

7th Annual

LEAD2025

Enriching Experiences for Women in Hematology & Oncology

Breast Cancer Review

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HR+/HER2 Negative

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Key updates in 2025 for HR+/HER2 negative Breast Cancer

Early Stage:

TRADE: dose escalation of abemaciclib in the adjuvant setting

Advanced / Metastatic:

- VERITAC-2: Ph3 study of vepdegestrant
- EMBER-3: Ph3 study of Imlunestrant ± abema
- SERENA-6: Ph3 study of Camizestrant for emerging ESR1
- INAVO-120: Ph3 Inavolisib overall survival update
- FINER: Ph3 study of ipatasertib

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Does a ramp up schedule reduce the side of effect of abemaciclib in the adjuvant setting?

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TRADE: Design

- **HR-positive, HER2-negative, early breast cancer**
- **Adjuvant abemaciclib is indicated based on patient risk/stage**

Screening

N=90

Adjuvant Endocrine Therapy

Abemaciclib 50mg BID	Abemaciclib 100mg BID	Abemaciclib 150mg BID
Days 1 – 14	Days 15 – 28	> 28 Days

→ **Endocrine Therapy + up to 2 years Abemaciclib**

Intra-patient dose escalation requirements: Absence of ongoing grade 3/4 or persistent grade 2 toxicity

Supportive care, including anti-diarrhea medication, provided as needed

PRIMARY ENDPOINT:

- **Composite Adverse Event Rate**: Discontinuation of adjuvant abemaciclib for any reason and/or inability to reach or maintain target dose of 150 mg BID by 12 weeks of therapy

SECONDARY ENDPOINTS:

- Treatment-emergent adverse effects, discontinuation / hold rates, incidence of grade ≥2 diarrhea, quality of life, adherence, dose intensity, correlative science

STATISTICAL DESIGN:

- **Experimental hypothesis**: **a dose-escalation schedule will significantly reduce the composite adverse event rate at 12 weeks from a baseline of 40%, based on monarchE**
- **Sample size**: 90 patients provides 92% power, against an alternative of 25%, with a 1-sided test at a significance level of 0.07, assuming drop-out rate of 10%

PRESENTED BY: Erica L. Mayer, MD, MPH

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Primary 12 week outcomes

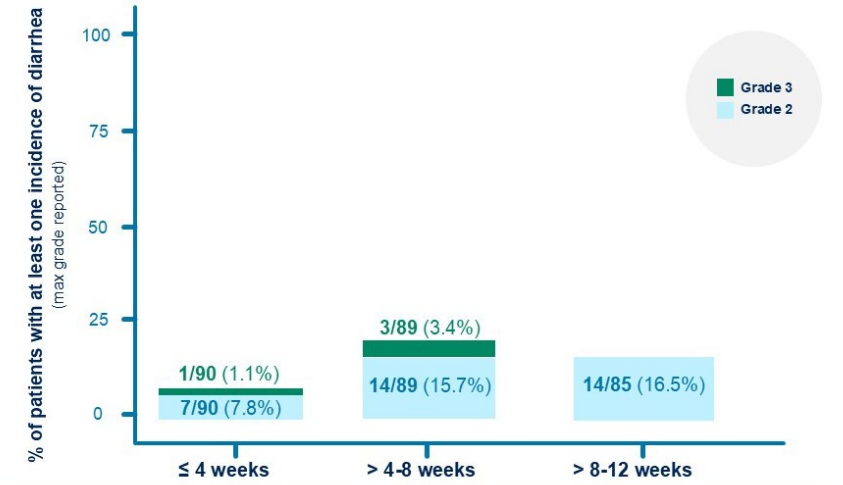
	12 week – TRADE N=89
Discontinued abemaciclib for any reason	6.7%
Discontinued abemaciclib for AEs	3.4%
Dose reduced abemaciclib	22.4%

Modest numerical improvement in the 12-week abemaciclib continuation rates 93% in TRADE vs 90% in monarchE

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TRADE - Toxicity data for diarrhea

