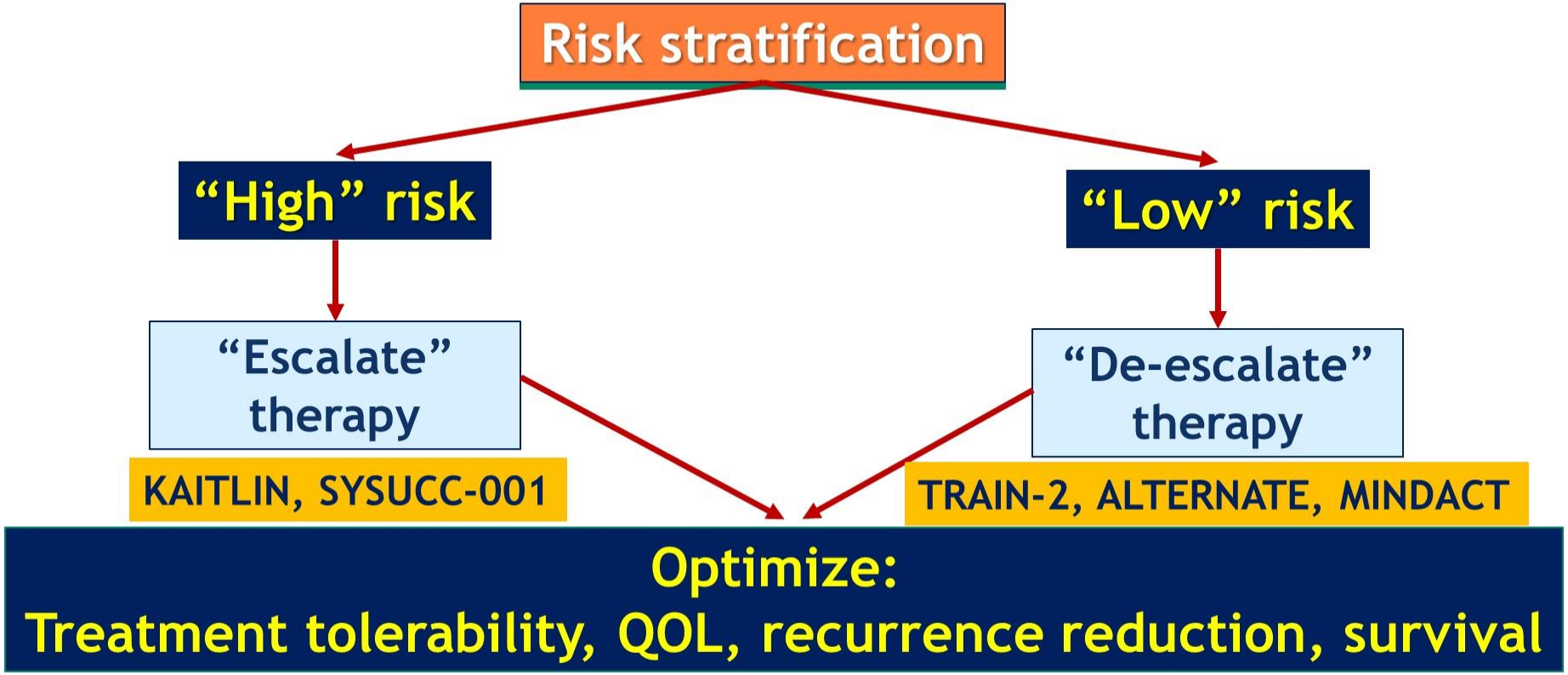
Novinky z letošního nejvýznamnějšího setkání onkologů

Shrnutí ze sekce časného karcinomu prsu

Katarína Petráková

Klinika komplexní onkologické péče MOÚ, Brno

Goal: Therapy Optimization



Primary Analysis of KAITLIN: A Phase 3 Study of Trastuzumab Emtansine (T-DM1) + Pertuzumab Versus Trastuzumab + Pertuzumab + Taxane, after Anthracyclines as Adjuvant Therapy for High-Risk HER2-Positive Early Breast Cancer

Nadia Harbeck[1]; Seock-Ah Im[2]; Carlos Barrios[3]; Hervé Bonnefoi[4]; Julie Gralow[5]; Masakazu Toi[6]; Paul A. Ellis[7]; Luca Gianni[8]; Sandra M. Swain[9]; Young-Hyuck Im[10]; Michelino De Laurentiis[11]; Zbigniew Nowecki[12]; Jigna Shah[13]; Thomas Boulet[14]; Haiying Liu[13]; Harrison Macharia[14]; Peter Trask[13]; Chunyan Song[13]; Eric P. Winer[15]; Ian E. Krop[15]

[1]Breast Center, Dept. OB&GYN, University of Munich (LMU), Munich, Germany; [2]Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Seoul, Korea; [3]Oncology Research Unit, Oncoclínicas, HSL, PUCRS, Porto Alegre, Brazil; [4]Institut Bergonié Unicancer and Bordeaux University, Bordeaux, France; [5]University of Washington, Seattle, WA, USA; [6]Graduate School of Medicine, Kyoto University, Kyoto, Japan; [7]Guy's Hospital and Sarah Cannon Research Institute, London, UK; [8]Michelangelo Foundation, Milan, Italy; [9]Georgetown University Medical Center, Washington, D.C., USA; [10]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea; [11]IRCCS Instituto Nazionale Tumori Fondazione Pascale, Naples, Italy; [12]Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland; [13]Genentech, Inc., South San Francisco, CA, USA; [14]F. Hoffmann-La Roche, Basel, Switzerland; [15]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA

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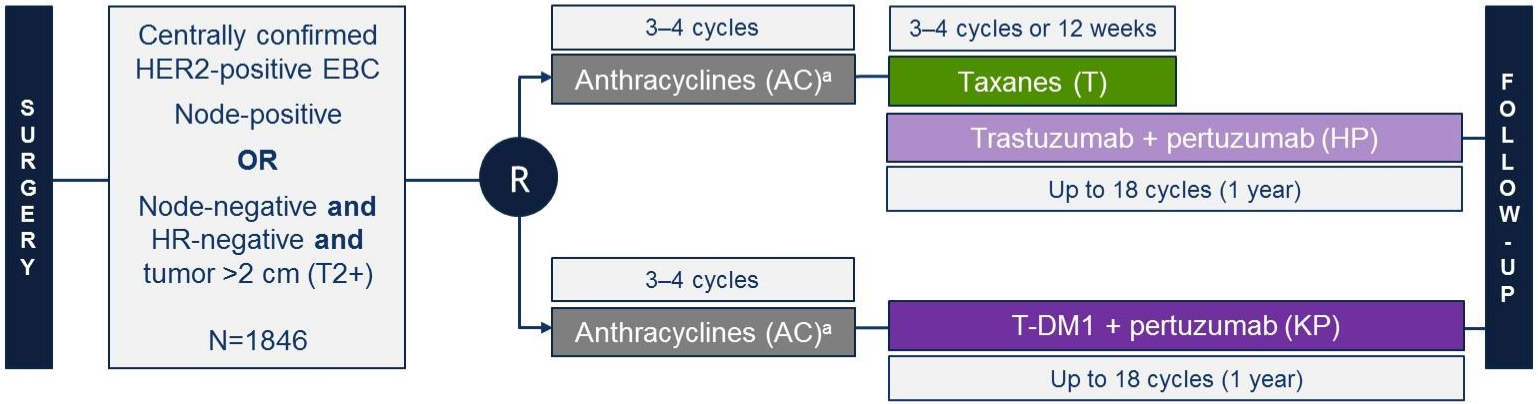
KAITLIN Study Design



Stratification factors:

- Region: United States/Canada, Western Europe/Australia/New Zealand, Asia, or rest of the world
- Nodal status: 0, 1–3, or ≥4 positive nodes
- Centrally assessed hormone receptor status: positive (ER-positive and/or PgR-positive) or negative (ER-negative and PgR-negative)
- Type of anthracycline: doxorubicin or epirubicin

[a]Anthracyclines (AC) = investigator's choice of FEC, AC, or EC [5-fluorouracil (F), epirubicin (E), cyclophosphamide (C), doxorubicin (A)].

