified member of the study team, to follow a diet prescribed to maintain the patients current weight. The energy (calorific) requirements to maintain the patients current weight may be estimated using the Harris-Benedict equation.

The distribution of calories among carbohydrates, proteins and fats in the prescribed diet are to be consistent with the recommendations of the Committee on Food and Nutrition of the American Diabetes Association. Those recommendations are:

Carbohydrate intake - 50% to 60% of total calories with the amount dependent on the impact on blood glucose and lipid levels in individual eating patterns.

Protein intake - 0.8% g/Kg body weight

Total fat and cholesterol - < 30% of total calories and cholesterol < 300 mg/day

The Harris-Benedict Equation to Calculate Basal Energy Expenditure (BEE).

The Harris-Benedict Equation is a frequently used starting point to estimate daily basal energy expenditure (BEE). It is based on the individual age, sex, weight, and height.

Calculating Basal Energy Expenditure:

Men: $BEE = 66 + (13.7 \times W) + (5 \times H) - (6.8 \times A)$

Women: $BEE = 655 + (9.6 \times W) + (1.7 \times H) - (4.7 \times A)$

W = Actual weight in Kg

H = Height in cm

A = Age in years

[Weight (Kg) = Weight in pounds $\times$ 0.454]

[Height (cm) = Height in inches $\div$ 0.394]

TOTAL ESTIMATED DAILY ENERGY REQUIREMENT = BEE x 1.3

For overweight individuals, an adjusted body weight instead of actual body weight should be used when utilising the Harris-Benedict equation. The adjusted body weight may be determined using the following formula:

$$\text{Adjusted IBW} = (\text{ABW} - \text{IBW}) \times 0.25 + \text{IBW}$$

ABW = Actual Body Weight in pounds

IBW = Ideal Body Weight in pounds

Assessing Comprehension of Diet Prescribed and Estimating Dietary Compliance

At each study visit, a suitably qualified member of the study team is to evaluate the patient for comprehension of their weight maintenance diet. Instruction should only be given/repeated for patients who demonstrate a lack of understanding of their diet.

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Rosiglitazone

BRL 49653

**A multicentre, open label extension study to assess the long term safety,
tolerability and efficacy of BRL 49653C when administered to patients with
Non-insulin Dependent Diabetes Mellitus (NIDDM)**

Incorporating Amendment No. 5 - Centres in France only
009

Clinical Protocol



*Clinical R & D, Europe, **Biometrics

SB Document Number: BRL-049653/RSD-10194Z/1

Issue Date: 22nd November 1996
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1999, 14 January 2000

Endorsements



Clinical Unit: Cardiopulmonary Therapeutic Team

Document No.: BRL-049653/RSD-10194Z/1

Drug Name: Rosiglitazone

Compound No: BRL 49653

Protocol Title: A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-insulin Dependent Diabetes Mellitus (NIDDM)

CPMS Number: 049653/009

SB Site Monitor:

Contact Information:

I, the undersigned, have reviewed this protocol, including Appendices, and I will conduct the clinical study as described and will adhere to the Ethical and Regulatory Considerations stated. I have read and understood the contents of the Investigator Brochure.

, Investigator

Date

Table of Contents

	Page
List of Appendices	5
Synopsis	6
1 Introduction	9
2 Objectives	10
2.1 Primary Objective(s)	10
2.2 Secondary Objective(s)	11
3 Study Design Overview	11
3.1 Study Design	11
3.2 Schedule of Assessments	12
4 Study Population	14
4.1 Planned Number of Subjects	14
4.2 Inclusion Criteria	14
4.3 Exclusion Criteria	14
5 Conduct of the Study	16
5.1 Ethical and Regulatory Considerations	16
5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)	16
5.1.2 Informed Consent	16
5.2 General Instructions	17
5.2.1 Concomitant Diabetes Medications	17
5.2.2 Study Visits	18
5.3 Outline of Study Procedures	19
5.4 Study Procedures	19
5.4.1 Visit 1 - Start of Study	20
5.4.2 Visits 2 to 18 - mid study visits (1 - 45 months)	21
5.4.3 Visit 19 - Final study visit (48 months)	22
5.4.4 Unscheduled Visits	23
5.5 Clinical Observations and Procedures	23
5.5.1 In-clinic dosing	23
5.5.2 Clinical laboratory testing for efficacy and safety	23
5.5.3 Measurement of blood pressure and heart rate	25
5.5.4 ECG measurements	25
5.5.5 Clinical laboratory blood and urine sampling and handling	25
5.5.6 Medical history and diet check	26
6 Study Medication and Administration	26
6.1 Study Medication	26
6.2 Dosage and Administration	26
6.3 Method of Blinding	27
6.4 Packaging	27

6.5	Labelling and Preparation	28
6.6	Storage	29
6.7	Drug Accountability	29
6.8	Assessment of Compliance	29
6.9	Treatment of Study Medication Overdose	30
6.10	Occupational Safety	30
6.11	Concomitant Medication/Treatment	30
7	Outcomes Research and Pharmacoeconomics	31
8	Adverse Experiences	31
8.1	Eliciting and Documenting Adverse Experiences	31
8.2	Assessment of Intensity	33
8.3	Assessment of Causality	34
8.4	Follow-up of Adverse Experiences	34
8.5	Serious Adverse Experiences	35
8.5.1	Definition of Serious Adverse Experiences	35
8.5.2	Reporting Serious Adverse Experiences	36
8.6	Reporting of Overdose	36
8.7	Pregnancy	36
9	Subject Completion and Withdrawal	37
9.1	Definitions	37
9.2	Procedures for Handling Withdrawals	37
9.3	Reasons for Withdrawal	38
10	Data Evaluation	39
10.1	Target Sample Size	39
10.2	Method of Randomization	39
10.3	Planned Efficacy Analysis	39
10.3.1	Primary Efficacy Variables	39
10.3.2	Secondary Efficacy Variables	40
10.3.3	Comparison of Interest	40
10.3.4	Methods of Analysis	40
10.3.5	Subject Populations/Dataset to be Analysed	41
10.4	Planned Safety Evaluation	41
10.5	Interim Analysis	41
11	Administrative Matters	42
12	References	43
13	Appendices	44

List of Appendices

	Page
Appendix A Declaration of Helsinki	45
Appendix B Administrative Matters.	50
Appendix C Sample Informed Consent Statement and Patient Information Leaflet	55
Appendix D Outline of Study Procedures.	65
Appendix E Echocardiography Results Table - 49653/006	67
Appendix F1 Definition of NIDDM.	68
Appendix F2 Calculation of Daily Calorific Requirement for Weight Maintenance	69

Synopsis

Compound/Protocol No.

BRL 49653/009

Protocol Title

A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM).

Rationale

The pathophysiology of NIDDM is characterised by aberrant insulin secretion from pancreatic β -cells and/or resistance to the action of insulin in peripheral tissues. Owing to the increased demands it places on insulin secretion, insulin resistance may be responsible for the progression of NIDDM by causing β -cell exhaustion. Insulin resistance is also commonly associated with the cardiovascular risk factors of hyperinsulinaemia, dyslipidaemia and hypertension.

BRL 49653 is a novel, orally active member of the thiazolidinedione class of antidiabetic agents. In animal models it lowers resistance to insulin in peripheral tissues, reducing hyperglycaemia and hyperinsulinaemia, with a concomitant improvement in lipid profile. Its activity in improving glycaemic status and reducing circulating levels of insulin has been confirmed in a large phase II study of NIDDM patients (for more details see [1.0 Introduction](#)).

BRL 49653C does not appear to increase secretion of insulin and hence its use would be expected to avoid the risk of exhausting pancreatic function. Furthermore, it would be predicted not to cause hypoglycaemia (a potential complication of treatment with insulin secretagogues).

BRL 49653 is being evaluated in a number of controlled clinical trials in which the duration of treatment ranges from a matter of weeks to 12 months. NIDDM is a condition requiring treatment over many years and it is necessary to assess the long term safety of the compound.

Objective(s)**Primary**

To evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM.

Secondary

To evaluate the long term efficacy of BRL 49653 in terms of glycaemia and lipidaemia.

Study Population

Patients who have completed a previous BRL 49653 study and who meet the entry criteria for this study will be invited to participate in this extension study. Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate. It is estimated that between 400 and 1000 patients will enter the study. Approximately 100 centers in Europe will participate.

Safety Parameters

Physical examination
Adverse experiences
Laboratory safety data
ECG parameters
Vital signs (systolic and diastolic blood pressure and heart rate)
Body weight

Efficacy Parameters

Fasting plasma glucose
HbA_{1c}
Fasting plasma insulin (specific)
Fasting lipid levels: (ie.total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and free fatty acids)
Urinary albumin (measured as a random sample in clinic at Visits 1, 5 and 7)

Dosing Schedule

Patients on monotherapy in the previous study will receive BRL 49653 4 mg bd. Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy in the previous study will receive BRL 49653 2 mg bd, in addition to their other hypoglycaemic therapy. For patients on combination therapy the dose of their other hypoglycaemic therapy may be altered during the study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it would improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

1 Introduction

Non-insulin dependent diabetes mellitus (NIDDM) occurs in 5% of 50-year-old-adults and 20% of the 80-year-old population[1] [2]. Aberrant insulin secretion from pancreatic β -cells, insulin resistance in peripheral tissues with reduced glucose uptake (particularly in muscle and liver), and excess hepatic glucose production are the primary pathogenic mechanisms believed to be responsible for the associated metabolic abnormalities[3] [4] [5] [6].

Currently available therapies for NIDDM include insulin and oral hypoglycemic agents (e.g. sulphonylureas, biguanides, and alpha-glucosidase inhibitors). BRL 49653C is a highly potent and orally active anti-diabetic thiazolidinedione compound. The thiazolidinediones represent a novel class of compounds that act as "insulin sensitizers" in target tissues. Unlike sulphonylureas, BRL 49653C has been shown to reduce elevated blood glucose without a concomitant increase in insulin levels.

In animal testing, repeat oral administration of BRL 49653C has been effective in reducing hyperglycemia, hyperinsulinemia, hypertriglyceridemia, and free fatty acids associated with insulin-resistant models of NIDDM. In the genetically obese mouse, the potency of BRL 49653C as an antihyperglycemic agent, was compared with other insulin sensitizers, and BRL 49653C was proven to be at least 100 times more potent than CS-045 (troglitazone) and at least 30 times more potent than pioglitazone. More detailed pre-clinical information is summarised in the Investigational Brochure[7].

As of January 1996, BRL 49653C had been administered to 140 subjects in seven Phase I and Clinical Pharmacology studies. Of these 140 subjects, 91 received one or more single doses of BRL 49653C up to 20 mg. This includes 10 healthy elderly males (≥ 65 years of age). Additionally, 36 obese, non-diabetic males and females received doses of up to 5 mg/day for 10 consecutive days, and 13 NIDDM patients received doses of up to 2 mg/day for seven consecutive days. In general, BRL 49653C was well tolerated when administered as single doses from 0.2 to 20 mg and in doses up to 5 mg when given daily for 10 days. More detailed information is summarised in the Investigational Brochure.

The safety, efficacy, and tolerability of BRL 49653C has been assessed in 379 NIDDM patients in a Phase II, double-blind, placebo controlled dose response study. Of the 379 randomised patients, 75, 73, 72, 79, and 80 patients received twice daily doses of placebo, 0.05 mg, 0.25 mg, 1 mg, and 2 mg, respectively.

Analysis of covariance showed highly significant ($p < 0.001$) treatment effects on lowering fasting plasma glucose (FPG) at twice daily doses of 1 mg and 2 mg. At the higher dose of 2 mg bid, the fasting plasma glucose was reduced by approximately 20% compared to placebo at week 12. The onset of effect was evident by week 1 and the rate of decline continued steadily through week 6. Doses of 0.05 mg bid and 0.25 mg bid were not effective in lowering blood glucose[8]. The decrease in FPG at the higher doses was reflected in lowered serum fructosamine and HgbA_{1C} values at week 12 compared to placebo.

Overall, treatment with BRL 49653C was safe and well tolerated at the twice daily doses of 0.5 mg to 2 mg when compared to placebo. The percentage of patients reporting adverse events in each of the treatment groups (64.6% to 68.4%) was similar to the placebo group (64%). Echocardiography (2D M-Mode) showed no difference in left ventricular mass between the BRL 49653C treatment groups and the placebo group ([Appendix E](#)). A small trend showing reduction in hemoglobin (from 14.5 to 14.3 g/100 ml) and hematocrit was observed at higher doses. The absolute reductions ($< 2\%$ from baseline) were not considered to be of clinical significance.

During the 12-week treatment period, a total of nine serious adverse experiences (SAEs) were reported: There were three SAEs in each of the placebo and 2.0 mg groups and one in each of the 0.05, 0.25 and 1.0 mg groups. Two deaths were reported during the study, both of which were attributed to an acute myocardial infarction. One case, a 52 year old male (2.0 mg group) was designated as possibly related to study medication by the investigator, and the other case, a 71 year old male (0.25 mg group), was considered unrelated to study medication by the investigator. All other SAEs were specified by the investigators as being unrelated to trial medication, apart from 1 case of exercise induced non-sustained ventricular tachycardia in a 56 year old male receiving placebo. Causal relationship was given as possibly related in this case.

Please refer to the Investigator Brochure for a review of the pre-clinical and clinical studies of BRL 49653C.

2 Objectives

2.1 Primary Objective(s)

To evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral

hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM.

2.2 Secondary Objective(s)

To evaluate the long term efficacy of BRL 49653 in terms of glycaemia and lipidaemia.

3 Study Design Overview

3.1 Study Design

This is a phase IIIA, multicentre, open label, study of BRL 49653C administered to patients with Non-insulin Dependent Diabetes Mellitus. Patients will receive study medication for up to 48 months.

Patients that satisfy the eligibility criteria, ([sections 4.2](#) and [4.3](#)) may enter the study. Each patient will have 15 visits during the study.

Patients on monotherapy in the previous study will receive BRL 49653 4 mg bd. Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

Patients on combination therapy in the previous study will receive BRL 49653 2 mg bd, in addition to their other hypoglycaemic therapy. For patients on combination therapy the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it would improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen. The use of insulin is prohibited during the study.

Doses of BRL 49653C tablets are to be taken one before breakfast (am) and one before their evening meal (pm). Timing of the doses of other hypoglycaemic agents (for patients on combination therapy) will be as per the investigator's normal clinical practice.

Patients will be assessed according to the schedule detailed in Outline of Study Procedures (on the next page), and [section 5.3](#) of the protocol.

3.2 Schedule of Assessments

	Visit 1	Visit 2 1 mo	Visit 3 2 mo	Visit 4 3 mo	Visit 5 6 mo	Visit 6 9 mo	Visit 7 12 mo
Demography	X						
Medical History	X						
Physical examination	X	X	X	X	X	X	X
AE check	X ¹	X	X	X	X	X	X
BP & HR	X ²	X	X	X	X	X	X
ECG	X ²				X		X
Weight	X ²			X	X	X	X
Compliance		X	X	X	X	X	X
Labs (blood & urine) - safety	X ²			X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X ²	X	X	X	X	X	X
Labs (blood) - efficacy - (other) ³	X ²				X		X
Urine Albumin	X				X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X

	Visit 8 15 mo	Visit 9 18 mo	Visit 10 21 mo	Visit 11 24 mo	Visit 12 27 mo	Visit 13 30 mo	Visit 14 33 mo
Demography							
Medical History							
Physical examination	X	X	X	X	X	X	X
AE check	X	X	X	X	X	X	X
BP & HR	X	X	X	X	X	X	X
ECG		X		X		X	
Weight	X	X	X	X	X	X	X
Compliance	X	X	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X	X	X
Labs (blood) - efficacy - (other)		X		X		X	
Urine Albumin		X		X		X	
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X

	Visit 15 36 mo	Visit 16 39 mo	Visit 17 42 mo	Visit 18 45 mo	Visit 19 48 mo
Demography					
Medical History					
Physical examination	X	X	X	X	X
AE check	X	X	X	X	X
BP & HR	X	X	X	X	X
ECG	X		X		X
Weight	X	X	X	X	X
Compliance	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X
Urine Albumin	X		X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X

If the patient withdraws early, then the Conclusion/Early Withdrawal assessment should be completed.

¹ Adverse events still ongoing at end of the previous study will be recorded at Visit 1 (in the Adverse Experience section).

¹ Concomitant Medication still ongoing at end of the previous study will be recorded at Visit 1 (in the Concomitant Medication section at the end of module 1).

² Where duplicated, Visit 1 assessments will be taken from the final visit for the preceding study.

³ Labs (efficacy - other) = Insulin, Lipids.

4 Study Population

4.1 Planned Number of Subjects

Patients who have completed a previous BRL 49653 study and who meet the entry criteria for this study will be invited to participate in this extension study.

Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate. It is estimated that between 400 and 1000 patients will enter the study.

Approximately 100 centers in Europe will participate.

4.2 Inclusion Criteria

Only patients who fulfil **all** the following criteria will be eligible for inclusion in the study.

- 1 Patients with NIDDM (as defined by the criteria of the National Diabetes Data Group [[Appendix F1](#)]) may enter the study if they have successfully completed a BRL 49653 protocol which specifies the availability of this open label extension study.
- 2 Patients must not have discontinued study medication in the preceding study for more than 10 days.
- 3 Study medication in the preceding study must have been found to be safe and well tolerated throughout its duration by both the investigator and the patient.
- 4 Female patients must be post menopausal, i.e. > 6 months without menstrual period, surgically sterile, or using hormonal contraceptives or intrauterine contraceptive devices. Female patients taking hormonal contraceptives must also use an additional barrier form or intrauterine form of birth control.
- 5 Subjects who have given written informed consent to participate.

4.3 Exclusion Criteria

Use of an investigational drug within 30 days or 5 half-lives (whichever is longer) preceding the first dose of study medication.

A patient will be excluded from the study if any of the following apply:

- 1 Patients who are pregnant or lactating, or who plan for pregnancy within the time frame of the study.
- 2 Patients who experienced any significant and/or serious Adverse Experience during the preceding protocol which, in the opinion of the investigator, could have been attributed to study medication.
- 3 A clinically significant laboratory abnormality was recorded during the preceding protocol which in the opinion of the investigator, would preclude long term treatment with BRL 49653.
- 4 The patient withdrew from the preceding study for any reason.
- 5 Any clinically significant abnormality identified in the end of study assessments for the preceding study (eg physical examination, electrocardiogram, etc. as appropriate) which in the judgement of the investigator would preclude safe completion of this study.
- 6 Symptomatic diabetic neuropathy of sufficient severity to require treatment for control of symptoms (e.g. painful peripheral neuropathy, symptomatic orthostatic hypotension, urinary retention, gastric stasis, pedal ulcers).
- 7 Diabetic retinopathy imminently requiring treatment for preserving or restoring vision.

5 Conduct of the Study

5.1 Ethical and Regulatory Considerations

The study will be conducted according to Good Clinical Practice guidelines and the Declaration of Helsinki, as amended (Protocol [Appendix A](#)).

5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)

ERCs/IRBs must be constituted according to the local laws/customs of each participating country.

This protocol will be submitted to an appropriate Committee or Board and their written unconditional approval obtained and submitted to the sponsor before commencement of the study. SB will supply relevant data for the investigator to submit to the hospital/university/independent ERC/IRB for the protocol's review and approval. Verification of the ERC/IRB's unconditional approval of the protocol and either the written informed consent statement or oral witnessed consent form with written information to be given to the subjects will be transmitted to the SB Study Monitor prior to shipment of drug supplies and CRFs to the site. This approval must refer to the study by exact protocol title and number, identify the documents reviewed and state the date of review.

The ERC/IRB must be informed by the investigator of all subsequent protocol amendments and of serious or unexpected adverse experiences occurring during the study which are likely to affect the safety of the subjects or the conduct of the study. Approval for such changes must be transmitted in writing to the SB Study Monitor via the investigator

5.1.2 Informed Consent

The principles of informed consent in the current edition of the Declaration of Helsinki (Protocol [Appendix A](#)) should be implemented in each clinical study before protocol-specified procedures are carried out.

Information should be given in both oral and written form whenever possible and deemed appropriate by the ERC/IRB. Subjects, their relatives, guardians or, if necessary, legal representatives must be given ample opportunity to enquire about details of the study.

The consent form generated by the investigator with the assistance of SB, must be approved (along with the protocol) by the ERC/IRB and be acceptable to SB. Consent forms must be in a language fully comprehensible to the prospective subject. Where appropriate, informed consent shall be documented by the use of a written consent form approved by the ERC/IRB and signed by the subject or the subject's legally authorised representative.

The written consent document will embody the elements of informed consent as described in the Declaration of Helsinki and will also comply with local regulations. This form may be read to the subject or the subject's legally authorised representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

Consent must be documented either by the subject's dated signature or by the signature of an independent witness who records the subject's assent. In either event, the signature confirms the consent is based on information that has been understood. Each subject's signed informed consent form must be kept on file by the investigator for possible inspection by Regulatory Authorities and/or SB professional and Regulatory Compliance persons.

A sample Informed Consent form is attached as [Appendix C](#).

5.2 General Instructions

5.2.1 Concomitant Diabetes Medications

The use of insulin is prohibited during the study.

Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

For patients on combination therapy, the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it is necessary in order to improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

5.2.2 Study Visits

Patient visits should be scheduled to occur in the morning. Patients are to be instructed to fast (i.e., refrain from eating and drinking) from 11:00 PM on the night before their visit until after blood specimen collection for clinical laboratory evaluation has been completed. Water consumption is permitted during the fasting period.

Laboratory assessments must be completed in the fasting condition. At any clinic visit, if the patient is not in a fasted condition, specimens for laboratory assessments are not to be collected. The patient should return to the clinic the following day in a fasted condition for laboratory specimen collection. Non-fasting blood samples should only be taken at scheduled visits if the patient is unable to return to the clinic the following day. The investigator must stress to the patient the importance of attending scheduled visits in a fasted state. Non-fasting blood samples will only be used in the analysis for parameters which are not affected by the fed/fasted state.

All laboratory samples will be sent by courier to a central laboratory (SmithKline Beecham Clinical Laboratories). Full guidance, training, and materials for storage and transportation of samples will be provided to all centres. Normal methods and quality control used for the tests will be provided for the sponsor by SmithKline Beecham Clinical Laboratories.