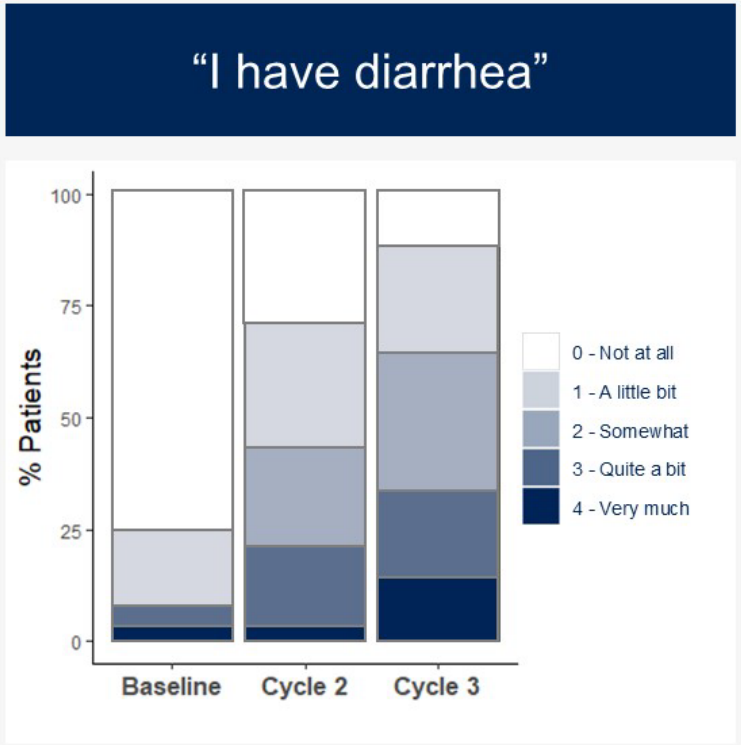
Rates of ≥ Grade 2 Treatment Emergent Diarrhea Each Month Into Treatment			
Timepoint (weeks)	**Number with diarrhea**	**Number receiving treatment**	**%**
≤ 4	8	90	8.9%
> 4 to ≤ 8	17	89	19.1%
> 8 to ≤12	14	85	16.5%

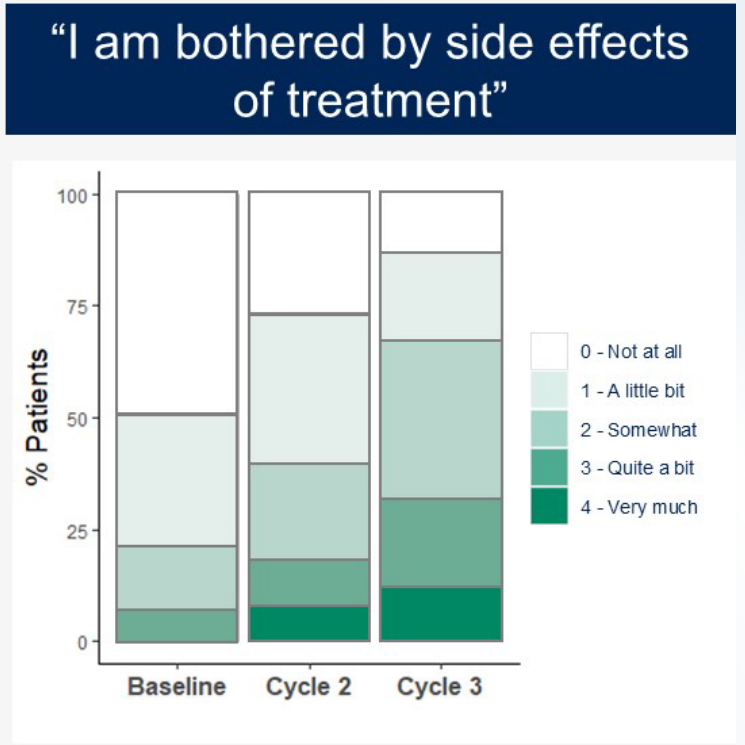


Median time to ≥ grade 2 diarrhea: 6.4 weeks (range 0.3 -11.9 weeks)

Mayer, ASCO 2025

TRADE - PROs





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TRADE- Conclusions

Dose escalating abemaciclib provides modest improvements in 12-week abemaciclib continuation rates.

Appear to be delaying time to peak AEs– further follow up will clarify these trends.

A reasonable option for some patients.

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What are the latest phase 3 results of novel oral SERDs or PROTACs?