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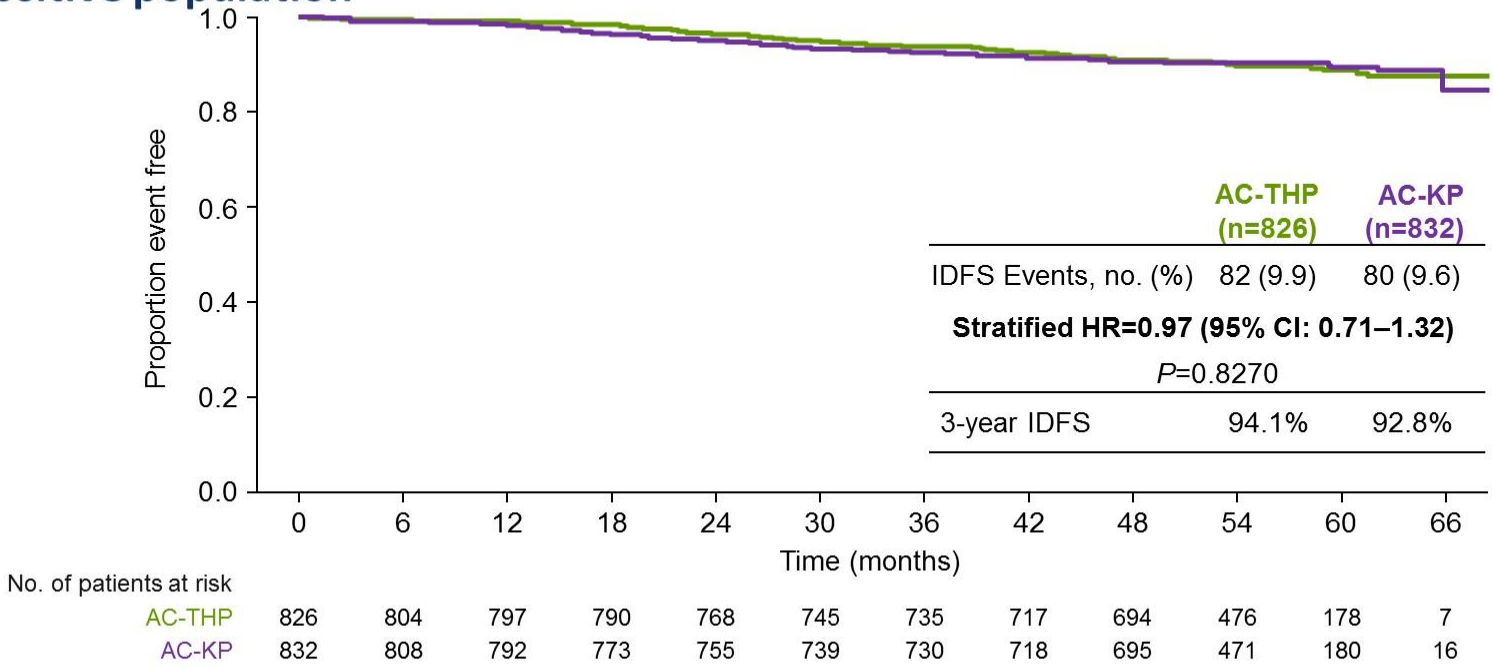
Primary Endpoint: IDFS, Node-Positive Disease

- **AC-KP did not reduce the risk of an IDFS event compared with AC-THP in the node-positive population**



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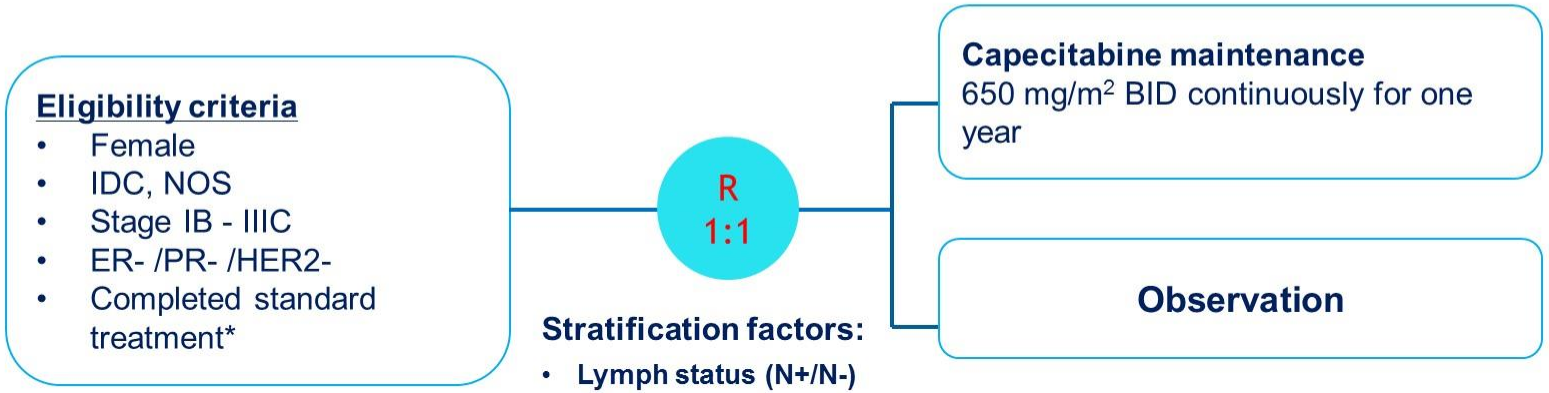
Phase III Trial of Metronomic Capecitabine Maintenance after Standard Treatment in Early Triple-Negative Breast Cancer (SYSUCC-001)

Xi Wang, Shu-Sen Wang, Heng Huang, Rou-Jun Peng, Li Cai, Li Zhao, Yin Lin, Jian Zeng, Le-Hong Zhang, Jun Tang, Yong-Li Ke, Xian-Ming Wang, Xin-Mei Liu, Qian-Jun Chen, An-Qin Zhang, Yan-Xia Shi, Ye Cao, Dan-Mei Pang, Fei Xu, Jia-Jia Huang, Cong Xue, Xin An, Wen Xia, Ruo-Xi Hong, Zhong-Yu Yuan; on behalf of the South China Breast Cancer Group

Study Design and Patient Population



*surgery, (neo)adjuvant chemotherapy (A and/or T based), RT

89% received A+T

93% received adjuvant chemotherapy

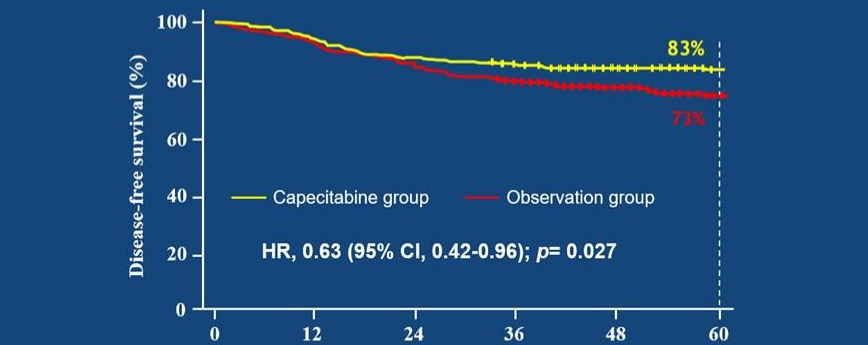
Primary endpoint: DFS
Secondary Endpoint: OS, distant DFS, safety

443 patients randomized with a median follow up of 57 mos

Patient characteristics	
Age	Mean 46 years
Lymph node status	62% node negative
Tumor size	25% ≤2cm, 57% 2.1-5 cm
Pathologic stage	26% stage I; 54% stage II; 19% stage III

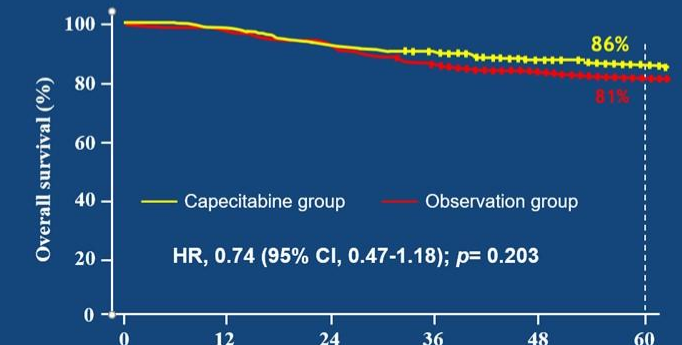
SYSUCC-001: Study Results

Disease-Free Survival (primary endpoint)



No. at risk						
Capecitabine	221	206	192	185	140	101
Observation	213	198	181	166	128	87

Overall Survival



No. at risk						
Capecitabine	221	215	204	197	146	105
Observation	213	209	196	183	141	98

- 5y improvement in DFS with capecitabine vs observation: **83% vs 73%, HR 0.63 (95% CI, 0.42-0.96); p= 0.027**
- No significant improvement in OS
- Subgroup analysis shows lower HR in more favorable risk patients: Stage I, <2cm tumors, LN negative
- Benefit of capecitabine not being driven by highest risk patients in this trial alone

