ESMO 2010
Best of Breast Cancer

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Objectives

- To highlight the key presentations in Breast Cancer
- To provide clinical context for these presentations
- To discuss clinical implications of this data

Key Focus

- The current landscape
- New Chemotherapy options
- Targeting
  - Her 2 positive disease
  - Triple Negative disease

Key Focus

- **The current landscape**
- **New Chemotherapy options**
- **Targeting**
  - **Her 2 positive disease**
  - **Triple Negative disease**

Evolution of chemotherapy options in MBC

S.Verma, C. Zielenski, and M. Martin

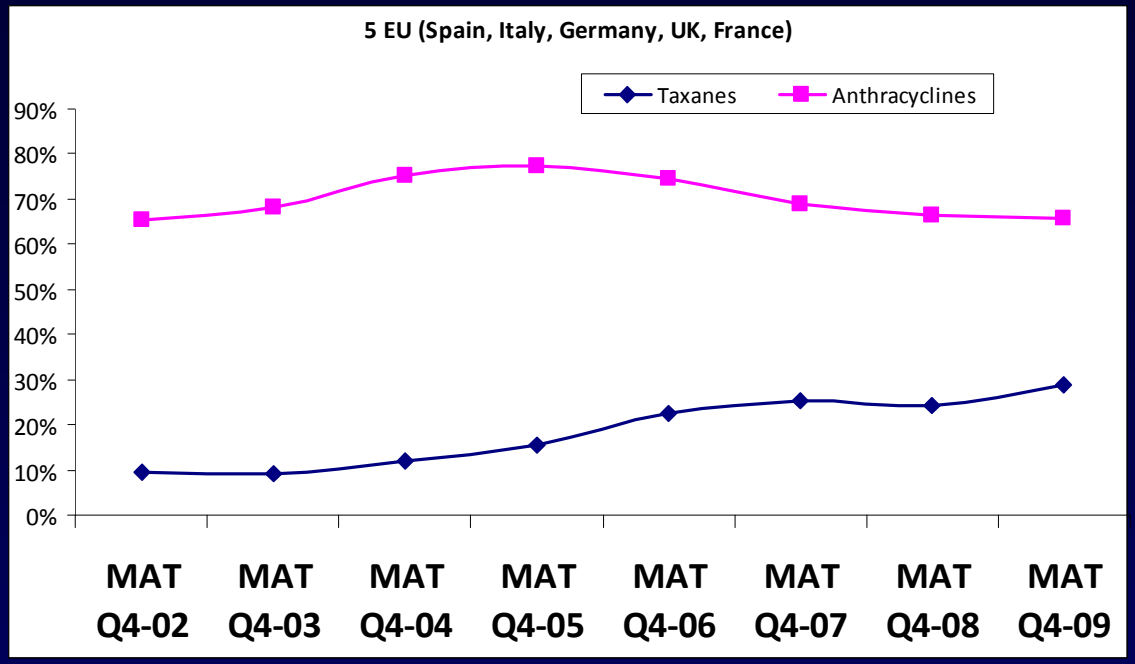
Background

- St. Gallen and NCCN guidelines recommend the use of taxanes, in addition to anthracyclines, in the (neo)adjuvant setting, which may be driving the evolution of treatment options in MBC
- Here we present the results of a review of clinical practice data from France, Germany, Italy, UK and Spain between 2002 and 2009 to determine whether an increase in the use of taxanes in EBC would lead to an increased uptake of other chemotherapies for first-line treatment

Objectives

- To identify trends in the number of patients receiving anthracyclines and taxanes for EBC
- To identify the use of these agents and other chemotherapies (capecitabine, gemcitabine or vinorelbine) for the first-line treatment of MBC

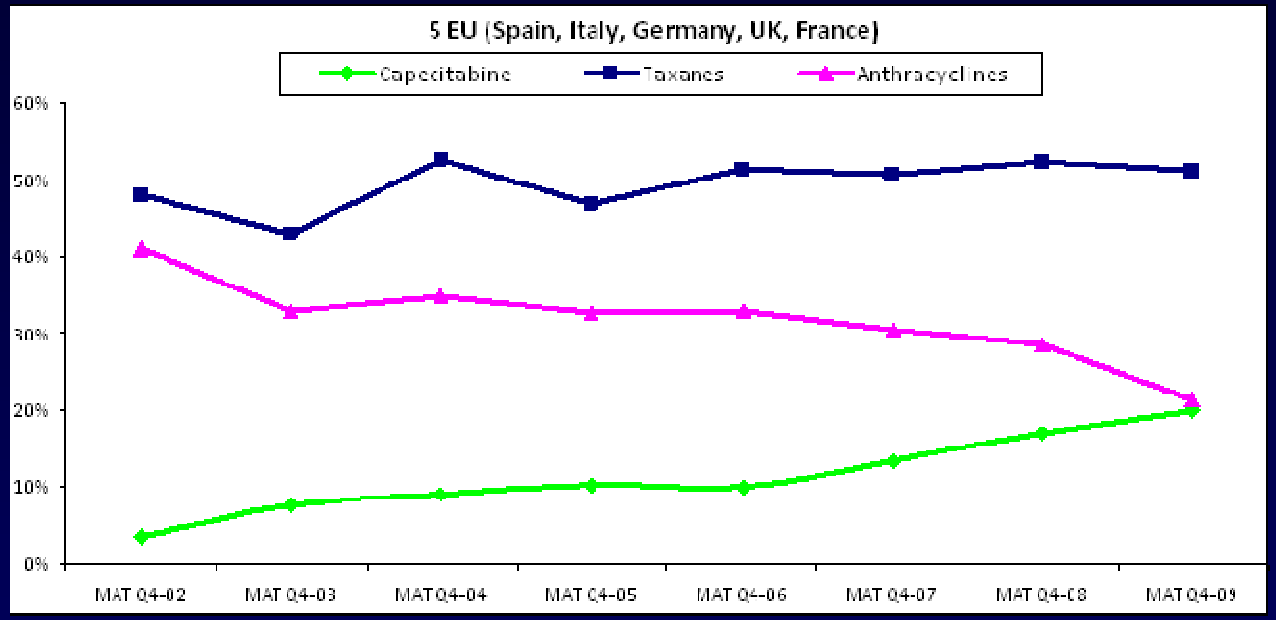
Changes in the number of patients receiving anthracyclines and taxanes as adjuvant and neoadjuvant treatment*



- **Between 2002 and 2009 the proportion of patients receiving anthracyclines as adjuvant or neoadjuvant therapy remained relatively stable at approximately 65%**
- **Over the same period, the proportion of patients receiving taxanes as adjuvant or neoadjuvant therapy increased dramatically from 10% to 29%**

Source: Synovate Healthcare Cancer Therapy Monitor - Europe - Main Monitor
MAT = moving annual total
*Hormonal therapies are excluded

Changes in the number of patients receiving anthracyclines and taxanes for first-line MBC



- The proportion of patients receiving anthracyclines as first-line therapy for MBC declined considerably between 2002 and 2009, from 41% to 21%, respectively
- However, the proportion of patients receiving taxanes in this setting remained stable across the 8-year period at approximately 50%
- The proportion of patients receiving capecitabine for MBC increased substantially from 4% in 2002 to 20% in 2009
  - vinorelbine use decreased from 15% to 10%
  - gemcitabine use remained steadily low at around 3%

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Novel Chemotherapy

- **Title: A Phase III study (EMBRACE) of Eribulin mesylate vs physician treatment choice for MBC (prev tx with A +T)**
- **Faculty C. Twelves**