Any result which falls outside the laboratory normal range will be considered abnormal. The investigator will indicate if this value is clinically significant. All laboratory tests with clinically abnormal values (i.e., beyond those expected with patients with NIDDM of this age group) occurring during the study will be repeated until the values return to normal. If this does not occur within a reasonable time, then the etiology will be identified and the sponsor informed.

Patients should be instructed **not** to take their morning dose of study medication on all study visit days, since they will be given this dose after all fasting laboratory specimens have been collected. Patients are to be reminded to bring their remaining study medication with them on study visit days.

As indicated above, for patients on combination therapy the investigator may alter the dose of the non-BRL 49653 hypoglycaemic agent if it is deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment. In order to ensure patient safety, the investigator should follow his/her normal

practice when making such a dose adjustment with respect to when the patient is next reviewed, arranging additional, unscheduled visits if necessary.

If a patient withdraws from the study before visit 19 then the Conclusion/Early Withdrawal assessment and the Study Conclusion/Withdrawal section should be completed in the case report form (CRF).

5.3 Outline of Study Procedures

Please refer to [Appendix D](#).

5.4 Study Procedures

Liver function test monitoring

In France all patients have already reached the stage of at least visit 8. This procedure therefore applies to visits 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 (18, 21, 24, 27, 30, 33, 36, 39, 42, 45 months of treatment)

Liver function tests (i.e ALT, AST, alkaline phosphatase and total bilirubin) should be reviewed at each of the above visits.

Patients who an ALT > 1.5 times the upper limit of normal, should have an evaluation of viral hepatitis (A, B and C) performed and liver function tests should be re-assessed within 1 week.

- If ALT remains > 1.5 times the upper limit of normal then liver function tests should be re-assessed after a further 2 weeks and monthly thereafter until ALT returns to less than 1.5 times the upper limit of normal.
- If ALT remains > 1.5 but < 3 times the upper limit of normal for 6 months, monitoring of liver function tests should be conducted every 3 months.
- If ALT becomes > 3 times the upper limit of normal, an evaluation of viral hepatitis (A, B and C) should be performed and liver function tests should be re-assessed within 1 week. If ALT remains > 3 times the upper limit of normal range, the patient should be withdrawn.

Visit 19 (48 months of treatment)

If at the final visit the ALT is > 1.5 times the upper limit of normal, an evaluation of viral hepatitis should be performed and liver function tests should be re-assessed within 1 week.

5.4.1 Visit 1 - Start of Study

At Visit 1 the investigator should perform the following:

- Obtain patient's written informed consent.
- Confirm the patient's eligibility and complete the checklist of the inclusion and exclusion criteria.
- Physical examination including standardized measurement of blood pressure, heart rate (Refer to [section 5.5](#)) and a pregnancy test (non-post menopausal women only).
- Measure body weight (without shoes).
- Take fasting blood and urine laboratory specimens ([section 5.5](#)).
- Check the patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#)).
- Standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patients case report form).

Where the above assessments duplicate those being performed on the same day as part of the final visit of the previous study, the results can be transcribed into the CRF for this study without having to re-perform the assessment.

Patients should be dispensed 5 weeks of treatment with BRL 49653 and instructed how to take it.

Visit 2 should be scheduled for 1 month $\pm$ 7 days' time. Patients should be instructed to bring all remaining study medication with them to each study visit.

5.4.2 Visits 2 to 18 - mid study visits (1 - 45 months)

General Instructions

Visits 2, 3 and 4 should be scheduled after 1, 2 and 3 months $\pm$ 7 days of treatment, respectively. Visits 5 to 18 should be scheduled after 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36, 39, 42 and 45 months $\pm$ 14 days of treatment (see outline of study procedures - [Appendix D](#)).

At each visit :

- Check the patient's diet (instruction only for patients without a weight maintenance diet - [Appendix F2](#)).
- Take fasting blood laboratory specimens for efficacy assessment of FPG and HbA1c ([section 5.5](#)).
- Check FPG results from the previous visit to ensure that they are no greater than 15 mmol/L in the first 3 months and no greater than 12 mmol/L in the remainder of the study (see [9.3](#) Reasons for Withdrawal)
- Standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#))
- Check compliance
- Check concomitant medication.
- Check for any adverse experiences.
- Schedule the next visit and dispense BRL 49653 medication (5 weeks of medication at visits 2 and 3; 15 weeks of medication at visits 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18).

Patients should be instructed to bring all remaining study medication with them to **each** study visit.

*Visit-Specific Instructions****Visits 4, 6, 8, 10, 12, 14, 16 and 18 (3, 9, 15, 21, 27, 33, 39 and 45 months' treatment)***

At Visits 4, 6, 8, 10, 12, 14, 16 and 18 in addition to the assessments listed under 'General Instructions' above, the investigator will:

- Weigh the patient (without shoes).
- Take fasting blood and urine laboratory specimens for safety assessment ([section 5.5](#)).

Visits 5, 7, 9, 11, 13, 15 and 17 (6, 12, 18, 24, 30, 36 and 42 months' treatment)

At Visits 5, 7, 9, 11, 13, 15 and 17 in addition to the assessments listed under 'General Instructions' above, the investigator will:

- Weigh the patient (without shoes).
- Take fasting blood and urine laboratory specimens for safety assessment, for 'efficacy - other', i.e. insulin and lipids and for urinary albumin ([section 5.5](#)).
- Perform a standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patients case report form).

5.4.3 Visit 19 - Final study visit (48 months)

At the final visit, Visit 19, (48 months) the following procedures will be performed:

- Physical examination including standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#)).
- Body weight (without shoes).
- Fasting blood and urine laboratory specimens for safety assessment, for FPG and HbA1c, for 'efficacy - other', i.e. insulin and lipids and for urinary albumin ([section 5.5](#)).
- Diet check, since previous.
- Standardized measurement of blood pressure and heart rate (Refer to [section 5.5](#)).

- Standard 12-lead electrocardiogram (ECG). (A copy of the ECG will be attached to the patient's case report form).
- Concomitant medication check.
- Check compliance
- Adverse experience check.
- Study conclusion record.

Note: Protocol-specified birth control methods must be continued for a minimum of 30 days after the patient receives the last dose of study medication.

5.4.4 Unscheduled Visits

For patients on combination therapy, the investigator may alter the dose of the non-BRL 49653 hypoglycaemic agent if it is deemed necessary in order to improve the patient's glycaemic control or tolerance of treatment.

In order to ensure patient safety, the investigator should follow his/her normal practice when making such a dose adjustment with respect to when the patient is next reviewed, arranging additional, unscheduled visits if necessary. All unscheduled visits will be recorded in the Unscheduled Visit section of the case report form.

5.5 Clinical Observations and Procedures

5.5.1 In-clinic dosing

Patients should be scheduled to attend study visit days in the morning (AM). Each patient should be fasting, (i.e. nothing to eat or drink since 11pm the night before), and should not have taken their morning dose of study medication. After all clinical laboratory tests are completed in the fasting condition, the patient will be dosed in the clinic from the supply of study medication.

5.5.2 Clinical laboratory testing for efficacy and safety

The following **fasting** laboratory tests will be performed at the times specified in the protocol:

SafetyBiochemistry

Total Protein	LDH	Uric Acid	Potassium	γ GT
Albumin	Total Bilirubin	Calcium	Chloride	
ALT (SGPT)	Urea Nitrogen	Phosphorus	Bicarbonate	
AST (SGOT)	Creatinine	Sodium	Alkaline Phosphatase	

Haematology

Platelet Count	<i>RBC Indices:</i>	<i>WBC Differential:</i>
RBC Count	MCV	Neutrophils
Haemoglobin	MCH	Lymphocytes
Haematocrit	MCHC	Monocytes
Reticulocyte count	WBC Count	Eosinophils
	Basophils	

Urinalysis

Appearance	Glucose	WBCs / HPF
Specific Gravity	Ketones	Squamous Epithelial Cells
pH	Occult Blood	
Protein	RBCs / HPF	

Hepatitis testing*

Hep A Antibody Total
Hep B Core Antibody Total
Hep C Antibody

Efficacy

Plasma Glucose	<i>Lipid levels:</i>
Haemoglobin A1c	Total Cholesterol
Specific insulin levels	HDL Cholesterol
Urinary albumin (spot sample)	LDL Cholesterol
	Triglycerides
	Free Fatty Acids

* to be performed if ALT >1.5 times upper limit of normal

A central laboratory will be used for the routine haematological and biochemical assessments. All centres within a country should send their samples to this designated laboratory. Samples must be **clearly labelled** with the patient's number, initials, protocol number, centre number, visit number and date. Full details for the preparation and shipment of samples will be provided by the central laboratory to the Investigator before the start of the study.

All laboratory tests with values that become significantly abnormal after study drug administration should be repeated until the values return to normal or baseline and are to be recorded as an adverse experience if deemed appropriate. If such values do not return to normal within a period judged reasonable by the Investigator, the aetiology should be identified and the sponsor notified.

5.5.3 Measurement of blood pressure and heart rate

The plethysmographic method (with a mercury column sphygmomanometer) must be used to measure blood pressure throughout the study. All measurements will be made on the patient's non-dominant arm supported at heart level, using the same cuff size. If the patient's arm circumference is > 32 cm, a large blood pressure cuff should be used. Diastolic blood pressure will be measured at the disappearance of Korotkoff sounds - phase V. If possible, measurement will be taken by the same staff member at each visit.

Blood pressure and heart rate will be measured after the patient sits quietly for at least 5 minutes.

5.5.4 ECG measurements

A 12-lead ECG will be recorded at Visits 1, 5, 7, 9, 11, 13, 15, 17 and 19 i.e. after 0, 6, 12, 18, 24, 30, 36, 42 and 48 months. Atrial and ventricular rate, PR, QRS and QT intervals, and axis deviation will be recorded in the CRF. A sample of each ECG recorded, clearly labelled with patient initials, patient number (if randomised), protocol number, centre number and date taken will be inserted into the appropriate plastic wallet in the CRF. All clinically significant abnormalities found at baseline should be documented, and any clinically significant ECG abnormalities occurring during the study should be documented on the adverse experience forms ([Section 8.0](#)).

5.5.5 Clinical laboratory blood and urine sampling and handling

At each study visit (visits 1 to 19), approximately 30 ml of blood will be obtained from an arm vein and collected into colour coded sample collection tubes. Samples will be obtained prior to dosing and the exact time of sample collection and the time of administration of the dose will be recorded on the CRF.

No more than one hour should elapse between blood withdrawal and freezing of the separated plasma. Blood samples will be centrifuged for approximately 15 minutes at approximately 4°C. If a refrigerated centrifuge is not available, the blood samples should be processed as quickly as possible and not left standing at

room temperature. The plasma will be transferred to a plain polypropylene tube labelled with the following information: Study centre number, patient number, week of study, date, and time of sample. Plasma samples will be stored frozen at approximately -70°C to await assay. If -70°C facilities are not available, then samples must be stored at -20°C and collected arranged with SmithKline Beecham Clinical Laboratories (SBCL) as soon as possible. Urine specimens will be collected at visits 1, 4, 5, 6 and 7. Urine samples will be sent to SBCL for albumin analysis. SBCL will provide the handling and transportation of the drug specimens to the central laboratory. As appropriate, urine will also be tested at each visit to check for pregnancy (women only). The investigator must read the laboratory manual for specific sampling and handling procedures.

5.5.6 Medical history and diet check

All relevant previous medical history will not need to be recorded again at Visit 1. This information was recorded on the case record form from the previous study. However, any new medical history will be documented at subsequent visits (including Visit 1). Standard medical terminology will be used to record all current conditions by diagnosis. Following the diet check at visit 1, instruction should only be given/repeated for patients who demonstrate a lack of understanding of their diet. At each subsequent visit, the patient must be encouraged to comply with their weight maintenance diet.

6 Study Medication and Administration

6.1 Study Medication

BRL 49653C will be supplied by SmithKline Beecham in the form of 2 mg tablets. For patients for whom the BRL 49653 is being added to pre-existing oral hypoglycaemic agents (i.e. the patients on combination therapy) the non-BRL 49653C agent will continue to be supplied by individual study centres.

The BRL 49653C 2 mg will be supplied as white, bi-convex, film coated (7 mm) tablets.

6.2 Dosage and Administration

The investigator must complete the number of tablets in the blank spaces before dispensing the study medication. Dosing instructions will be as follows:

Take tablet(s) in the morning **BEFORE** breakfast and tablet(s) in the evening **BEFORE** a meal.

On the morning of a clinic visit do not take any medication.

Return all empty medication packs and remaining medication at the next clinic visit.

6.3 Method of Blinding

The study will not be blinded, study medication (BRL 49653) will be provided open label.

6.4 Packaging

Study medication will be presented in HDPE bottles which will contain an overage for each period of the study, to allow for some flexibility of the intervals between visits.

Medication for each patient will be packed in bottles containing: 70 x BRL 49653 2 mg tablets

The following number of containers will be dispensed to the patient at each visit:

Visit	Period of treatment	No of tablets to dispense - 2mg bd	No of tablets to dispense - 4mg bd
1	4wks $\pm$ 7 days	1 x 70	2 x 70
2	4wks $\pm$ 7 days	1 x 70	2 x 70
3	4wks $\pm$ 7 days	1 x 70	2 x 70
4	3months $\pm$ 2 weeks	3 x 70	6 x 70
5	3months $\pm$ 2 weeks	3 x 70	6 x 70
6	3months $\pm$ 2 weeks	3 x 70	6 x 70
7	3months $\pm$ 2 weeks	3 x 70	6 x 70
8	3months $\pm$ 2 weeks	3 x 70	6 x 70
9	3months $\pm$ 2 weeks	3 x 70	6 x 70
10	3months $\pm$ 2 weeks	3 x 70	6 x 70
11	3months $\pm$ 2 weeks	3 x 70	6 x 70
12	3months $\pm$ 2 weeks	3 x 70	6 x 70
13	3months $\pm$ 2 weeks	3 x 70	6 x 70
14	3months $\pm$ 2 weeks	3 x 70	6 x 70
15	3months $\pm$ 2 weeks	3 x 70	6 x 70
16	3months $\pm$ 2 weeks	3 x 70	6 x 70
17	3months $\pm$ 2 weeks	3 x 70	6 x 70
18	3months $\pm$ 2 weeks	3 x 70	6 x 70

For patients for whom the BRL 49653 is being added to pre-existing oral hypoglycaemic agents (i.e. the patients on combination therapy) the non-BRL 49653C agent will continue to be supplied by individual study centres.

6.5 Labelling and Preparation

A two-panel double-blind label consisting of a fixed portion and a tear-off portion will be attached to each study medication pack. The Investigator or his/her designate will remove the tear-off label from each pack at the time of dispensing and attach it to the appropriate page in the CRF.

Labels will contain:

- patient identification (to be added at time of dispensing)
- protocol number
- clinical trial supply job number
- dosage directions
- expiry date (*only if required by local regulations*)
- any locally required regulatory statements
- Keep out of reach of children

- For Clinical Trial Use Only
- SB address

6.6 Storage

Study medication will be stored between 15°C and 30°C in a secured, supervised location. A log for recording receipt of and use of study medications will be maintained by the designated personnel at the investigator site.

6.7 Drug Accountability

At the time of delivery of medication to the study site, the Investigator or his/her designate or pharmacist (where appropriate) will sign a Drug Receipt Form to confirm that the supplies for the study have been received. This will specify job or lot numbers, quantities shipped/delivered and the date of receipt. The form will also contain a statement confirming that the investigational products will be handled and stored safely and properly. The investigator/pharmacist must also ensure that the investigational products will only be dispensed to patients in accordance with the protocol, and that any unused products, including placebo, will be returned to SB.

The Investigator or his/her designate or pharmacist (where appropriate) will record all study medication dispensed on a Drug Accountability Form. At the end of the study, reconciliation must be made between the amount of medication supplied, dispensed and subsequently returned to SB. Any discrepancies must be accounted for. A certificate of return must be signed incorporating the assurance from the Investigator or Pharmacist that all used and unused investigational products have been returned. Supplies will in the majority of cases, be returned to the local SB site for subsequent destruction. In exceptional cases, supplies may be destroyed at the centre. Destruction should only be performed by authorised personnel who are aware of any possible hazardous effects and following receipt of written approval from the local SB office. The procedure should be documented in full, in writing.

6.8 Assessment of Compliance

The number of BRL 49653 tablets dispensed at each clinic visit will be recorded and patient will be instructed to return any unused drug at the next visit. Counts

of tablets returned will be made at the beginning of Visits 2 to 19. Compliance will be calculated for BRL 49653 tablets as follows:

$$\frac{\{\text{No. dispensed} - \text{No. returned}\}}{Y \times \{\text{No. days since the last visit}\}} \times 100$$

where Y = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)
where Y = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

6.9 Treatment of Study Medication Overdose

The dose of BRL 49653C considered to be an overdose has not been defined. Treatment of suspected or confirmed overdose should be symptomatic.

For reporting of overdosage, see [section 8.6](#).

6.10 Occupational Safety

Study drugs are not expected to pose significant occupational safety risks to investigational staff under normal conditions of use and administration. However, precautions should be taken to avoid direct skin contact, eye contact and generating aerosols or mists. In case of unintentional occupational exposure, treat as if the material contained the active pharmaceutical even though it is absent from placebo formulations. A Material Safety Data Sheet (MSDS) describing occupational hazards and recommended handling precautions for the active formulated pharmaceutical(s) as well as the placebo are available upon request by contacting [REDACTED]. In case of occupational exposure, contact the site monitor or medical monitor for the study.

6.11 Concomitant Medication/Treatment

The use of insulin is prohibited during the study.

Patients on monotherapy BRL 49653 will not be permitted to take other hypoglycaemic agents for the duration of the study.

For patients on combination therapy, the dose of their other hypoglycaemic therapy may be altered during this study if necessary but it may not be switched for another treatment nor may a further hypoglycaemic agent be added. Thus, for

example, a patient starting the study on glibenclamide and BRL 49653 2 mg bd may have the dose of the glibenclamide increased or decreased (if in the investigator's opinion it is necessary in order to improve the patient's glycaemic control or tolerance of the combination) but the glibenclamide could not be switched for another sulphonylurea, nor could metformin be added to make a 3-drug regimen.

The use of fibrates or statins will be allowed without restriction during the study. Dosage levels of all other concomitant medications should, if medically appropriate, remain unchanged while the patient is enrolled in the study. All concomitant medication taken during the study must be recorded in the case report form with indication, daily dose and dates of administration. If dosage change of concomitant medication is necessary, information pertaining to the change must also be documented on the patient's case report form (concomitant medication pages).

Any patient exhibiting signs or symptoms of congestive heart failure should be managed with loop diuretics. If s(he) fails adequately to respond to the loop diuretics, then study medication should be discontinued and the patient withdrawn from the study. Patients who develop oedema on study in the absence of heart failure (no heart sound, cardiomegaly, nor raised jugular-venous pressure) will be permitted to continue in the study if it is the investigator's judgement that it is not in the patient's best interest to discontinue.

7 Outcomes Research and Pharmacoeconomics

Outcomes research and pharmacoeconomics will not be analysed in this study.

8 Adverse Experiences

The recording of adverse experiences is an important aspect of study documentation. Detailed guidelines are set out below.

8.1 Eliciting and Documenting Adverse Experiences

It is the responsibility of the investigator to document all adverse experiences which occur during the investigation.

An adverse experience includes any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical study whether associated with the study medication, active comparator or placebo and whether or not considered drug related. This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the significant worsening of the disease under investigation that is not recorded elsewhere in the case record form under specific efficacy assessments. Anticipated day-to-day fluctuations of pre-existing conditions, including the disease under study, that do not represent a clinically significant exacerbation or worsening need not be considered adverse experiences. Discrete episodes of chronic conditions occurring during a study period should be reported as adverse experiences in order to assess changes in frequency or severity.

Adverse experiences should be documented in terms of a medical diagnosis(es). When this is not possible, the adverse experience should be documented in terms of signs and/or symptoms observed by the investigator or reported by the patient at each study visit.

Any pre-existing conditions or signs and/or symptoms present in a patient prior to the start of the study should be recorded on the Medical/Surgical history form within the patient's case report form (CRF).

Adverse experiences which occur after informed consent is obtained, but prior to starting active or randomised treatment will be documented on the 'Baseline signs and symptoms' report form as instructed by the SB clinical study monitor. All adverse experiences occurring after administration of the first dose of study medication (i.e., active drug, placebo, comparator drug) and on or before the final visit, must be reported on the Adverse Experience form in the subject's CRF. All subsequent adverse experiences, whether no drug (i.e. during reference 'run-in' or 'wash-out' period) or when active drug or placebo is being administered, must be reported REGARDLESS OF WHETHER OR NOT THEY ARE CONSIDERED DRUG RELATED.

Serious adverse experiences which occur during the clinical study or within 30 days or five half lives, whichever is the longer, of receiving the last dose of study medication, whether or not related to study drug, must be reported.

Instances of death, cancer or congenital abnormality if brought to the attention of the Investigator AT ANY TIME after cessation of study medication AND

considered by the Investigator to be possibly related to study medication, should be reported to the Study Monitor.

At each visit/assessment, adverse experiences will be evaluated by the Investigator. Adverse experiences not previously documented in the study will be recorded in the adverse experience record form within the patient's CRF. The nature of each experience, date and time (where appropriate) of onset, outcome, course (i.e. intermittent or constant), maximum intensity, action taken with respect to dosage and relationship to treatment should be established. Details of changes to the dosage schedule or any corrective treatment should be recorded on the appropriate pages of the CRF.

Adverse experiences already documented in the CRF (i.e., at a previous assessment) and designated as 'ongoing' should be reviewed at subsequent visits as necessary. If these have resolved, the documentation in the CRF should be completed. If an adverse experience increases in frequency or severity during a study period, a new record of the experience will be started.

For studies in which there is a delay of greater than 30 days between dosing, and during this time no protocol specific procedures required (e.g. vaccine studies), adverse experiences will be recorded for a period of 30 days only after each dosage administration (See [section 8.5](#) for qualification with regard to serious AEs).