Presented By Angela DeMichele at TBD

Context of Capecitabine adjuvant trials

CREATE-X (positive)	SYSUCC-001 (positive)	GEICAM (negative)
ER+/TNBC (32%)	TNBC	TNBC
Residual dx after NAC	93% adjuvant chemo	80% adjuvant chemo
1250 mg/m2 d1-14 q 3 wk for 6-8 cycles	650 mg/m^2 BID continuously for one year	1000mg/m2 day 1-14/q3 wks) x 8 cycles
95% anthracycline+taxane	89% anthracycline+taxane	67% anthracycline+taxane
57% pre-menopausal	67% pre-menopausal	32% pre-menopausal
NA	62% node negative	55% node negative
NA	73% grade 3	71% grade 3
unknown	unknown	26% non-basal
5 yr DFS/OS (control) 56%/70%	5 yr DFS/OS (control) 73%/81%	5 yr DFS/OS (control) 77%/86%
5 yr DFS/OS (cape) 70%/79%	5 yr DFS/OS (cape) 83%/86%	5 yr DFS/OS (cape) 80%/86%

Three-year follow-up of neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2-blockade for HER2-positive breast cancer (TRAIN-2): a randomized phase 3 trial

A. van der Voort[1], M.S. van Ramshorst[1,2], E. van Werkhoven[1], I.A. Mandjes[1], I. Kemper[1], A.J. Vulink[3], I.A. Oving[4], A.H. Honkoop[5], L.W. Tick[6], A.J. van de Wouw[7], C.M. Mandigers[8], L.J. van Warmerdam[9], J. Wesseling[1], M.J. Vrancken Peeters[1], S.C. Linn[1], G.S. Sonke[1]

[1]The Netherlands Cancer Institute, Amsterdam; [2]Onze Lieve Vrouwe Gasthuis, Amsterdam; [3]Reinier de Graaf Gasthuis, Delft; [4]Ziekenhuisgroep Twente, Almelo; [5]Isala, Zwolle; [6]Maxima Medical Center, Eindhoven; [7]VieCuri Medical Center, Venlo; [8]Canisius Wilhelmina Hospital, Nijmegen; [9]Catharina Cancer Centre, Eindhoven

on behalf of the Dutch Breast Cancer Research Group (BOOG 2013-03)

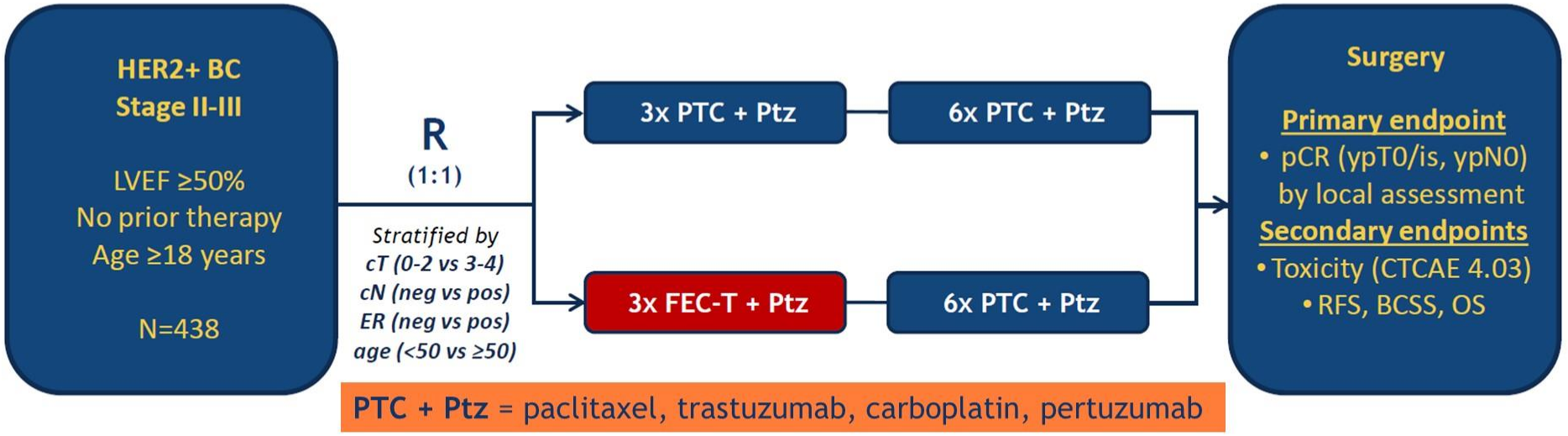
CONQUER CANCER® THE ASCO FOUNDATION MERIT AWARD RECIPIENT

Kathleen I. Pritchard, MD, Endowed Merit Award

*Supported by **Dr. Kathleen Pritchard Medicine Professional Corporation***

Presented By Angela DeMichele at TBD

TRAIN-2: study design

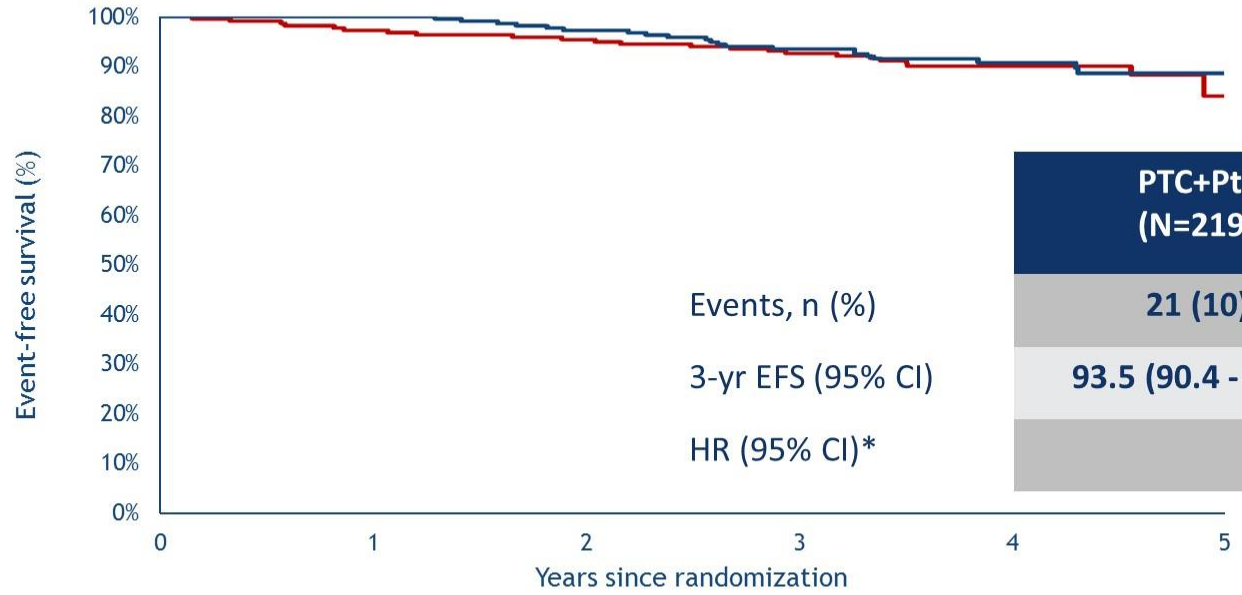


van Ramshorst et al, *Lancet Oncol* 2018; van Ramshorst et al, *Eur J Cancer* 2017

ClinicalTrials.gov identifier: NCT01996267

Presented By Angela DeMichele at TBD

Event-free survival



	PTC+Ptz (N=219)	FEC-T+Ptz (N=219)
Events, n (%)	21 (10)	23 (11)
3-yr EFS (95% CI)	93.5 (90.4 - 96.6)	92.7 (88.3 - 96.2)
HR (95% CI)*	0.90 (0.50 - 1.63)	