Background

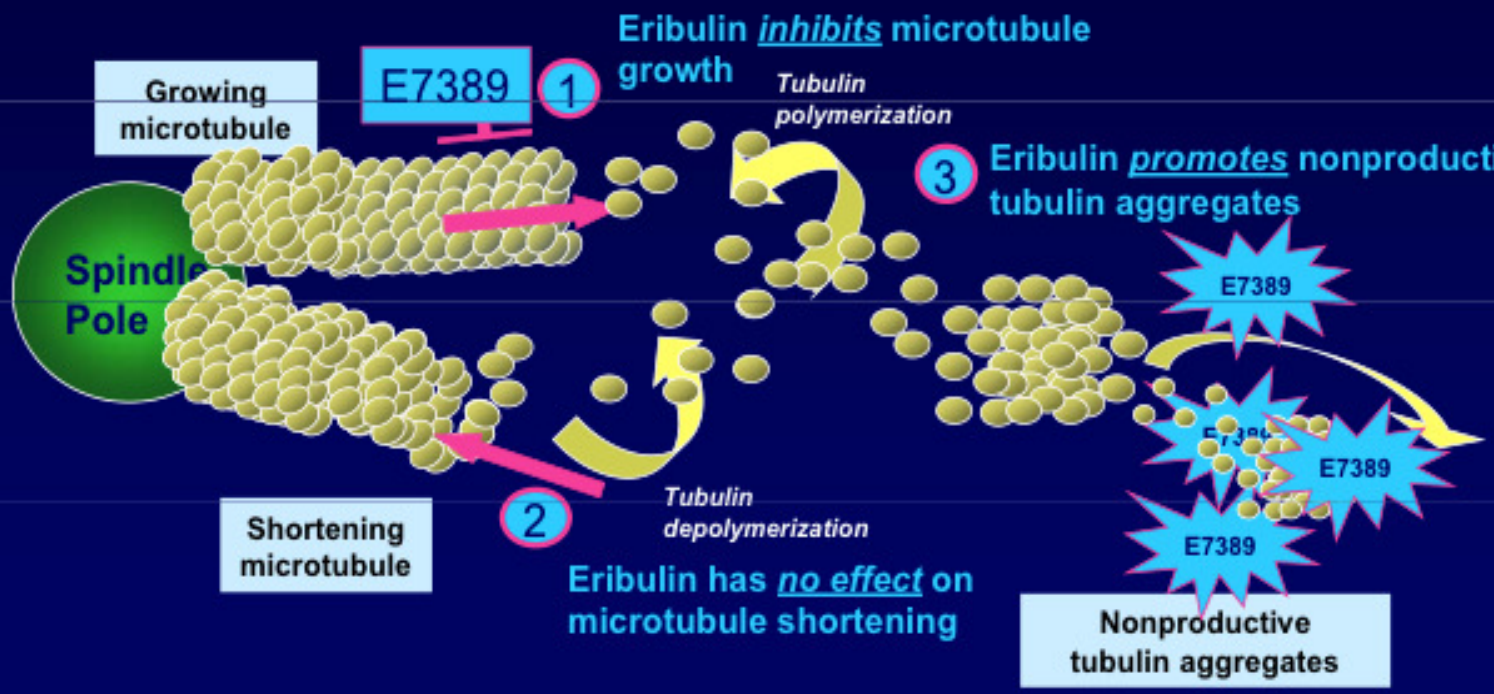
- We have made significant advances in patients with EBC and have integrated many of our effective agents in the adjuvant setting
- We need more effective therapies after a patient with MBC progresses on anthracyclines, taxanes and capecitabine

Eribulin As a Novel Antimicrotubule Cytotoxic Agent

- Eribulin is a synthetic analogue of the marine natural product halichondrin B
- Eribulin is a microtubule dynamics inhibitor with a novel mechanism of action (it suppresses microtubule growth and it sequesters tubulin into nonfunctional aggregates)

Mechanism of Action

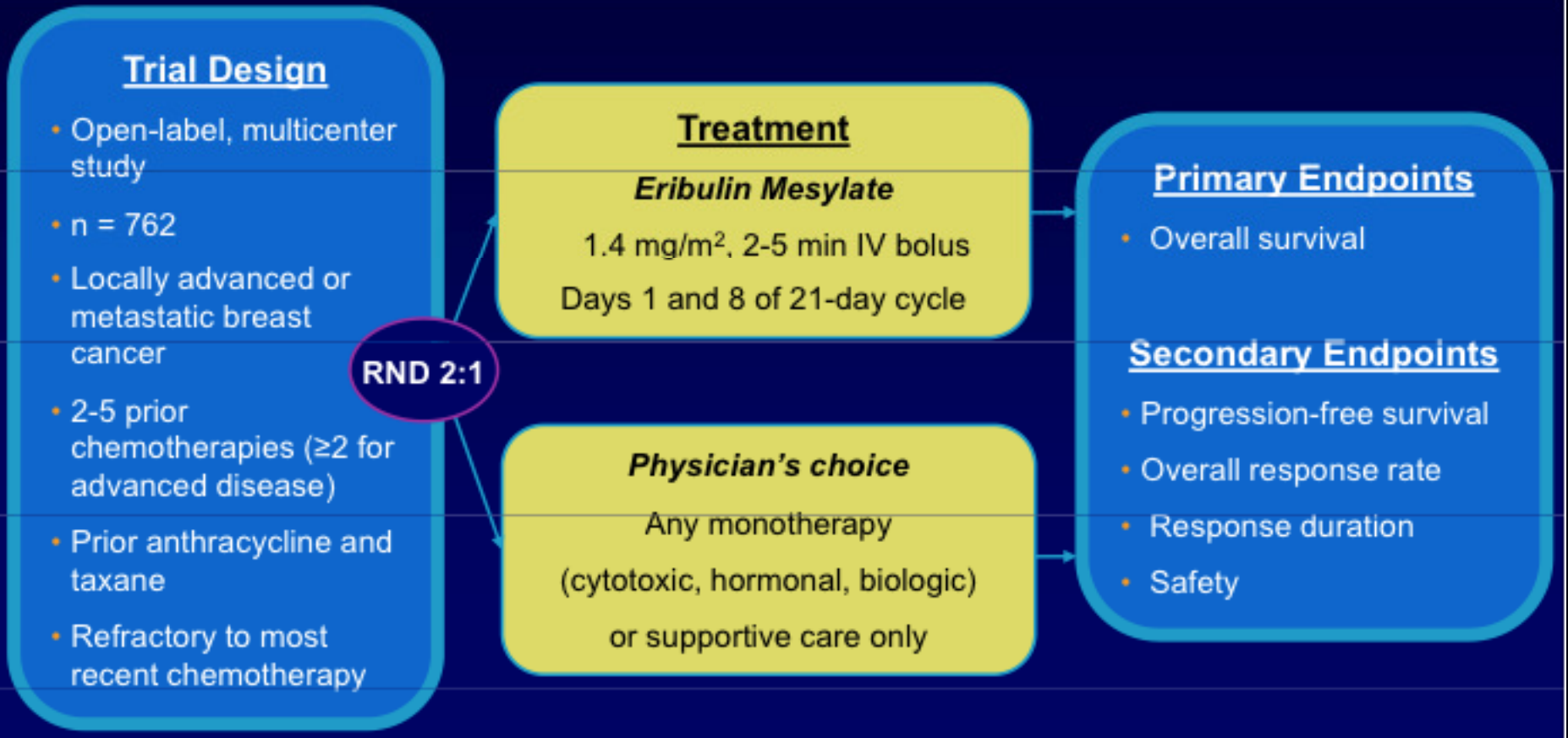
Inhibits microtubule polymerization; inhibits proliferation and promotes apoptosis



Eribulin Mesylate (E7389)
Ongoing Pivotal Clinical Trial Program

305 Study- Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389

(EMBRACE)



Results

N= 762 patients

At least two prior metastatic chemo regimens

75% of patients had prior capecitabine

	Eribulin	Physician choice	
OS	13.1 m	10.6 m	HR 0.81 p=0.04
PFS	3.7 m	2.2.m	HR0.87 p=0.14
RR	12.2%	4.7%	

Toxicity

Main toxicity associated with this agent

– FN 3.0%, Grade ¾ Neuropathy – 8.2%

Main Conclusions

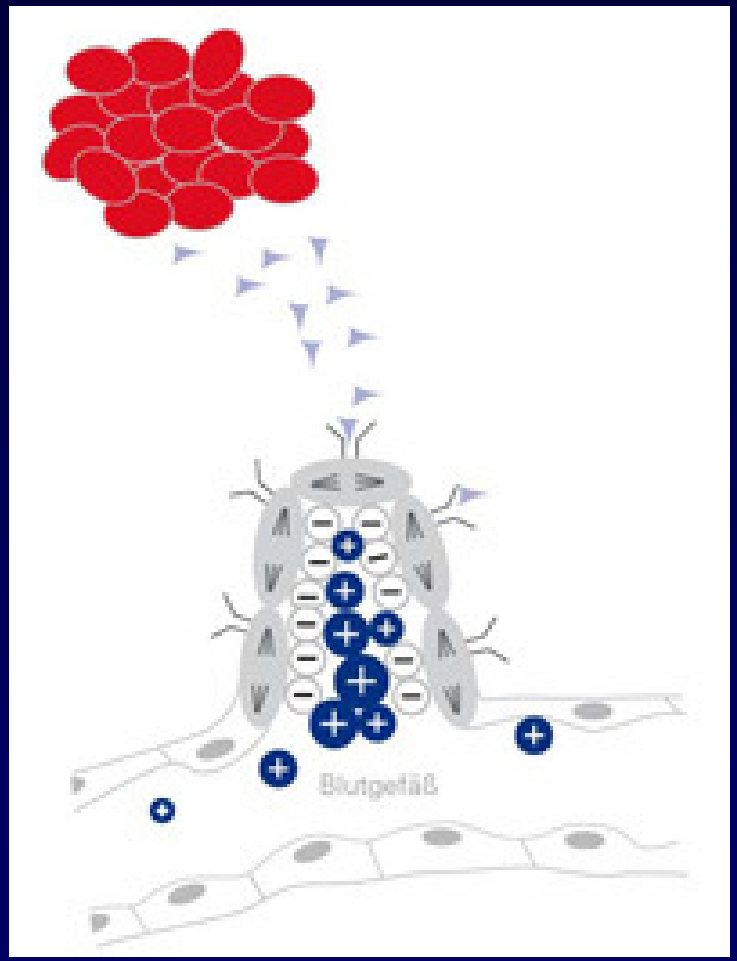
- First Phase III single-agent study in heavily pre-treated MBC to meet its primary endpoint of prolonged overall survival
- ‘Real world” design
  - 25-50% of patients had been given treatment that they had previously
- Statistically and clinically significant results
- New option for women with heavily pre-treated MBC

Perspective and Clinical Impact

- This novel chemotherapy will be a substantial advance for our patients with MBC
- The challenge now will be to have this therapy approved and funded in a timely manner
- We do need to study this drug in earlier lines of therapy and in combination with other targeted agents.
- Are there particular subgroups who are more likely to benefit?
- Do post-progression treatments differ markedly between the two groups?