As a consistent method of soliciting AEs, ask the subject a non-leading questions such as:

"Have you felt different in any way since starting the new treatment/or since the last visit?"

8.2 Assessment of Intensity

Maximum intensity should be assigned to one of the following categories:

Mild: An adverse experience which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: An adverse experience which is sufficiently discomforting to interfere with normal everyday activities.

Severe: An adverse experience which prevents normal everyday activities.

8.3 Assessment of Causality

Every effort should be made by the investigator to explain each adverse experience and assess its relationship, if any, to study drug treatment. Causality should be assessed using the following categories: not related, unlikely, suspected (*reasonable possibility*), probable.

Not related: The adverse experience is definitely not related to the test drug.

Unlikely: There are other, more likely causes and the drug is not suspected as a cause.

Suspected (*reasonable possibility*): A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but *there is a reasonable possibility that the experience was caused by the drug*.

Probable: There *probably* is a direct cause and effect relationship between the adverse experience and the study drug.

The degree of certainty with which an adverse experience is attributed to drug treatment (or alternative causes, e.g. natural history of the underlying diseases, concomitant therapy, etc.) will be determined by how well the experience can be understood in terms of one or more of the following:

- Known pharmacology of the drug.
- Reaction of similar nature being previously observed with this drug or class of drug.
- The experience having often been reported in literature for similar drugs as drug related e.g. skin rashes, blood dyscrasia.
- The experience being related by time to drug ingestion terminating with drug withdrawal (dechallenge) or reproduced on rechallenge.

8.4 Follow-up of Adverse Experiences

Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilized. Reports relative to the subsequent course of an AE noted for any subject must be submitted to the clinical study monitor.

8.5 Serious Adverse Experiences

8.5.1 Definition of Serious Adverse Experiences

A serious adverse experience is any event which is fatal, life threatening, disabling/incapacitating or results in hospitalisation, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug will be documented as a serious event.

Life threatening - definition:

An adverse experience is life threatening if the subject was at immediate risk of death from the event as it occurred (i.e., it does not include a reaction that if it had occurred in a more serious form might have caused death). For example, drug induced hepatitis that resolved without evidence of hepatic failure would not be considered life threatening even though drug induced hepatitis can be fatal.

Disability/incapacitating - definition:

An adverse experience is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the subject's ability to carry out normal life functions.

Hospitalisation - definition

AEs requiring hospitalisation should be considered serious. Hospitalisation for elective surgery or routine clinical procedures that are not the result of an AE (e.g., elective surgery for a pre-existing condition) need not be considered AEs and should be recorded on the medical/surgical procedures form. If anything untoward is reported during the procedure, that occurrence must be reported as an AE, either 'serious' or 'non-serious' according to the usual criteria.

In general, hospitalisation signifies that the subject has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out-patient setting. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE should be considered serious.

Routine Clinical Procedure - definition

One which is defined in the protocol as a procedure which may take place during the study period and should not interfere with the study drug administration or any of the ongoing protocol specific procedures.

8.5.2 Reporting Serious Adverse Experiences

Any serious adverse experiences which occur at any time during the clinical study or within 30 days or five half lives, whichever is the longer, of receiving the last dose of study medication, whether or not related to the study medication, must be reported by the investigator to the study monitor by telephone within 24 hours:

Investigators should not wait to receive additional information to fully document the event before notifying SmithKline Beecham of a serious adverse experience. The telephone report should be followed by a full written summary utilising the SB serious AE worksheet detailing relevant aspects of the adverse experiences in question. Where applicable, information from relevant hospital case records and autopsy reports should be obtained.

Instances of death, cancer or congenital abnormality if brought to the attention of the Investigator AT ANY TIME after cessation of study medication AND considered by the Investigator to a previous clinical trial, should be reported to the site monitor.

8.6 Reporting of Overdose

Any instance of overdosage (suspected or confirmed and irrespective of whether or not it involved study medication) must be communicated to SmithKline Beecham within 24 hours and be fully documented as a serious adverse experience. Details of any signs or symptoms and their management should be recorded including details of any antidote(s) administered.

8.7 Pregnancy

Subjects who become pregnant during the study should discontinue the study immediately, unless the protocol states otherwise. Subjects should be instructed to notify the investigator if it is determined after completion of the study that they become pregnant either during the treatment phase of the study or within 30 days (or five half-lives after the treatment period) whichever is longer. Whenever possible a pregnancy should be followed to term, any premature terminations

reported, and the status of the mother and child should be reported to SmithKline Beecham after delivery.

9 Subject Completion and Withdrawal

9.1 Definitions

- All patients will be considered to have completed the current study upon completion of 48 months' treatment and of the assessments and procedures scheduled at Visit 19.
- Any patient who enters the study, (i.e. gives written informed consent) but does not, **for any reason** complete the study according to the definition given above, will be considered as a withdrawal, irrespective of whether they have received any study medication.

9.2 Procedures for Handling Withdrawals

Bottles of medication assigned to patient(s) who have been withdrawn, and which have been opened, will not be re-used.

Patients who terminate their participation in the study due to adverse experiences should be followed up as appropriate ([Section 8.4](#)) in order to determine the final outcome.

All patients who withdrew or are withdrawn from the study after receiving study medication should return for a follow-up visit wherever possible and the Conclusion/Early Withdrawal assessment and procedures should be completed in the CRF.

Case Report Forms of **all** patients entered into the study must be kept and the reasons for withdrawal will be noted on the Study Conclusion page for all enrolled patients who do not complete the study. In addition, the date of last dose of study medication must be recorded on the Study Conclusion page for all patients withdrawn from the study.

9.3 Reasons for Withdrawal

Every effort must be made by the Investigator to keep patients in the study. However, a patient may be discontinued prior to completion of the study for the following reasons:

- Adverse experience (see [Section 8.0](#)). NB a patient with clinical evidence of anaemia (Hb < 11 g/dL for males, < 10 g/dL for females or a fall in Hb of ≥ 1.5 g/dL for males, ≥ 1.0 g/dL for females) experiencing angina or exacerbation of pre-existing angina should be withdrawn from the study.
- Lack of efficacy (i.e. insufficient therapeutic effect), as defined below:
 - Patients with a fasting plasma glucose ≥ 15 mmol/L on 2 consecutive occasions at any time during the first 3 months of treatment (the second test to be performed within 7 days of recording a value of 15 mmol/L).
 - For months 3-48 of treatment, patients with a fasting plasma glucose ≥ 12 mmol/L on 2 consecutive occasions (the second test to be performed within 7 days of recording a value of 12 mmol/L).
 - Fasting blood glucose has increased to a level that is deemed by the investigator to be a safety risk to the patient.
 - Patients will be withdrawn if they require insulin.
 - Any other metabolic disorder deemed by the investigator to be a safety risk to the patient.
- A protocol violation, including lack of compliance visit schedule or treatment prohibited concomitant medications.
- Patient lost to follow-up.
- The patient requested an early discontinuation.
- Termination of the study by SmithKline Beecham.
- Other (reason to be documented in the CRF).

All adverse experiences leading to withdrawal of a patient must be fully documented and followed-up as appropriate (see [Section 8.0](#)). To ensure that all

withdrawals due to Adverse Experiences are correctly identified, "Adverse Experience" should only be checked as the reason for withdrawal on the Study Conclusion page for those patients for whom an Adverse Experience was considered to be the direct cause of the patient withdrawing from the study. This is particularly important when Adverse Experiences are ongoing at the time of withdrawal but the reason for withdrawal is not related to the Adverse Experiences.

10 Data Evaluation

The primary objective is to evaluate the long term safety and tolerability of BRL 49653 administered as 4 mg bd monotherapy, or as 2 mg bd in combination with other oral hypoglycaemic agents, for up to 48 months in the treatment of patients with NIDDM. The secondary objective is to evaluate the long term efficacy of BRL 49653 in terms of glycaemia.

10.1 Target Sample Size

Patients who have completed a previous BRL 49653 study and who meet the eligibility criteria for this study will be invited to participate in this extension study. Approximately 1000 patients with NIDDM, completing previous BRL 49653 studies will be invited to participate, if eligible. It is estimated that between 400 and 1000 patients will enter the study. Approximately 100 centers in Europe will participate.

10.2 Method of Randomization

Treatment allocation is not randomised.

10.3 Planned Efficacy Analysis

10.3.1 Primary Efficacy Variables

The primary efficacy variable is change from baseline in HbA_{1c} at month 48. There are 2 baselines: open-label baseline and double-blind baseline. Double-blind baseline is defined as the baseline before the double-blind medication was issued in the previous study. Because all assessments should be performed before open-label medication is issued, open-label baseline will be defined as those results obtained on the first day of open-label medication but prior to the ingestion

of medication. If test results are not available for the first day of open-label medication, then the values obtained on the nearest preceding date will be considered as open-label baseline.

10.3.2 Secondary Efficacy Variables

The secondary efficacy variables are analysed as change from baseline at month 48 (as defined in 10.3.1) for:

- fasting plasma glucose
- fasting specific insulin levels
- urinary albumin
- lipid levels (i.e., total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and fatty acids)

10.3.3 Comparison of Interest

Because this study consists of a non-randomised, pre-selected population of patients all receiving BRL 49653, hypothesis testing will not be performed. However, patients will be grouped according to whether they are receiving BRL 49653 4 mg bd as monotherapy or 2 mg bd in combination with another oral hypoglycaemic agent. In addition, these groups will be presented according to the treatment they received in the preceding protocols. See table below using protocol 49653/020 as an example of the previous protocol (in protocol 49653/020 patients are randomised to receive monotherapy BRL 49653 4 mg bd, 2 mg bd or glibenclamide).

Treatment Group	BRL49653 Dose Protocol 020	BRL 49653 Dose Protocol 009
020 2 mg/4 mg	020 2 mg bid	4 mg bid
020 4 mg/4 mg	020 4 mg bid	4 mg bid
020 glibenclamide/4 mg	020 glibenclamide	4 mg bid

10.3.4 Methods of Analysis

Descriptive statistics for each treatment group will be used to summarise the efficacy variables. For each time period, graphs will be constructed for mean change in efficacy variables from baseline (as defined in 10.3.1). Time periods will be defined as relative time from the double blind baseline in the previous study.

10.3.5 Subject Populations/Dataset to be Analysed

Data will be analysed with the patients who take at least one dose of study medication after entering the study. The interim analysis will be done for the same patient population. Missing values will be kept missing (last value will not be carried forward).

10.4 Planned Safety Evaluation

Evaluation of safety data will include all patients who received study medication. Clinical interpretation will be based upon review of displays of adverse events and laboratory values. Principal considerations in this evaluation will be time to onset, and investigator-reported relationship of either adverse events or laboratory abnormalities to study medication. Other safety parameters, such as patient withdrawals, ECGs, and laboratory values, will be summarised.

Adverse experiences documented in the previous protocols as 'continuing at end of study' will be transcribed onto the 49653/009 case report form. Because the onset of these experiences will have been prior to the start of open-label medication, these experiences will be considered as pre-therapy for reporting of 49653/009 data.

Body weight and vital signs (i.e. systolic, diastolic blood pressure and heart rate), and ECGs will be analysed as change from baseline at month 48.

Reports of hypoglycaemia will be grouped into:

- Adverse event reports of hypoglycaemia.
- Adverse event reports of hypoglycaemia plus a plasma glucose of < 50 mg/dL.
- Adverse event reports of hypoglycaemia with third party intervention/hospitalisation.

These will be summarised across the treatment groups as part of the safety assessment.

10.5 Interim Analysis

For administrative reasons, interim descriptions of the data will be required prior to the NDA/MAA filing.

However, there is no intention to stop the study based on these interim descriptions of the data.

The analyses for these interim descriptions will be performed as described above (10.0 - 10.4) using the data that has been collected at the time of the clinical cut-off.

11 Administrative Matters

To comply with Good Clinical Practice Guidelines, important administrative obligations relating to Investigator responsibilities, monitoring, archiving data, audits, confidentiality and publications must be fulfilled as given in [Appendix B](#).

12 References

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CONFIDENTIAL

BRL-049653/RSD-
100TV9/1/CPMS-009

CONFIDENTIAL

BRL-049653/RSD-
10194Z/1

13 Appendices

Appendix A Declaration of Helsinki

World Medical Association DECLARATION OF HELSINKI

Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects

Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964
and amended by the
29th World Medical Assembly
Tokyo, Japan, October 1975
35th World Medical Assembly
Venice, Italy, October 1983
41st World Medical Assembly
Hong Kong, September 1989
and the
48th General Assembly
Somerset West, Republic of South Africa, October 1996.

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human

subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In

that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity make it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replace that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the

experimental protocol for transmission the independent committee (see [1,2](#)).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers -- either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Appendix B Administrative Matters

I Responsibilities Of The Investigator

To ensure that he/she has sufficient time to conduct and complete the study, and has adequate staff and appropriate facilities which are available for the duration of the study, and to ensure that other studies do not divert essential subject/patients or facilities away from the study at hand.

To submit an up-to-date curriculum vitae and other credentials (e.g. medical license number in the United States) to the sponsor and - where required - to relevant authorities.

To acquire the normal ranges for laboratory tests performed locally and, if required by local regulations, obtain the Laboratory Licence or Certification.

To prepare and maintain adequate case histories designed to record observations and other data pertinent to the study.

II Protocol Amendments

No changes to the study protocol will be allowed unless discussed in detail with the SmithKline Beecham (SB) Medical Monitor and filed as an amendment/modification to this protocol.

Any amendment/modification to the protocol will be adhered to by the participating centre (or all participating centres) and will apply to all subjects following approval as appropriate by the Ethical Review Committee or Institutional Review Board.

III Sponsor's Termination Of Study

SB reserves the right to discontinue the clinical study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be tendered.

IV Case Report Form Instructions

Prior to screening the first potential participant, the investigator will provide a list showing the signature and handwritten initials of all individuals authorised to make or change entries on case report forms (CRFs). If the authorised individuals should change during the study, the investigator is to inform SB.

CRFs will be supplied by SB for recording all data. It is the responsibility of the investigator or co-investigator to ensure that CRFs are legible and completely filled in with a black ink ballpoint pen. The subject's identification (2-3 alphabetic letters representing initials or first letter of subject's name), the patient identification (PID) if not already pre-printed and the visit date, will be entered on the CRF Header Pages as required.

Errors must be corrected by drawing a single line through the incorrect entry and writing in the new value/data positioned as close to the original as possible. The correction must then be initialled, dated and justified by the authorised individual making the change. Do not obliterate, write over, or erase the original entry when making a correction.

When a subject completes a visit, it is anticipated that relevant sections of the CRF will be completed by the investigator (or designated staff) within 24 hours of the last data becoming available, but in no case later than 5 days. Similarly, when a subject completes a study, it is anticipated that all relevant CRF pages will be completed within 24 hours of the last data becoming available, but in no case later than 5 days. This also applies to forms for potential study participants who were not randomised to a treatment group.

As soon as the subject has completed/withdrawn from the study and the CRF is completed the principal investigator or designated physician(s) under his/her supervision will sign the adverse experience page(s) as well as study conclusion page of the CRF to confirm that they have reviewed the data and that the data are completed and accurate. If sections of a CRF are to be brought into SB prior to study conclusion, a section conclusion signature is required.

An original (top copy) CRF must be submitted for all subjects who have undergone protocol specific procedures, whether or not the subject completed the study.

While completed CRFs will be reviewed by an SB professional monitor at study site, errors detected by subsequent in-house CRF review may necessitate clarification or correction of errors and documentation and approval by the investigator.

Any questions or comments related to the CRF should be directed to the assigned study monitor.

V Monitoring By SmithKline Beecham (i.e. the Sponsor)

Monitoring visits by a professional representative of the sponsor will be scheduled to take place before entry of the first subject, during the study at appropriate intervals and after the last subject is completed.

These visits are for the purpose of verifying adherence to the protocol and the completeness and exactness of data entered on the CRF and Drug Inventory Forms. The monitor will verify CRF entries by comparing them with the hospital/clinic/office records which will be made available for this purpose. The monitor will retrieve completed CRF sections at each visit. Adequate time and space for these visits must be made available by the investigator.

Investigator must ensure provision of reasonable space and adequate qualified personnel for monitoring visits.

VI Archiving Of Data

The investigator must retain subject records and CRFs as well as drug disposition records in an easily retrievable form until disposal has been agreed in writing with SB. The investigator must have a 'key' linking the subject's study identification number (i.e. treatment number) to the subject's clinical file. If the investigator moves or retires, he/she must nominate someone in writing to be responsible for record keeping. Archived data may be held on microfiche or electronic record, provided that a back-up exists and a hard copy can be obtained from it if required.

SB agrees to retain a copy of the protocol, documentation, approvals and all other documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out.

VII Audits

For the purpose of compliance with Good Clinical Practice and Regulatory Agency Guidelines it may be necessary for SB or a Drug Regulatory Agency to conduct a site audit. This may occur at any time from start to after conclusion of the study.

When an investigator signs the protocol, he agrees to allow the Drug Regulatory Agency and SB auditors to inspect his/her study records. Furthermore, if an investigator refuses an inspection, his data will not be accepted in support of a New Drug Registration and/or Application.

SB has a substantial investment in clinical studies. Having the highest quality data and studies are essential aspects of drug development. SB has a Regulatory Compliance staff who audit investigational sites. Regulatory Compliance assesses the quality of data with regard to accuracy, adequacy and consistency. In addition, Regulatory Compliance assures that SB sponsored studies are in accordance with the relevant Good Clinical Practices regulations/guidelines are being followed.

To accomplish these functions, Regulatory Compliance selects investigational sites to audit. These audits usually take 1 to 2 days. The SB audits entail review of source documents supporting the adequacy and accuracy of CRFs, review of documentation required to be maintained, and checks on drug accountability. The SB audit therefore helps prepare an investigator for a possible regulatory agency inspection as well as assuring SB of the validity of the database across investigational sites.

The Inspector will be especially interested in the following items:

- Log of visits from the sponsor's representatives.
- ERC/IRB approval.
- Test article accountability.
- Approved study protocol and amendments.
- Informed consent of the subjects.
- Medical records supportive of CRF data.
- Reports to the ERC/IRB and the sponsor.
- Record retention.

SB will gladly help investigators prepare for an inspection.

VIII Confidentiality And Publication

You agree that all information communicated to you by SB is the exclusive property of SB and you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed by you or such person to any third party without the prior written consent of SB. You shall communicate the results of the work promptly to SB.

We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall so request you will delay publication for a maximum of six months to enable us to protect our rights in such information or material. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to a journal or scientific meeting, should be sent to the

study monitor prior to submission. SB will undertake to comment on such documents within four weeks.

All rights and interests worldwide in any inventions, know-how or other intellectual or industrial property rights which arise during the course of and/or as a result of the clinical study which is the subject of this Protocol or which otherwise arise from the information or materials supplied under this Agreement, shall be assigned to, vest in and remain the property of SmithKline Beecham plc.

Appendix C Sample Informed Consent Statement and Patient Information Leaflet

WRITTEN INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

INVESTIGATOR:

STUDY TITLE: A multicentre, open label extension study to assess the long term safety, tolerability and efficacy of BRL 49653C when administered to patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM).

PROTOCOL NO.: 49653 / 009

SPONSOR: SmithKline Beecham Pharmaceuticals ("The Company").

INFORMATION

1. DESCRIPTION/PURPOSE OF THE STUDY

This is a medical research study.

Its purpose is to determine the long term safety and effectiveness of BRL 49653C ("the product"), an anti-diabetic drug, at two different doses, one dose as monotherapy and the other dose as combination therapy with other hypoglycaemic agents.

The study will last for less than 49 months.

Approximately 400 to 1000 other patients will take part in this study.

The study will involve a minimum of fifteen visits to the clinic and the following tests will be carried out:

A physical examination.

An electrocardiogram (ECG) will be performed seven times during the study. The ECG test will be performed at Visits 1, 5, 7, 9, 11, 13, 15, 17 and 19. The ECG test will be used to check your heart.

At each visit, approximately 30 ml of blood will be taken through a needle in your vein for laboratory tests; a urine sample will be collected at visit 1 and at visits 4 to 19.

The protocol has been reviewed and accepted by an independent ethics review committee.

2. RISKS ASSOCIATED WITH THE STUDY

All drugs may cause side-effects in some patients. The most common side-effect of BRL 49653C, "the product", known to "the Company" at this time is headache. It is possible that treatment with BRL 49653C could lower your blood sugar too much. This could make you feel tired, dizzy, sweaty, and or nauseated (sick). Also, it could cause your heart to feel that it is racing. These signs and symptoms are referred to as hypoglycaemia (low blood sugar). If such sugar changes persist, the study physician may remove you from the study so that you can be treated with medication chosen by your own doctor.

In a study of 380 patients, BRL 49653C was associated with other side effects. These side effects were seen in patients taking BRL 49653C and were also seen in patients taking a non-active drug (placebo). The side effects for both active drug and non-active drug (placebo) occurred in a similar number of cases and at a similar strength.

Certain procedures, including heart rate and blood pressure monitoring, form part of the clinical study. These investigations would normally be carried out by a physician in routine examination of your condition. In addition, electrocardiogram (ECG) recordings will be made and three blood samples (approximately 30 ml total) will be taken.

The drugs used in this study may involve other risks that are not known at the present-time.

Liver Monitoring

Another member of the same class of drugs, troglitazone, has been found to cause liver injury in some patients. However, we have not seen evidence of a pattern of liver injury with rosiglitazone.

In America, rosiglitazone is a marketed drug and to date approximately 250,000 patients have been treated with it. Amongst the 250,000 patients treated so far, a few liver-related events have been observed. These events have been reviewed by a panel of independent experts and they concluded that these cases do not suggest that rosiglitazone causes liver injury. So far, in clinical trials, more than 3300 people have taken rosiglitazone for at least 6 months and over 2000 people have taken it for at least 12 months. In these patients, there have been no reports of damage to the liver caused by treatment with this drug.

A few patients have had either small or moderate increases in their liver enzymes. However, most of these patients continued in the clinical trials without experiencing any further increase in their liver enzymes.

As a precaution, liver tests will be performed at least every two months during the first year of this study and at least every 6 months after that. However, they may be checked more frequently, if your doctor thinks it appropriate.

If you experience unexplained nausea, vomiting, abdominal pain, fatigue, loss of appetite and/or dark-colored urine, inform your doctor.