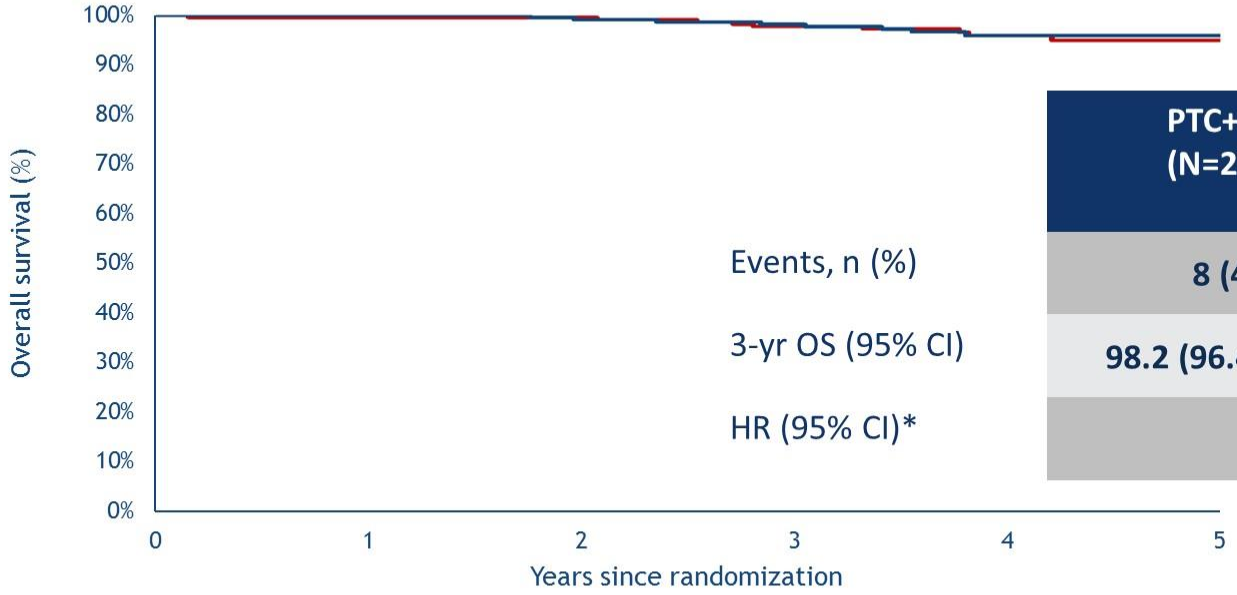
No. at risk

PTC+Ptz	219	219	212	203	106	19
FEC-T+Ptz	219	213	209	200	103	17

*HR <1 favors PTC+Ptz

Presented By Angela DeMichele at TBD

Overall survival



	PTC+Ptz (N=219)	FEC-T+Ptz (N=219)
Events, n (%)	8 (4)	9 (4)
3-yr OS (95% CI)	98.2 (96.4 - 100)	97.7 (95.7 - 99.7)
HR (95% CI)*	0.91 (0.35 - 2.36)	

No. at risk

PTC+Ptz	219	219	216	213	110	21
FEC-T+Ptz	219	218	218	211	111	20

*HR <1 favors PTC+Ptz

EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

MINDACT: Long-term results of the large prospective trial testing the 70-gene signature MammaPrint as guidance for adjuvant chemotherapy in breast cancer patients

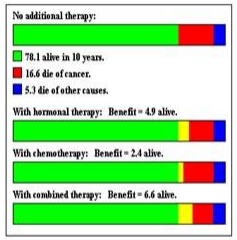
EORTC-10041/BIG3-04 (EudraCT Number2005-002625-31)

F. Cardoso, L. van 't Veer, C. Poncet, J. Lopes Cardozo, S. Delaloge, J. Pierga, P. Vuylsteke, E. Brain, G. Viale, S. Kümmel, I. Rubio, G. Zoppoli, A. Thompson, E. Matos, K. Zaman, F. Hilbers, A. Dudek-Perić, B. Meulemans, M.Piccart-Gebhart, E. Rutgers, on behalf of all MINDACT investigators

Presented By Angela DeMichele at TBD

EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

MINDACT TRIAL DESIGN

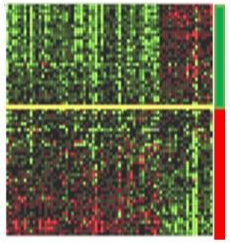


Registration & Screening
Surgery

N= 6693

Clinical-Pathological (C) risk
(Adjuvant! Online)

Genomic (G) risk
(70-gene signature)



C-low/G-low

Discordant cases
C-low/G-high or C-high/G-low

C-high/G-high

1st randomization to treatment
use Clinical vs. Genomic risk

MINDACT population:
HR+/HER2- 81%
HER2+ 9.5%
TNBC 9.6%

No Chemotherapy

2nd randomization
Anthracycline –based vs. Capecitabine-Docetaxel

Chemotherapy

HR+

Endocrine therapy

HR+

3rd randomization
Tamoxifen 2y / Letrozole 5y vs. Letrozole 7y

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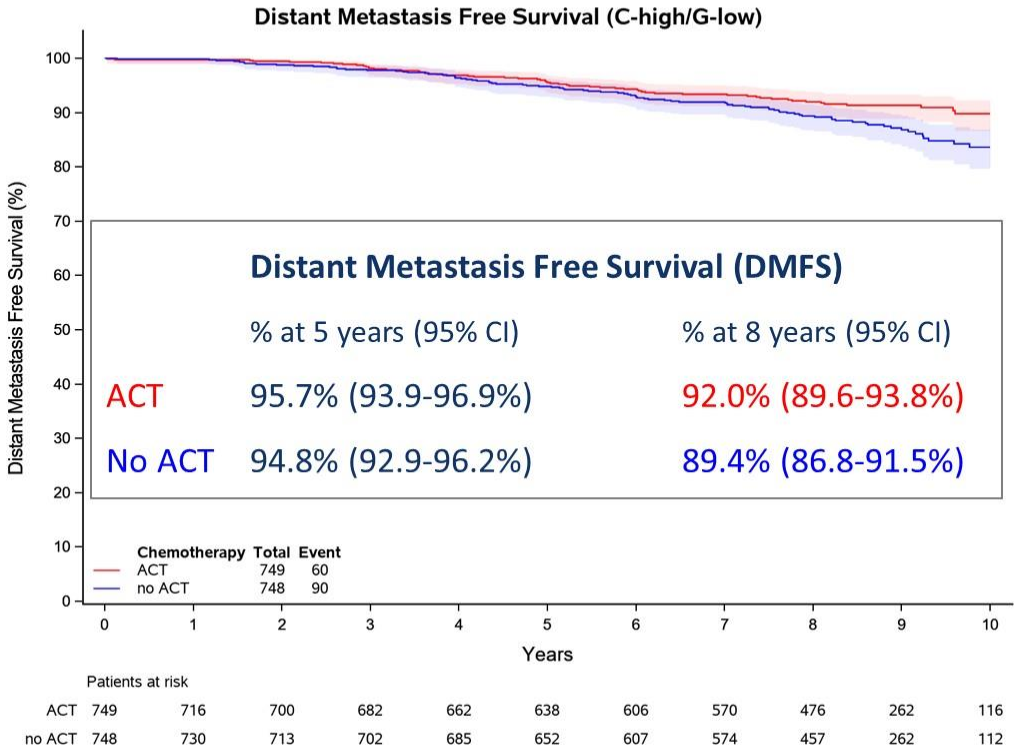
SECONDARY ENDPOINT
DMFS C-High/G-Low risk (ITT population) CT vs no CT



Absolute difference in DMFS between CT and no CT groups:

- at 5 years: **0.9 ± 1.1** % points
- at 8 years: **2.6 ± 1.6** % points

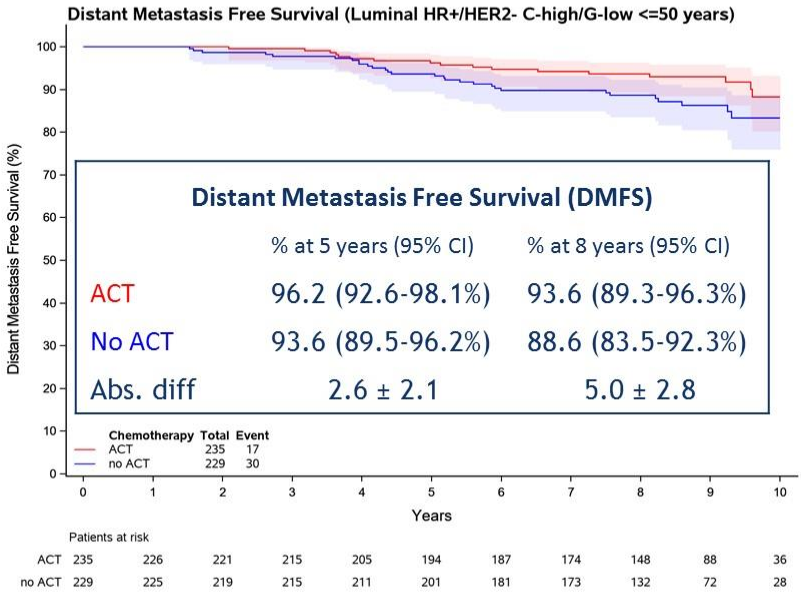
Type of first event (n = 150)

- distant recurrences: 74.7%
- death of any cause: 25.3%

Presented By Angela DeMichele at TBD

DMFS in C-High / G-Low risk patients with luminal cancers (HR+/HER2-) stratified by age
ITT population

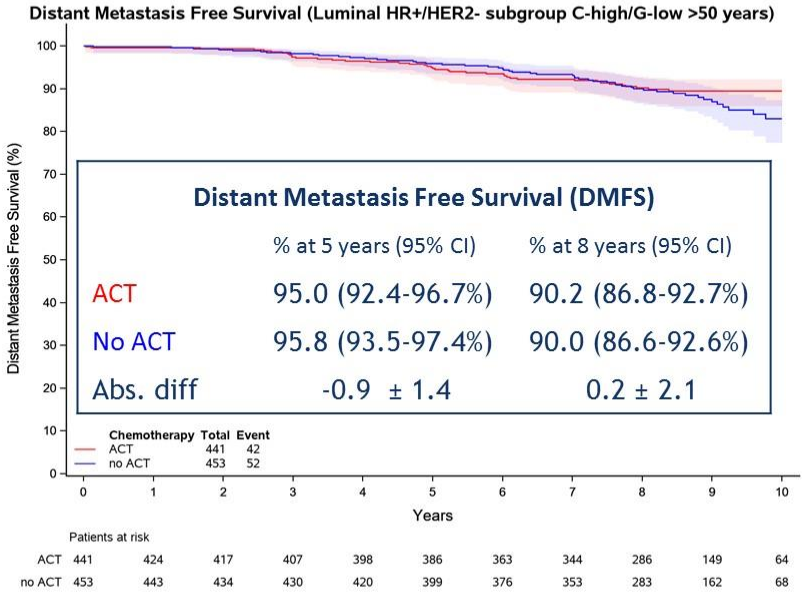
Age ≤50 years



Distant Metastasis Free Survival (DMFS)