EndoTAG

- Novel targeted chemotherapy drug
- Impairs tumor microvasculature by targeting newly formed tumor microvasculature
- Embedded paclitaxel



EndoTAG in Advanced Breast Cancer

- Study population: TNBC Advanced Breast Cancer
  - <1 previous chemo
  - N=143 (2:1)
  - Randomized to
    - Wkly Paclitaxel
    - Wkly Pac and EndoTAG
    - EndoTag alone
  - Primary Objective: PFS

Results

	CBR	wk16PFS
Wkly Pac + EndoTag	76%	59%
Wkly Pac	58%	48%
EndoTag alone	58%	34%

Study comments

- This agent appears efficacious
- It may be best to combine this with other active chemotherapeutics or targeted agents
- Justifies further study in taxane-sensitive malignancies

Key Focus

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TDM4374g

A Phase II Study of Trastuzumab-DM1 (T-DM1), a Novel HER2 Antibody–Drug Conjugate, in Patients with HER2+ Metastatic Breast Cancer who Were Previously Treated with an Anthracycline, a Taxane, Capecitabine, Lapatinib, and Trastuzumab

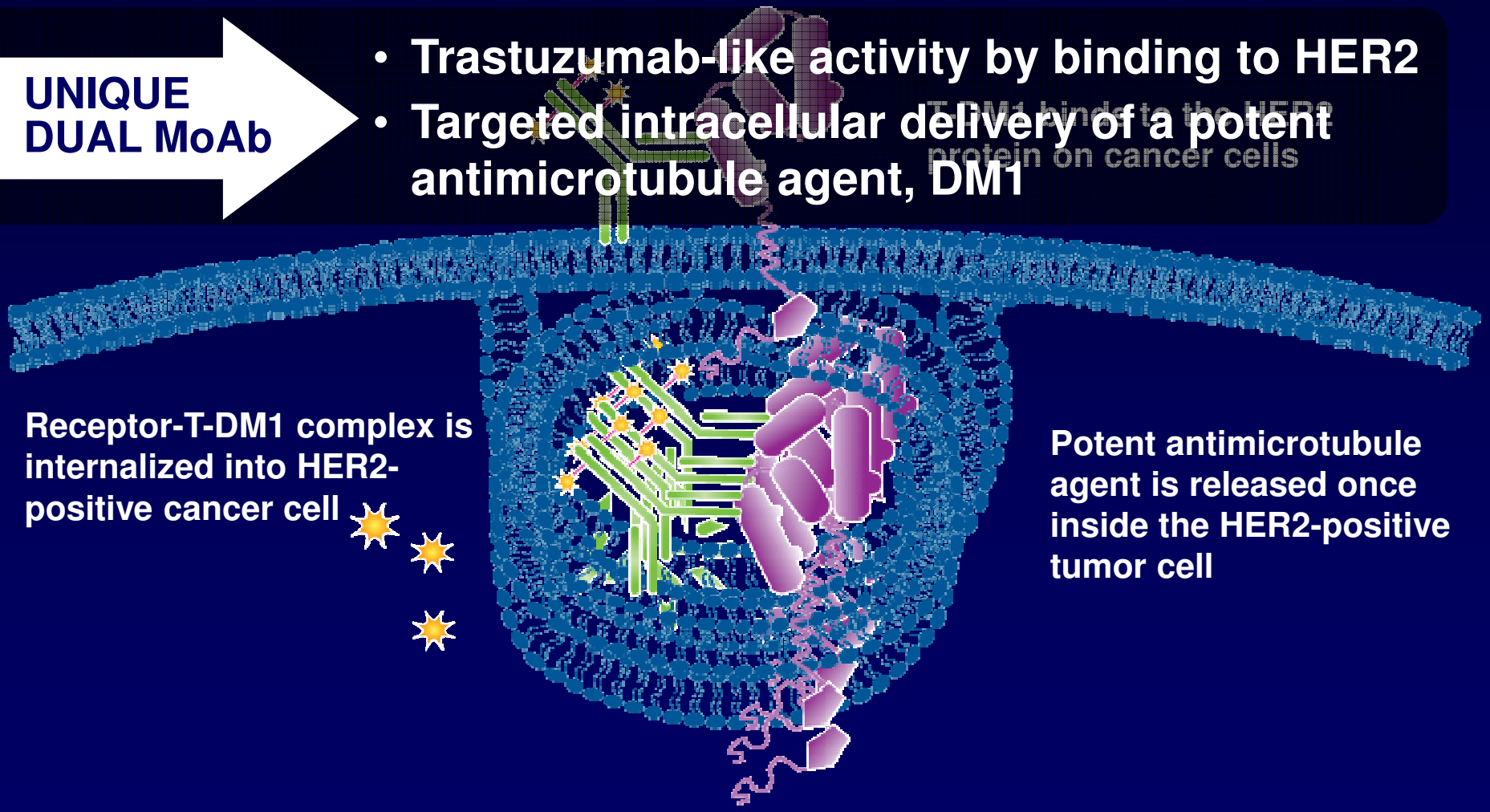
Ian Krop,[1] Patricia LoRusso,[2] Kathy D. Miller,[3] Shanu Modi,[4] Denise Yardley,[5] Gladys Rodriguez,[6] Sam Agresta,[7] Michael Lu,[7] Maoxia Zheng,[7] Lukas Amler,[7] Eric Winer,[1] Hope Rugo[8]

[1]Dana Farber Cancer Institute, Boston, MA; [2]Karmanos Cancer Institute, Detroit, MI; [3]Indiana University Melvin and Bren Simon Cancer Center, Indianapolis, IN; [4]Memorial Sloan-Kettering Cancer Center, New York, NY; [5]Sarah Cannon Research Institute, Nashville, TN; [6]South Texas Oncology/Hematology, San Antonio, TX; [7]Genentech, South San Francisco, California; [8]University of California–San Francisco Comprehensive Cancer Center, San Francisco, CA

T-DM1 Selectively Delivers a Highly Toxic Payload to HER2-Positive Tumor Cells

UNIQUE DUAL MoAb

- Trastuzumab-like activity by binding to HER2
- Targeted intracellular delivery of a potent antimicrotubule agent, DM1



Receptor-T-DM1 complex is internalized into HER2-positive cancer cell

Potent antimicrotubule agent is released once inside the HER2-positive tumor cell

Baselga J, et al. *Nat Rev Cancer.* 2009;9:463-475.

Study Design

- Multi-institutional, open-label, single-arm Phase II trial (N=100)
- HER2+ MBC pts:
  - Prior exposure to an anthracycline, a taxane, capecitabine, lapatinib and trastuzumab
  - Two HER2-directed regimens in the metastatic setting
  - Progressive disease on last regimen received
- T-DM1 at 3.6 mg/kg IV Q3W
- Primary endpoint: ORR assessed by IRF
- Secondary endpoints:
  - ORR by investigator assessment
  - Progression-free survival (PFS)
  - Duration of Response (DoR)
  - Clinical Benefit Rate (CBR)
- Follow-up: 30 days post last dose unless SAE (90 days)

Prior Chemotherapy and Anti-HER2 Therapy

Median number of agents for metastatic disease (range)*	7.0 (3–17)
Median number of agents in all therapy setting (range)*	8.5 (5–19)
Number of patients who received all 5 prior agents, n (%)**	109 (99.1)
Prior trastuzumab Median duration of prior trastuzumab in metastatic setting, months (range)	19.7 (1.8–115.8)
Prior lapatinib Median duration of prior lapatinib in metastatic setting, months (range)	6.8 (0.2–23.3)

* Includes all non-hormonal agents intended for the treatment of metastatic breast cancer

* * One patient did not receive a taxane.