If this occurs in between scheduled study visits, telephone your doctor immediately. Your doctor may ask you to return to the clinic and/or to stop taking study medication.

Lipids, Anaemia and Oedema

A small number of patients taking rosiglitazone developed increases in cholesterol, decreases in red blood cell count (anaemia), or fluid accumulation (oedema). Most of these side effects were mild or moderate, and patients were rarely withdrawn from the study by the doctor for these side effects. During the study, you will be examined by the study doctor and your cholesterol and blood counts will be checked on a regular basis. If you experience shortness of breath, tightness or pain in the chest you should contact your study doctor immediately. If you currently suffer from angina and you feel the frequency of the angina is increasing, you should contact your study doctor immediately.

3. BENEFITS ASSOCIATED WITH THE STUDY

There is no guarantee that you will benefit by participating in this study; however, you and other patients in the future may benefit from this study and any future medical research. Such benefits include the possibility that your condition may

improve and that this study may help develop a new therapy for others with similar conditions.

Visits, procedures (tests) related to the study, and study medications will be provided at no charge to you. If you complete the current study, you may have the option of continuing the study, if it is extended.

4. ALTERNATIVE THERAPY

There are alternative therapies for your diabetes. If you have questions about other therapies, ask your doctor for additional information.

5. CONFIDENTIALITY AND SOURCE DOCUMENT REVIEW

Your participation in the study will be treated as confidential and any records or results relating to the study shall not be disclosed to any third party other than representatives of "the Company" or its affiliated companies or regulatory bodies for medicines in the UK or elsewhere, for the purposes of effecting registration of "the product" or for the purposes of medical research, or as may otherwise be required in law.

Your identity will remain confidential.

"The Company" will ensure that it complies with any national data protection regulations.

6. RIGHT TO ASK QUESTIONS AND/OR WITHDRAW FROM THE STUDY

You have the right to ask questions concerning the potential and/or known hazards of this study at any time. You will be informed of any significant new information pertaining to your safety.

If you have any questions concerning this study, please contact:

Name Tel. No.

You have the right to withdraw from the study at any time and do not have to give a reason for so doing.

Should you wish to withdraw from the study at any time, your routine medical care will not be affected in any way.

Your doctor may withdraw you from the study at any time if it is felt to be in your best interest.

If you should withdraw voluntarily from the study or are asked by the doctor to leave the study, you must return all unused study medications. You will be asked questions about your experience with the study drug. You also may be asked to co-operate in having whatever laboratory tests and physical examinations the doctor considers necessary.

7. COMPENSATION (MEDICAL/FINANCIAL) TO BE PROVIDED

If you become ill or injured as a result of participation in this clinical study, medical treatment will be provided, and the costs of such treatment will be paid by "the Company". If you have any questions concerning the availability of compensation/medical care, or if you think you have experienced a research-related illness or injury, contact:

Name: (Investigator) Tel. No.:

8. COSTS

The Company will reimburse you for any additional costs incurred as a participant in this study i.e. travel expenses to and from the clinic.

9. VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled.

You may discontinue your participation in the study at any time without loss of benefits to which you are otherwise entitled.

You are entitled to receive a signed copy of this form.

CONSENT

I, ..., have read and understand all the preceding information describing this medical research study and all my questions have been answered to my satisfaction. I have read the Patient Information Leaflet relating to this study. I voluntarily consent to participate in this study.

Dr. has explained to me this study in detail. I voluntarily consent to participate in this trial.

Signature of Patient
(Parent/Legal Representative)

Date: _____

SAMPLE PATIENT INFORMATION LEAFLET

Thank you for your interest in our study. The purpose of it is to find out whether a new drug, BRL 49653C (the drug code number), is useful in treating patients such as yourself, who have non-insulin dependant diabetes mellitus (NIDDM).

ABOUT THE INVESTIGATIONAL DRUG AND THE STUDY

BRL 49653C is an investigational drug. This means that it has not been approved by the regulatory authorities for sale, but it may be tested in medical research studies such as this one. BRL 49653C is a new type of drug called an "insulin sensitizer" which can help make the insulin your body produces work better and help to decrease your blood sugar levels.

It has been shown in other studies that BRL 49653C may be able to help control your diabetes. This medical research study is therefore being run to try and help your diabetes safely using BRL 49653C.

As many as 400 to 1000 patients at about 100 centres in Europe may take part in this study. The whole study, from first visit to last visit, is approximately 48 months long. If you agree to take part, you will be asked to take regular study medication.

The study is called "open" because you will receive active study medication. You (and all the other patients) will take BRL 49653C in the morning and then again in the evening. **IT IS IMPORTANT THAT YOU TAKE YOUR MEDICATION AS DIRECTED BY THE STUDY DOCTOR.** If you were taking two types of study medication for your diabetes in the previous study, for example, you were also taking a sulphonylurea, then you will be asked to continue to take this. If you were taking study medication on its own during the previous study, then you will not need to change your therapy.

During this study you may experience side effects of study medications. It is possible that treatment with BRL 49653C could lower your blood sugar too much. This could make you feel tired, dizzy, sweaty, and/or nauseated (sick). Also, it could cause your heart to feel as if it is racing. These signs and symptoms are referred to as hypoglycaemia (low blood sugar). If such blood sugar changes continue, the study doctor may remove you from the study so that you can be treated with medication chosen by your own doctor.

So far, BRL 49653C has been given to more than 4500 patients in controlled clinical trials and more than 250000 patients in the US. In the previous studies,

headache was the most common side effect; however, BRL 49653C may have other side effects, some of which are not yet known. The side effects which were seen in patients taking BRL 49653C, were also seen in patients taking a non-active drug (placebo). The side effects for both active drug and non-active drug (placebo) occurred in a similar number of cases and at a similar strength. To date, no studies have been reported to show how BRL 49653C interacts with other prescribed medications or over-the counter medications that you may be taking.

At this time, we do not know the effect of BRL 49653C on the developing foetus. Therefore, there is a risk that if you become pregnant, you could have a miscarriage, or your baby could be deformed. Pregnancy **must** be avoided during the study and for at least 30 days after you take the last dose of study medication. Women must agree not to become pregnant during the study, and only women who agree not to become pregnant will be allowed to participate. At any time, if you suspect that you are pregnant while participating in the study, you must call your doctor immediately and discontinue the study medication because of the unknown risk to the developing foetus. Your doctor will start alternative treatment for your diabetes following withdrawal from the study.

STUDY PROCEDURES

If you decide to take part in the study, then your last visit in the previous study will be the first visit in this new study, i.e. you will not need to attend an extra visit at the start. However, at this visit, all the aims of the new study and procedures involved will be explained to you in full by your doctor. Please feel free to ask your doctor any questions. You should only consent to participate when you are satisfied that everything about the study has been explained to you by the study doctor.

At the first visit, the study doctor or a member of the study staff will ask you how you felt since the last visit. All the procedures scheduled to take place for the previous study will be completed at the first visit. You will have a medical examination which will include an electrocardiogram (ECG). The ECG test (pictures of the heart) will be repeated four more times during the study.

After the first visit you will come to the clinic again for 19 more visits (in the morning). For approximately 9 hours prior to these visits (after 11:00 pm at night until your visit the next morning), you will be asked not to eat or drink (water is allowed). At each visit, blood will be taken through a needle in your vein for laboratory tests. In all, approximately one cup full of blood (possibly a little more if additional tests are needed) will be taken during the study but your body will

quickly make up for this small loss. A urine specimen will also be collected at visit 1, and at visits 4 to 19. If appropriate (women only), a small amount of urine will also be used at each study visit to test that you are not pregnant.

At the first visit you will receive your study medication and instructions on how to take it. You may also receive guidance on your diet if required from a qualified member of the study team. You should not change your previous diet habits unless told to do so.

If you were taking two types of study medication for your diabetes in the previous study, then you will be asked to take two tablets of BRL 49653C each day, together with your other medication. At the start of breakfast in the morning (am) you will take one tablet of BRL 49653C together with your other diabetes medication, and in the evening (pm) you will take one tablet of BRL 49653C before your meal.

If you were taking only one type of study medication for your diabetes in the previous study, then you will be asked to take four tablets of BRL 49653C each day. At the start of breakfast in the morning (am) you will take two tablets of BRL 49653C, and in the evening (pm) you will take two more tablets of BRL 49653C before your meal.

On the day of your visit you will not take your morning dose of study medication at home, but will be given it in the clinic after your tests have been completed. You must remember not to eat or drink (water is allowed) after 11:00 pm the night before your visit (this includes breakfast on the day of your visit). It is important to tell the study doctor if you have had anything to eat or drink (except water) within 9 hours of the visit or if you have taken your morning study medication by mistake. You must also remember to bring all your study medication to the clinic at each visit.

BENEFITS

There is no guarantee that you will benefit by participating in this study; however, you and other patients in the future may benefit from this study and any future medical research. Such benefits include the possibility that your condition may improve and that this study may help develop a new therapy for others with similar conditions.

Clinic visits, procedures related to the study, and study medications will be provided at no charge to you. If you complete the current study, you may have the option of continuing the study, if it is extended.

ALTERNATIVE TREATMENT

Other medications are available to treat diabetes. If you have questions about other treatments, ask your doctor for more information.

CONFIDENTIALITY OF INFORMATION

Your participation in the study will be treated as confidential, and any records or results relating to the study shall not be disclosed to any third party other than representatives of "the Company" or its affiliated companies or regulatory bodies. This means that your identity and your medical records will remain confidential.

We hope you will consider taking part in this study and we thank you for your interest even if you decide not to participate. Your doctor will be able to answer any questions about the study that you may have.

Appendix D Outline of Study Procedures

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
	1 mo	2 mo	3 mo	6 mo	9 mo	12 mo	
Demography	X						
Medical History	X						
Physical examination	X	X	X	X	X	X	X
AE check	X ¹	X	X	X	X	X	X
BP & HR	X ²	X	X	X	X	X	X
ECG	X ²				X		X
Weight	X ²			X	X	X	X
Compliance		X	X	X	X	X	X
Labs (blood & urine) - safety	X ²			X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X ²	X	X	X	X	X	X
Labs (blood) - efficacy - (other) ³	X ²				X		X
Urine Albumin	X				X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X

	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
	15 mo	18 mo	21 mo	24 mo	27 mo	30 mo	33 mo
Demography							
Medical History							
Physical examination	X	X	X	X	X	X	X
AE check	X	X	X	X	X	X	X
BP & HR	X	X	X	X	X	X	X
ECG		X		X		X	
Weight	X	X	X	X	X	X	X
Compliance	X	X	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X	X	X
Labs (blood) - efficacy - (other)		X		X		X	
Urine Albumin		X		X		X	
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X	X	X

	Visit 15	Visit 16	Visit 17	Visit 18	Visit 19
	36 mo	39 mo	42 mo	45 mo	48 mo
Demography					
Medical History					
Physical examination	X	X	X	X	X
AE check	X	X	X	X	X
BP & HR	X	X	X	X	X
ECG	X		X		X
Weight	X	X	X	X	X
Compliance	X	X	X	X	X
Labs (blood & urine) - safety	X	X	X	X	X
Labs (blood) - efficacy (FPG, HbA1c)	X	X	X	X	X
Labs (blood) - efficacy - (other)	X		X		X
Urine Albumin	X		X		X
Urine Pregnancy Test (women of child bearing potential)	X	X	X	X	X

If the patient withdraws early, then the Conclusion/Early Withdrawal assessment should be completed.

¹ Adverse events still ongoing at end of the previous study will be recorded at Visit 1 (in the Adverse Experience section).

¹ Concomitant Medication still ongoing at end of the previous study will be recorded at Visit 1 (in the Concomitant Medication section at the end of module 1).

² Where duplicated, Visit 1 assessments will be taken from the final visit for the preceding study.

³ Labs (efficacy - other) = Insulin, Lipids.

**Appendix E Echocardiography Results Table -
49653/006**

	Placebo	2mg bid
Baseline	159.73	154.64
week 6	158.04	153.74
week 12	157.86	151.64

Mean values for LV mass (g) at week 12

Appendix F1 Definition of NIDDM

Class: Non-insulin dependent types (NIDDM) Type II.

Former terminology: Adult-onset diabetes, maturity-onset diabetes, maturity-onset-type diabetes, MOD, ketosis-resistant diabetes stable diabetes.

Associated factors: There are probably multiple aetiologies for this class, the common outcome being derangement of carbohydrate metabolism. Evidence on familial aggregation of diabetes implies genetic factors, and this class includes diabetes presenting in children and adults in which autosomal dominant inheritance has been clearly established (formerly termed the MODY type, maturity-onset diabetes in the young). Environmental factors superimposed on genetic susceptibility are probably involved in the onset of the NIDDM types. Obesity is suspected as an etiologic factor and is recommended as a criterion for dividing NIDDM into two subclasses, according the presence or absence of obesity.

Clinical characteristics: Persons in this subclass are not insulin-dependent or ketosis-prone, although they may use insulin for correction of symptomatic or persistent hyperglycaemia and they can develop ketosis under special circumstances such as episodes of infection or stress. Serum insulin levels may be normal, elevated, or depressed. In the preponderance of cases, onset is after age 40, but NIDDM is known to occur at all ages. About 60-90% of NIDDM subjects are obese and constitute a subtype of NIDDM; in these patients, glucose tolerance is often improved by weight loss. Hyperinsulinaemia and insulin resistance characterize some patients in this subtype.

Diagnostic criteria: Diagnosis of diabetes in adults should be based on:

- 1 unequivocal elevation of plasma glucose concentration together with the classical symptoms of diabetes, or
- 2 elevated fasting plasma glucose concentration on more than one occasion, or
- 3 elevated plasma glucose concentration after an oral glucose challenge on more than one occasion.

Appendix F2 Calculation of Daily Calorific Requirement for Weight Maintenance

Patients may be instructed by a Registered Dietician, a qualified nutrition professional, or suitably qualified member of the study team, to follow a diet prescribed to maintain the patients current weight. The energy (calorific) requirements to maintain the patients current weight may be estimated using the Harris-Benedict equation.

The distribution of calories among carbohydrates, proteins and fats in the prescribed diet are to be consistent with the recommendations of the Committee on Food and Nutrition of the American Diabetes Association. Those recommendations are:

Carbohydrate intake - 50% to 60% of total calories with the amount dependent on the impact on blood glucose and lipid levels in individual eating patterns.

Protein intake - 0.8% g/Kg body weight

Total fat and cholesterol - < 30% of total calories and cholesterol < 300 mg/day

The Harris-Benedict Equation to Calculate Basal Energy Expenditure (BEE).

The Harris-Benedict Equation is a frequently used starting point to estimate daily basal energy expenditure (BEE). It is based on the individual age, sex, weight, and height.

Calculating Basal Energy Expenditure:

Men: $BEE = 66 + (13.7 \times W) + (5 \times H) - (6.8 \times A)$

Women: $BEE = 655 + (9.6 \times W) + (1.7 \times H) - (4.7 \times A)$

W = Actual weight in Kg

H = Height in cm

A = Age in years

[Weight (Kg) = Weight in pounds x 0.454]

[Height (cm) = Height in inches ÷ 0.394]

TOTAL ESTIMATED DAILY ENERGY REQUIREMENT = BEE x 1.3

For overweight individuals, an adjusted body weight instead of actual body weight should be used when utilising the Harris-Benedict equation. The adjusted body weight may be determined using the following formula:

$$\text{Adjusted IBW} = (\text{ABW} - \text{IBW}) \times 0.25 + \text{IBW}$$

ABW = Actual Body Weight in pounds

IBW = Ideal Body Weight in pounds

Assessing Comprehension of Diet Prescribed and Estimating Dietary Compliance

At each study visit, a suitably qualified member of the study team is to evaluate the patient for comprehension of their weight maintenance diet. Instruction should only be given/repeated for patients who demonstrate a lack of understanding of their diet.

Blank Case Report Form (CRF)

Protocol 49653/009	Centre Number 	Patient Number 	Patient Initials

CONFIDENTIAL



PROTOCOL 49653/009

VISITS 1 TO 7

**A MULTICENTRE OPEN LABEL STUDY TO ASSESS THE LONG
TERM SAFETY, TOLERABILITY AND EFFICACY OF BRL49653
WHEN ADMINISTERED TO PATIENTS WITH NON-INSULIN
DEPENDENT DIABETES MELLITUS.**

GENERAL INSTRUCTIONS

- Write clearly in capital letters using a black ball point pen and press firmly so that all copies are legible
- Do not write in shaded areas
- Answer ALL questions on every page
- Enter "N/A" if information requested is not available
- Initial and date all changes, additions or deletions. Use a single pen stroke to remove an incorrect entry
- Enter the patient number and patient initials on all pages on which information has been entered and the centre number where required

Do not enter additional data/information after the set of CRF pages has been split/separated

The cover flap or plastic writing board should be used to divide each set of pages before writing on them with a ball point pen

DATE

Please use the following three-letter abbreviations for the months :

January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

e.g.

01	JAN	96
Day	Mth	Yr

 = 1st January 1996

TIME

Unless specified otherwise, please use the 24 hour clock :

e.g.

15	30
24hr	min

 = 3.30 p.m.

PATIENT INITIALS

Please use the following format :

e.g.

 =

ROUTE KEY FOR PRIOR/CONCOMITANT MEDICATION PAGE

PO = By mouth	SL = Sublingual	TD = Transdermal
IV = Intravenous	IT = Intrathecal	IH = Inhaled
IM = Intramuscular	VA = Vaginal	SC = Subcutaneous
IAR = Intra-arterial	NA = Nasal	PR = Rectal
TO = Topical	IA = Intra-articular injection	ID = Intradermal

SUMMARY CHART OF STUDY PROCEDURES (OPEN BOXES)**PROTOCOL 49653/009**

Mark open boxes to confirm that each procedure has been completed.

PROCEDURE	Visit 1 Month 0	Visit 2 Month 1	Visit 3 Month 2	Visit 4 Month 3	Visit 5 Month 6	Visit 6 Month 9	Visit 7 Month 12
Physical Examination	¹						
Adverse Experience Check	²						
Concomitant Medication Check	²						
Blood Pressure and Heart Rate	¹						
ECG	¹						
Weight	¹						
Compliance Check							
Laboratory tests (safety) (blood and urine)	¹						
Laboratory tests (efficacy - FPG, HbA1c) (blood)	¹						
Laboratory tests (efficacy - other) ³ (blood)	¹						
Urine Sample Test (albumin)							
Urine Pregnancy Test							

NB: If the patient withdraws early, then (where possible) all assessments should be performed in the Early Withdrawal Assessment.

- ¹ Where duplicated, Visit 1 assessments will be taken from the final visit assessments for the preceding study.
² Adverse Experiences and Concomitant Medications still ongoing at the end of the previous study, will be recorded at Visit 1 in the Adverse Experience and Concomitant Medication sections at the back of Module 1.
³ Labs (efficacy - other) = Insulin and Lipids.

MODULE 1 - VISIT 1 AND VISIT 2



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 1

Module 1	- Visit 1, Visit 2 and any Unscheduled Visits
CRF Pages	- 1 - 15
Unprocessed Forms	- Visit 1 : SBCL Laboratory Report ECG
	- Visit 2 : SBCL Laboratory Report

VISIT 1



Page 1

Protocol 49653/009	Centre Number [][]	Patient Number [][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Visit 1

INCLUSION/EXCLUSION CRITERIA*Complete the following inclusion/exclusion criteria***INCLUSION CRITERIA**

	Yes	No
1. The patient has NIDDM and has successfully completed a BRL 49653 protocol which specifies the availability of this open label extension study.	☐	☐
2. The patient has not discontinued study medication in the preceding study for more than 10 days.	☐	☐
3. The patient and investigator have found the study medication to be safe and well tolerated in the preceding study, throughout its duration.	☐	☐
4. The patient is male or female who is not of child bearing potential (post menopausal, ie. > 6 months without menstrual period, surgically sterile, or using hormonal contraceptives or intrauterine contraceptive devices. Female patients taking hormonal contraceptives must also use an additional barrier form or intrauterine form of birth control).	☐	☐
5. The patient has given written informed consent to participate.	☐	☐

*Do not admit the patient to this study if any "No" box has been marked***EXCLUSION CRITERIA**

	Yes	No
1. The patient is pregnant or lactating, or planning a pregnancy within the time frame of the study.	☐	☐
2. The patient experienced any significant and/or serious Adverse Experience during the preceding protocol which, in the opinion of the investigator, could have been attributed to study medication.	☐	☐
3. A clinically significant laboratory abnormality was recorded during the preceding protocol which in the opinion of the investigator, would preclude long term treatment with BRL 49653.	☐	☐
4. The patient withdrew from the preceding study for any reason.	☐	☐
5. The patient had any clinically significant abnormality identified in the end of study assessments for the preceding study (e.g. physical examination, electrocardiogram, etc. as appropriate) which in the judgement of the investigator would preclude safe completion of this study.	☐	☐

*Do not admit the patient to this study if any "Yes" box has been marked**continued on next page*



Page 2

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 1

INCLUSION/EXCLUSION CRITERIA (Continued)**EXCLUSION CRITERIA (Continued)**

	Yes	No
6. The patient has symptomatic diabetic neuropathy of sufficient severity to require treatment for control of symptoms (e.g. painful peripheral neuropathy, symptomatic orthostatic hypotension, urinary retention, gastric stasis, pedal ulcers).	☐	☐
7. The patient has diabetic retinopathy imminently requiring treatment for preserving or restoring vision.	☐	☐

Do not admit the patient to this study if any "Yes" box has been marked

I have assessed the patient and checked the inclusion/exclusion criteria and the patient:

- ☐ is eligible to participate in the study.
- ☐ is not eligible to participate in the study.

Investigator's Signature _____ Date [][][][][][]
Day Mth Yr

Important : If the patient is eligible for Visit 1, encourage the patient to maintain their usual dietary habits.

INSTRUCTIONS TO THE INVESTIGATOR

- All assessments in the previous study must be completed (excluding Follow-Up). In addition, all sections must be completed for Visit 1 in study 49653/009.
- Copy all relevant information from the end of treatment assessment in the previous study into the Visit 1 assessment. You do not need to repeat blood tests and vital sign measurements.

PREVIOUS STUDY DETAILS

Please record the protocol number from the previous study.