	% at 5 years (95% CI)	% at 8 years (95% CI)
ACT	96.2 (92.6-98.1%)	93.6 (89.3-96.3%)
No ACT	93.6 (89.5-96.2%)	88.6 (83.5-92.3%)
Abs. diff	2.6 ± 2.1	5.0 ± 2.8

Age >50 years



Distant Metastasis Free Survival (DMFS)

	% at 5 years (95% CI)	% at 8 years (95% CI)
ACT	95.0 (92.4-96.7%)	90.2 (86.8-92.7%)
No ACT	95.8 (93.5-97.4%)	90.0 (86.6-92.6%)
Abs. diff	-0.9 ± 1.4	0.2 ± 2.1

5% difference **NO difference**

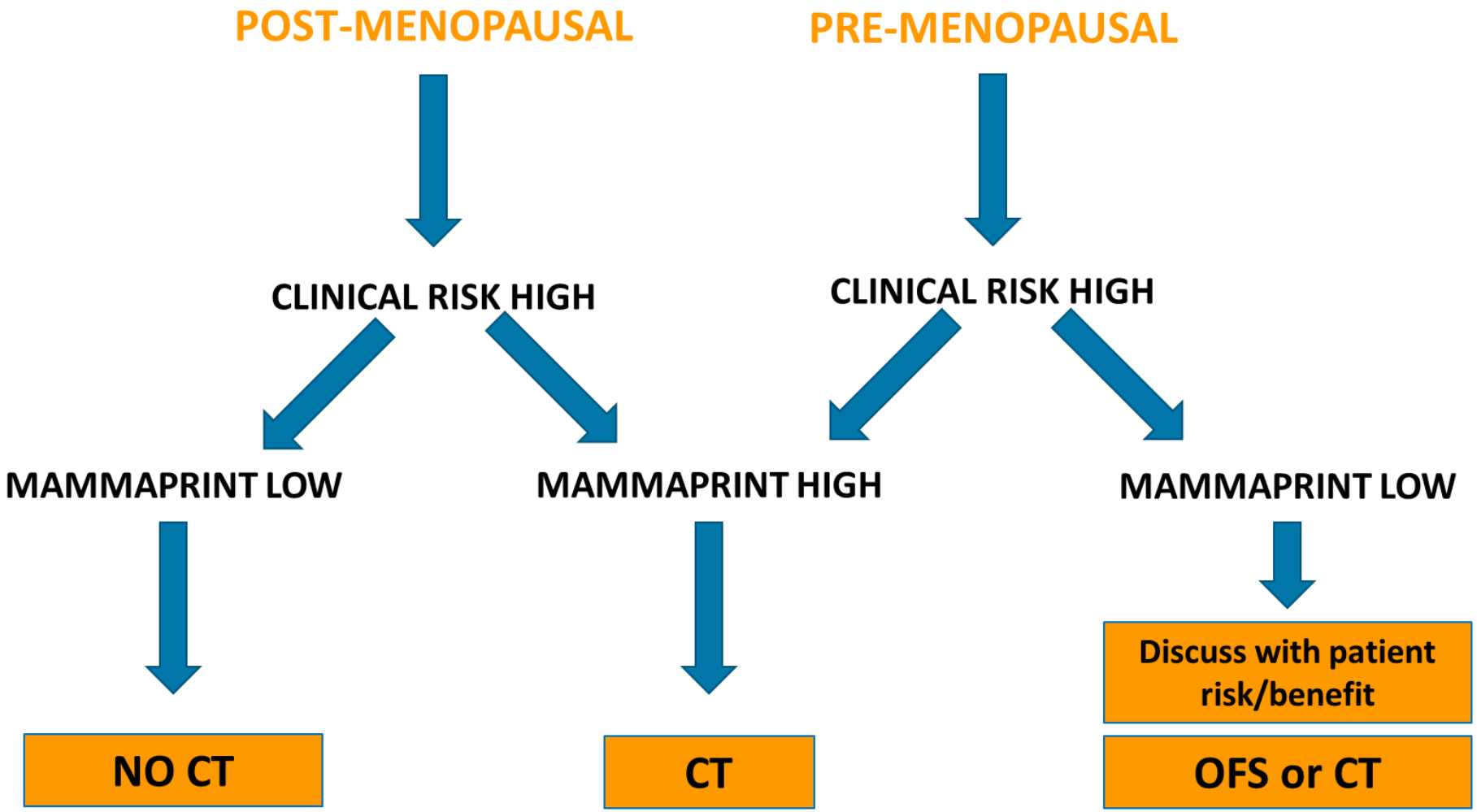
Presented By Angela DeMichele at TBD

Take Home Points: Tools for Precision Adjuvant Therapy

MINDACT: Mammaprint in ER+:

- Patients with C-High/G-Low disease continue to do well without chemotherapy at 8-yr follow up (95.1% (93.1-96.6%))
  - Small DMFS gain for CT in C-High/G-Low (2.6%)
- **Postmenopausal women:**
  - DMFS gain of 0.2% (± 2.3%) with CT favors omitting CT in C-High/G-Low
- **Premenopausal women:**
  - DMFS gain 5% (± 2.8%) with CT warrants consideration; May be due to lack of OFS in non-CT arm;
  - Must weigh this in individual decisions

Návrh na implementaci studie MINDACT do klinické praxe



Metastatický karcinom prsu

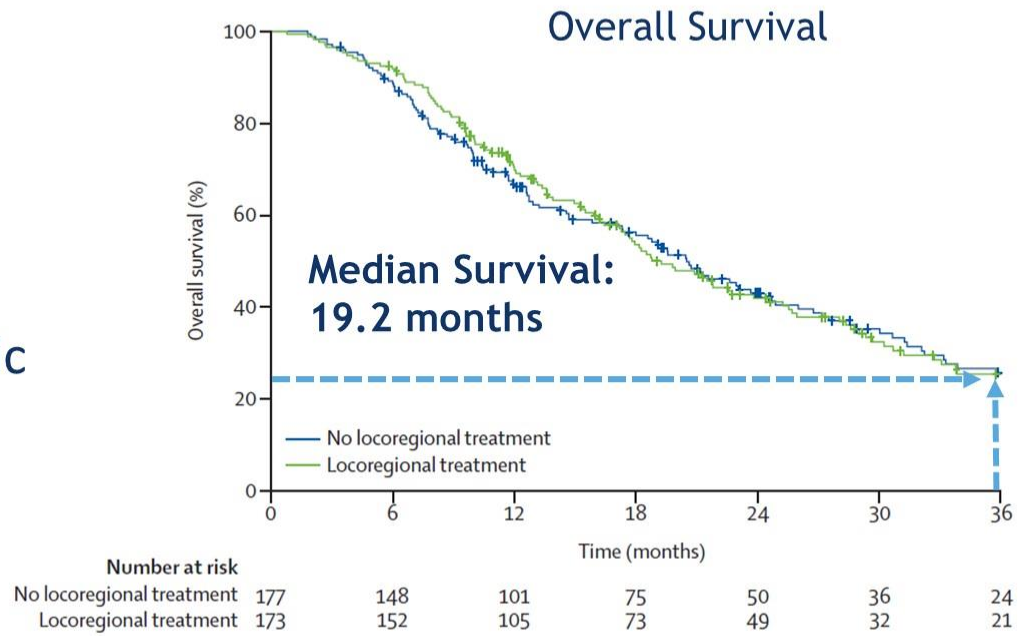
Tata Memorial Hospital Trial: Surgical Resection After Complete or Partial Response to 6 Cycles of Anthracycline-based Combination Chemotherapy

- 716 presented 2005-2013
- 415 (60%) complete or partial response
- 350 Randomized Population:
  - Median age 48, 53% post menopausal
  - 75% had > 3 metastatic sites
  - 72 % single organ mets. ,
    - Bone only 28%, Visceral 40%
    - Solitary mets ineligible
  - 59% HR+, 30% HER2+,
- **Primary endpoint: 2 year Overall Survival**

Badwe et al., Lancet Oncol 16: 2015

No Improvement in Survival from Local Regional Therapy
Tata Memorial Hospital Trial

