1. Study Description

GSK Medicine /Product: Mepolizumab

Study Number: 219821

eTrack / CTMS abbreviated title: MEPOLYP: - Real-world effectiveness of mepolizumab with Severe Eosinophilic Asthma (SEA) and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Study Title: MEPOLYP: - Real-world effectiveness of MEpolizumab in patients with severe eosinophilic asthma and comorbid chronic rhinosinusitis with or without nasal POLYPs

Study Period: 30 November 2023 and 15 July 2024

Objectives and Study Outcomes:

Primary Objectives:

1. Evaluate the change of clinically significant asthma exacerbations rates defined as deterioration in asthma requiring (1) use of systemic corticosteroids and/or (2) emergency department (ED) visit and/or hospital admission, between the 12-month pre-mepolizumab treatment period and the 12-month post-exposure period, after initiating mepolizumab in cohorts 1 and 2.

Primary Outcome Measure(s): Title & Description	Timeframe
Number of clinically significant asthma exacerbations in the 12-month pre-exposure period	12-month pre-exposure period
Number of clinically significant asthma exacerbations in the 12-month post-exposure period	12-month post-exposure period

Secondary Objectives:

1. Evaluate the change in rate of asthma exacerbations that required ED visits or hospitalization between the 12-month pre-mepolizumab treatment period and the 12-month post-exposure period after initiating mepolizumab in cohorts 1 and 2.
2. Evaluate the change in rate of asthma exacerbations that required hospitalization between the 12-month pre-mepolizumab treatment period and the 12-month post-exposure period after initiating mepolizumab in cohorts 1 and 2.
3. Compare the median oral corticosteroids (OCS) maintenance dose, when available, in the 12-month pre-mepolizumab treatment period with the median OCS maintenance dose at 6 and at 12-months after mepolizumab initiation in cohorts 1 and 2.
4. Compare Forced Expiratory Volume in 1 Second (FEV1) values, when available, in the pre-mepolizumab treatment period (using the historical value nearest to the index date in the pre-exposure period) with FEV1 values at 6-months and 12-months after mepolizumab initiation in cohorts 1 and 2.
5. Compare Asthma Control Test (ACT) scores, when available, in the pre-mepolizumab treatment period (using the historical score nearest to the index date in the pre-exposure period) with ACT scores, at 6-months and 12-months in cohorts 1 and 2.
6. Describe participant demographic, clinical and disease characteristics at initiation of mepolizumab in cohorts 1 and 2.
7. Describe pre-mepolizumab asthma treatment patterns (e.g., OCS, inhaled corticosteroids [ICS], inhaled treatments) in the pre-mepolizumab treatment period in cohorts 1 and 2.

Secondary Outcome Measure(s): Title & Description	Timeframe
Number of asthma exacerbations that required Emergency Room (ER) visits or hospitalization	12-months pre- and post-exposure period

Number of asthma exacerbations that required hospitalization	12-months pre- and post-exposure period
Maintenance OCS dose at 6-months post-exposure period	At 6-months post-exposure period
Maintenance OCS dose at 12-months pre- and post-exposure period	At 12-months pre- and post-exposure period
FEV1 value at 6-months pre- and post-exposure periods	At 6-months pre- and post-exposure period
FEV1 value at 12-months pre- and post-exposure periods	At 12-months pre- and post-exposure period
ACT value at 6-months pre- and post-exposure period	At 6-months pre- and post-exposure period
ACT value at 12-months pre- and post-exposure period	At 12-months pre- and post-exposure period
Time since onset of SEA and CRSwNP to index date	At Baseline (12-months pre-exposure period)
Body mass index (BMI)	At Baseline (12-months pre-exposure period)
Smoking status	At Baseline (12-months pre-exposure period)
Clinical characteristics	At Baseline (12-months pre-exposure period)
Type 2 (T2) biomarkers	At Baseline (12-months pre-exposure period)
Comorbidities assessed during the entire pre-exposure period	12-months pre-exposure period
Nasal polyp-related events assessed during the entire pre-exposure period	12-months pre-exposure period
Treatment history assessed during the entire pre-exposure period	12-months pre-exposure period
Pre-mepolizumab asthma treatment patterns in the pre-mepolizumab treatment period	12-months pre-exposure period
Pre-mepolizumab asthma treatment patterns in OCS, ICS and intranasal corticosteroids (INCS) treatments	12-months pre-exposure period
Indication: Asthma	
Study Investigators / Centers: GSK conducted study	
Data Sources & Research Methods: This study examined real-world utilization and effectiveness of mepolizumab in Severe Asthma and an Eosinophilic Phenotype (SAEP) participants by pooling data from established European data cohorts (Belgium Severe Asthma Registry [BSAR] [Liège data only], REAL world effectiveness of mepolizumab In paTIent care [REALITI-A], REal-worlD Effectiveness and Safety [REDES], REal-LIfe study of mepolizumab in participants with severe eosinophilic asTHma in Greece [RELIght], Swiss Severe Asthma Registry [SSAR]) including participants from multiple European countries.	
Study Design: This study was an observational, multi-center retrospective cohort study.	