Protocol Number [4][9][6][5][3] / [][][]

Do not change the patient number. Use the same patient number and centre number from the previous study for this study. Record the same patient number (and centre number where indicated) at the top of each page.



Page 3

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 1

VISIT REMINDERS

- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state.

CONSENT

Date of written informed consent

[][]	[][]	[][]
Day	Mth	Yr

ADVERSE EXPERIENCES

Please record **all ongoing** adverse experiences in the Adverse Experience section at the back of this module. All adverse experience information recorded at this visit (Visit 1) must be identical to the information recorded for the last visit in the previous study.

DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

- ☐ No
☐ Yes

→ If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.

FASTING LABORATORY TESTS

Do not take bloods. Blood samples from the end of treatment visit in the previous study will be used for this visit.

For SB Lab Code Number

However, remember to take urine samples at this visit (see procedures chart).

Please perform a pregnancy test (women of child bearing potential only)

Urine samples date [][][][][][]
Day Mth Yr

Please use the laboratory kit and investigator manual for study 009 to take bloods. Do not use the kit or manual from the previous study.

Are there any clinically significant abnormal laboratory values, (including a positive pregnancy test)?

- ☐ No
☐ Yes

→ If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this visit.



Page 4

Protocol 49653/009		Patient Number	Patient Initials		Visit 1

VITAL SIGNS

Do not repeat vital signs. Transcribe results from the end of treatment visit in the previous study.

Weight (without shoes) (kg)
.

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	

INSTRUCTIONS TO THE INVESTIGATOR

- Please record **all ongoing** concomitant medication in the Concomitant Medication section at the back of this **module**. (For patients previously in a combination study do not record concomitant sulphonylurea therapy).
- All concomitant medication information recorded at this visit (Visit 1) must be identical to the information recorded for the last visit in the previous study.



Protocol		Patient Number		Patient Initials		Date ECG Performed		Page	5
49653/009						Day Mth Yr Visit 1			

ELECTROCARDIOGRAM

The ECG should be performed after the patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
					☐ + ☐ -

Interpretation

☐ (F74301) Within normal limits

☐ Abnormal → Mark appropriate boxes below
Rhythm

- ☐ (F73360) Sinus arrhythmia
☐ (F73310) Sinus bradycardia
☐ (F73380) Sinus tachycardia
☐ (F73440) Wandering atrial pacemaker
☐ (F73450) Premature atrial contractions
☐ (F73510) Paroxysmal atrial tachycardia
☐ (F73530) Chronic ectopic atrial tachycardia
☐ (F73550) Multifocal atrial tachycardia
☐ (F73560) Atrial flutter
☐ (F73570) Atrial fibrillation
☐ (F73610) Junctional (AV nodal) premature contractions
☐ (F73650) Junctional (AV nodal) tachycardia
☐ (F73150) Supraventricular tachycardia
☐ (F73860) Accelerated idioventricular rhythm
☐ (F73710) Premature Ventricular Contractions (NOS)
☐ (F73720) Unifocal PVC's
☐ (F73730) Multifocal PVC's
☐ (F73711) Ventricular couplets
☐ (F73750) Bigeminy
☐ (F73870) Ventricular tachycardia
☐ (F73880) Ventricular fibrillation
☐ (F73340) Sick sinus syndrome
☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
☐ (F73950) Second degree AV block, Type I
☐ (F73960) Second degree AV block, Type II
☐ (F73970) Third degree AV block
☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
☐ (F74130) Left Axis deviation

QRS

- ☐ (F74010) Right bundle branch block
☐ (F74020) Left bundle branch block
☐ (F74030) Left anterior hemiblock
☐ (F74040) Left posterior hemiblock
☐ (F74002) Intraventricular conduction delay
☐ (F74212) Left ventricular hypertrophy
☐ (F74211) Right ventricular hypertrophy
☐ (F74308) Q-wave > 0.04 sec
☐ (F74222) R-wave amplitude increased
☐ (F74225) R-wave amplitude decreased
☐ (F74313) Prolonged QT-interval
☐ (F74318) Poor R-wave progression
☐ (M54750) Myocardial infarction, old
☐ (M54751) Anterior ☐ (M54754) Inferior
☐ (M54752) Lateral ☐ (M54755) Septal
☐ (M54753) Posterior

ST-T

- ☐ (F74291) Nonspecific ST-T changes
☐ (F74294) ST segment depression > 1mm
☐ (F74295) ST segment elevation > 1mm
☐ (F74350) T-wave flat
☐ (F74351) T-wave inversion
☐ (F74352) T-wave peaked
☐ (F74340) U-wave
☐ (F74360) Digitalis effect
☐ (F74260) Myocardial ischemia
☐ (F74261) Anterior ☐ (F74264) Inferior
☐ (F74262) Lateral ☐ (F74265) Septal
☐ (F74263) Posterior
☐ (M54720) Myocardial infarction, acute
☐ (M54721) Anterior ☐ (M54724) Inferior
☐ (M54722) Lateral ☐ (M54725) Septal
☐ (M54723) Posterior

Other interpretations not listed _____

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module



Protocol 49653/009		Patient Number		Patient Initials		Page 6
						Visit 1

INSTRUCTIONS TO THE INVESTIGATOR

Which study did the patient come from (please mark one box below)?

- ☐ Combination Therapy Study → Dispense BRL 49653C 2mg bd and check the patient has sufficient concomitant hypoglycaemic therapy.
- ☐ Monotherapy Study → Dispense BRL 49653C 4mg bd.

49653 DISPENSING

Give the patient the first dose of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 1, Months 1 to 3

Attach labels here

Patient Initials				
Visit Number				

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 1 month (+/- 7 days) for Visit 2.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

VISIT 2



Page 7

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Visit 2

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 8

Protocol 49653/009		Patient Number [][][][][]	Patient Initials [][][][]		Visit 2

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. Results must be fasting.

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

☐ No → If 'No' please take samples.

☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day.
(* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][] [][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

☐ No

☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 15\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][]	[][][] / [][][]	[][][]



Page 9

Protocol 49653/009		Patient Number	Patient Initials		Visit 2

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 10

Protocol 49653/009		Patient Number	Patient Initials		Visit 2

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

49653 DISPENSING - ALL PATIENTS

Re-dispense the study medication that was given to the patient at Visit 1. Do not dispense new study medication.



Page 11

Protocol 49653/009		Patient Number	Patient Initials		Visit 2

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 1 month (+/- 7 days) for Visit 3.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back **ALL** unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 12

Protocol 49653/009		Patient Number	Patient Initials	

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 1. (Please print clearly).

- ☐ No concomitant medication
- ☐ All concomitant medications listed as ongoing in the CRF from the previous study have been re-entered below (also list any new concomitant medications)

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

<i>MILD</i>	<i>Adverse experience which is easily tolerated</i>
<i>MODERATE</i>	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
<i>SEVERE</i>	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

<i>NOT RELATED</i>	<i>The adverse experience is definitely not related to the test drug</i>
<i>UNLIKELY</i>	<i>There are other more likely causes and the drug is not suspected as a cause</i>
<i>SUSPECTED (REASONABLE POSSIBILITY)</i>	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
<i>PROBABLE</i>	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

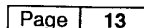
A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Protocol	Patient Number	Patient Initials		
49653/009				

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i>	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 14

Protocol 49653/009		Patient Number 	Patient Initials 	

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 15

Protocol 49653/009		Patient Number 	Patient Initials 	

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 2 - VISIT 3 AND VISIT 4



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 2

Module 2	- Visit 3, Visit 4 and any Unscheduled Visits
CRF Pages	- 16 - 29
Unprocessed Forms	- Visit 3 : SBCL Laboratory Report
	- Visit 4 : SBCL Laboratory Report

VISIT 3



					Page	16
Protocol 49653/009	Centre Number 	Patient Number 	Patient Initials 	Visit Date Day Mth Yr 	Visit 3	

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.

DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 17

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 3

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 15\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	



Page 18

Protocol 49653/009		Patient Number	Patient Initials		Visit 3

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 19

Protocol 49653/009		Patient Number		Patient Initials		Visit 3

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

49653 DISPENSING - ALL PATIENTS

Re-dispense the study medication that was given to the patient at Visit 1. Do not dispense new study medication.



Page 20

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 3

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 1 month (+/- 7 days) for Visit 4.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back **ALL** unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

VISIT 4



						Page	21
Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]		Visit 4	

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.

DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

→ If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.

☐ Yes



Page 22

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][][]		Visit 4

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any **clinically significant abnormal** laboratory values?

- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 15\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][] / [][][][]	[][][][][][]



Page 23

Protocol 49653/009		Patient Number	Patient Initials		Visit 4

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 24

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 4

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date Day Mth Yr	End Date Day Mth Yr	Dose	Unit	Frequency Per Day
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	

49653 DISPENSING - ALL PATIENTS

Give the patient the first dose of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 4, Months 4, 5 and 6

Attach labels here	Patient Initials Visit Number



Page 25

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 4

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐

No

→ If 'No' please encourage the patient to be compliant.

☐

Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 5.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal

SB **SmithKline Beecham**
Pharmaceuticals

Page 26

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 2. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 2.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							
					[][][][][][][]	[][][][][][][]	☐
For SB							

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

<i>MILD</i>	<i>Adverse experience which is easily tolerated</i>
<i>MODERATE</i>	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
<i>SEVERE</i>	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

<i>NOT RELATED</i>	<i>The adverse experience is definitely not related to the test drug</i>
<i>UNLIKELY</i>	<i>There are other more likely causes and the drug is not suspected as a cause</i>
<i>SUSPECTED (REASONABLE POSSIBILITY)</i>	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
<i>PROBABLE</i>	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 27

Protocol 49653/009	Patient Number [][][][][]	Patient Initials [][][][]

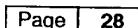
ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [][] episodes ☐ Constant	☐ Intermittent → No. of [][] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] [][][] Day Mth Yr	



Protocol	Patient Number	Patient Initials		
49653/009				

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i>	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Protocol		Patient Number	Patient Initials		
49653/009					

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (<i>please print clearly</i>)		
For SmithKline Beecham		
Onset Date and Time	[][] Day [][] Mth [][] Yr [][] 24hr:min	[][] Day [][] Mth [][] Yr [][] 24hr:min
End Date and Time <i>(If ongoing please leave blank)</i>	[][] Day [][] Mth [][] Yr [][] 24hr:min	[][] Day [][] Mth [][] Yr [][] 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes [][] ☐ Constant	☐ Intermittent → No. of episodes [][] ☐ Constant
Intensity (<i>maximum</i>)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][] Day [][] Mth [][] Yr	

MODULE 3 - VISIT 5



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 3

Module 3	- Visit 5 and any Unscheduled Visits
CRF Pages	- 30 - 39
Unprocessed Forms	- Visit 5 : SBCL Laboratory Report ECG

VISIT 5



								Page	30
Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][][]			Visit 5		

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.

DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes

→ If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 31

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][]	Visit 5

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only). Please take a urine sample at this visit.

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

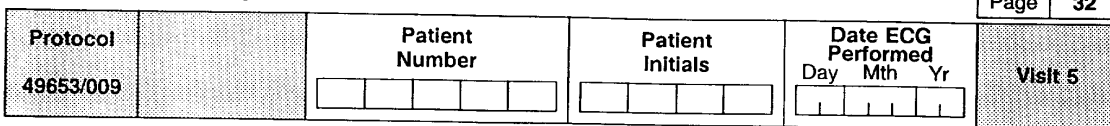
- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][][] / [][][][][]	[][][][][][]



The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
					☐ + ☐ -

☐ (F74301) Within normal limits

☐ Abnormal → Mark appropriate boxes below

☐	(F73360) Sinus arrhythmia
☐	(F73310) Sinus bradycardia
☐	(F73380) Sinus tachycardia
☐	(F73440) Wandering atrial pacemaker
☐	(F73450) Premature atrial contractions
☐	(F73510) Paroxysmal atrial tachycardia
☐	(F73530) Chronic ectopic atrial tachycardia
☐	(F73550) Multifocal atrial tachycardia
☐	(F73560) Atrial flutter
☐	(F73570) Atrial fibrillation
☐	(F73610) Junctional (AV nodal) premature contractions
☐	(F73650) Junctional (AV nodal) tachycardia
☐	(F73150) Supraventricular tachycardia
☐	(F73860) Accelerated idioventricular rhythm
☐	(F73710) Premature Ventricular Contractions (NOS)
☐	(F73720) Unifocal PVC's
☐	(F73730) Multifocal PVC's
☐	(F73711) Ventricular couplets
☐	(F73750) Bigeminy
☐	(F73870) Ventricular tachycardia
☐	(F73880) Ventricular fibrillation
☐	(F73340) Sick sinus syndrome
☐	(F73190) Pacemaker rhythm

☐ (F74214) Left atrial hypertrophy, P mitrale
☐ (F74213) Right atrial hypertrophy, P pulmonale

☐ (F73930) First degree AV block
☐ (F73950) Second degree AV block, Type I
☐ (F73960) Second degree AV block, Type II
☐ (F73970) Third degree AV block
☐ (F74090) Wolff-Parkinson-White syndrome

☐ (F74120) Right Axis deviation

☐ (F74130) Left Axis deviation

Other interpretations not listed

Were any clinically important changes noted at this examination?

☐ No☐ Yes

☐ Improvement

☐ Worsening

Enter details in the Adverse Experience section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.

☐	(F74010) Right bundle branch block	
☐	(F74020) Left bundle branch block	
☐	(F74030) Left anterior hemiblock	
☐	(F74040) Left posterior hemiblock	
☐	(F74002) Intraventricular conduction delay	
☐	(F74212) Left ventricular hypertrophy	
☐	(F74211) Right ventricular hypertrophy	
☐	(F74308) Q-wave > 0.04 sec	
☐	(F74222) R-wave amplitude increased	
☐	(F74225) R-wave amplitude decreased	
☐	(F74313) Prolonged QT-interval	
☐	(F74318) Poor R-wave progression	
☐	(M54750) Myocardial infarction, old	
☐	(M54751) Anterior	☐ (M54754) Inferior
☐	(M54752) Lateral	☐ (M54755) Septal
☐	(M54753) Posterior	

☐ (F74291) Nonspecific ST-T changes

☐ (F74294) ST segment depression > 1mm

☐ (F74295) ST segment elevation > 1mm

☐ (F74350) T-wave flat

☐ (F74351) T-wave inversion

☐ (F74352) T-wave peaked

☐ (F74340) U-wave

☐ (F74360) Digitalis effect

☐ (F74260) Myocardial ischemia

☐ (F74261) Anterior ☐ (F74264) Inferior

☐ (F74262) Lateral ☐ (F74265) Septal

☐ (F74263) Posterior

☐ (M54720) Myocardial infarction, acute

☐ (M54721) Anterior ☐ (M54724) Inferior

☐ (M54722) Lateral ☐ (M54725) Septal

☐ (M54723) Posterior



Protocol 49653/009		Patient Number	Patient Initials		Visit 5

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 34

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 5

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date Day Mth Yr	End Date Day Mth Yr	Dose	Unit	Frequency Per Day
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	

49653 DISPENSING - ALL PATIENTS

Give the patient their new set of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 5, Months 7, 8 and 9

Attach labels here	Patient Initials Visit Number



Page 35

Protocol 49653/009		Patient Number	Patient Initials		Visit 5

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.

☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 6.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 36

Protocol 49653/009		Patient Number	Patient Initials	

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 4. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 4.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)			
					Day	Mth	Yr	Day	Mth	Yr	
For SB											
For SB											
For SB											
For SB											
For SB											
For SB											
For SB											
For SB											
For SB											

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

<i>MILD</i>	<i>Adverse experience which is easily tolerated</i>
<i>MODERATE</i>	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
<i>SEVERE</i>	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

<i>NOT RELATED</i>	<i>The adverse experience is definitely not related to the test drug</i>
<i>UNLIKELY</i>	<i>There are other more likely causes and the drug is not suspected as a cause</i>
<i>SUSPECTED (REASONABLE POSSIBILITY)</i>	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
<i>PROBABLE</i>	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal*
- 2 - life threatening*
- 3 - disabling/incapacitating*
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)*
- 5 - prolongs a hospital stay*
- 6 - associated with congenital abnormality*
- 7 - cancer*
- 8 - associated with overdose*
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event*

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 37

Protocol 49653/009	Patient Number [][][][][]	Patient Initials [][][][][]

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] Day Mth Yr [][] 24hr:min	[][][][] Day Mth Yr [][] 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] Day Mth Yr [][] 24hr:min	[][][][] Day Mth Yr [][] 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [] episodes ☐ Constant	☐ Intermittent → No. of [] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] Day Mth Yr	



Protocol		Patient Number	Patient Initials		
49653/009					

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (<i>please print clearly</i>)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time <i>(If ongoing please leave blank)</i>	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (<i>maximum</i>)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date :	



Protocol	Patient Number	Patient Initials		
49653/009				

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i>	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of ☐ Constant episodes	☐ Intermittent → No. of ☐ Constant episodes
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i>	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 4 - VISIT 6



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 4

Module 4	- Visit 6 and any Unscheduled Visits
CRF Pages	- 40 - 48
Unprocessed Forms	- Visit 6 : SBCL Laboratory Report

VISIT 6



Page 40

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Visit 6

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 41

Protocol 49653/009		Patient Number	Patient Initials		Visit 6

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time
Day Mth Yr 24hr:min

Are there any **clinically significant abnormal** laboratory values?

- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	



Page 42

Protocol		Patient Number	Patient Initials		Visit 6
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 43

Protocol 49653/009		Patient Number	Patient Initials		Visit 6

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date Day Mth Yr	End Date Day Mth Yr	Dose	Unit	Frequency Per Day
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	

49653 DISPENSING - ALL PATIENTS

Give the patient their new set of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 6, Months 10, 11 and 12

Attach labels here

Patient Initials	
Visit Number	



Page 44

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 6

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

Compliance = $\frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)
Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.

☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 7.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back **ALL** unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 45

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 5. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 5.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	<i>Adverse experience which is easily tolerated</i>
MODERATE	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 46

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][][]

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [] episodes ☐ Constant	☐ Intermittent → No. of [] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] [][][] [][][] Day Mth Yr	



Page 47

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][][]

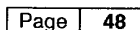
ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [][] episodes ☐ Constant	☐ Intermittent → No. of [][] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] [][][] [][][] Day Mth Yr	



Protocol		Patient Number	Patient Initials		
49653/009					

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time		
End Date and Time (If ongoing please leave blank)		
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i>	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i>	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date :	

MODULE 5 - VISIT 7



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 5

Module 5	- Visit 7 and any Unscheduled Visits
CRF Pages	- 49 - 58
Unprocessed Forms	- Visit 7 : SBCL Laboratory Report ECG

VISIT 7



Page 49

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date	Visit 7
49653/009				Day Mth Yr	

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 50

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 7

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only). Please take a urine sample at this visit.

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

☐ No → If 'No' please take samples.

☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

☐ No

☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][][] / [][][][][]	[][][][][]



Protocol 49653/009		Patient Number	Patient Initials	Date ECG Performed Day Mth Yr	Page 51 Visit 7

ELECTROCARDIOGRAM

The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
					☐ + ☐ -

Interpretation ☐ (F74301) Within normal limits

☐ Abnormal → Mark appropriate boxes below

Rhythm

- ☐ (F73360) Sinus arrhythmia
☐ (F73310) Sinus bradycardia
☐ (F73380) Sinus tachycardia
☐ (F73440) Wandering atrial pacemaker
☐ (F73450) Premature atrial contractions
☐ (F73510) Paroxysmal atrial tachycardia
☐ (F73530) Chronic ectopic atrial tachycardia
☐ (F73550) Multifocal atrial tachycardia
☐ (F73560) Atrial flutter
☐ (F73570) Atrial fibrillation
☐ (F73610) Junctional (AV nodal) premature contractions
☐ (F73650) Junctional (AV nodal) tachycardia
☐ (F73150) Supraventricular tachycardia
☐ (F73860) Accelerated idioventricular rhythm
☐ (F73710) Premature Ventricular Contractions (NOS)
☐ (F73720) Unifocal PVC's
☐ (F73730) Multifocal PVC's
☐ (F73711) Ventricular couplets
☐ (F73750) Bigeminy
☐ (F73870) Ventricular tachycardia
☐ (F73880) Ventricular fibrillation
☐ (F73340) Sick sinus syndrome
☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
☐ (F73950) Second degree AV block, Type I
☐ (F73960) Second degree AV block, Type II
☐ (F73970) Third degree AV block
☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
☐ (F74130) Left Axis deviation

Other interpretations not listed

Were any clinically important changes (since the previous test) noted at this examination?

☐ No

☐ Yes →

☐ Improvement

☐ Worsening →

Enter details in the Adverse Experience
section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.



Page 52

Protocol 49653/009		Patient Number	Patient Initials		Visit 7

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients ONLY).



Page 53

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 7

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	



Page 54

Protocol 49653/009		Patient Number	Patient Initials		Visit 7

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐ No

→ If 'No' please encourage the patient to be compliant.

☐ Yes
INSTRUCTIONS TO THE INVESTIGATOR

- Please discuss dispensing of additional study medication and further study arrangements with your local monitor.
- Please ensure that you record any serious adverse experiences up to 30 days after the last dose of 49653 has been given.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 55

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][]

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 6. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 6.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			
For SB					[][][][][][]	[][][][][][]	[]			

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	<i>Adverse experience which is easily tolerated</i>
MODERATE	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 56

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 57

Protocol 49653/009		Patient Number	Patient Initials	

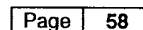
ADVERSE EXPERIENCES (Non-serious)

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If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
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Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Protocol	Patient Number	Patient Initials		
49653/009				

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (<i>please print clearly</i>)		
For SmithKline Beecham		
Onset Date and Time	[][] [][] [][] Day Mth Yr [][] [][] 24hr:min	[][] [][] [][] Day Mth Yr [][] [][] 24hr:min
End Date and Time <i>(If ongoing please leave blank)</i>	[][] [][] [][] Day Mth Yr [][] [][] 24hr:min	[1] [][] [][] Day Mth Yr [][] [][] 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [][] episodes ☐ Constant	☐ Intermittent → No. of [][] episodes ☐ Constant
Intensity (<i>maximum</i>)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][] [][] [][] [][] Day Mth Yr	

MODULE 6 - EARLY WITHDRAWAL / STUDY CONCLUSION



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 6

Module 6	- Early Withdrawal / Study Conclusion
CRF Pages	- 59 - 69
Unprocessed Forms	- Early Withdrawal : SBCL Laboratory Report ECG

EARLY WITHDRAWAL

***(Complete for patients who have withdrawn
early from the study)***



Page 59

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Withdrawal Visit

VISIT REMINDERS

- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this section.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this section.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes



Protocol 49653/009		Patient Number		Patient Initials		Page 60
						Withdrawal Visit

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only). Please take a urine sample at this visit.