- No improvement in OS
- Improved local regional progression-free survival:
  - Local therapy: ~ 85%
  - No Local therapy: ~40%
- Resource Constrained Systemic Therapy
  - 8% of HER2+ MBC received anti-HER2 therapy
  - 5% received Taxane or other CT



Median follow-up 23 months

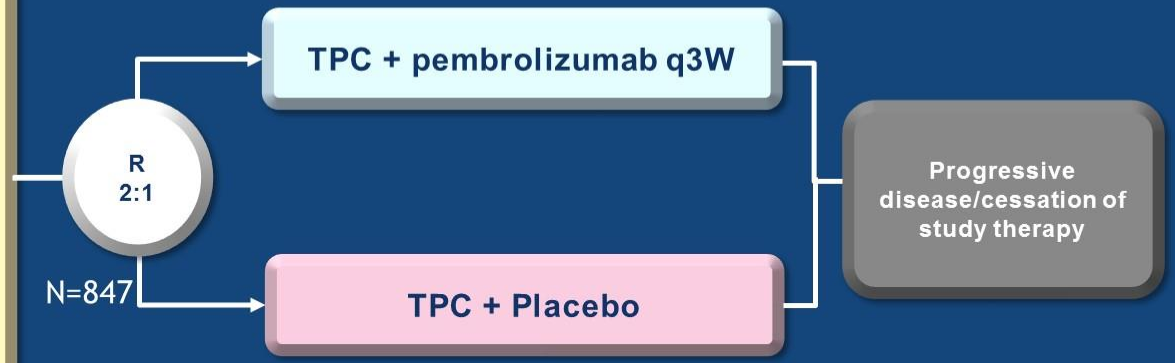
Badwe et al., Lancet Oncol 16: 2015

Presented By Julia White at TBD

KEYNOTE 355: Pembrolizumab + chemo for 1L mTNBC

Key Eligibility Criteria

- Central determination of TNBC and PD-L1 expression
- Previously untreated inoperable or metastatic TNBC
- Completion of treatment with curative intent ≥6 months prior to recurrence
- No active CNS metastases



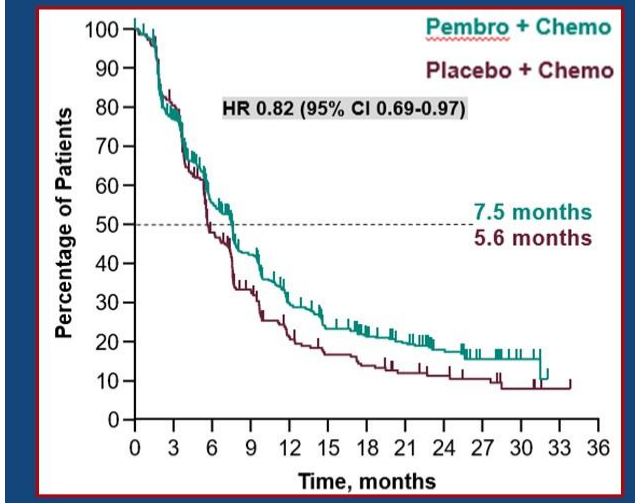
Stratification Factors:

- Chemotherapy on study (taxane vs gemcitabine/carboplatin)
- PD-L1 tumor expression (CPS ≥1 vs CPS <1)
- Prior treatment with same class chemotherapy in the neoadjuvant or adjuvant setting (yes vs no)

TPC: treatment of physician's choice chemo

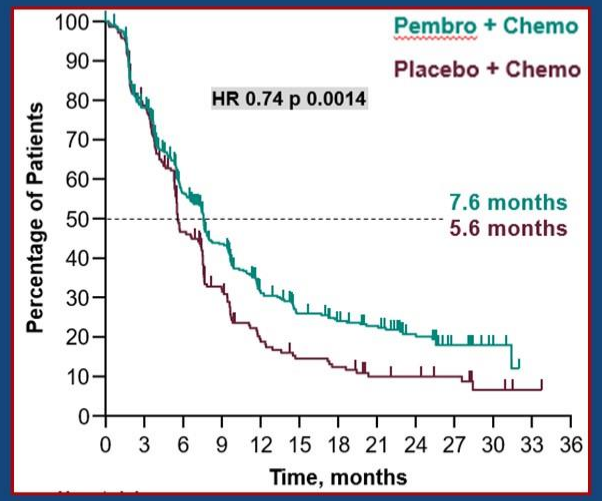
KEYNOTE 355: Progression-free survival

ITT



Statistical significance was not tested due to the prespecified hierarchical testing strategy

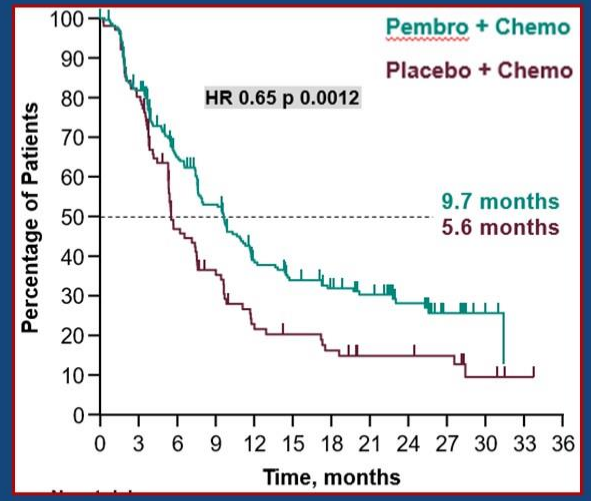
PD-L1 CPS ≥1



Prespecified *P* value boundary of 0.00111 not met

75% of pts

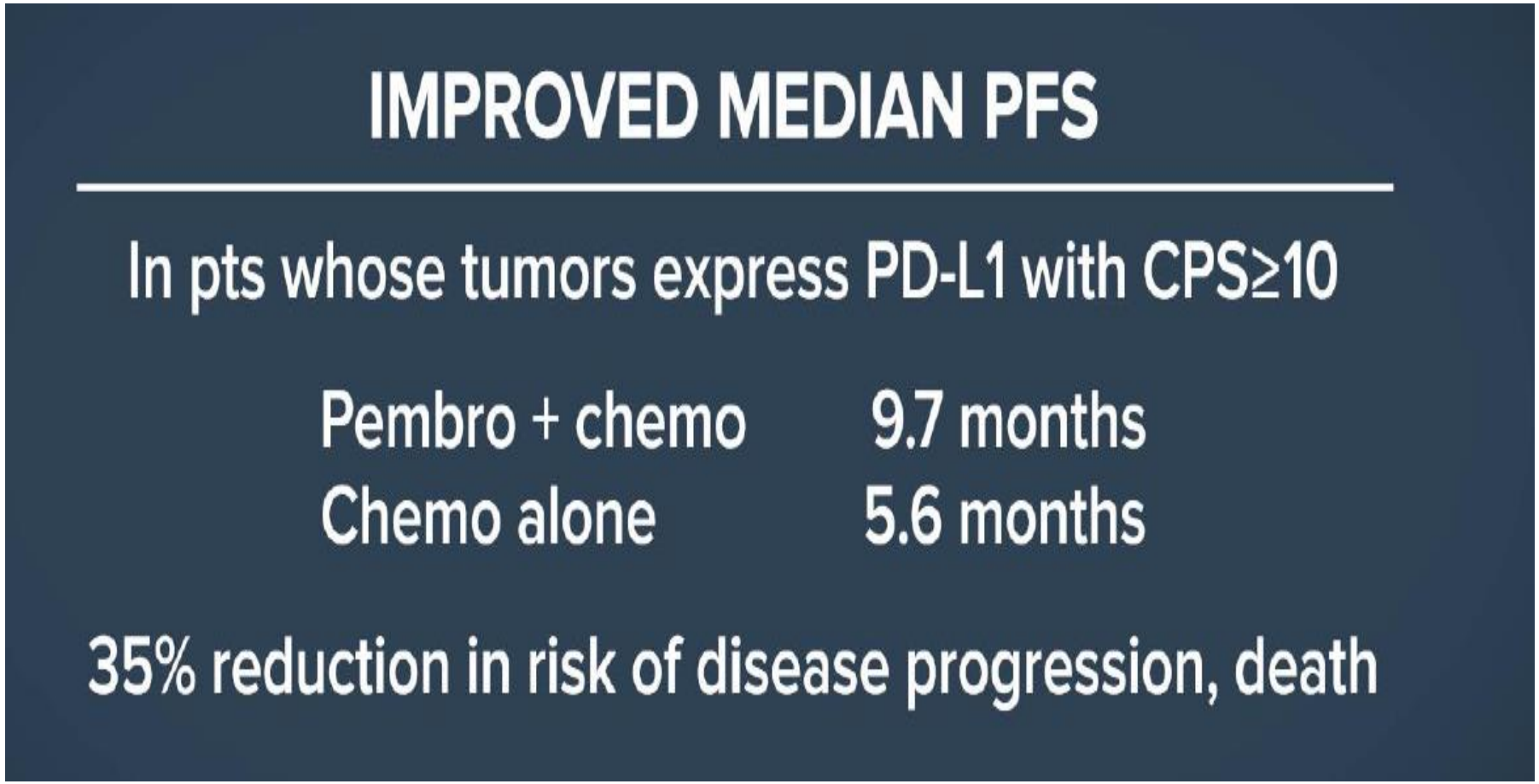
PD-L1 CPS ≥10



Prespecified *P* value boundary of 0.00411 met

38% of pts

KEYNOTE-355 – výsledky



HR+ MBC and CDK4/6 Inhibitors

What's With the Backbone?