Study Population:

Inclusion Criteria:

- Informed consent
- Participants must have had a current clinical diagnosis of SEA and be either included in prior published material or newly enrolled into the registry
- Physician decision to prescribe treatment with mepolizumab
- Relevant records available for at least 12-months prior to index date and at least 12-months post-index date
- Adults aged 18 years or over

Exclusion Criteria:

- Any mention of participant participation in an interventional clinical trial during the observational study period

Study Exposure: Participants clinically diagnosed with SEA and treated with mepolizumab without CRSwNP (Cohort 1) or comorbid SEA with CRSwNP (Cohort 2).

Data Analysis Methods: Data were analyzed using Statistical Analysis Software (SAS) version 9.3 or higher. The number of exacerbations in the pre- and post-exposure period was analyzed using a Negative Binomial regression. Comparison of categorical variables between pre-and post-exposure periods were performed using the Chi-squared test or Fisher's exact test. Depending on distribution of variables, either a t-test (for normal distribution) or the Wilcoxon sum of ranks/Mann-Whitney U test for non-normal distributions were considered.

Limitations:

1. One hundred seventy-five participants did not meet the inclusion requirement of having relevant records available for at least 12-months pre- and 12-months post-mepolizumab initiation.
2. Information was missing in European cohorts for clinical characteristics, medical and treatment history as well as secondary and exploratory outcomes such as clinically significant asthma exacerbations at 24 months post-mepolizumab initiation.
3. Differences in Baseline characteristics between European cohorts and lower numbers of participants included from some European cohorts (due to an overlap in participants or missing written informed consent) could have influenced the results.

2. Study Results – Demographics & Baseline Characteristics

-	Cohort 1 (SAEP-CRSwNP)	Cohort 2 (SAEP+CRSwNP)
Total N	621	416
Age at index, years		
Mean (SD)	55.7 (13.3)	55.2 (12.2)
Gender, n (%)		
Female	438 (70.5)	247 (59.4)
Male	183 (29.5)	169 (40.6)
N: Number of total participants analyzed, n: Number of actual participants analyzed, SD: Standard deviation, %: Percentage		

3. Study Results – Outcome Measures

3.1. Primary Outcome Results

Outcome Measure Description	Number of clinically significant asthma exacerbations in the 12-month pre-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP) (N=609)		Cohort 2 (SAEP+CRSwNP) (N=410)	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	220	4.70 (4.6)	183	4.20 (3.6)
REDES	171	4.60 (3.5)	147	4.30 (3.6)
RELIght	99	4.40 (1.8)	47	4.60 (2.0)
BSAR	107	3.44 (2.1)	28	2.36 (1.5)
SSAR	12	3.33 (3.5)	5	2.00 (2.3)

3.2. Primary Outcome Results

Outcome Measure Description	Number of clinically significant asthma exacerbations in the 12-month post-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP) (N=510)		Cohort 2 (SAEP+CRSwNP) (N=401)	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	220	1.40 (1.8)	182	0.90 (1.7)
REDES	171	1.20 (1.6)	147	0.70 (1.1)

RELIght	99	1.30 (1.7)	47	1.10 (1.5)
BSAR	86	0.69 (1.0)	20	0.25 (0.7)
SSAR	12	0.38 (0.9)	5	0.20 (0.4)

3.3. Secondary Outcome Results

Outcome Measure Description	Number of asthma exacerbations that required ER visits or hospitalization have been reported.