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

☐ No → If 'No' please take samples.

☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day.
(* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time

Day	Mth	Yr	24hr:min

Are there any clinically significant abnormal laboratory values?

☐ No

☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

VITAL SIGNS

Weight (without shoes) (kg)

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	



Page 61

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][][]	Date ECG Performed Day Mth Yr [][][][][][]	Withdrawal Visit [][][][][][]

ELECTROCARDIOGRAM

The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
[][][][]	[][][][]	[][][][]	[][][][]	[][][][]	☐ + ☐ - [][][][]

Interpretation ☐ (F74301) Within normal limits
☐ Abnormal → Mark appropriate boxes below

Rhythm

- ☐ (F73360) Sinus arrhythmia
☐ (F73310) Sinus bradycardia
☐ (F73380) Sinus tachycardia
☐ (F73440) Wandering atrial pacemaker
☐ (F73450) Premature atrial contractions
☐ (F73510) Paroxysmal atrial tachycardia
☐ (F73530) Chronic ectopic atrial tachycardia
☐ (F73550) Multifocal atrial tachycardia
☐ (F73560) Atrial flutter
☐ (F73570) Atrial fibrillation
☐ (F73610) Junctional (AV nodal) premature contractions
☐ (F73650) Junctional (AV nodal) tachycardia
☐ (F73150) Supraventricular tachycardia
☐ (F73860) Accelerated idioventricular rhythm
☐ (F73710) Premature Ventricular Contractions (NOS)
☐ (F73720) Unifocal PVC's
☐ (F73730) Multifocal PVC's
☐ (F73711) Ventricular couplets
☐ (F73750) Bigeminy
☐ (F73870) Ventricular tachycardia
☐ (F73880) Ventricular fibrillation
☐ (F73340) Sick sinus syndrome
☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
☐ (F73950) Second degree AV block, Type I
☐ (F73960) Second degree AV block, Type II
☐ (F73970) Third degree AV block
☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
☐ (F74130) Left Axis deviation

Other interpretations not listed _____

Were any clinically important changes (since the previous test) noted at this examination?

☐ No

☐ Yes →

☐ Improvement

☐ Worsening →

Enter details in the Adverse Experience section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.



Protocol 49653/009		Patient Number	Patient Initials	Page 62	Withdrawal Visit

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient was taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient was taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 63

Protocol 49653/009	Patient Number	Patient Initials	Withdrawal Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----								mg	



Page 64

Protocol 49653/009		Patient Number	Patient Initials		Withdrawal Visit

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)
 Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

Please ensure that you record any serious adverse experiences up to 30 days after the last dose of 49653 has been given.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 65

Protocol 49653/009		Patient Number	Patient Initials	

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken since the end of the previous visit. (Please print clearly)

☐ No concomitant medication changes since the end of the previous visit.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	Adverse experience which is easily tolerated
MODERATE	Adverse experience sufficiently discomforting to interfere with daily activity
SEVERE	Adverse experience which prevents normal everyday activities

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	The adverse experience is definitely not related to the test drug
UNLIKELY	There are other more likely causes and the drug is not suspected as a cause
SUSPECTED (REASONABLE POSSIBILITY)	A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug
PROBABLE	There probably is a direct cause and effect relationship between the adverse experience and the study drug

SERIOUS ADVERSE EXPERIENCE (SAE)

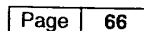
A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Protocol	Patient Number	Patient Initials			Page	66
49653/009						

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (<i>please print clearly</i>)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time <i>(If ongoing please leave blank)</i>	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> →	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of ☐ Constant episodes	☐ Intermittent → No. of ☐ Constant episodes
Intensity (<i>maximum</i>)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> →	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date :	



Page 67

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 68

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][][]

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] [][][] Day Mth Yr 24hr:min	[][][][] [][][] Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [][] episodes ☐ Constant	☐ Intermittent → No. of [][] episodes ☐ Constant
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Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] [][][] Day Mth Yr	

STUDY CONCLUSION

(Complete for all patients; including early withdrawals)



Page 69

Protocol 49653/009		Patient Number 	Patient Initials 		

STUDY CONCLUSION

Did the patient complete the study according to the protocol?

☐ Yes☐ No → If 'No' please mark the **primary** cause of withdrawal. (Mark one box only).

- ☐ 1 Adverse experience (complete AE form)
- ☐ 2 Insufficient therapeutic effect
- ☐ 3 Protocol deviation (including non-compliance)
- ☐ 4 Lost to follow-up
- ☐ 7 Other - specify: _____

Date of final visit

Day	Mth	Yr	

Date of final dose

Day	Mth	Yr	

INVESTIGATOR SIGNATURE

I certify that I have reviewed the data on this case report form and that all information is complete and accurate.

Investigator's Signature _____

Day	Mth	Yr	

UNSCHEDULED VISITS



Page 70

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date Day Mth Yr	Unscheduled Visit
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.

VITAL SIGNS

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	



Page 71

Protocol 49653/009		Patient Number	Patient Initials		Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No → If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes → If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 72

Protocol 49653/009		Patient Number	Patient Initials		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date Day Mth Yr	End Date Day Mth Yr	Dose	Unit	Frequency Per Day
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----				mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.



								Page	73
Protocol 49653/009	Centre Number	Patient Number		Patient Initials		Visit Date Day Mth Yr		Unscheduled Visit	

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.

VITAL SIGNS

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	



Page 74

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No → If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes → If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
[][][][][][]	[][][][][][]	4mg	Tablet	bd
[][][][][][]	[][][][][][]			
[][][][][][]	[][][][][][]			

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
[][][][][][]	[][][][][][]	2mg	Tablet	bd
[][][][][][]	[][][][][][]			
[][][][][][]	[][][][][][]			

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 75

Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.



Page 76

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.
VITAL SIGNS**Blood Pressure**

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)		Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic	Diastolic	
[][]:[][]	[][][] / [][][]	[][][]	[][][]



Protocol 49653/009		Patient Number	Patient Initials	Page 77
				Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No → If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes → If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date			End Date			Single Dose	Units	Frequency Per Day
Day	Mth	Yr	Day	Mth	Yr			
						2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients ONLY).



Page 78

Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

INSTRUCTIONS FOR REPORTING SERIOUS ADVERSE EXPERIENCES (SAE)

SAEs MUST BE REPORTED TO SMITHKLINE BEECHAM WITHIN 24 HOURS

COMPLETE THE SAE PAGES OPPOSITE

Please complete these pages as fully and accurately as possible in order to minimise the time you spend dealing with data queries

If the SAE is still ongoing at the time of reporting, please leave 'Experience Course' blank and update it later

SIGN AND DATE THE SAE PAGE**PLEASE ENSURE THAT ALL OF THE INFORMATION ON THE FOLLOWING CRF PAGES IS COMPLETE**

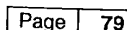
- Demography
- Significant Medical/Surgical History and Physical Examination
- Study Medication Record
- Concomitant Medication
- Form D (if applicable)

PHOTOCOPY THE SAE PAGES AND THE CRF PAGES SPECIFIED ABOVE
(Do not separate the NCR pages)

FAX A COPY OF THE SAE PAGES AND ALL OF THE CRF PAGES SPECIFIED ABOVE TO :

Your local SB CRA/Medical Monitor (see Investigator Site File for appropriate fax number)

If no photocopier OR fax is available please telephone your local SB CRA/Medical monitor within 24 hours



Protocol No.		Centre Number	Patient Number	Patient Initials	SB Receipt Date
49653/009					Day Mth Yr

Person Reporting SAE _____ (Please print clearly)		AEGIS Number _____																												
Serious Adverse Experience (Please print clearly)		Specify reason(s) for considering this a serious AE. Mark all that apply. <table border="0"> <tr><td>1</td><td>☐</td><td>fatal</td></tr> <tr><td>2</td><td>☐</td><td>life threatening</td></tr> <tr><td>3</td><td>☐</td><td>disabling/incapacitating</td></tr> <tr><td>4</td><td>☐</td><td>results in hospitalisation (excluding elective surgery or routine clinical procedures)</td></tr> <tr><td>5</td><td>☐</td><td>hospitalisation prolonged</td></tr> <tr><td>6</td><td>☐</td><td>congenital abnormality</td></tr> <tr><td>7</td><td>☐</td><td>cancer</td></tr> <tr><td>8</td><td>☐</td><td>overdose</td></tr> <tr><td>9</td><td>☐</td><td>Investigator considers serious or a significant hazard, contraindication, side effect or precaution</td></tr> </table>		1	☐	fatal	2	☐	life threatening	3	☐	disabling/incapacitating	4	☐	results in hospitalisation (excluding elective surgery or routine clinical procedures)	5	☐	hospitalisation prolonged	6	☐	congenital abnormality	7	☐	cancer	8	☐	overdose	9	☐	Investigator considers serious or a significant hazard, contraindication, side effect or precaution
1	☐			fatal																										
2	☐			life threatening																										
3	☐			disabling/incapacitating																										
4	☐			results in hospitalisation (excluding elective surgery or routine clinical procedures)																										
5	☐	hospitalisation prolonged																												
6	☐	congenital abnormality																												
7	☐	cancer																												
8	☐	overdose																												
9	☐	Investigator considers serious or a significant hazard, contraindication, side effect or precaution																												
For SmithKline Beecham																														
Onset Date and Time _____ Day Mth Yr 24hr:min																														
End Date and Time (If ongoing please leave blank) _____ Day Mth Yr 24hr:min																														
Outcome If patient died, please complete Form D <table border="0"> <tr><td>1</td><td>☐</td><td>Resolved</td></tr> <tr><td>2</td><td>☐</td><td>Ongoing</td></tr> <tr><td>3</td><td>☐</td><td>Died</td></tr> </table>		1	☐	Resolved	2	☐	Ongoing	3	☐	Died																				
1	☐	Resolved																												
2	☐	Ongoing																												
3	☐	Died																												
Experience Course <table border="0"> <tr><td>1</td><td>☐</td><td>Intermittent</td><td rowspan="2">→ No. of episodes _____</td></tr> <tr><td>2</td><td>☐</td><td>Constant</td></tr> </table>		1	☐	Intermittent	→ No. of episodes _____	2	☐	Constant																						
1	☐	Intermittent	→ No. of episodes _____																											
2	☐	Constant																												
Intensity (maximum) <table border="0"> <tr><td>1</td><td>☐</td><td>Mild</td></tr> <tr><td>2</td><td>☐</td><td>Moderate</td></tr> <tr><td>3</td><td>☐</td><td>Severe</td></tr> </table>		1	☐	Mild	2	☐	Moderate	3	☐	Severe																				
1	☐	Mild																												
2	☐	Moderate																												
3	☐	Severe																												
Action Taken with Respect to Investigational Drug <table border="0"> <tr><td>1</td><td>☐</td><td>None</td></tr> <tr><td>2</td><td>☐</td><td>Dose reduced</td></tr> <tr><td>3</td><td>☐</td><td>Dose increased</td></tr> <tr><td>4</td><td>☐</td><td>Drug interrupted/restarted</td></tr> <tr><td>5</td><td>☐</td><td>Drug stopped</td></tr> </table>		1	☐	None	2	☐	Dose reduced	3	☐	Dose increased	4	☐	Drug interrupted/restarted	5	☐	Drug stopped	Did the SAE abate ? ☐ Yes ☐ No If study medication was interrupted, stopped or dose reduced: Was study medication reintroduced (or dose increased) ☐ Yes ☐ No If yes, did SAE recur ☐ Yes ☐ No													
1	☐	None																												
2	☐	Dose reduced																												
3	☐	Dose increased																												
4	☐	Drug interrupted/restarted																												
5	☐	Drug stopped																												
Relationship to Investigational Drug <table border="0"> <tr><td>1</td><td>☐</td><td>Not related</td></tr> <tr><td>2</td><td>☐</td><td>Unlikely</td></tr> <tr><td>3</td><td>☐</td><td>Suspected (reasonable possibility)</td></tr> <tr><td>4</td><td>☐</td><td>Probable</td></tr> </table>		1	☐	Not related	2	☐	Unlikely	3	☐	Suspected (reasonable possibility)	4	☐	Probable	Assessment Could the SAE be associated with : ☐ Protocol design or procedures (but not to study drug) Please specify _____ ☐ Another condition (eg, condition under study, intercurrent illness) Please specify _____ ☐ Another drug Please specify _____ ☐ Unknown cause																
1	☐	Not related																												
2	☐	Unlikely																												
3	☐	Suspected (reasonable possibility)																												
4	☐	Probable																												
Corrective Therapy If 'Yes', record details in the Prior & Concomitant Medication section <table border="0"> <tr><td>☐ Yes</td><td>☐ No</td></tr> </table>		☐ Yes	☐ No																											
☐ Yes	☐ No																													
Was patient withdrawn due to this specific SAE ? <table border="0"> <tr><td>☐ Yes</td><td>☐ No</td></tr> </table>		☐ Yes	☐ No																											
☐ Yes	☐ No																													



Page 80

Protocol No. 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]

SERIOUS ADVERSE EXPERIENCE (SAE) (cont)**Relevant Laboratory Data**

Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal Range
	Day Mth Yr			
	Day Mth Yr			
	Day Mth Yr			
	Day Mth Yr			

Remarks (Please provide a brief narrative description of the SAE, attaching extra pages eg. hospital discharge summary if necessary)

If applicable, was randomisation code broken at investigational site ? ☐ No ☐ Yes

Randomisation / Study Medication Number : [][][][][][]

Investigator's Signature : _____ Date

Day	Mth	Yr

Please PRINT name _____

SB Medical Monitor's Signature : _____ Date

Day	Mth	Yr

Please PRINT name _____

49653/009	CASE REPORT FORM	VISITS 1 TO 7
49653/009	CASE REPORT FORM	VISITS 1 TO 7
49653/009	CASE REPORT FORM	VISITS 1 TO 7
49653/009	CASE REPORT FORM	VISITS 1 TO 7

Protocol	Centre Number	Patient Number	Patient Initials
49653/009			

CONFIDENTIAL



PROTOCOL 49653/009

YEAR 2 : VISIT 7 (49653 DISPENSING) AND VISITS 8 TO 11

**A MULTICENTRE OPEN LABEL STUDY TO ASSESS THE LONG
TERM SAFETY, TOLERABILITY AND EFFICACY OF BRL49653
WHEN ADMINISTERED TO PATIENTS WITH NON-INSULIN
DEPENDENT DIABETES MELLITUS.**

GENERAL INSTRUCTIONS

- Write clearly in capital letters using a black ball point pen and press firmly so that all copies are legible
- Do not write in shaded areas
- Answer ALL questions on every page
- Enter "N/A" if information requested is not available
- Initial and date all changes, additions or deletions. Use a single pen stroke to remove an incorrect entry
- Enter the patient number and patient initials on all pages on which information has been entered and the centre number where required

Do not enter additional data/information after the set of CRF pages has been split/separated

The cover flap or plastic writing board should be used to divide each set of pages before writing on them with a ball point pen

DATE

Please use the following three-letter abbreviations for the months :

January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

e.g.

0	1	J	A	N	9	8
Day	Mth				Yr	

 = 1st January 1998

TIME

Unless specified otherwise, please use the 24 hour clock :

e.g.

1	5	3	0
24hr:min			

 = 3.30 p.m.

PATIENT INITIALS

Please use the following format :

e.g.

 =

ROUTE KEY FOR PRIOR/CONCOMITANT MEDICATION PAGE

PO = By mouth	SL = Sublingual	TD = Transdermal
IV = Intravenous	IT = Intrathecal	IH = Inhaled
IM = Intramuscular	VA = Vaginal	SC = Subcutaneous
IAR = Intra-arterial	NA = Nasal	PR = Rectal
TO = Topical	IA = Intra-articular injection	ID = Intradermal

SUMMARY CHART OF STUDY PROCEDURES (OPEN BOXES)**PROTOCOL 49653/009 - YEAR 2, VISITS 8 TO 11**

Mark open boxes to confirm that each procedure has been completed.

PROCEDURE	Visit 8 Month 15	Visit 9 Month 18	Visit 10 Month 21	Visit 11 Month 24
Physical Examination				
Adverse Experience Check				
Concomitant Medication Check				
Blood Pressure and Heart Rate				
ECG				
Weight				
Compliance Check				
Laboratory tests (safety)(blood and urine)				
Laboratory tests (efficacy - FPG, HbA1c) (blood)				
Laboratory tests (efficacy - other) ¹ (blood)				
Urine Sample Test (albumin)				
Urine Pregnancy Test				

¹ Labs (efficacy - other) = Insulin + Lipids

NB: If the patient withdraws early, then (where possible) all assessments should be performed in the Early Withdrawal Assessment.

MODULE 7 - VISIT 7 (49653 DISPENSING) AND VISIT 8



Protocol 49653/009	Centre Number <table border="1"><tr><td></td><td></td><td></td></tr></table>				Patient Number <table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>								

MODULE 7

Module 7	- Visit 7 (49653 Dispensing), Visit 8 and any Unscheduled Visits
CRF Pages	- 82 - 91
Unprocessed Forms	- Visit 8 : SBCL Laboratory Report

**VISIT 7
(49653 DISPENSING)**

VISIT 7 (49653 DISPENSING)



Page 82

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 7

49653 DISPENSING - ALL PATIENTS

Give the patient their new set of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 7, Months 13, 14 and 15

Attach labels here

Patient Initials	
Visit Number	

VISIT 8

VISIT 8



Page 83

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date	Visit 8
49653/009				Day Mth Yr 	

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 84

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 8

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS

Weight (without shoes) (kg)
[][][][] . [][]

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][]	[][][][] / [][][][]	[][][][]



Page 85

Protocol		Patient Number	Patient Initials		Visit 8
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 86

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 8

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

49653 DISPENSING - ALL PATIENTS

Give the patient the first dose of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 8, Months 16, 17 and 18

Attach labels here	Patient Initials Visit Number



Page 87

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 8

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where $N = 2$, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where $N = 4$, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 9.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back **ALL** unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

**CONCOMITANT
MEDICATION****ROUTE KEY :**

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 88

Protocol 49653/009		Patient Number 	Patient Initials 		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 7. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 7.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)				
					Day	Mth	Yr	Day	Mth	Yr		
For SB												
For SB												
For SB												
For SB												
For SB												
For SB												
For SB												
For SB												

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	<i>Adverse experience which is easily tolerated</i>
MODERATE	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

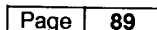
- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

**ADVERSE
EXPERIENCES**

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Protocol		Patient Number	Patient Initials		
49653/009					

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of ☐ Constant episodes	☐ Intermittent → No. of ☐ Constant episodes
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____ Date : Day Mth Yr		



Page 90

Protocol		Patient Number	Patient Initials	
49653/009				

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
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Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 91

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 8 - VISIT 9



Protocol 49653/009	Centre Number <table border="1"><tr><td></td><td></td><td></td></tr></table>				Patient Number <table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>								

MODULE 8

Module 8	- Visit 9 and any Unscheduled Visits
CRF Pages	- 92 - 101
Unprocessed Forms	- Visit 9 : SBCL Laboratory Report ECG

VISIT 9

VISIT 9



Page 92

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Visit 9

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes

→ If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 93

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 9

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

☐ No → If 'No' please take samples.

☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

☐ No

☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS

Weight (without shoes) (kg)
[][][][][][]

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][][][] / [][][][][][]	[][][][][][]



Page 94

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][]	Date ECG Performed Day Mth Yr [][][][][][]	Visit 9

ELECTROCARDIOGRAM

The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
[][][][]	[][][][]	[][][][]	[][][][]	[][][][]	☐ + ☐ - [][][][]

Interpretation

☐ (F74301) Within normal limits☐ Abnormal → Mark appropriate boxes below**Rhythm**

- ☐ (F73360) Sinus arrhythmia
- ☐ (F73310) Sinus bradycardia
- ☐ (F73380) Sinus tachycardia
- ☐ (F73440) Wandering atrial pacemaker
- ☐ (F73450) Premature atrial contractions
- ☐ (F73510) Paroxysmal atrial tachycardia
- ☐ (F73530) Chronic ectopic atrial tachycardia
- ☐ (F73550) Multifocal atrial tachycardia
- ☐ (F73560) Atrial flutter
- ☐ (F73570) Atrial fibrillation
- ☐ (F73610) Junctional (AV nodal) premature contractions
- ☐ (F73650) Junctional (AV nodal) tachycardia
- ☐ (F73150) Supraventricular tachycardia
- ☐ (F73860) Accelerated idioventricular rhythm
- ☐ (F73710) Premature Ventricular Contractions (NOS)
- ☐ (F73720) Unifocal PVC's
- ☐ (F73730) Multifocal PVC's
- ☐ (F73711) Ventricular couplets
- ☐ (F73750) Bigeminy
- ☐ (F73870) Ventricular tachycardia
- ☐ (F73880) Ventricular fibrillation
- ☐ (F73340) Sick sinus syndrome
- ☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
- ☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
- ☐ (F73950) Second degree AV block, Type I
- ☐ (F73960) Second degree AV block, Type II
- ☐ (F73970) Third degree AV block
- ☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
- ☐ (F74130) Left Axis deviation

Other interpretations not listed

QRS

- ☐ (F74010) Right bundle branch block
- ☐ (F74020) Left bundle branch block
- ☐ (F74030) Left anterior hemiblock
- ☐ (F74040) Left posterior hemiblock
- ☐ (F74002) Intraventricular conduction delay
- ☐ (F74212) Left ventricular hypertrophy
- ☐ (F74211) Right ventricular hypertrophy
- ☐ (F74308) Q-wave > 0.04 sec
- ☐ (F74222) R-wave amplitude increased
- ☐ (F74225) R-wave amplitude decreased
- ☐ (F74313) Prolonged QT-interval
- ☐ (F74318) Poor R-wave progression
- ☐ (M54750) Myocardial infarction, old
- ☐ (M54751) Anterior ☐ (M54754) Inferior
- ☐ (M54752) Lateral ☐ (M54755) Septal
- ☐ (M54753) Posterior

ST-T

- ☐ (F74291) Nonspecific ST-T changes
- ☐ (F74294) ST segment depression > 1mm
- ☐ (F74295) ST segment elevation > 1mm
- ☐ (F74350) T-wave flat
- ☐ (F74351) T-wave inversion
- ☐ (F74352) T-wave peaked
- ☐ (F74340) U-wave
- ☐ (F74360) Digitalis effect
- ☐ (F74260) Myocardial ischemia
- ☐ (F74261) Anterior ☐ (F74264) Inferior
- ☐ (F74262) Lateral ☐ (F74265) Septal
- ☐ (F74263) Posterior
- ☐ (M54720) Myocardial infarction, acute
- ☐ (M54721) Anterior ☐ (M54724) Inferior
- ☐ (M54722) Lateral ☐ (M54725) Septal
- ☐ (M54723) Posterior

Were any clinically important changes (since the previous test) noted at this examination?