PRESENTED AT: 2020 ASCO ANNUAL MEETING

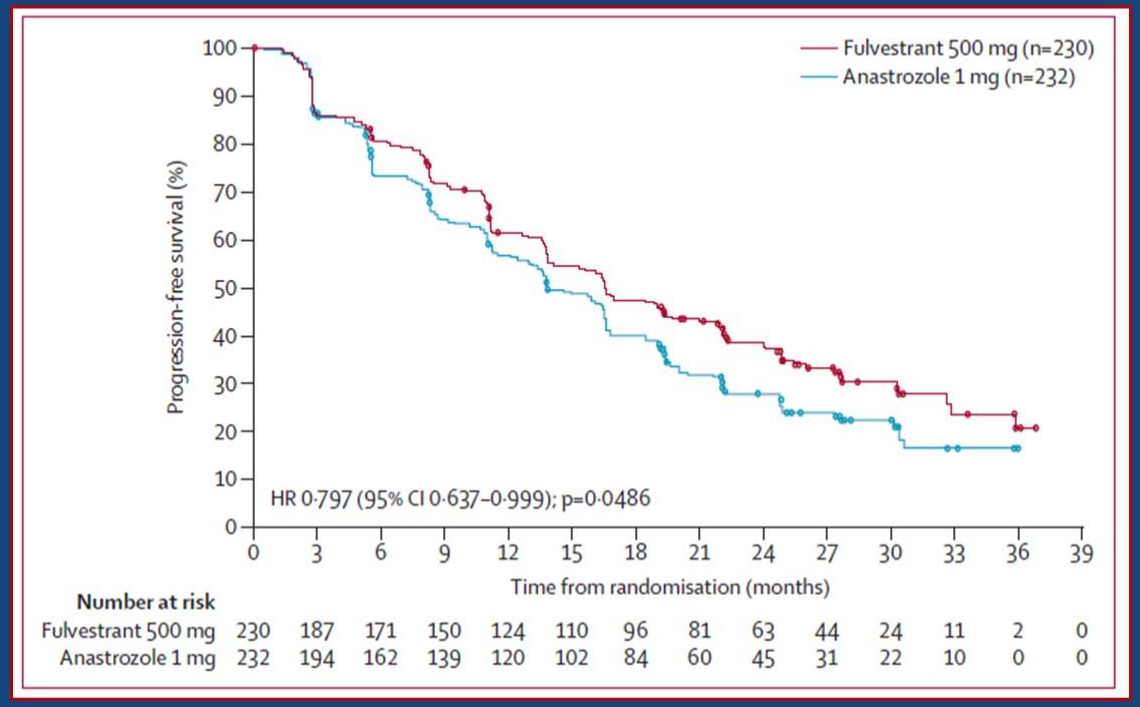
#ASCO20

PRESENTED BY:

Presented By Erika Hamilton at TBD

FALCON: Fulvestrant beats AI for 1st line HR+ MBC

Postmenopausal women with HR+/HER2- MBC without **any** prior hormonal therapy

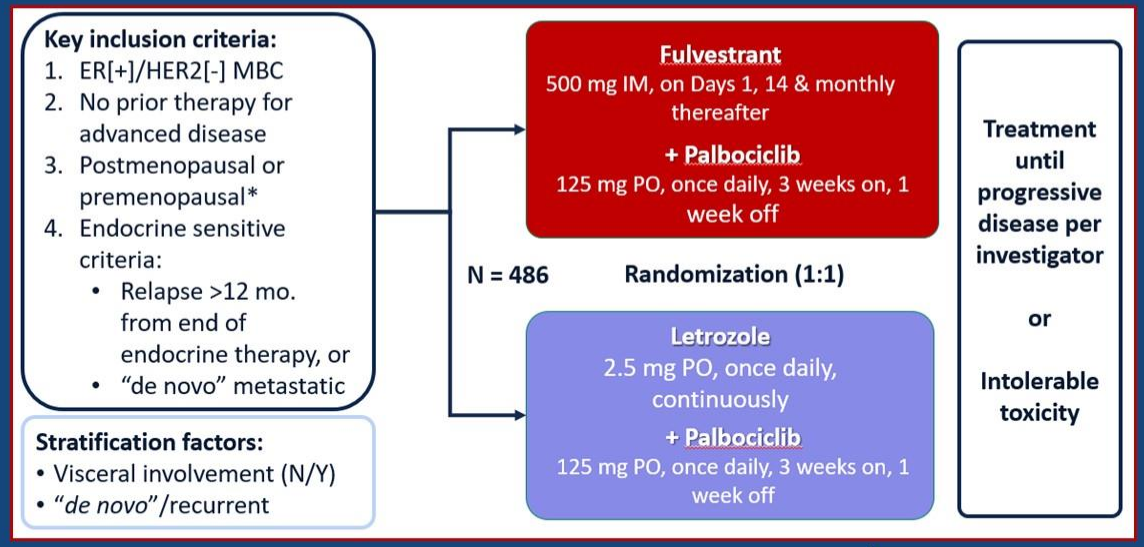


Median PFS:
16.6 mo: Fulvestrant
13.8 mo: Anstrozole

OS data not reported as yet

JFR Robertson et al. Lancet 2016; 388:2997-3005

But what about when you combine with CDK4/6i for 1st line MBC?



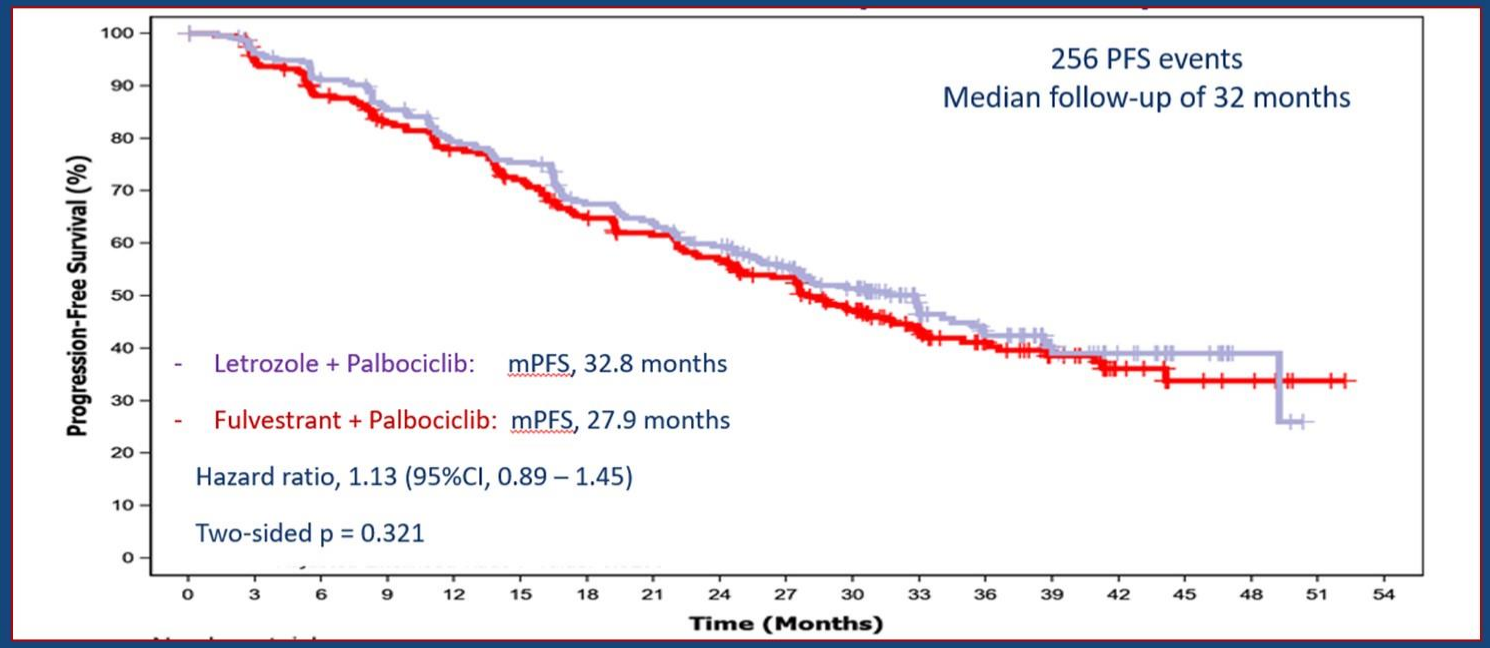
PARSIFAL: Fulvestrant or Letrozole in combination with Palbociclib