-	Cohort 1 (SAEP-CRSwNP)*				Cohort 2 (SAEP+CRSwNP)#			
-	Pre-exposure		Post-exposure (12-months)		Pre-exposure		Post-exposure (12-months)	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	220	0.9 (1.8)	220	0.2 (0.6)	183	0.6 (1.5)	182	0.1 (0.4)
REDES	171	1.7 (2.2)	171	0.4 (0.9)	147	1.4 (2.0)	147	0.2 (0.7)
RELIGHT	99	0.0 (0.1)	99	0.0 (0.2)	47	0.1 (0.4)	47	0.1 (0.4)
BSAR	109	0.18 (0.7)	87	0.24 (0.8)	33	0.12 (0.6)	23	0.09 (0.3)
SSAR	NA	NA	NA	NA	NA	NA	NA	NA
*: Without NP; #: With NP; NA: Not applicable								

3.4. Secondary Outcome Results

Outcome Measure Description	Number of asthma exacerbations that required hospitalization have been reported.

-	Cohort 1 (SAEP-CRSwNP)*				Cohort 2 (SAEP+CRSwNP)#			
-	Pre-exposure		Post-exposure (12-months)		Pre-exposure		Post-exposure (12-months)	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	220	0.5 (1.3)	220	0.2 (0.5)	183	0.3 (0.8)	182	0.1 (0.3)
REDES	171	0.4 (0.8)	171	0.1 (0.3)	147	0.3 (0.7)	147	0.1 (0.3)
RELIGHT	99	0.1 (0.5)	99	0.0 (0.1)	47	0.0 (0.1)	47	0.0 (0.1)
BSAR	109	0.18 (0.7)	87	0.24 (0.8)	33	0.12 (0.6)	23	0.09 (0.3)
SSAR	NA	NA	NA	NA	NA	NA	NA	NA
*: Without NP; #: With NP; NA: Not applicable								

3.5. Secondary Outcome Results

Outcome Measure Description	Maintenance OCS dose at 6-months post-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP)				Cohort 2 (SAEP+CRSwNP)			
-	Pre-exposure		Post-exposure (6-months)		Pre-exposure		Post-exposure (6-months)	
Data Cohort	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	66	12.2 (10.4)	210	3.6 (7.4)	74	7.8 (5.2)	177	2.3 (4.0)
REDES	71	13.1 (9.3)	66	6.1 (7.3)	52	9.1 (9.2)	57	4.3 (6.2)
RELIGHT	0	NA	0	NA	0	NA	0	NA
BSAR	101	1.72 (4.4)	95	0.91 (3.8)	33	0.73 (2.9)	31	0.26 (0.9)
SSAR	NA	NA	NA	NA	NA	NA	NA	NA
NA: Not applicable								

3.6. Secondary Outcome Results

Outcome Measure Description	Maintenance OCS dose at 12-months pre- and post-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP)*				Cohort 2 (SAEP+CRSwNP)#			
-	Pre-exposure		Post-exposure (12-months)		Pre-exposure		Post-exposure (12-months)	
Data Cohort	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	66	12.2 (10.4)	212	3.1 (6.7)	74	7.8 (5.2)	177	1.8 (3.7)
REDES	71	13.1 (9.3)	65	4.8 (6.9)	52	9.1 (9.2)	54	3.4 (5.6)
RELIGHT	0	NA	0	NA	0	NA	0	NA
BSAR	101	1.72 (4.4)	85	0.40 (1.6)	33	0.73 (2.9)	23	0.0 (0.0)
SSAR	NA	NA	NA	NA	NA	NA	NA	NA
*: Without NP; #: With NP; NA: Not applicable								

3.7. Secondary Outcome Results

Outcome Measure Description	FEV1 value at 6-months pre- and post-exposure periods have been reported.