☐ No☐ Yes →☐ Improvement☐ Worsening →

Enter details in the Adverse Experience section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.



Protocol 49653/009		Patient Number 	Patient Initials 		Visit 9

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 9

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----	[][][][][]	[][][][][]					mg		
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----	[][][][][]	[][][][][]					mg		
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----	[][][][][]	[][][][][]					mg		

49653 DISPENSING - ALL PATIENTS

Give the patient their new set of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 9, Months 19, 20 and 21

Attach labels here	Patient Initials	[][][][][]
	Visit Number	[][]



Protocol 49653/009		Patient Number	Patient Initials		Visit 9

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 10.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 98

Protocol 49653/009		Patient Number 	Patient Initials 		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 8. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 8.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							
For SB							

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

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SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED

SB SmithKline Beecham
 Pharmaceuticals

Page 99

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis not symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 100

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome If patient died, STOP: go to SAE section and follow instructions given there	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 9 - VISIT 10



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 9

Module 9	- Visit 10 and any Unscheduled Visits
CRF Pages	- 102 - 110
Unprocessed Forms	- Visit 10 : SBCL Laboratory Report

VISIT 10

VISIT 10



Page 102

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Visit 10

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes → If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 103

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][]	Visit 10

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No → If 'No' please take samples.
- ☐ Yes → If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

- ☐ No
- ☐ Yes → If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS

Weight (without shoes) (kg)
[][][][][][] . [][]

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][][][] / [][][][][][]	[][][][][][]



Protocol		Patient Number	Patient Initials		Visit 10
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 105

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 10

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

49653 DISPENSING - ALL PATIENTS

Give the patient their new set of study medication in the clinic, (after blood has been drawn). Record study medication information below.

- 1) Attach the tear-off labels from the medication bottles in the appropriate blank space below.
- 2) Transcribe the details from the labels to the appropriate box.

Visit 10, Months 22, 23 and 24

Attach labels here	Patient Initials Visit Number



Page 106

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 10

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

☐

No

→ If 'No' please encourage the patient to be compliant.

☐

Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Arrange for the patient to return in 3 months (+/- 14 days) for Visit 11.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back **ALL** unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal

CONCOMITANT
MEDICATION



Page 107

Protocol		Patient Number	Patient Initials		
49653/009					

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 9. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 9.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										
For SB										

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	<i>Adverse experience which is easily tolerated</i>
MODERATE	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED

**ADVERSE
EXPERIENCES**



Page 108

Protocol 49653/009		Patient Number [][][][][]	Patient Initials [][][][]		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][] Day Mth Yr [][] 24hr:min	[][][] Day Mth Yr [][] 24hr:min
End Date and Time (If ongoing please leave blank)	[][][] Day Mth Yr [][] 24hr:min	[][][] Day Mth Yr [][] 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [] episodes ☐ Constant	☐ Intermittent → No. of [] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][] Day [][] Mth [][] Yr	



Page 109

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)			
For SmithKline Beecham			
Onset Date and Time	 Day Mth Yr	 24hr:min	 Day Mth Yr
End Date and Time (If ongoing please leave blank)	 Day Mth Yr	 24hr:min	 Day Mth Yr
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died	
Experience Course	☐ Intermittent → No. of ☐ Constant	☐ Intermittent → No. of ☐ Constant	
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe	
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No	
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No	
Investigator's Signature _____		Date : Day Mth Yr	



Page 110

Protocol 49653/009		Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 10 - VISIT 11



Protocol	Centre Number	Patient Number			
49653/009					

MODULE 10

Module 10	- Visit 11 and any Unscheduled Visits
CRF Pages	- 111 - 120
Unprocessed Forms	- Visit 11 : SBCL Laboratory Report ECG

VISIT 11

VISIT 11



Page 111

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date	Visit 11
49653/009				Day Mth Yr 	

VISIT REMINDERS

- If the patient withdraws at this visit or before this visit, then do not complete this visit. Complete the Early Withdrawal and Study Conclusion sections at the back of this CRF.
- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this module.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this module.

DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes

→ If 'No', encourage the patient to comply with the dietary allowance and stress the importance of this to the study.



Page 112

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 11

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only).

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

☐ No —→ If 'No' please take samples.

☐ Yes —→ If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day.
(* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

☐ No

☐ Yes —→ If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

Check the fasting plasma glucose result from the previous visit. If the result is $\geq 12\text{mmol/L}$ then read protocol section 9.3.

VITAL SIGNS

Weight (without shoes) (kg)
[][][][][][] . [][]

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][][][]	[][][][][][] / [][][][][][]	[][][][][][]



Page 113

Protocol 49653/009		Patient Number 	Patient Initials 	Date ECG Performed Day Mth Yr 	Visit 11

ELECTROCARDIOGRAM

The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis

Interpretation ☐ (F74301) Within normal limits

☐ Abnormal → Mark appropriate boxes below

Rhythm

- ☐ (F73360) Sinus arrhythmia
- ☐ (F73310) Sinus bradycardia
- ☐ (F73380) Sinus tachycardia
- ☐ (F73440) Wandering atrial pacemaker
- ☐ (F73450) Premature atrial contractions
- ☐ (F73510) Paroxysmal atrial tachycardia
- ☐ (F73530) Chronic ectopic atrial tachycardia
- ☐ (F73550) Multifocal atrial tachycardia
- ☐ (F73560) Atrial flutter
- ☐ (F73570) Atrial fibrillation
- ☐ (F73610) Junctional (AV nodal) premature contractions
- ☐ (F73650) Junctional (AV nodal) tachycardia
- ☐ (F73150) Supraventricular tachycardia
- ☐ (F73860) Accelerated idioventricular rhythm
- ☐ (F73710) Premature Ventricular Contractions (NOS)
- ☐ (F73720) Unifocal PVC's
- ☐ (F73730) Multifocal PVC's
- ☐ (F73711) Ventricular couplets
- ☐ (F73750) Bigeminy
- ☐ (F73870) Ventricular tachycardia
- ☐ (F73880) Ventricular fibrillation
- ☐ (F73340) Sick sinus syndrome
- ☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
- ☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
- ☐ (F73950) Second degree AV block, Type I
- ☐ (F73960) Second degree AV block, Type II
- ☐ (F73970) Third degree AV block
- ☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
- ☐ (F74130) Left Axis deviation

Other interpretations not listed _____

Were any clinically important changes (since the previous test) noted at this examination?

☐ No

☐ Yes →

☐ Improvement

☐ Worsening →

Enter details in the Adverse Experience section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.



Protocol 49653/009		Patient Number	Patient Initials		Visit 11

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 115

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Visit 11

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][][]			[][][][][][]				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][][]			[][][][][][]				mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][][]			[][][][][][]				mg	



Page 116

Protocol 49653/009		Patient Number 	Patient Initials 		Visit 11

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

- Please discuss dispensing of additional study medication and further study arrangements with your local monitor.
- Please ensure that you record any serious adverse experiences up to 30 days after the last dose of 49653 has been given.

CONCOMITANT
MEDICATION**CONCOMITANT MEDICATION**

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal



Page 117

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken after the end of Visit 10. (Please print clearly).

☐ No concomitant medication changes since the end of Visit 10.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
					[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	
For SB										
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For SB										
* For Route, see tab for acceptable abbreviations.										

ADVERSE EXPERIENCES (Non-serious)**DEFINITIONS****INTENSITY (Maximum)**

MILD	Adverse experience which is easily tolerated
MODERATE	Adverse experience sufficiently discomforting to interfere with daily activity
SEVERE	Adverse experience which prevents normal everyday activities

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	The adverse experience is definitely not related to the test drug
UNLIKELY	There are other more likely causes and the drug is not suspected as a cause
SUSPECTED (REASONABLE POSSIBILITY)	A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug
PROBABLE	There probably is a direct cause and effect relationship between the adverse experience and the study drug

SERIOUS ADVERSE EXPERIENCE (SAE)

A SAE is any experience which is :-

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE

**ADVERSE
EXPERIENCES**

Use each form for a maximum of two experiences

PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 118

Protocol 49653/009		Patient Number 	Patient Initials 		

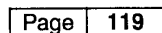
ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Protocol 49653/009	Patient Number 	Patient Initials 		

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of ☐ Constant episodes	☐ Intermittent → No. of ☐ Constant episodes
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 120

Protocol 49653/009	Patient Number 	Patient Initials 		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

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Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of episodes ☐ Constant	☐ Intermittent → No. of episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

MODULE 11 - EARLY WITHDRAWAL / STUDY CONCLUSION / UNSCHEDULED VISIT / SAE



Protocol 49653/009	Centre Number <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					Patient Number <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>									

MODULE 11

Module 11	- Early Withdrawal / Study Conclusion / Unscheduled Visit / SAE
CRF Pages	- 121 - 142
Unprocessed Forms	- Early Withdrawal : SBCL Laboratory Report ECG

EARLY WITHDRAWAL

***(Complete for patients who have withdrawn
early from the study)***

EARLY WITHDRAWAL



Page 121

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Withdrawal Visit

VISIT REMINDERS

- Patients must not have taken their morning dose of study medication on the day of the visit.
- On the morning of this visit, the patient should have refrained from eating or drinking from 11:00 p.m. the night before in order to collect a fasting blood sample. Reschedule the patient to return to the clinic the following day if the patient is not in the fasting state. Only take non fasted blood samples if the patient is not able to return to the clinic the next day.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section at the back of this section.
ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section at the back of this section.
DIABETIC DIET FOR WEIGHT MAINTENANCE

Has the patient complied with their specific dietary allowance?

☐ No

☐ Yes



Page 122

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		Withdrawal Visit

FASTING LABORATORY TESTS

Place the SBCL laboratory report in the wallet at the back of this book. **Results must be fasting.**

For SB Lab Code Number

Please perform a pregnancy test (women of child bearing potential only). Please take a urine sample at this visit.

Has the patient eaten or drunk anything, (except water), from 11pm the night before this visit?

- ☐ No —→ If 'No' please take samples.
- ☐ Yes —→ If 'Yes' please do not take samples*. Ask the patient to return to the clinic the next day. (* Only take non fasted samples if the patient is not able to return to the clinic the next day).

Samples date and time [][][][][][] [][][][][]
Day Mth Yr 24hr:min

Are there any clinically significant abnormal laboratory values?

- ☐ No
- ☐ Yes —→ If 'Yes' please record the findings and/or diagnosis in the Adverse Experience section at the back of this module.

VITAL SIGNS

Weight (without shoes) (kg)
[][][][] . [][]

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][][][]	[][][][] / [][][][]	[][][][]



Page 123

Protocol 49653/009	Patient Number [][][][][][]	Patient Initials [][][][][][]	Date ECG Performed Day Mth Yr [][][][][][]	Withdrawal Visit

ELECTROCARDIOGRAM

The ECG should be performed after patient has been in a supine position for 5 minutes

Atrial Rate beats/min	Ventricular Rate beats/min	PR (msec)	QRS (msec)	Uncorrected QT (msec)	Axis
[][][][]	[][][][]	[][][][]	[][][][]	[][][][]	☐ + ☐ - [][][][]

Interpretation
☐ (F74301) Within normal limits

☐ Abnormal → Mark appropriate boxes below
Rhythm

- ☐ (F73360) Sinus arrhythmia
- ☐ (F73310) Sinus bradycardia
- ☐ (F73380) Sinus tachycardia
- ☐ (F73440) Wandering atrial pacemaker
- ☐ (F73450) Premature atrial contractions
- ☐ (F73510) Paroxysmal atrial tachycardia
- ☐ (F73530) Chronic ectopic atrial tachycardia
- ☐ (F73550) Multifocal atrial tachycardia
- ☐ (F73560) Atrial flutter
- ☐ (F73570) Atrial fibrillation
- ☐ (F73610) Junctional (AV nodal) premature contractions
- ☐ (F73650) Junctional (AV nodal) tachycardia
- ☐ (F73150) Supraventricular tachycardia
- ☐ (F73860) Accelerated idioventricular rhythm
- ☐ (F73710) Premature Ventricular Contractions (NOS)
- ☐ (F73720) Unifocal PVC's
- ☐ (F73730) Multifocal PVC's
- ☐ (F73711) Ventricular couplets
- ☐ (F73750) Bigeminy
- ☐ (F73870) Ventricular tachycardia
- ☐ (F73880) Ventricular fibrillation
- ☐ (F73340) Sick sinus syndrome
- ☐ (F73190) Pacemaker rhythm

P-Wave Morphology

- ☐ (F74214) Left atrial hypertrophy, P mitrale
- ☐ (F74213) Right atrial hypertrophy, P pulmonale

Conduction

- ☐ (F73930) First degree AV block
- ☐ (F73950) Second degree AV block, Type I
- ☐ (F73960) Second degree AV block, Type II
- ☐ (F73970) Third degree AV block
- ☐ (F74090) Wolff-Parkinson-White syndrome

Axis

- ☐ (F74120) Right Axis deviation
- ☐ (F74130) Left Axis deviation

Other interpretations not listed

Were any clinically important changes (since the previous test) noted at this examination?

☐ No

☐ Yes →

☐ Improvement

☐ Worsening →

Enter details in the Adverse Experience section at the back of this module

Please sign and insert the original ECG tracings labelled with date taken, protocol number, centre number and patient initials into the plastic wallet at the back of this module.



Protocol 49653/009		Patient Number	Patient Initials		Withdrawal Visit

INSTRUCTIONS TO THE INVESTIGATOR

- If the patient was taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient was taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Protocol 49653/009		Patient Number [][][][][]	Patient Initials [][][][]		Withdrawal Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date Day Mth Yr	End Date Day Mth Yr	Dose	Unit	Frequency Per Day
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][]	[][][][][]		mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][]	[][][][][]		mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, <i>specify</i> -----	[][][][][]	[][][][][]		mg	



Page 126

Protocol 49653/009		Patient Number 	Patient Initials 		Withdrawal Visit

49653 COMPLIANCE - ALL PATIENTS

Tablets Dispensed (X)	Tablets Returned (Y)	Tablets Taken (X-Y)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of tablets taken}}{(N \times \text{Days since last visit})} \times 100$$

Where N = 2, for patients on combination therapy (taking 1 x 2 mg tablet bd)

Where N = 4, for patients on monotherapy (taking 2 x 2 mg tablet bd)

Has the patient's compliance been $\geq 80\%$ and $\leq 120\%$?

- ☐ No $\longrightarrow$ If 'No' please encourage the patient to be compliant.
- ☐ Yes

INSTRUCTIONS TO THE INVESTIGATOR

Please ensure that you record any serious adverse experiences up to 30 days after the last dose of 49653 has been given.

CONCOMITANT MEDICATION

NOTE: The use of insulin and oral antidiabetic medications, (except designated hypoglycaemic therapy), are prohibited during the study.

ROUTE KEY :

PO = by mouth
IV = intravenous
IM = intramuscular
IAR = intra-arterial
TO = topical
SL = sublingual
IT = intrathecal
VA = vaginal
NA = nasal
IA = intra-articular injection
TD = transdermal
IH = inhaled
SC = subcutaneous
PR = rectal
ID = intradermal

CONCOMITANT
MEDICATION



Page 127

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		

CONCOMITANT MEDICATION

Please record any changes in concomitant medication taken since the end of the previous visit. (Please print clearly)

☐ No concomitant medication changes since the end of the previous visit.

Any new medical illness/diagnosis (or symptoms in the absence of a diagnosis) should be recorded on the Adverse Experience Form utilising the same terminology.

If a medication was marked 'Continuing' at a previous visit, but has since had a dosage change or has been stopped, it must be recorded as a change below with the start and end date.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (e.g. bid, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of a diagnosis)	Start Date (be as precise as possible)			End Date (or if Continuing mark box)		
					Day	Mth	Yr	Day	Mth	Yr
					[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	☐
For SB										
					[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	☐
For SB										
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For SB										
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For SB										
					[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	[][][][][][]	☐
For SB										

* For Route, see tab for acceptable abbreviations.

ADVERSE EXPERIENCES (Non-serious)ADVERSE
EXPERIENCES**DEFINITIONS****INTENSITY (Maximum)**

MILD	<i>Adverse experience which is easily tolerated</i>
MODERATE	<i>Adverse experience sufficiently discomforting to interfere with daily activity</i>
SEVERE	<i>Adverse experience which prevents normal everyday activities</i>

RELATIONSHIP TO INVESTIGATIONAL DRUG

NOT RELATED	<i>The adverse experience is definitely not related to the test drug</i>
UNLIKELY	<i>There are other more likely causes and the drug is not suspected as a cause</i>
SUSPECTED (REASONABLE POSSIBILITY)	<i>A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but there is a reasonable possibility that the experience was caused by the drug</i>
PROBABLE	<i>There probably is a direct cause and effect relationship between the adverse experience and the study drug</i>

SERIOUS ADVERSE EXPERIENCE (SAE)**A SAE is any experience which is :-**

- 1 - fatal
- 2 - life threatening
- 3 - disabling/incapacitating
- 4 - results in hospitalisation (excluding elective surgery or routine clinical procedures)
- 5 - prolongs a hospital stay
- 6 - associated with congenital abnormality
- 7 - cancer
- 8 - associated with overdose
- 9 - In addition any event which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event

IF A SAE OCCURS, PLEASE GO TO THE SAE SECTION IMMEDIATELY AND FOLLOW THE INSTRUCTIONS GIVEN THERE
Use each form for a maximum of two experiences
PLEASE REMEMBER ALL QUESTIONS ON ADVERSE EXPERIENCES FORM SHOULD BE COMPLETED



Page 128

Protocol 49653/009		Patient Number [][][][][]	Patient Initials [][][][][]		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	[][][][] Day Mth Yr [][] 24hr:min	[][][][] Day Mth Yr [][] 24hr:min
End Date and Time (If ongoing please leave blank)	[][][][] Day Mth Yr [][] 24hr:min	[][][][] Day Mth Yr [][] 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [] episodes ☐ Constant	☐ Intermittent → No. of [] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : [][][] Day Mth Yr	



Page 129

Protocol		Patient Number	Patient Initials	
49653/009				

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

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Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	 Day Mth Yr 24hr:min	 Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
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Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If "Yes", record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	



Page 130

Protocol 49653/009		Patient Number [][][][][][]	Patient Initials [][][][][]		

ADVERSE EXPERIENCES (Non-serious)

Record any adverse experiences (using **standard medical terminology**) observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit ?" Provide the diagnosis **not** symptoms where possible. One adverse experience per column.

If you consider this to be a serious adverse experience (SAE), please do not enter on this page but enter in the SAE section (See opposite for definitions of an SAE).

If no adverse experiences occurred during the study, please sign form below and mark this box. ☐

Adverse Experience (please print clearly)		
For SmithKline Beecham		
Onset Date and Time	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
End Date and Time (If ongoing please leave blank)	Day Mth Yr 24hr:min	Day Mth Yr 24hr:min
Outcome <i>If patient died, STOP: go to SAE section and follow instructions given there</i> ←	☐ Resolved ☐ Ongoing ☐ Died	☐ Resolved ☐ Ongoing ☐ Died
Experience Course	☐ Intermittent → No. of [] episodes ☐ Constant	☐ Intermittent → No. of [] episodes ☐ Constant
Intensity (maximum)	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Action Taken with Respect to Investigational Drug	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped	☐ None ☐ Dose reduced ☐ Dose increased ☐ Drug interrupted/restarted ☐ Drug stopped
Relationship to Investigational Drug	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable	☐ Not related ☐ Unlikely ☐ Suspected (reasonable possibility) ☐ Probable
Corrective Therapy <i>If 'Yes', record details in the Concomitant Medication section and/or Resource Utilisation section if appropriate</i> ←	☐ Yes ☐ No	☐ Yes ☐ No
Was patient withdrawn due to this specific AE ?	☐ Yes ☐ No	☐ Yes ☐ No
Investigator's Signature _____	Date : Day Mth Yr	

STUDY CONCLUSION

STUDY CONCLUSION

(Complete for all patients; including early withdrawals)



Page 131

Protocol		Patient Number	Patient Initials		
49653/009					

STUDY CONCLUSION

Did the patient complete the study according to the protocol?

☐ Yes☐ No → If 'No' please mark the **primary** cause of withdrawal. (Mark one box only).

1	☐	Adverse experience (complete AE form)
2	☐	Insufficient therapeutic effect
3	☐	Protocol deviation (including non-compliance)
4	☐	Lost to follow-up
7	☐	Other - specify: _____

Date of final visit

Day	Mth	Yr

Date of final dose

Day	Mth	Yr

INVESTIGATOR SIGNATURE

I certify that I have reviewed the data on this case report form and that all information is complete and accurate.

Investigator's Signature _____

Day	Mth	Yr

UNSCHEDULED VISITS

UNSCHEDULED VISITS



Page 132

Protocol 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	Visit Date Day Mth Yr [][][][][]	Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.