* If premenopausal, ovarian suppression was required

Prior therapies

Characteristics	All patients (N=486)	Fulvestrant+Palbociclib (N=243)	Letrozole+Palbociclib (N=243)
Prior therapies in EBC, n (%)			
Chemotherapy			
Neoadjuvant	46 (9.5)	25 (10.3)	21 (8.6)
Adjuvant	144 (29.6)	73 (30)	71 (29.2)
Endocrine therapy			
Tamoxifen	177 (36.4)	87 (35.8)	90 (37.0)
Aromatase inhibitors	117 (24.1)	65 (26.7)	52 (21.4)
Both	70 (14.4)	39 (16.0)	31 (12.8)

PARSIFAL: PFS ITT Analysis

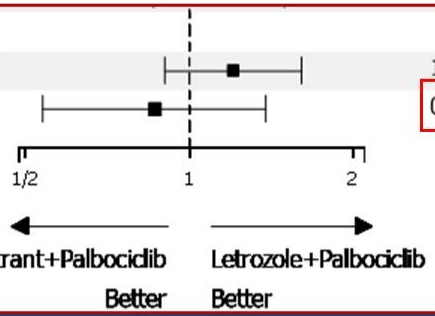


Fulvestrant/palbociclib ⚡ Letrozole/palbociclib

PARSIFAL: Outcomes based on prior AI therapy

Pre-specified subgroup analysis

Subgroup	Fulvestrant Palbociclib no. of patients (%)	Letrozole Palbociclib no. of patients (%)	Hazard ratio (95% CI)	Interaction p-value	Fulvestrant Palbociclib Median (months)	Letrozole Palbociclib Median (months)
Prior aromatase inhibitors therapy						
No	178 (73.3)	191 (78.6)	1.21 (0.90-1.61)	0.2409	28.9	32.8
Yes	65 (26.7)	52 (21.4)	0.86 (0.54-1.39)		27.5	19.3



Alpelisib + Fulvestrant in Patients With *PIK3CA*-Mutated Hormone-Receptor Positive (HR+), Human Epidermal Growth Factor Receptor-2-Negative (HER2–) Advanced Breast Cancer (ABC) Previously Treated With Cyclin-Dependent Kinase 4/6 Inhibitor (CDKi) + Aromatase Inhibitor (AI): BYLieve Study Results

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Abstract 1006

Presented By Hope Rugo at TBD

BYLieve: A Phase 2, Open-Label, 3-Cohort, Noncomparative Trial (NCT03056755)

BYLieve
Alpelisib (BYL719) In patients with PIK3CA mutant, HR+, HER2- adVanced brEast cancer

Goal: In the post-CDKi setting, assess the efficacy and safety of alpelisib + ET (fulvestrant or letrozole) in patients with *PIK3CA*-mutated HR+, HER2– ABC

Men or pre-/postmenopausal[a] women with HR+, HER2– ABC with a *PIK3CA* mutation

- Last line of prior therapy: CDKi + ET, systemic chemotherapy or ET
- ECOG PS ≤2
- Measurable disease (per RECIST v1.1) or ≥1 predominantly lytic bone lesion

Patients who received CDKi + AI as immediate prior treatment (N=112)[b]
(Cohort A)
Alpelisib 300 mg oral QD + fulvestrant 500 mg[c]

Patients who received CDKi + fulvestrant as immediate prior treatment (N=112)
(Cohort B)
Alpelisib 300 mg oral QD + letrozole 2.5 mg[d]

Patients who progressed on/after AI and received chemotherapy or ET as immediate prior treatment (N=112)
(Cohort C)
Alpelisib 300 mg oral QD + fulvestrant 500 mg[c]

Primary endpoint

- Proportion of patients alive without PD at 6 months (RECIST v1.1) in each cohort
- **Secondary endpoints include**

(assessed in each cohort)

- PFS
- PFS2
- ORR, CBR, DOR
- OS
- Safety

Treatment crossover between cohorts is not permitted

[a]Men in the letrozole cohort and premenopausal women also received goserelin 3.6 mg SC every 28 days or leuprolide 7.5 mg IM every 28 days for adequate gonadal suppression. [b]Enrollment in each cohort continued until at least 112 patients with a centrally confirmed *PIK3CA* mutation was reached. [c]IM on D1 and D15 of Cycle 1 and D1 for all other cycles thereafter. [d]Oral QD.
ABC, advanced breast cancer; AI, aromatase inhibitor; CDKi, cyclin-dependent kinase inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, endocrine therapy; CBR, clinical benefit rate; D, day; DOR, duration of response; IM, intramuscularly; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, PFS on next-line treatment; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; RECIST, Response Evaluation Criteria In Solid Tumors; SC, subcutaneously; QD, once daily.

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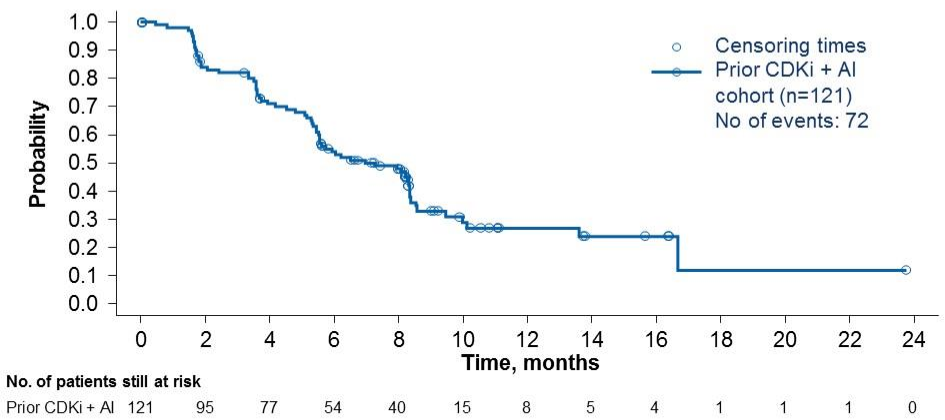
Efficacy: Primary Endpoint and PFS Results

BYLieve
Alpelisib (BYL719) In patients with PIK3CA mutant, HR+, HER2- adVanced brEast cancer

Endpoint	Prior CDKi + AI (Cohort A) (n=121)
Primary endpoint: Patients who were alive without disease progression at 6 mo	**50.4%** (n=61; 95% CI, 41.2-59.6)
Secondary endpoint: Median PFS	**7.3 mo** [n=72 (59.5%) with event]; 95% CI, 5.6-8.3)



The primary endpoint for the prior CDKi + AI cohort was met (lower bound of 95% CI was > 30%), with 50.4% of patients alive without disease progression at 6 months

- In SOLAR-1, 44.4% of patients in the *PIK3CA*-mutant cohort with prior CDKi treated with alpelisib plus fulvestrant were alive without disease progression at 6 months

AI, aromatase inhibitor; CDKi, cyclin-dependent kinase inhibitor; CI, confidence interval; PFS, progression-free survival; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

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Efficacy: Response Rates

BYLieve
Alpelisib (BYL719) In patients with PIK3CA mutant, HR+, HER2- adVanced brEast cancer

Response rates, n (%)	Prior CDKi + AI (Cohort A) Study Treatment: Alpelisib + Fulvestrant	
Best overall response	**All patients with centrally confirmed *PIK3CA* mutation (n=121)**	**Patients with measurable disease at baseline (n=100)**
Complete response (CR)	0	0
Partial response (PR)	21 (17.4)	21 (21.0)
Neither CR nor PD[a] (NCR/NPD)	16 (13.2)	0
Stable disease (SD)	55 (45.5)	55 (55.5)
Progressive disease (PD)[b]	14 (11.6)	11 (11.0)
Unknown (UNK)	15[c] (12.4)	13 (13.0)
Overall response rate (ORR: CR + PR)	21 (17.4); 95% CI (11.1-25.3)	21 (21.0); 95% CI (13.5-30.3)
Clinical benefit rate (CBR: CR + PR + [SD+NCR/NPD≥24 wk])	55 (45.5); 95% CI (36.4-54.8)	42 (42.0); 95% CI (32.2-52.3)

[a]Refers to presence of lesions not fulfilling criteria for target lesions at baseline or abnormal nodal lesions (ie,≥10 mm), unless there is unequivocal progression of the non-target lesions (PD) or it is not possible to determine progression unequivocally (UNK).
[b]Refers to neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions that would qualify for PD.
[c]11 patients had no valid post-baseline tumor assessment; 1 patient was coded as SD by investigator too early since that occurred before 6 weeks of the start date of study treatment; 2 patients had started the new antineoplastic treatment before first post-baseline tumor assessment; 1 patient was coded as PD by investigator too late since the algorithm has shown PD.

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