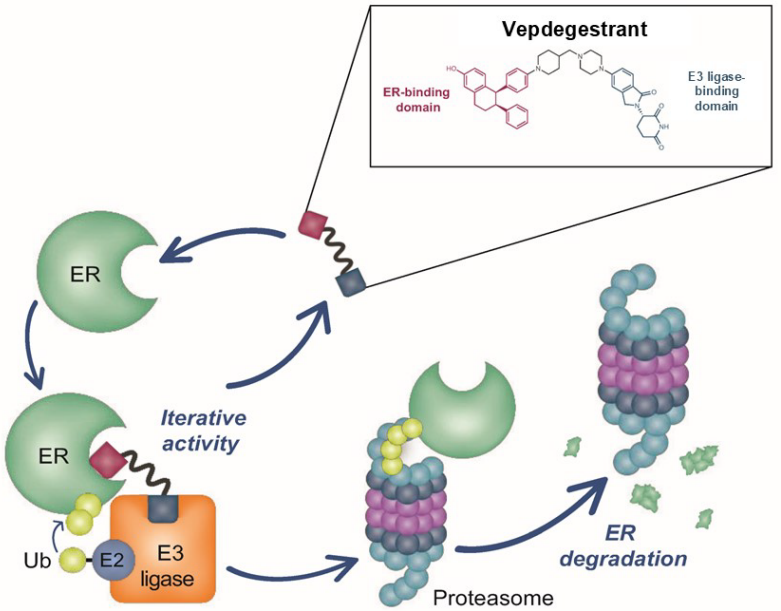
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Vepdegestrant, a PROTAC ER Degrader, vs Fulvestrant in ER+/HER2- Advanced Breast Cancer: Results of the Global, Randomized, Phase 3 VERITAC-2 Study

Erika P Hamilton[1], Michelino De Laurentiis[2], Komal Jhaveri[3], Xichun Hu[4], Sylvain Ladoire[5], Anne Patsouris[6], Claudio Zamagni[7], Jiuwei Cui[8], Marina Cazzaniga[9], Timucin Cil[10], Katarzyna Jerzak[11], Christian Fuentes[12], Tetsuhiro Yoshinami[13], Alvaro Rodriguez-Lescure[14], Olga Valota[15], Dongrui R Lu[16], Marcella Martignoni[15], Janaki Parameswaran[17], Xin Zhi[17], Mario Campone[18]

Background

- There is no established consensus for treatment of ER+/HER2- advanced breast cancer after progression on first-line ET[1]
- Fulvestrant, a SERD that is administered IM due to poor solubility,[2] has limited PFS benefit following disease progression on a CDK4/6i + ET[3,4]
- Vepdegestrant is a selective, oral PROTAC ER degrader that targets WT and mutant ER[5,6]
- In a first-in-human, phase 1/2 study (NCT04072952), vepdegestrant was well tolerated and demonstrated encouraging clinical activity in heavily pretreated patients with ER+/HER2- advanced breast cancer[7]



Vepdegestrant has a unique MOA that directly harnesses the ubiquitin-proteasome system to degrade ER[8]

CDK4/6i=cyclin-dependent kinase 4/6 inhibitor; ER=estrogen receptor; ET=endocrine therapy; HER2=human epidermal growth factor receptor 2; IM=intramuscularly; MOA=mechanism of action; PROTAC=PROteolysis TArgeting Chimera; SERD=selective estrogen receptor degrader; Ub=ubiquitin; WT=wild type.

1. Al Sukhun S, et l. *JCO Glob Oncol*. 2024;10:e2300285. 2. Nathan MR, Schmid P. Oncol Ther. 2017;5(1):17-29. 3. Lindeman GJ, et al. Clin Cancer Res. 2022;28(15):3256-67. 4. Bidard FC, et al. J Clin Oncol. 2022;40(28):3246-3256. 5. Békés M, et al. Nat Rev Drug Discov 2022;21(3):181-200. 6. Gough SM, et al. *Clin Cancer Res*. 2024;30(16):3549-3563. 7. Hurvitz SA, et al. SABCS. 2023; PO3-05-08. 8. Hamilton EP, et al. Futur Oncol. 2024;20(32):2447–55.