AEs that Occurred in >10% Patients

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	All Grades
AEs (%)						
Fatigue	30.0	27.3	4.5	0	0	61.8
Nausea	26.4	10.0	0.9	0	0	37.3
Thrombocytopenia	11.8	13.6	5.5	1.8	0	32.7
AST Increased	11.8	11.8	2.7	0	0	26.4
Constipation	20.0	2.7	0.9	0	0	23.6
Pyrexia	13.6	8.2	0.9	0	0	22.7
Epistaxis	19.1	2.7	0.9	0	0	22.7
Headache	18.2	3.6	0	0	0	21.8
Hypokalemia	19.1	0.9	0.9	0	0	20.9
Decreased appetite	12.7	7.3	0.9	0	0	20.9
Dry mouth	17.3	2.7	0	0	0	20.0
Anemia	7.3	10.9	1.8	0	0	20.0

Antitumor Activity in Treated Patients

Tumor Response	IRF (N=110)	Investigator (N=110)
Objective Response Rate, %	34.5	32.7
(95% CI)	(26.1–43.9)	(24.1–42.1)
CR	0	4.5
PR	34.5	28.2
SD*	44.5	50.9
PD	18.2	14.5
UE	1.8	0.9
Missing	0.9	0.9
Clinical Benefit Rate, %	48.2	46.4
(95% CI)	(38.8–57.9)	(37.1–56.1)

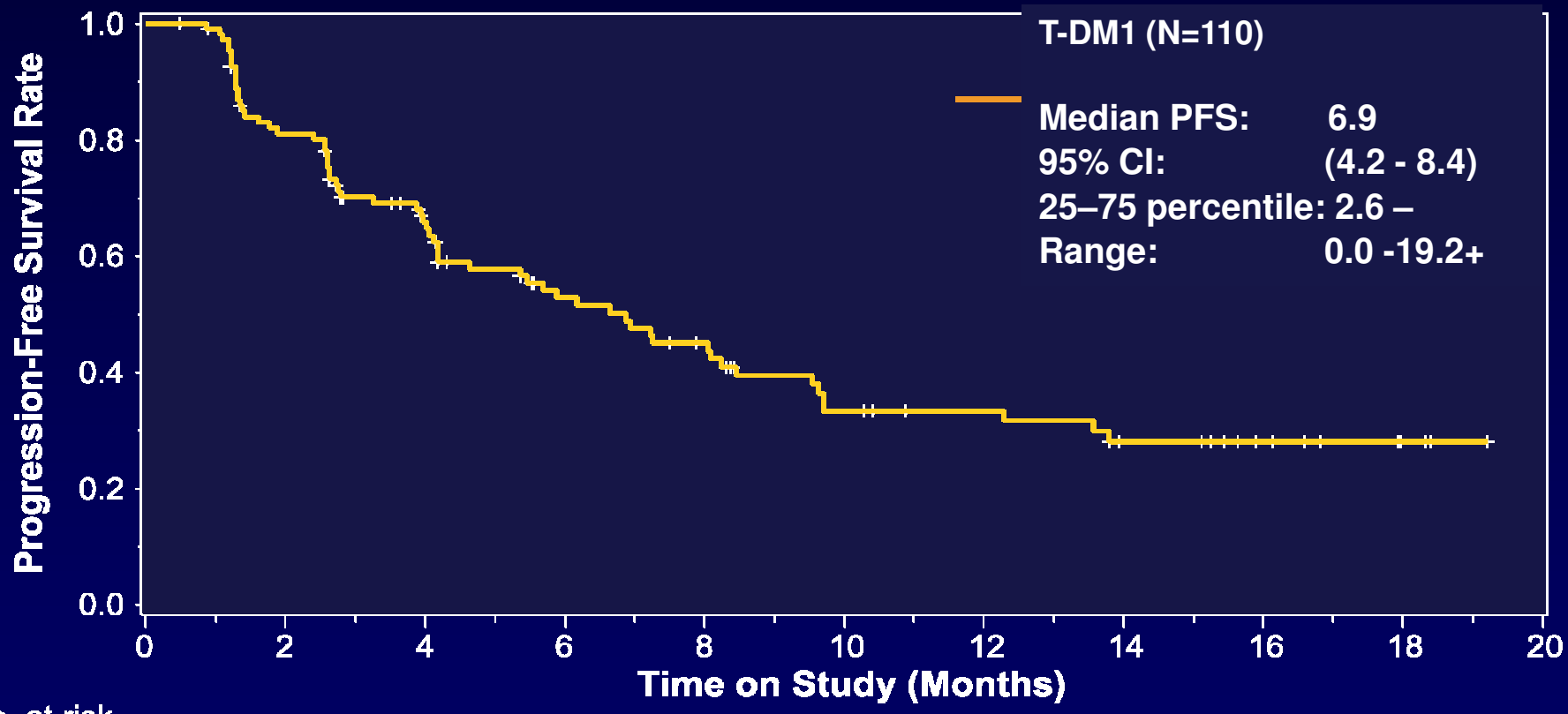
IRF - Independent Review Facility
Objective Response - CR or PR determined by two consecutive tumor assessments at least 28 days apart.
Clinical Benefit - objective response or SD maintained for at least 6 months.
*Including unconfirmed PRs.

Antitumor Activity in Treated Patients by Retrospectively Confirmed HER2 Status

	IRF	INV
Patients centrally confirmed as HER2 +	n=80	n=80
ORR, %	41.3	40.0
Clinical benefit rate, %	55.0	53.8
Patients with unconfirmed HER2 status	n=15	n=14
ORR, %	20.0	13.3
Clinical benefit rate, %	26.7	20.0

IRF - Independent Review Facility
Objective Response = CR or PR determined by two consecutive tumor assessments at least 28 days apart.
Clinical Benefit = objective response or SD maintained for at least 6 months.

K-M Plot of Progression-Free Survival Treated Patients, IRF Assessment



No. at risk

T-DM1	109	83	59	41	33	22	19	14	8	3	0

N	110
Number progressed	63 (57.3%)
Number censored	47 (42.7%)

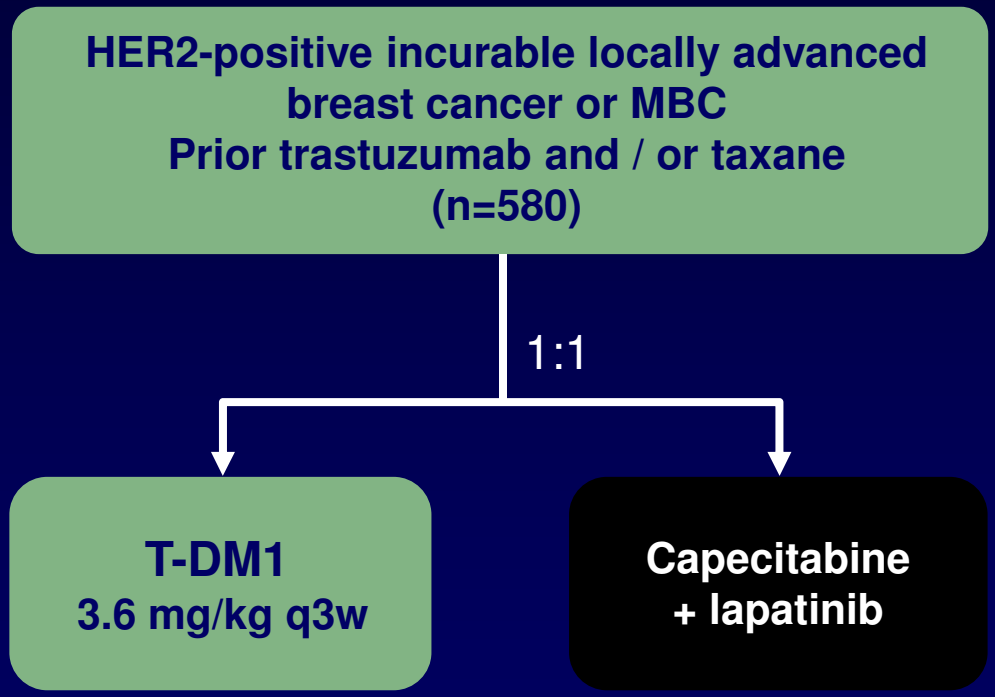
EMILIA: ongoing Phase III study of T-DM1 vs capecitabine + lapatinib in the 2nd-line setting

Primary end points

- PFS (independent assessment)
- Safety

Secondary end points

- OS
- PFS (investigator assessment)
- ORR
- CBR
- DoR
- Quality of life
- TTF



www.clinicaltrials.gov

TDM4450g

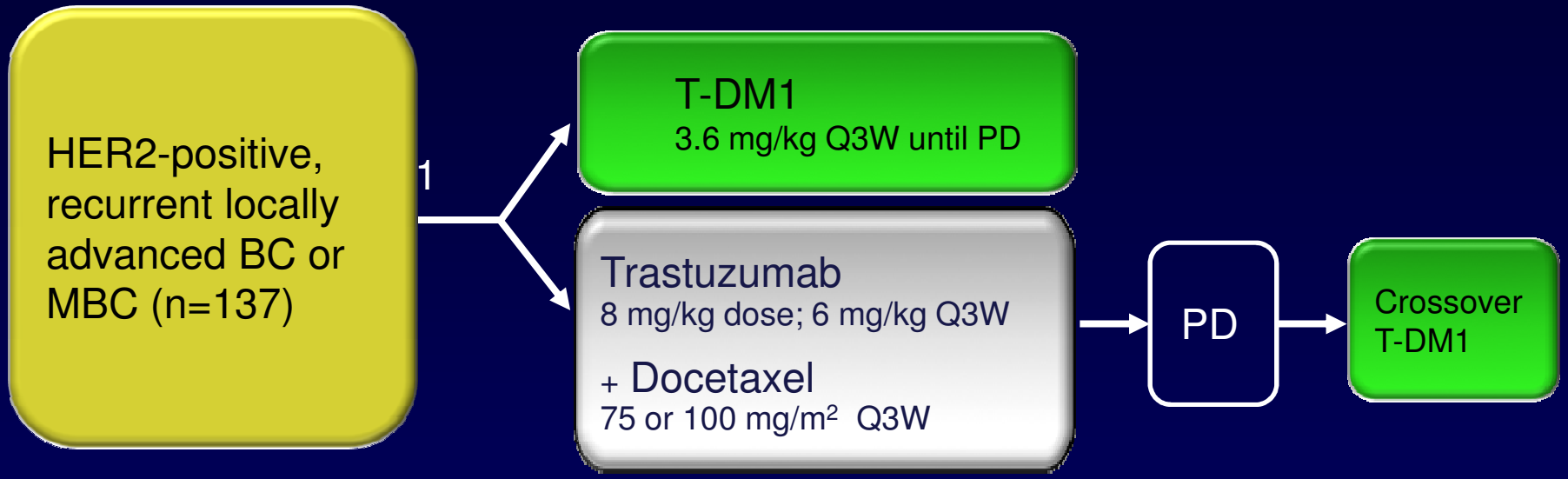
Efficacy and Safety of Trastuzumab-DM1 Versus Trastuzumab plus Docetaxel in HER2-Positive Metastatic Breast Cancer Patients with No Prior Chemotherapy for Metastatic Disease: Preliminary Results of a Randomized, Multicenter, Open-Label Phase 2 Study