-	Cohort 1 (SAEP-CRSwNP)				Cohort 2 (SAEP+CRSwNP)			
mL	**Pre-exposure**		**Post-exposure (6-months)**		**Pre-exposure**		**Post-exposure (6-months)**	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	39	1902.1 (746.1)	57	2069.9 (723.7)	34	2579.1 (1120.8)	47	2536.3 (1080.0)
REDES	117	1844.5 (664.4)	99	2008.4 (749.3)	95	2222.7 (756.9)	73	2162.3 (700.8)
RELIGHT	97	1851.7 (742.0)	90	2015.6 (894.5)	47	1825.4 (621.3)	46	2211.4 (835.9)
BSAR	105	1767 (704.0)	92	1789 (737.0)	27	2260 (701.0)	24	2420 (43.0)
SSAR	21	2103.3 (1025.6)	NA	NA	6	2650 (952.1)	NA	NA
NA: Not applicable, mL: Milliliter								

3.8. Secondary Outcome Results

Outcome Measure Description	FEV1 value at 12-months pre- and post-exposure periods have been reported.

-	Cohort 1 (SAEP-CRSwNP)				Cohort 2 (SAEP+CRSwNP)			
mL	**Pre-exposure**		**Post-exposure (12-months)**		**Pre-exposure**		**Post-exposure (12-months)**	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	39	1902.1 (746.1)	74	2116.1 (741.5)	34	2579.1 (1120.8)	55	2549.1 (1005.9)
REDES	117	1844.5 (664.4)	110	2041.0 (713.5)	95	2222.7 (756.9)	81	2213.1 (645.1)
RELIGHT	97	1851.7 (742.0)	97	2076.8 (797.2)	47	1825.4 (621.3)	47	2308.1 (779.6)
BSAR	105	1767 (704.0)	83	1978 (738.0)	27	2260 (701.0)	20	2352 (631.0)
SSAR	21	2103.3 (1025.6)	19	2368 (864.0)	6	2650 (952.1)	4	2840 (1065.6)

3.9. Secondary Outcome Results

Outcome Measure Description	ACT value at 6-months pre- and post-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP)				Cohort 2 (SAEP+CRSwNP)			
mL	**Pre-exposure**		**Post-exposure (6-months)**		**Pre-exposure**		**Post-exposure (6-months)**	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	0	NA	0	NA	0	NA	0	NA
REDES	149	13.6 (4.9)	140	19.8 (4.2)	130	14.6 (5.2)	124	20.8 (3.6)
RELIGHT	99	15.4 (4.6)	93	20.1 (4.2)	47	14.9 (3.6)	46	21.0 (4.0)
BSAR	103	10.8 (4.67)	91	15.5 (5.3)	31	13.1 (5.7)	29	18.8 (5.6)
SSAR	12	19.33 (5.5)	NA	NA	NA	NA	NA	NA
NA: Not applicable								

3.10. Secondary Outcome Results

Outcome Measure Description	ACT value at 12-months pre- and post-exposure period have been reported.

-	Cohort 1 (SAEP-CRSwNP)				Cohort 2 (SAEP+CRSwNP)			
mL	**Pre-exposure**		**Post-exposure (12-months)**		**Pre-exposure**		**Post-exposure (12-months)**	
Data Cohorts	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
REALITI-A	0	NA	0	NA	0	NA	0	NA
REDES	149	13.6 (4.9)	152	20.4 (4.2)	130	14.6 (5.2)	134	21.0 (3.7)
RELIGHT	99	15.4 (4.6)	99	21.4 (3.5)	47	14.9 (3.6)	47	21.6 (3.6)
BSAR	103	10.8 (4.67)	81	16.3 (5.6)	31	13.1 (5.7)	21	17.7 (5.4)
SSAR	12	19.33 (5.5)	16	21.63 (3.8)	NA	NA	3	19 (5.2)
NA: Not applicable								

3.11. Secondary Outcome Results

Outcome Measure Description	Time since onset of SEA and CRSwNP to index date (in years) have been reported.