PRESENTED BY: Erika P Hamilton, MD

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VERITAC-2: Global Phase 3 Trial of Vep

N= 634
- 43% with ESR1 mut
- 79% with 1 prior line of ET
- 100% prior CDKi
  - 48% prior palbociclib
  - 32% prior ribociclib
  - 20% prior abemaciclib

Key Eligibility Criteria

- Age ≥18 years old
- ER+/HER2- advanced or metastatic breast cancer
- Prior therapy:
  - 1 line of CDK4/6i + ET
  - ≤1 additional ET
  - Most recent ET for ≥6 months
  - No prior SERD (eg, fulvestrant, elacestrant)
  - No prior chemotherapy for advanced or metastatic disease
- Radiological progression during or after the last line of therapy

Randomization (1:1)

28-day Treatment Cycles

Vepdegestrant (n=313)
200 mg orally (once daily)

Fulvestrant (n=311)
500 mg IM
(days 1 and 15 of cycle 1; day 1 of subsequent cycles)

Stratification Factors:
- *ESR1* mutation[a] (yes vs no)
- Visceral disease (yes vs no)

Primary Endpoint:
- PFS by BICR in
  - *ESR1*m population
  - All patients

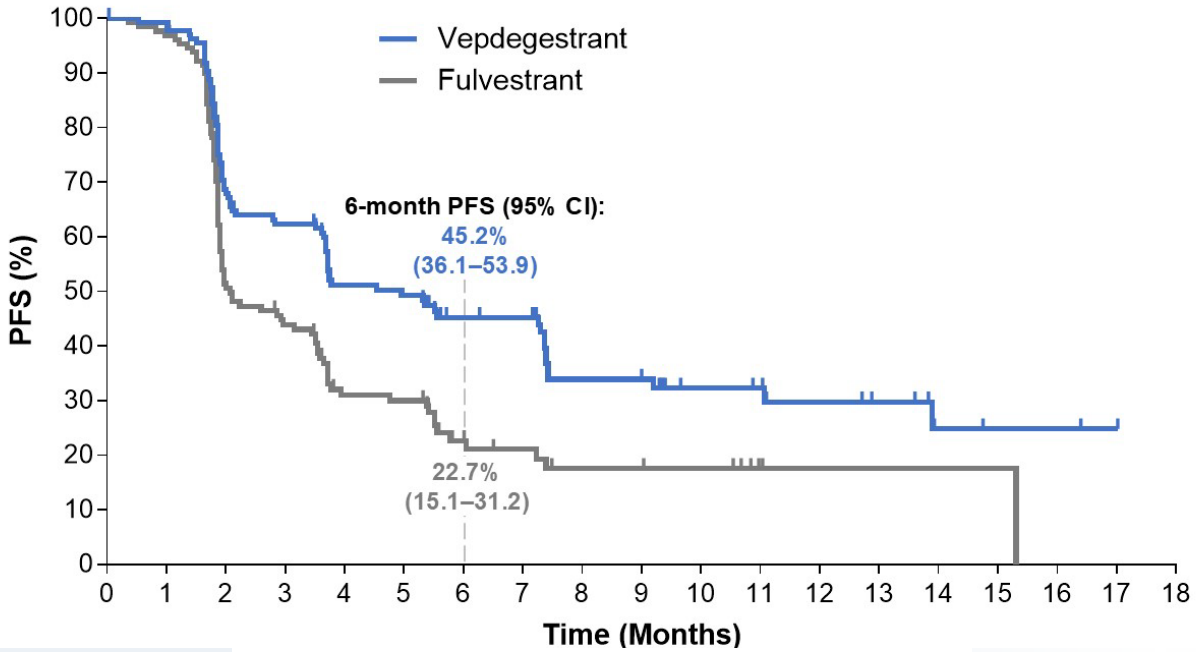
Secondary Endpoints:
- OS (key secondary)
- CBR and ORR by BICR
- AEs

Data cutoff date: Jan 31, 2025
Clinicaltrials.gov: NCT05654623

[a]*ESR1*m status was assessed in ctDNA by Foundation Medicine, except in China, where Origmed testing was used.
AE=adverse event; BICR=blinded independent central review; CBR=clinical benefit rate; CDK4/6i=cyclin-dependent kinase 4/6 inhibitor; ER=estrogen receptor; *ESR1*=estrogen receptor 1 gene; *ESR1*m=estrogen receptor 1 gene mutation; ET=endocrine therapy; HER2=human epidermal growth factor receptor 2; IM=intramuscularly; ORR=objective response rate; OS=overall survival; PFS=progression-free survival, SERD=selective estrogen receptor degrader.