VITAL SIGNS

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
[][]:[][]	[][][] / [][][]	[][][]



Protocol 49653/009		Patient Number [][][][][]	Patient Initials [][][][]		Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No → If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes → If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
[][][][][][]	[][][][][][]	4mg	Tablet	bd
[][][][][][]	[][][][][][]			
[][][][][][]	[][][][][][]			

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
[][][][][][]	[][][][][][]	2mg	Tablet	bd
[][][][][][]	[][][][][][]			
[][][][][][]	[][][][][][]			

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients **ONLY**).



Page 134

Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.



Page 135

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date Day Mth Yr	Unscheduled Visit
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.

VITAL SIGNS

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	



Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No —→ If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes —→ If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients ONLY).



Page 137

Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.



Page 138

Protocol	Centre Number	Patient Number	Patient Initials	Visit Date Day Mth Yr	Unscheduled Visit
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

- Complete this assessment in accordance with the instructions detailed on the previous page.
- Inform your local monitor at monitor visits that you have completed an unscheduled assessment.

CONCOMITANT MEDICATION

Has there been a change in the patient's concomitant medication since the last visit?

☐ No

☐ Yes → If 'Yes' please record details in the Concomitant Medication section corresponding to the previous '**scheduled**' visit.

ADVERSE EXPERIENCES

Record any adverse experiences (using standard terminology), observed or elicited by the following direct question to the patient : "Have you felt different in any way since the last visit?"

☐ No

☐ Yes → If 'Yes' please record details in the Adverse Experience section corresponding to the previous '**scheduled**' visit.

VITAL SIGNS

Blood Pressure

Prior to any blood pressure measurements being taken, patients should have rested in the clinic for at least five minutes. Blood pressure must be measured in the same arm at each visit.

Time of measurement	Sitting Blood Pressure (after 5 minutes sitting) (mmHg)	Heart Rate (after 5 minutes sitting) (bpm)
24hr:min	Systolic Diastolic	
	/	



Protocol		Patient Number	Patient Initials		Unscheduled Visit
49653/009					

INSTRUCTIONS TO THE INVESTIGATOR

Has the patient interrupted their 49653 medication, or their hypoglycaemic therapy?

- ☐ No → If 'No', do not complete 49653 record or hypoglycaemic therapy record sections.
- ☐ Yes → If 'Yes', please record information in the 49653 / hypoglycaemic therapy record(s).

- If the patient is taking 49653 4mg bd, please complete the 4mg section **ONLY**.
- If the patient is taking 49653 2mg bd, please complete the 2mg section **ONLY**.

49653 RECORD - 4MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		4mg	Tablet	bd

49653 RECORD - 2MG BD PATIENTS ONLY

The start date is the day of last visit. The end date is the day before this visit. If a dose interruption occurs, record the end date. Record the re-start date of study medication on the next line.

Start Date Day Mth Yr	End Date Day Mth Yr	Single Dose	Units	Frequency Per Day
		2mg	Tablet	bd

Also complete the hypoglycaemic therapy record on the next page (2mg bd patients ONLY).



Page 140

Protocol 49653/009		Patient Number 	Patient Initials 		Unscheduled Visit

HYPOGLYCAEMIC THERAPY RECORD - 49653 2MG BD PATIENTS ONLY

The start date is the day of the last visit. The end date is the day before this visit.

Medication	Start Date			End Date			Dose	Unit	Frequency Per Day
	Day	Mth	Yr	Day	Mth	Yr			
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	
☐ glibenclamide ☐ glipazide ☐ gliclazide ☐ other, specify -----								mg	

INSTRUCTIONS TO THE INVESTIGATOR

- Do not dispense new 49653 medication. Check the patient has the medication dispensed at the previous scheduled visit.
- Arrange for the patient to return for the next scheduled visit.
- Remind the patient not to eat or drink, (water is allowed), from 11:00pm on the night before their next visit.
- Ask the patient to bring back ALL unused medication and all packaging to the next visit.
- Remind the patient not to take their morning dose of study medication on the day of the next visit.

INSTRUCTIONS FOR REPORTING SERIOUS ADVERSE EXPERIENCES (SAE)

SAEs MUST BE REPORTED TO SMITHKLINE BEECHAM WITHIN 24 HOURS

COMPLETE THE SAE PAGES OPPOSITE

Please complete these pages as fully and accurately as possible in order to minimise the time you spend dealing with data queries

If the SAE is still ongoing at the time of reporting, please leave 'Experience Course' blank and update it later

SIGN AND DATE THE SAE PAGE**PLEASE ENSURE THAT ALL OF THE INFORMATION ON THE FOLLOWING CRF PAGES IS COMPLETE**

- Demography
- Significant Medical/Surgical History and Physical Examination
- Study Medication Record
- Concomitant Medication
- Form D (if applicable)

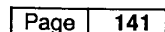
PHOTOCOPY THE SAE PAGES AND THE CRF PAGES SPECIFIED ABOVE

(Do not separate the NCR pages)

FAX A COPY OF THE SAE PAGES AND ALL OF THE CRF PAGES SPECIFIED ABOVE TO :

Your local SB CRA/Medical Monitor (see Investigator Site File for appropriate fax number)

If no photocopier OR fax is available please telephone your local SB CRA/Medical monitor within 24 hours



Protocol No.	Centre Number	Patient Number	Patient Initials	SB Receipt Date
49653/009				 Day Mth Yr

Person Reporting SAE _____ (Please print clearly)		AEGIS Number _____	
Serious Adverse Experience (Please print clearly)		Specify reason(s) for considering this a serious AE. Mark all that apply. 1 ☐ fatal 2 ☐ life threatening 3 ☐ disabling/incapacitating 4 ☐ results in hospitalisation (excluding elective surgery or routine clinical procedures) 5 ☐ hospitalisation prolonged 6 ☐ congenital abnormality 7 ☐ cancer 8 ☐ overdose 9 ☐ Investigator considers serious or a significant hazard, contraindication, side effect or precaution	
For SmithKline Beecham			
Onset Date and Time _____ Day _____ Mth _____ Yr _____ 24hr:min			
End Date and Time (If ongoing please leave blank) _____ Day _____ Mth _____ Yr _____ 24hr:min			
Outcome If patient died, please complete Form D 1 ☐ Resolved 2 ☐ Ongoing 3 ☐ Died			
Experience Course 1 ☐ Intermittent → No. of _____ episodes 2 ☐ Constant			
Intensity (maximum) 1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe			
Action Taken with Respect to Investigational Drug 1 ☐ None 2 ☐ Dose reduced 3 ☐ Dose increased 4 ☐ Drug interrupted/restarted 5 ☐ Drug stopped		Did the SAE abate? ☐ Yes ☐ No If study medication was interrupted, stopped or dose reduced: Was study medication reintroduced (or dose increased) ☐ Yes ☐ No If yes, did SAE recur ☐ Yes ☐ No	
Relationship to Investigational Drug 1 ☐ Not related 2 ☐ Unlikely 3 ☐ Suspected (reasonable possibility) 4 ☐ Probable		Assessment Could the SAE be associated with : ☐ Protocol design or procedures (but not to study drug) Please specify _____ ☐ Another condition (eg, condition under study, intercurrent illness) Please specify _____ ☐ Another drug Please specify _____ ☐ Unknown cause	
Corrective Therapy If 'Yes', record details in the Prior & Concomitant Medication section ☐ Yes ☐ No			
Was patient withdrawn due to this specific SAE ? ☐ Yes ☐ No			



Page 142

Protocol No. 49653/009	Centre Number [][][]	Patient Number [][][][][]	Patient Initials [][][][]	

SERIOUS ADVERSE EXPERIENCE (SAE) (cont)**Relevant Laboratory Data**

Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal Range
	[][][][][] Day Mth Yr			
	[][][][][] Day Mth Yr			
	[][][][][] Day Mth Yr			
	[][][][][] Day Mth Yr			

Remarks (Please provide a brief narrative description of the SAE, attaching extra pages eg. hospital discharge summary if necessary)

If applicable, was randomisation code broken at investigational site ? ☐ No ☐ Yes

Randomisation / Study Medication Number : [][][][][][]

Investigator's Signature : _____ **Date** [][][][][]
(confirming that the above data are accurate and complete) Day Mth Yr

Please PRINT name _____

SB Medical Monitor's Signature : _____ **Date** [][][][][]
Day Mth Yr

Please PRINT name _____

49653/009 **CASE REPORT FORM** **YEAR 2 : VISITS 7 (49653 dispensing) and 8 TO 11**

49653/009 **CASE REPORT FORM** **YEAR 2 : VISITS 7 (49653 dispensing) and 8 TO 11**

49653/009 **CASE REPORT FORM** **YEAR 2 : VISITS 7 (49653 dispensing) and 8 TO 11**

49653/009 **CASE REPORT FORM** **YEAR 2 : VISITS 7 (49653 dispensing) and 8 TO 11**

00000



Protocol		Patient Number	Patient Initials		
49653/009		0 0 0 0 0			

LIVER FUNCTION AND SEROLOGY TESTING RECORD

Attach the Quest Laboratory labels for any re-test done in the boxes below and record the date and the visit number for which the re-test was taken.

Sample Date
Day Month Yr

Visit Number

RE-TEST ONLY

*Please attach the
Laboratory Label here*

RE-TEST ONLY

*Please attach the
Laboratory Label here*

Sample Date
Day Month Yr

Visit Number

RE-TEST ONLY

*Please attach the
Laboratory Label here*

RE-TEST ONLY

*Please attach the
Laboratory Label here*

Sample Date
Day Month Yr

Visit Number

RE-TEST ONLY

*Please attach the
Laboratory Label here*

RE-TEST ONLY

*Please attach the
Laboratory Label here*

Sample Date
Day Month Yr

Visit Number

RE-TEST ONLY

*Please attach the
Laboratory Label here*

RE-TEST ONLY

*Please attach the
Laboratory Label here*

Sample Date
Day Month Yr

Visit Number

RE-TEST ONLY

*Please attach the
Laboratory Label here*

RE-TEST ONLY

*Please attach the
Laboratory Label here*

This section contained Principal Investigator's Curriculum Vitae and has been excluded to protect Principal Investigator privacy.

Certificates of Analysis

**Certificate of Analysis**

Product Name	BRL-49653-C Tablet	
Batch Number	[REDACTED]	Strength 2.0mg
Analytical Reference	P96/2414	Formula AG
Date of Manufacture	6 April 1996	Use By 6 April 1998

Test	Result
Description	White film coated round biconvex tablet.
Identity	The chromatogram obtained from a sample is concordant with a reference chromatogram of authentic BRL-49653-C, similarly prepared and run.
Uniformity of Content	Complies with Ph. Eur and USP.
Dissolution	Complies with USP, Q=75% at 45 minutes.
BRL-49653 Content	Mean content of ten tablets is 2.00mg per tablet (100% of label claim).
Degradation	No individual degradation product was greater than 0.5% and total degradation products were not greater than 1.0% on an area normalised basis.

This product conforms with Release Specification CPSC/PDSG/0297/02 and has been manufactured and tested in accordance with Good Manufacturing Practice.

Based on the results of ongoing stability studies, the shelf-life of this product has been extended. This certificate, with the extended Use By date, supersedes the one issued on 6 June 1996.

Approved by [REDACTED] on 20 January 1997
[REDACTED] B.Sc CChem MRSC 20 January 1997
Quality Assurance

1 of 1



Mundells, Welwyn Garden City, Hertfordshire, England AL7 1EY, Tel: [REDACTED] Fax: [REDACTED]
SmithKline Beecham plc. Registered in London No. 2027369. Registered Office: 1 New Hallam Court, Brimford, Macclesfield, Cheshire SK10 9EP



**Certificate of Analysis**

Product Name	BRL-49653-C Tablet	
Batch Number	[REDACTED]	Strength 2.0mg
Analytical Reference	HA 97/0517	Formula AG
Date Of Manufacture	13 June 1997	

Test	Result
Description	A white film coated round biconvex tablet.
Identification	The chromatogram obtained from a sample is concordant with a reference chromatogram of authentic BRL-49653-C, similarly prepared and run.
Uniformity Of Content	Complies with Ph.Eur and USP.
Dissolution	Complies with USP, Q = 75% at 45 minutes.
BRL-49653-C Content	Mean content of 10 tablets is 1.96 mg/tablet (98 % of label claim).
Degradation	No individual degradation product greater than 0.5% and total degradation products not greater than 1.0% on an area normalised basis.

This product conforms with Release Specification CPSC/PDSG/0297/02 and has been manufactured and tested in accordance with Good Manufacturing Practice.

Approved by [REDACTED] on 15 August 1997
[REDACTED] B.Sc CChem MRSC 15 August 1997
Quality Assurance

1 of 1



[REDACTED] New Frontiers Science Park (South), Third Avenue, Harlow, Essex CM19 5AW. 15/08/97

Telephone [REDACTED] International: [REDACTED] Fax [REDACTED] International: [REDACTED]

SmithKline Beecham plc. Registered in London 2337953. Registered Office: New Horizons Court, Brentford, Middlesex TW8 9EP



**Certificate of Analysis**

Product Name BRL49653-C Tablet
Batch Number [REDACTED] **Strength** 2.0mg
Analytical Reference HA98/2441 **Formula** AG
Date Of Manufacture 28 October 1998

Test	Result
Description	White film coated round biconvex tablet.
Identification	The chromatogram obtained from a sample is concordant with a reference chromatogram of authentic BRL49653-C, similarly prepared and run.
Uniformity Of Content	Complies with Ph.Eur and USP
Dissolution	Complies with USP, Q = 75% at 45 minutes.
BRL49653 Content	Mean content of ten tablets is 2.01mg/tablet (101 % of label claim)
Degradation	No individual degradation product greater than 0.5% and total degradation products not greater than 1.0% on an area normalised basis.

This product conforms with Release Specification CPSC/PDSG 0297/02 and has been manufactured and tested in accordance with Good Manufacturing Practice.

Approved by [REDACTED] on 11 January 1999
[REDACTED] BPharm MSc MRPharmS 11 January 1999
Regulatory Support (Quality Assurance)

**Certificate of Analysis**

Product Name	BRL49653-C Tablet	
Batch Number	[REDACTED]	Strength 2mg
Analytical Reference	MD98/0284	Formula AG
Date Of Manufacture	22 January 1998	

Test	Result
Description	White film coated round biconvex tablet.
Identification	The chromatogram obtained from a sample is concordant with a reference chromatogram of authentic BRL49653-C, similarly prepared and run.
Uniformity Of Content	Complies with Ph.Eur and USP
Dissolution	Complies with USP, Q = 75% at 45 minutes.
BRL49653 Content	Mean content of 10 tablets is 1.99mg/ tablet (100 % of label claim)
Degradation	No individual degradation product greater than 0.5% and total degradation products not greater than 1.0% on an area normalised basis.

This product conforms with Release Specification CPSC/PDSG 0297/02 and has been manufactured and tested in accordance with Good Manufacturing Practice.

Approved by [REDACTED] on 03 June 1998
[REDACTED] BPharm MSc MRPharmS 03 June 1998
Regulatory Support (Quality Assurance)



**Certificate of Analysis**

Product Name BRL49653-C Tablet
Batch Number [REDACTED] **Strength** 2mg
Analytical Reference MD98/0285 **Formula** AG
Date Of Manufacture 22 January 1998

Test	Result
Description	White film coated round biconvex tablet.
Identification	The chromatogram obtained from a sample is concordant with a reference chromatogram of authentic BRL49653-C, similarly prepared and run.
Uniformity Of Content	Complies with Ph.Eur. and USP
Dissolution	Complies with USP, Q = 75% at 45 minutes.
BRL49653 Content	Mean content of 10 tablets is 2.01mg/tablet (100 % of label claim)
Degradation	No individual degradation product greater than 0.5% and total degradation products not greater than 1.0% on an area normalised basis.

This product conforms with Release Specification CPSC/PDSG 0297/02 and has been manufactured and tested in accordance with Good Manufacturing Practice.

Approved by [REDACTED] on 03 June 1998
[REDACTED] BPharm MSc MRPharmS 03 June 1998
Regulatory Support (Quality Assurance)

1 of 1



New Frontiers Science Park (South), Third Avenue, Harlow, Essex CM19 5AW
Telephone [REDACTED] International: [REDACTED] Fax: [REDACTED] International: [REDACTED]
SmithKline Beecham plc. Registered in London 12270513. Registered Office: [REDACTED]

03/06/98



Appendix B: Patient Data Listings of Demographic and Baseline Characteristics

Listing	Title
B.L1	Patient Disposition, All Patients
B.L2	Demographic Characteristics At Double Blind Baseline, All Patients
B.L3	Medical History At Double Blind Baseline, All Patients
B.L4	Prior And Concomitant Medication At Open Label Baseline, All Patients
B.L5	Exposure And Compliance To Study Medication During The Open Label Study, All Patients

Available On Request

Appendix C: Patient Data Listings of Efficacy

Listing	Title
C.L1	Laboratory Efficacy Data, All Patients

Available On Request

Appendix D: Patient Data Listings of Adverse Experiences

Listing	Title
D.L1	Adverse Experiences Ongoing At The Open Label Baseline, All Patients
D.L2	On-Therapy (Started During The Open Label Study) Adverse Experiences, All Patients
D.L3	Post-Therapy (More Than 1 Day After The Last Dose Of Open Label Medication) Adverse Experiences, All Patients
D.L4	Adverse Experiences Leading To Withdrawal, All Patients
D.L5	Non-Fatal Serious Adverse Experiences Ongoing At The Open Label Baseline, All Patients
D.L6	Non-Fatal On-Therapy (Started During The Open Label Study) Serious Adverse Experiences, All Patients
D.L7	Non-Fatal Post-Therapy (More Than 1 Day After Last Dose Of Open Label Medication) Serious Adverse Experiences, All Patients

Available On Request

Appendix E: Patient Data Listings of Vital Signs and Electrocardiograms

Listing	Title
E.L1a	Vital Signs, All Patients
E.L1b	Ecg, All Patients
E.L3	Abnormal Ecgs At Double Blind Baseline, Open Label Baseline And On-Therapy, All Patients
E.L4	Abnormal Ecgs At Double Blind Baseline, Open Label Baseline And Post Therapy, All Patients

Available On Request

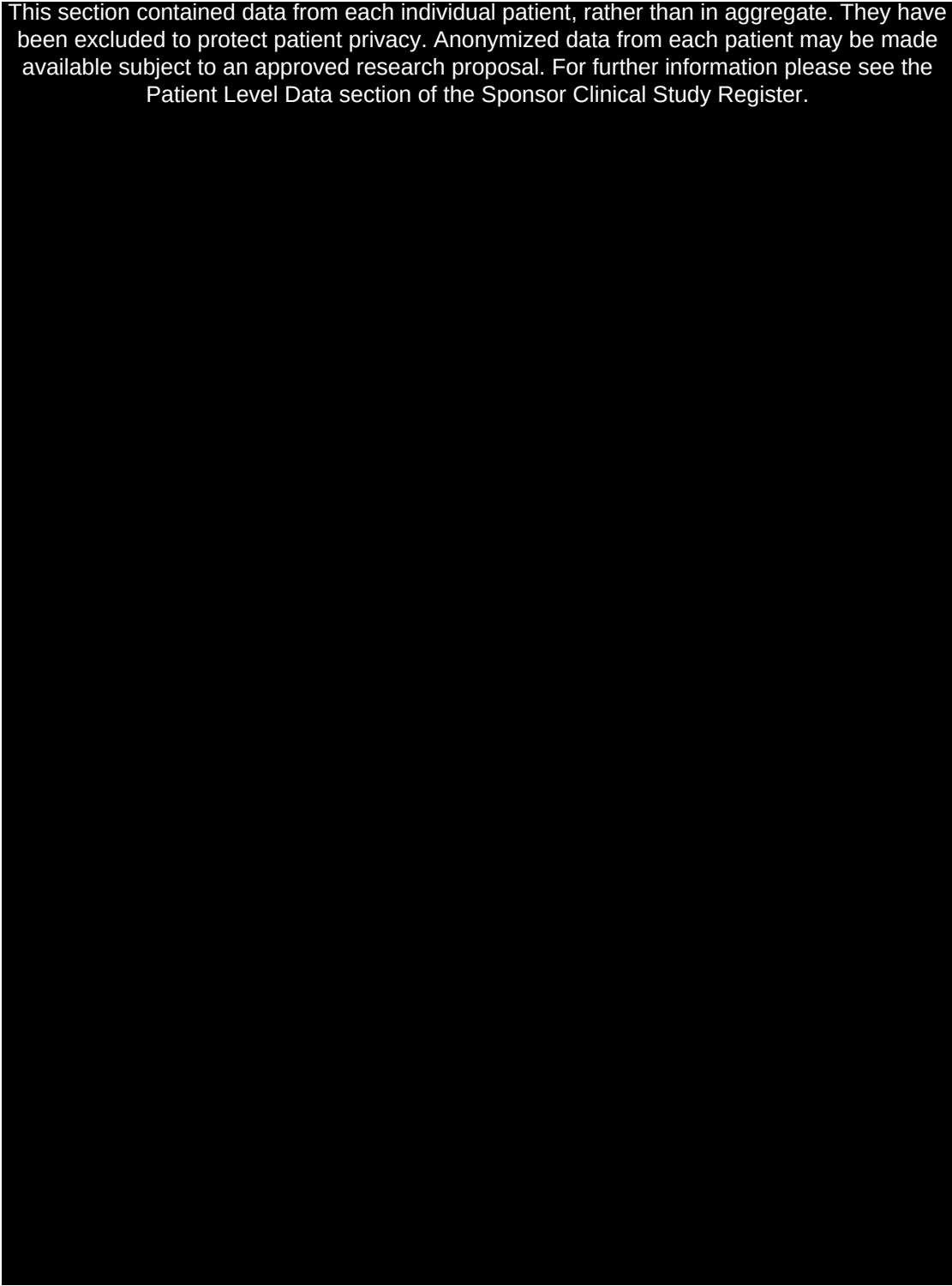
Appendix F: Patient Data Listings of Laboratory Tests

Listing	Title
F.L1	Laboratory Safety Data, All Patients

Available On Request

Appendix G: Annotated CRFs for Patients with Serious Nonfatal Adverse Experiences and Adverse Experiences Leading to Withdrawal or Death

This section contained data from each individual patient, rather than in aggregate. They have been excluded to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the Sponsor Clinical Study Register.



This section contained Principal Investigator's Curriculum Vitae and has been excluded to protect Principal Investigator privacy.