EA Perez,[1] L Dirix,[2] J Kocsis,[3] L Gianni,[4] J Lu,[5] J Vinholes,[6] V Ng,[7] C Linehan,[7] S Agresta,[7] S Hurvitz[8]

[1]Mayo Clinic, Jacksonville, FL, USA; [2]Sint-Augustinus Hospital, Antwerp, Belgium; [3]Semmelweis University Hospital, Budapest, Hungary; [4]Istituto Nazionale dei Tumori, Milan, Italy; [5]Division of Hematology and Oncology, State University of New York at Stony Brook, Stony Brook, NY, USA; [6]Clinica de Oncologia de Porto Alegre, Brasil; [7]Genentech, Inc., South San Francisco, CA, USA; [8]UCLA Translational Oncology Research International, Los Angeles, CA, USA

Perez EA, et al. Abstr LBA3. ESMO 2010

Study Design



- **Randomized, phase II, international, open-label study**
- **HER2-positive, measurable disease required**
- **Stratification factors**
  - **World region, prior adjuvant trastuzumab therapy, disease-free interval**
- **Primary endpoints: PFS by INV, safety**
- **Key Secondary endpoints: ORR, clinical benefit, OS, QOL, symptom control**

Perez EA, et al. Abstr LBA3. ESMO 2010

Prior Trastuzumab and Taxane Therapy Randomized Patients

	T-DM1 (n=67)	Trastuzumab + Docetaxel (n=70)
Prior Trastuzumab Treatment, n (%)		
Yes	13 (19.4)	18 (25.7)
No	54 (80.6)	52 (74.3)
Prior Taxane Treatment, n (%)		
Yes	22 (32.8)	28 (40.0)
No	45 (67.2)	42 (60.0)
Prior Trastuzumab and/or Taxane Treatment, n (%)		
Yes	24 (35.8)	31 (44.3)
No	43 (64.2)	39 (55.7)

Perez EA, et al. Abstr LBA3. ESMO 2010

Objective Response by Investigator (ITT)

Randomized Patients

	T-DM1 (n=67)	Trastuzumab + Docetaxel (n=70)
Patients with an Objective Response,* n (%)	**32 (47.8)**	**29 (41.4)**
95% CI	(35.4, 60.3)	(30.2, 53.8)
Patients with Clinical Benefit,† n (%)	**37 (55.2)**	**40 (57.1)**
95% CI	(43.1, 67.2)	(44.8, 68.9)
Objective Responses, n (%)		
Complete Response	3 (4.5)	1 (1.4)
Partial Response	29 (43.3)	28 (40.0)
Stable Disease‡	22 (32.8)	29 (41.4)
Progressive Disease	8 (11.9)	4 (5.7)
Unable to Evaluate	4 (6.0)	4 (5.7)

* Objective response = complete or partial response based on RECIST 1.0 determined on two consecutive tumor assessments at least 4 weeks apart

† Clinical benefit = objective response or maintained stable disease for at least 6 months from start of study treatment

‡ Stable disease includes 11 patients with unconfirmed partial response (5 in T-DM1 arm and 6 in the trastuzumab + docetaxel arm)

Perez EA, et al. Abstr LBA3. ESMO 2010

AE Summary

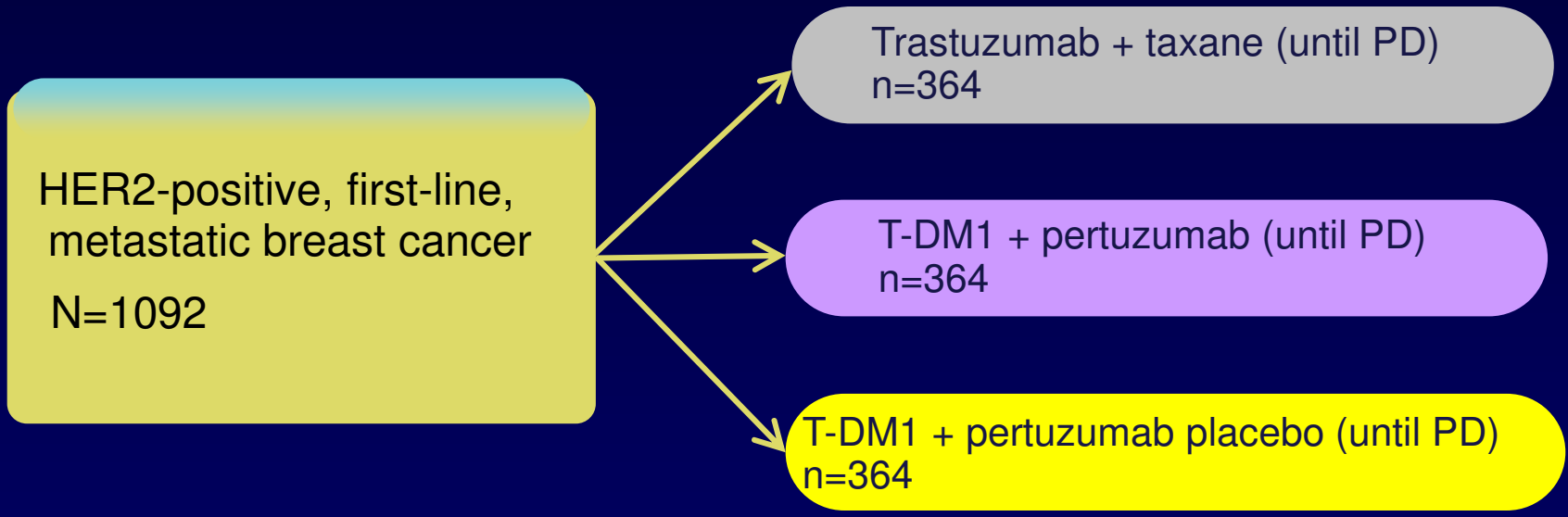
Safety Evaluable Patients

	T-DM1 (n=67)	Trastuzumab+Docetaxel (n=68)
Any AE, n (%)	63 (94.0)	68 (100.0)
Grade ≥3 AE	**25 (37.3)**	**51 (75.0)**
Serious AE*	13 (19.4)	15 (22.1)
Three most common AEs (any grade) in T-DM1 arm		
Nausea	32 (47.8)	27 (39.7)
Fatigue	31 (46.3)	29 (46.2)
Pyrexia	24 (35.8)	14 (20.6)
Three most common AEs (any grade) in trastuzumab + docetaxel arm		
Alopecia	1 (1.5)	45 (66.2)
Neutropenia	5 (7.5)	39 (57.4)
Diarrhea	7 (10.4)	31 (45.6)

* AEs that result in death, are life-threatening, require inpatient hospitalization or prolongation of existing hospitalization, result in persistent or significant disability/incapacity, or are congenital anomalies/birth defects

Perez EA, et al. Abstr LBA3. ESMO 2010

1st Line mBC Phase III MARIANNE Study: BO22589/TDM4788g



- Primary endpoints: PFS as assessed by IRF; Safety
- Secondary endpoints: OS; PFS by investigator; patient reported outcomes analysis; biomarkers

Perez EA, et al. Abstr LBA3. ESMO 2010

Her 2 directed therapy

- There is clear evidence that we need to continue to block Her2 pathway
- There is a strong need for us to encourage provincial bodies to fund these active therapies
- There is a need for chemotherapy with an Anti-Her2 approach and T-DM1 may provide with this combination with minimal toxicity

Key Focus

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  - Triple Negative disease

Biologic agents

Bevacizumab for TNBC

Trial / Arm	Median PFS (mo) in TNBC Subset
E2100	
Paclitaxel (n=110)	5.3
Paclitaxel + bevacizumab (n=122)	10.6
AVADO	
Docetaxel + placebo (n=52)	5.4
Docetaxel + bevacizumab 15 mg/kg (n=58)	8.2
RIBBON-1	
Taxane/anthracycline + placebo (n=46)	6.2
Taxane/anthracycline + bevacizumab (n=96)	6.5
Capecitabine + placebo (n=50)	4.2
Capecitabine + bevacizumab (n=87)	6.1
ATHENA	
Taxane-based regimen + bevacizumab (n=577)	7.2*

*Median PFS vs non-TNBC subgroup.