-	n	Cohort 1 (SAEP-CRSwNP) (n=18)	n	Cohort 2 (SAEP+CRSwNP) (N=1)
Time since onset of SEA to index date (in years), Mean (SD)	18	20.4 (20.2)	1	1.9 (NA*)
Time since onset of CRSwNP to index date (in years), Mean (SD)	0	NA	0	NA
*: SD could not be calculated for single participant, NA=Not applicable				

3.12. Secondary Outcome Results

Outcome Measure Description	BMI have been reported.

BMI, kg/m^2	Cohort 1 (SAEP-CRSwNP) (N=618)	Cohort 2 (SAEP+CRSwNP) (N=414)
Mean (SD)	29.2 (6.9)	27.4 (5.6)
kg/m^2: kilogram per square meter		

3.13. Secondary Outcome Results

Outcome Measure Description	Smoking status at Baseline have been reported.

n (%)	Cohort 1 (SAEP-CRSwNP) (N=621)	Cohort 2 (SAEP+CRSwNP) (N=416)
Current	26 (4.2)	5 (1.2)
Former	210 (33.8)	145 (34.9)
Never Smoked	379 (61.0)	255 (61.3)
Unknown	6 (1.0)	11 (2.6)

3.14. Secondary Outcome Results

Outcome Measure Description	Clinical characteristics have been reported.

Clinical characteristics	Cohort 1 (SAEP-CRSwNP) (N=621)		Cohort 2 (SAEP+CRSwNP) (N=416)	
-	n	Mean (SD)	n	Mean (SD)
Peripheral BEC (cells/µL)	532	583.3 (558.1)	384	725.1 (712.7)
Total IgE (kU/L)	424	539.7 (1668.1)	291	383.1 (751.4)

FEV1 (pre-bronchodilator) at Baseline (mL)	237	1830.6 (712.3)	225	2034.7 (825.1)
FEV1 (post-bronchodilator) at Baseline (mL)	379	1845.2 (727.3)	209	2208.5 (829.8)
FeNO (ppb)	382	50.8 (45.7)	247	59.3 (46.6)
BEC: blood eosinophil count, cells/µL: cells per microliter, IgE: Immunoglobulin E, kU/L: 1000 units/liter, FeNO: Fractional Exhaled Nitric Oxide, ppb: parts per billion				

3.15. Secondary Outcome Results

Outcome Measure Description	Type 2 (T2) biomarkers data was not available for any cohort within 90 days of the index date.

3.16. Secondary Outcome Results

Outcome Measure Description	Comorbidities assessed during the entire pre-exposure period have been reported.

Comorbidities, n (%)	**n**	**Cohort 1 (SAEP-CRSwNP) (n=621)**	**n**	**Cohort 2 (SAEP+CRSwNP) (N=416)**
AERD, No	0	NA	0	NA
AERD, Yes		NA		NA
COPD, No	518	481 (92.9)	365	354 (97.0)
COPD, Yes		37 (7.1)		11 (3.0)
Diabetes, No	338	294 (87.0)	206	189 (91.7)
Diabetes, Yes		44 (13.0)		17 (8.3)
Churg Strauss Syndrome, No	334	325 (97.3)	203	178 (87.7)
Churg Strauss Syndrome, Yes		9 (2.7)		25 (12.3)
EGPA, No	271	261 (96.3)	147	142 (96.6)
EGPA, Yes		10 (3.7)		5 (3.4)
Hyper eosinophilic syndrome, No	513	509 (99.2)	365	357 (97.8)
Hyper eosinophilic syndrome, Yes		4 (0.8)		8 (2.2)
CRS, No	131	125 (95.4)	39	26 (66.7)
CRS, Yes		6 (4.6)		13 (33.3)
- CRSwNP, No	109	109 (100.0)	39	26 (66.7)
- CRSwNP, Yes		0 (0.0)		13 (33.3)
- CRSsNP, No	109	104 (95.4)	33	33 (100.0)
- CRSsNP, Yes		5 (4.6)		0 (0.0)
Vasculitis, No	211	208 (98.6)	178	171 (96.1)
Vasculitis, Yes		3 (1.4)		7 (3.9)

Gastro esophageal reflux syndrome, No	606	433 (71.5)	399	271 (67.9)
Gastro esophageal reflux syndrome, Yes		173 (28.5)		128 (32.1)
Allergic rhinitis, No	401	288 (71.8)	233	165 (70.8)
Allergic rhinitis, Yes		113 (28.2)		68 (29.2)
Anxiety, No	484	383 (79.1)	344	289 (84.0)
Anxiety, Yes		101 (20.9)		55 (16.0)
Depression, No	507	409 (80.7)	350	312 (89.1)
Depression, Yes		98 (19.3)		38 (10.9)
Atopic dermatitis, No	512	429 (83.8)	383	348 (90.9)
Atopic dermatitis, Yes		83 (16.2)		35 (9.1)
Bronchiectasis, No	193	166 (86.0)	153	120 (78.4)
Bronchiectasis, Yes		27 (14.0)		33 (21.6)
Eosinophilic esophagitis, No	212	211 (99.5)	176	173 (98.3)
Eosinophilic esophagitis, Yes		1 (0.5)		3 (1.7)
Obesity (Yes/No: Yes if BMI >30), No	618	244 (39.5)	414	294 (71.0)
Obesity (Yes/No: Yes if BMI >30), Yes		374 (60.5)		120 (29.0)
Sensitization to common inhalants, No	1	0 (0.0)	5	2 (40.0)
Sensitization to common inhalants, Yes		1 (100.0)		3 (60.0)
Allergy diagnosis, No	414	266 (64.3)	341	223 (65.4)
Allergy diagnosis, Yes		148 (35.7)		118 (34.6)
AERD: Aspirin Exacerbated Respiratory Disease, COPD: Chronic Obstructive Pulmonary Disease, EGPA: Eosinophilic Granulomatosis with Polyangiitis, CRS: Chronic Rhinosinusitis, CRSwNP: Chronic Rhinosinusitis with Nasal Polyps, CRSsNP: Chronic Rhinosinusitis without Nasal Polyps, NA: Not applicable				

3.17. Secondary Outcome Results

Outcome Measure Description	Nasal polyp-related events assessed during the entire pre-exposure period have been reported.

-	n	Cohort 1 (SAEP-CRSwNP) (n=621)	n	Cohort 2 (SAEP+CRSwNP) (N=416)
Nasal polyp surgery (polypectomy), Yes	500	0 (0.0)	369	296 (80.2)
Nasal polyp surgery (polypectomy), No		500 (100.0)		73 (19.8)
If yes, type of surgery				
Functional endoscopic sinus surgery	0	NA	3	0 (0.0)
Endoscopic polyp removal		NA		3 (100.0)

Number of polyps removed, Mean (SD)	0	NA	0	NA
Median size of polyps removed (in centimeter), Mean (SD)	0	NA	0	NA
Surgical complications, Yes	0	NA	0	NA
Surgical complications, No		NA		NA
Time since last surgery (in days), Yes	0	NA	0	NA
Time since last surgery (in days), No		NA		NA
NA: Not applicable				

3.18. Secondary Outcome Results

Outcome Measure Description	Treatment history assessed during the entire pre-exposure period have been reported.

n (%)	**n**	**Cohort 1 (SAEP-CRSwNP) (n=621)**	**n**	**Cohort 2 (SAEP+CRSwNP) (N=416)**
Mepolizumab treatment, Yes	599	0 (0.0)	415	1 (0.2)
Mepolizumab treatment, No		599 (100.0)		414 (99.8)
Other Asthma/CRSwNP related treatment, Yes	608	571 (93.9)	415	398 (95.9)
Other Asthma/CRSwNP related treatment, No		37 (6.1)		17 (4.1)
History of previous biological treatments, Yes	109	3 (2.8)	36	4 (11.1)
History of previous biological treatments, No		106 (97.2)		32 (88.9)
Presence of NSAID intolerance, Yes	193	9 (4.7)	153	33 (21.6)
Presence of NSAID intolerance, No		184 (95.3)		120 (78.4)