No survival data in TNBC

#279PD

Meta-analysis of patients previously treated with taxanes from three randomised trials of bevacizumab and first-line chemotherapy as treatment for metastatic breast cancer

DW Miles[1], G. Romieu[2], V. Dieras[3], D. Chen[4], A.-A. Duenne[5], J. O'Shaughnessy[6]

[1]London, UK, [2]Montpellier, France, [3]Paris, France, [4]South San Francisco, CA, USA, [5]Basel, Switzerland, [6]Dallas, TX, USA

Figure 1. Kaplan–Meier estimate of PFS (ITT population)

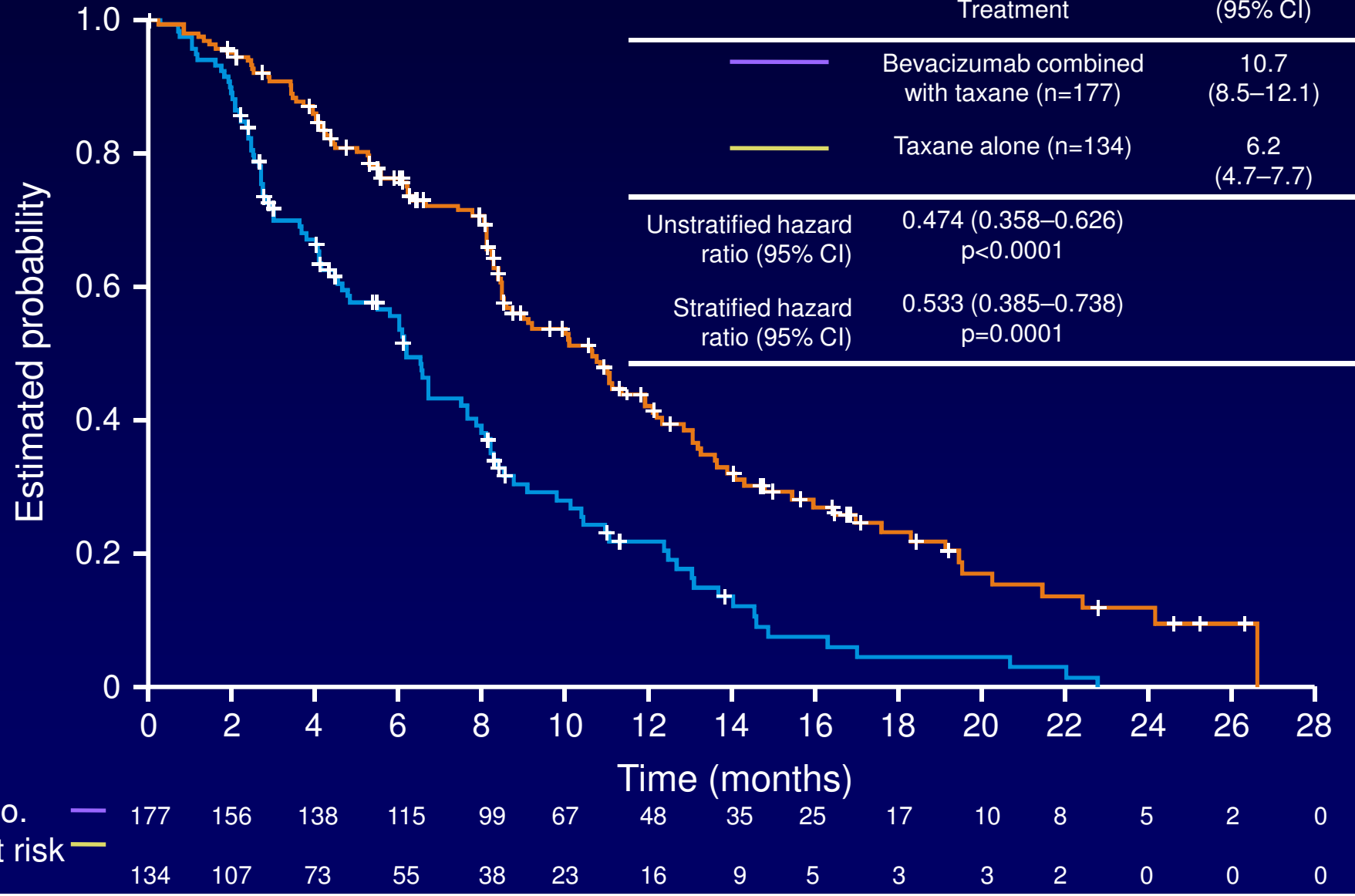


Figure 4. Kaplan–Meier estimate of OS (ITT population)

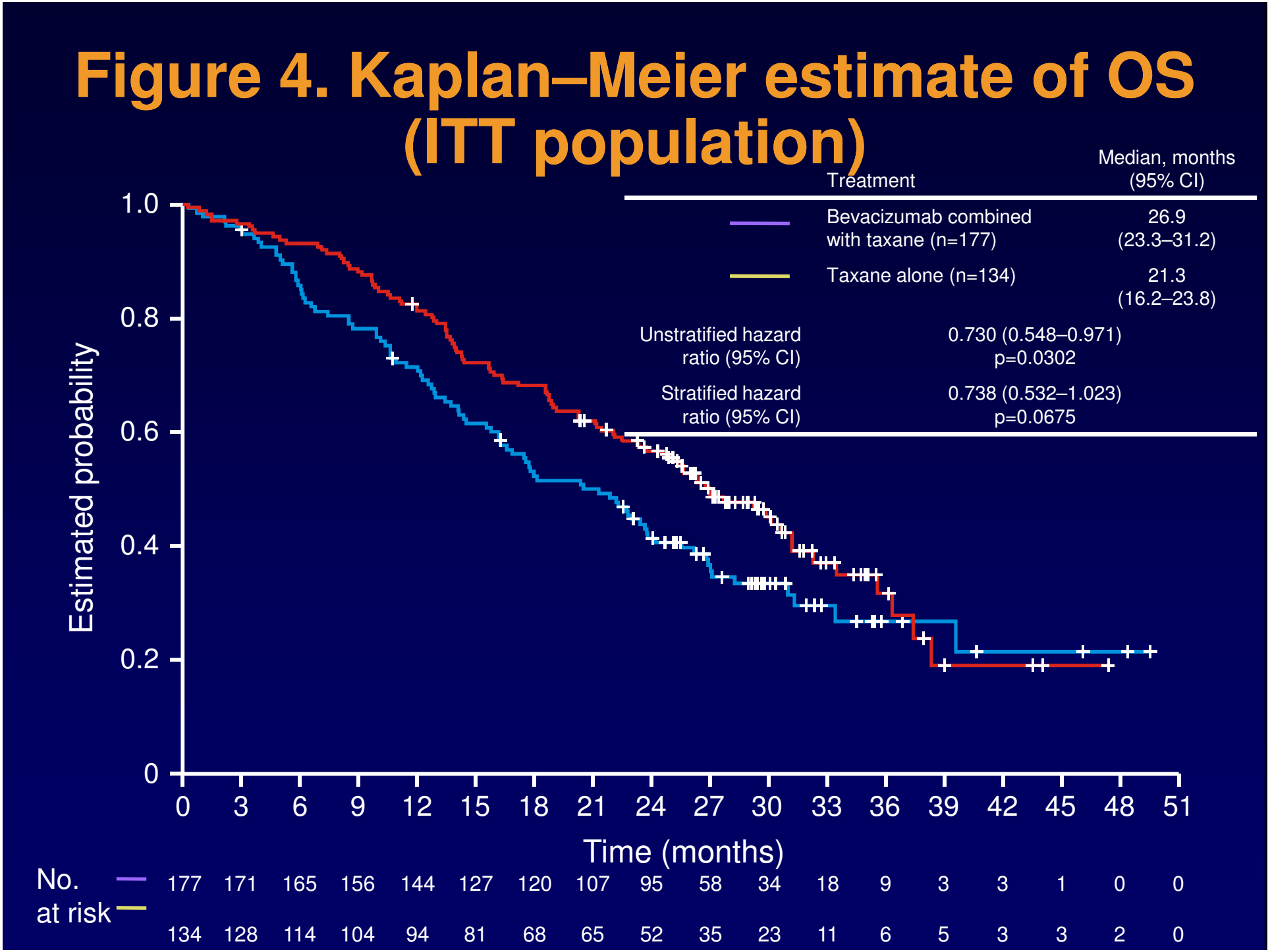
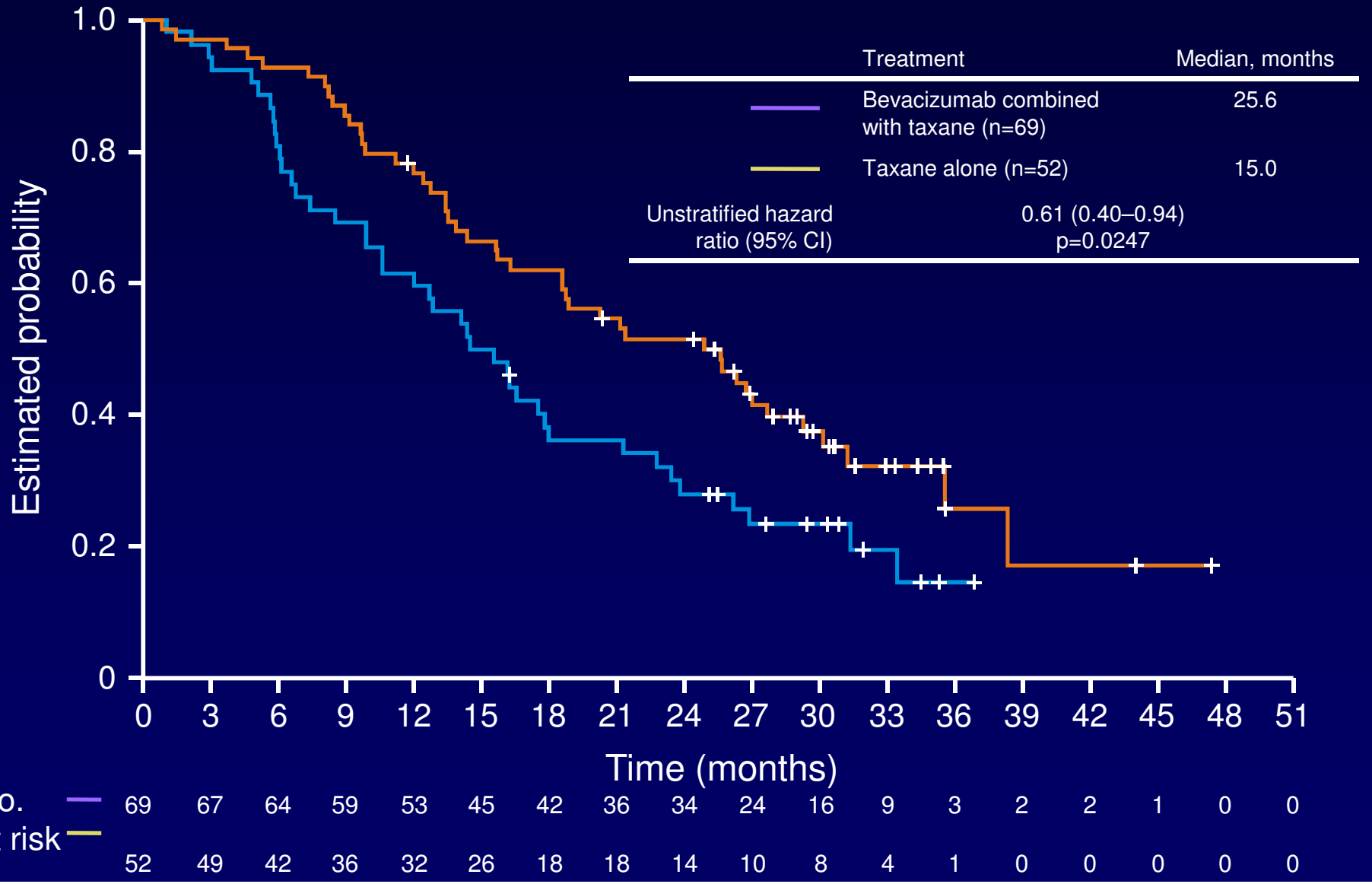