3.19. Secondary Outcome Results

Outcome Measure Description	Pre-mepolizumab asthma treatment patterns in the pre-mepolizumab treatment period have been reported.

n (%)	**n**	**Cohort 1 (SAEP-CRSwNP)**	**n**	**Cohort 2 (SAEP+CRSwNP)**

		(n=621)		(N=416)
Use of OCS, Yes	618	242 (39.2)	414	159 (38.4)
Use of OCS, No		376 (60.8)		255 (61.6)
Use of ICS mono, Yes	558	530 (95.0)	392	383 (97.7)
Use of ICS mono, No		28 (5.0)		9 (2.3)
Use of INCS, Yes	85	7 (8.2)	27	9 (33.3)
Use of INCS, No		78 (91.8)		18 (66.7)
Use of ICS combination (ICS and Bronchodilator), Yes	107	92 (86.0)	33	31 (93.9)
Use of ICS combination (ICS and Bronchodilator), No		15 (14.0)		2 (6.1)
Use of bronchodilator (without corticosteroids), Yes	85	83 (97.6)	27	25 (92.6)
Use of bronchodilator (without corticosteroids), No		2 (2.4)		2 (7.4)
Use of other medications for asthma/CRSwNP, Yes	85	42 (49.4)	27	4 (14.8)
Use of other medications for asthma/CRSwNP, No		43 (50.6)		23 (85.2)

3.20. Secondary Outcome Results

Outcome Measure Description	Pre-mepolizumab asthma treatment patterns in OCS, ICS and INCS have been reported.

-	n	Cohort 1 (SAEP-CRSwNP) (n=621)	n	Cohort 2 (SAEP+CRSwNP) (N=416)
OCS, Mean (SD)				
Mean daily dose of OCS during the pre-exposure period	123	3.6 (9.2)	39	1.8 (6.9)
Maintenance OCS daily dose at Baseline	238	8.0 (9.6)	159	6.7 (7.2)
Total daily dose of OCS during the pre-exposure period	239	9.6 (10.3)	181	7.5 (7.1)
Total cumulative dose of OCS during the pre-exposure period	76	1201.2 (1911.0)	60	1210.7 (2911.9)
Frequencies of prescriptions for OCS	109	0.2 (0.7)	33	0.1 (0.6)

during the pre-exposure period				
Total treatment duration for OCS (in days)	0	NA	0	NA
ICS, Mean (SD)				
Mean daily dose of ICS during the pre-exposure period	560	1163.4 (950.2)	391	945.9 (657.1)
Total cumulative dose of ICS during the pre-exposure period	0	NA	0	NA
Frequencies of prescriptions for ICS during the pre-exposure period	0	NA	0	NA
Total treatment duration for ICS (in days)	0	NA	0	NA
INCS, Mean (SD)				
Mean daily dose of INCS during the pre-exposure period	0	NA	0	NA
Total cumulative dose of INCS during the pre-exposure period	0	NA	0	NA
Frequencies of prescriptions for INCS during the pre-exposure period	0	NA	0	NA
Total treatment duration for INCS (in days)	0	NA	0	NA
NA: Not applicable				

Conclusion: This study demonstrated a consistent benefit of mepolizumab across primary and secondary analyses. The effectiveness of mepolizumab was found in both SAEP participants with and without comorbid CRSwNP in terms of significant reductions in clinically relevant asthma exacerbations over a period of 12-months, stabilization in asthma exacerbations by 24 months and achieving clinical remission criteria at 12-months. Mepolizumab showed a 30% additional benefit in the rate of clinically relevant asthma exacerbations in SAEP participants with CRSwNP compared to those without CRSwNP at 12-months post-mepolizumab initiation.