Figure 6. Kaplan–Meier estimate of OS (hormone receptor-negative population)



Biologic agents

EGFR Inhibition for TNBC

Efficacy data from phase II trials

	TBCRC 001 (n=102)		O'Shaugnessy et al (n=78)	
	Cetuximab	Carboplatin + Cetuximab	Irinotecan + Carboplatin	Irinotecan + Carboplatin + Cetuximab
ORR,%	6	18	49	30
Clinical benefit, %	10	27	NR	NR
PFS, mo	2		5.1	4.7

NR=not reported; PFS=progression-free survival; RR=response rate; TBCRC=Translational Breast Cancer Research Consortium

- TNBC strongly associated with EGFR expression
- EGFR inhibitors combined with platinum
- Current data conflicting

Carey et al. ASCO 2008; abstr 1009;
O'Shaughnessy et al. SABCS 2007; abstr 308.

EGFR Inhibitors in Triple Negative Results of Randomized Phase II Study (BALI-1)

- **Study Design**
  - **<1 prior MBC**
  - **Measurable disease**
  - **Randomized Phase II – 2:1 Radomization**
    - **Cisplatin q 3wks**
    - **Cisplatin + Cetuximab**
  - **PRIMARY ENDPOINT: RR**
  - **Cross over allowed**
  - **73% received treatment in the first line setting and 27% in the second line setting**

EGFR Inhibitors in Triple Negative Results of Randomized Phase II Study (BALI-1)

Results (n=181)

	RR	PFS
Cisplatin alone	10%	1.5 m
Cis + Cetuximab	20%	3.7 m

HR 0.67 (p=0.03)

Final Efficacy and Safety Results of a Randomized Phase II Study of the PARP Inhibitor Iniparib (BSI-201) in Combination with Gemcitabine/Carboplatin (G/C) in Metastatic Triple Negative Breast Cancer (TNBC)

J O'Shaughnessy,[1,2,3] C Osborne,[1,2,3] J Pippen,[1,2,3] M Yoffe,[3,4] D Patt,[2,3,5] G Monaghan,[3,6] C Rocha,[7] BM Sherman,[7] C Bradley[7]

[1]Baylor Sammons Cancer Center, [2]Texas Oncology, Dallas, TX; [3]US Oncology, Dallas, TX; [4]Cancer Centers of North Carolina, Raleigh, North Carolina; [5]Texas Oncology Cancer Center, Austin, Texas; [6]Kansas City Cancer Center, Kansas City, Missouri; [7]BiPar Sciences, Inc., South San Francisco, CA

Study Design Multi-center, open-label, randomized

- Metastatic TNBC (ie, hormone receptor and HER2 negative) with measurable disease
- 0-2 prior chemotherapy regimens for metastatic disease
- No prior treatment with gemcitabine, carboplatin, cisplatin, PARP inhibitor
- Stable brain metastases allowed
- ECOG PS 0–1

Randomization (1:1)

Gemcitabine (1000 mg/m^2, IV, d 1, 8) Carboplatin (AUC 2, IV, d 1, 8)* Every 3 weeks	Iniparib (5.6 mg/kg, IV, d 1, 4, 8, 11) Gemcitabine (1000 mg/m^2, IV, d 1, 8) Carboplatin (AUC 2, IV, d 1, 8) Every 3 weeks
N=62	N=61

RESTAGING
Every 2 Cycles

* Patients randomized to gem/carbo alone could crossover to receive gem/carbo + Iniparib (BSI-201) at disease progression

NCT00540358

Patient and Disease Characteristics

	Gem-Carbo N=62	Iniparib + Gem-Carbo N=61
Age, years, mean (range)	54 (26-80)	55 (34-76)
ECOG PS 0 / 1	68% / 32%	69% / 30%
Median no. of metastatic sites	3	3
Metastatic sites, no. (%)		
Bone	23 (37%)	20 (33%)
Lymph nodes	39 (63%)	40 (66%)
Lung	32 (52%)	38 (62%)
Liver	28 (45%)	24 (39%)
Brain	6 (10%)	2 (3%)

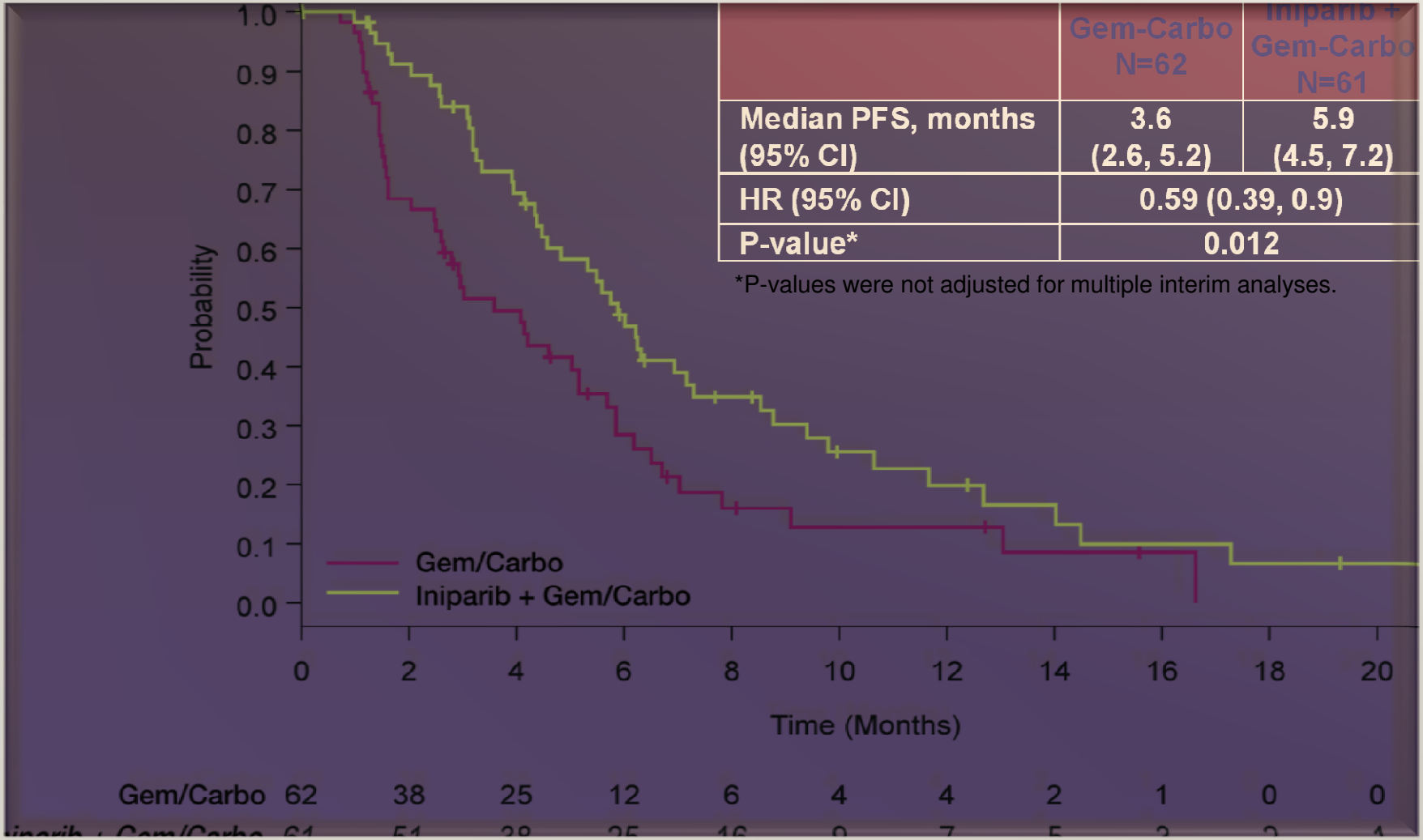
Response and Clinical Benefit (ITT Population)

	Gem-Carbo N = 62	Iniparib + Gem-Carbo N=61	P-value*
Overall response rate	**20 (32.3%)**	**32 (52.5%)**	**0.023**
Complete response	1 (1.6%)	2 (3.3%)	
Partial response	19 (30.6%)	30 (49.2%)	
Stable disease	13 (21.0%)	11 (18.0%)	
Progressive disease	18 (29.0%)	10 (16.4%)	
Not evaluable†	11 (17.7%)	8 (13.1%)	
SD ≥ 6 months	1 (1.6%)	2 (3.3%)	
Clinical benefit rate (CBR)	**21 (33.9%)**	**34 (55.7%)**	**0.015**

*P-values were not adjusted for multiple interim analyses.
†Evaluable patients were those who completed at least one cycle of treatment and had both baseline and post-treatment assessment of tumor size.

- 30 of the 62 patients (48%) in the gem-carbo arm crossed over to receive iniparib + gem-carbo

Progression-Free Survival: (ITT Population)

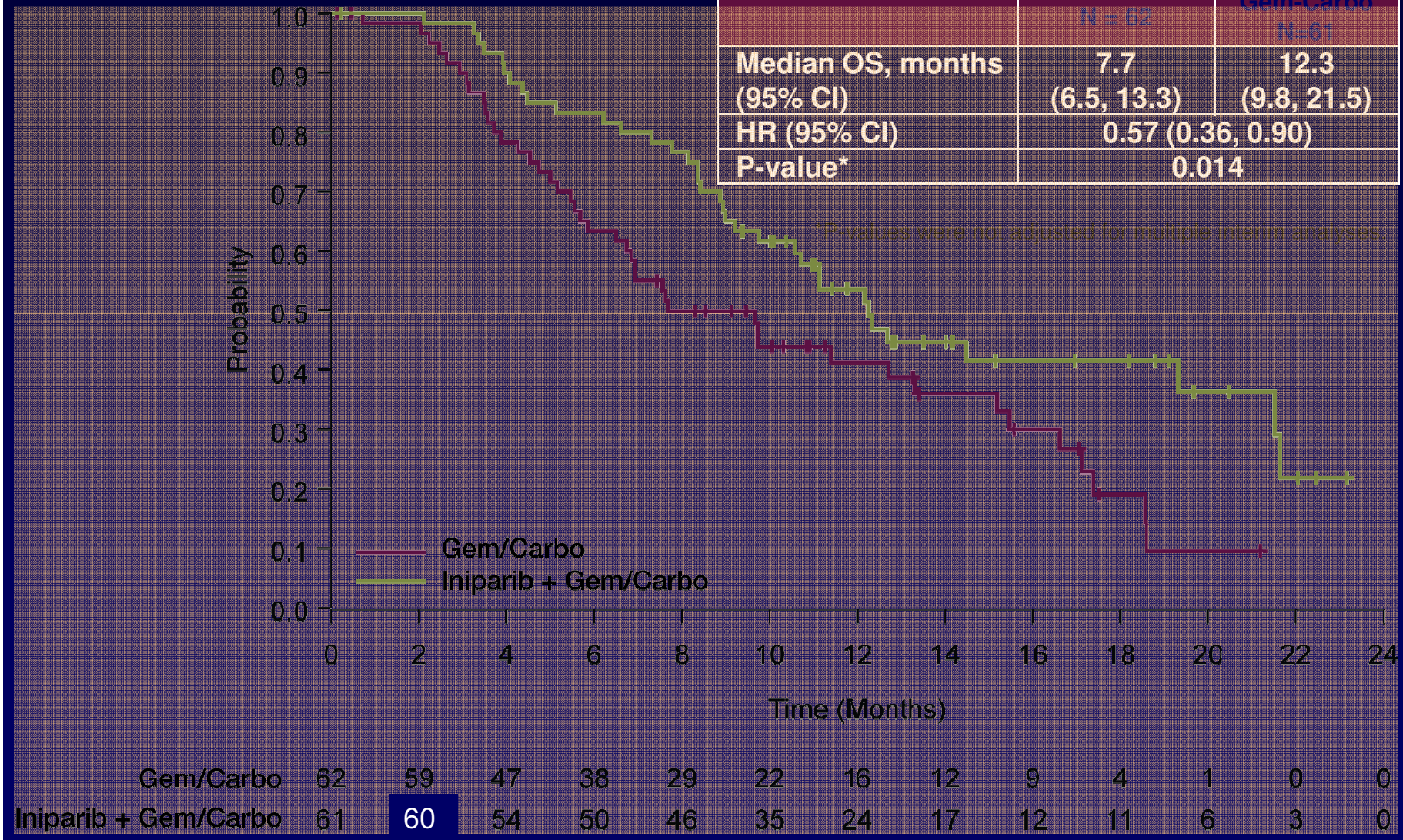


	Gem-Carbo N=62	Iniparib + Gem-Carbo N=61
Median PFS, months (95% CI)	3.6 (2.6, 5.2)	5.9 (4.5, 7.2)
HR (95% CI)	0.59 (0.39, 0.9)	
P-value*	0.012	

*P-values were not adjusted for multiple interim analyses.

Overall Survival (ITT Population)

	Gem-Carbo N = 62	Iniparib + Gem-Carbo N=61
Median OS, months (95% CI)	7.7 (6.5, 13.3)	12.3 (9.8, 21.5)
HR (95% CI)	0.57 (0.36, 0.90)	
P-value*	0.014	



Outcome in Crossover Patients

	No. of Patients, %
Crossover from gem-carbo to iniparib	30
Median number cycles of iniparib (range)	1.5 (1-8)
Discontinued treatment after 1 or 2 cycles	25 (83)
ORR	
Partial response (unconfirmed)	1 (3)
Stable disease	4 (13)
Progressive disease	18 (60)
Not evaluable	7 (23)

Some unanswered questions?

- Do PARP-Inhibitors need DNA damaging stimulus?
  - Single agents vs. in combination with chemo
- Will they be effective in a broader subgroup of patients?
  - Non-TN
  - ? Lung
- What are the long-term toxicities associated with these agents?
  - ? Increase risk of tumorogenesis
- Oral vs. IV

Summary
Triple Negative – Advanced Stage

- Triple Negative MBC is associated with a average survival of around 9 months
- We still need to consider our ‘classic’ chemotherapy drugs
  - Re-challenge with taxanes
  - Capecitabine
- There is emerging evidence of biologics
  - Bevacizumab
  - EGFR - Inhibitors
  - PARP Inhibitors
- Platinums as single agents or in combination should be considred

Conclusion

- There is a number of new emerging therapies for our patients with advanced breast cancer
- The challenge will be on how best to identify biological markers to determine who will benefit the most from these treatments
- It is imperative that we design innovative clinical trials and encourage patient participation

Hold the Date

Discussion