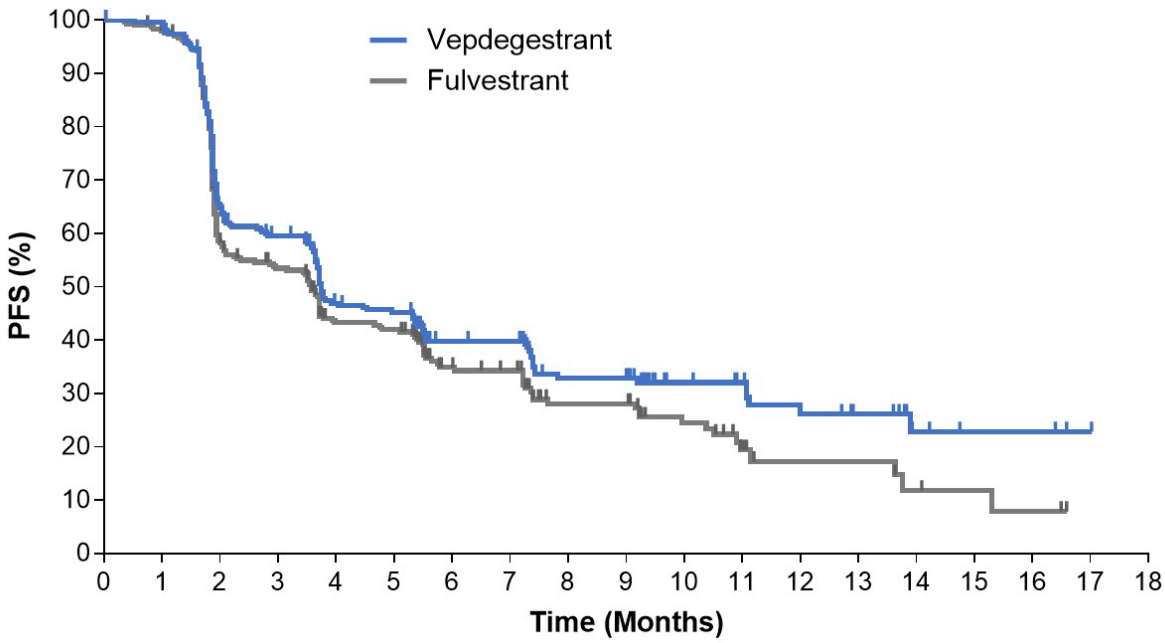
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VERITAC-2 Primary Endpoint: PFS by BICR in Patients With *ESR1*m



	Vepdegestrant n=136	Fulvestrant n=134
Median follow-up, months	7.4	6.0
Events, n (%)	79 (58)	95 (71)
Median PFS, months (95% CI)	**5.0 (3.7–7.4)**	**2.1 (1.9–3.5)**
Stratified HR (95% CI)	**0.57 (0.42–0.77)**	
	2-sided *P*<0.001	

VERITAC-2 Primary Endpoint: PFS by BICR in All Patients



	Vepdegestrant n=313	Fulvestrant n=311
Median follow-up, months	7.4	7.2
Events, n (%)	186 (59)	198 (64)
Median PFS, months (95% CI)	**3.7 (3.6–5.3)**	**3.6 (2.2–3.8)**
Stratified HR (95% CI)	**0.83 (0.68–1.02)**	
	2-sided *P*=0.07	

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EMBER-3 Study Design

N= 874
- 37.3% with *ESR1*mut
- 35.7% were treatment in naïve in metastatic setting
- 60% prior CDKi
  - 65% prior palbociclib

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ER+, HER2- ABC

Men and Pre-[a]/Post-menopausal women

Prior therapy:
- **Adjuvant**: Recurrence on or within 12 months of completion of AI ± CDK4/6i
- **ABC:** Progression on first-line AI ± CDK4/6i
- No other therapy for ABC

Stratification Factors:
- Prior CDK4/6i therapy (Y/N)
- Visceral metastases (Y/N)
- Region[c]

R 1:1:1[b] N=874

- **A** — Imlunestrant 400 mg QD
- **B** — SOC ET[d,e] Fulvestrant or Exemestane
- **C[b]** — Imlunestrant 400 mg QD + abemaciclib[e]

Primary Endpoints

Investigator-assessed PFS for[f]:
- A vs B in patients with *ESR1*m[g]
- A vs B in all patients
- C vs A in all[h] patients

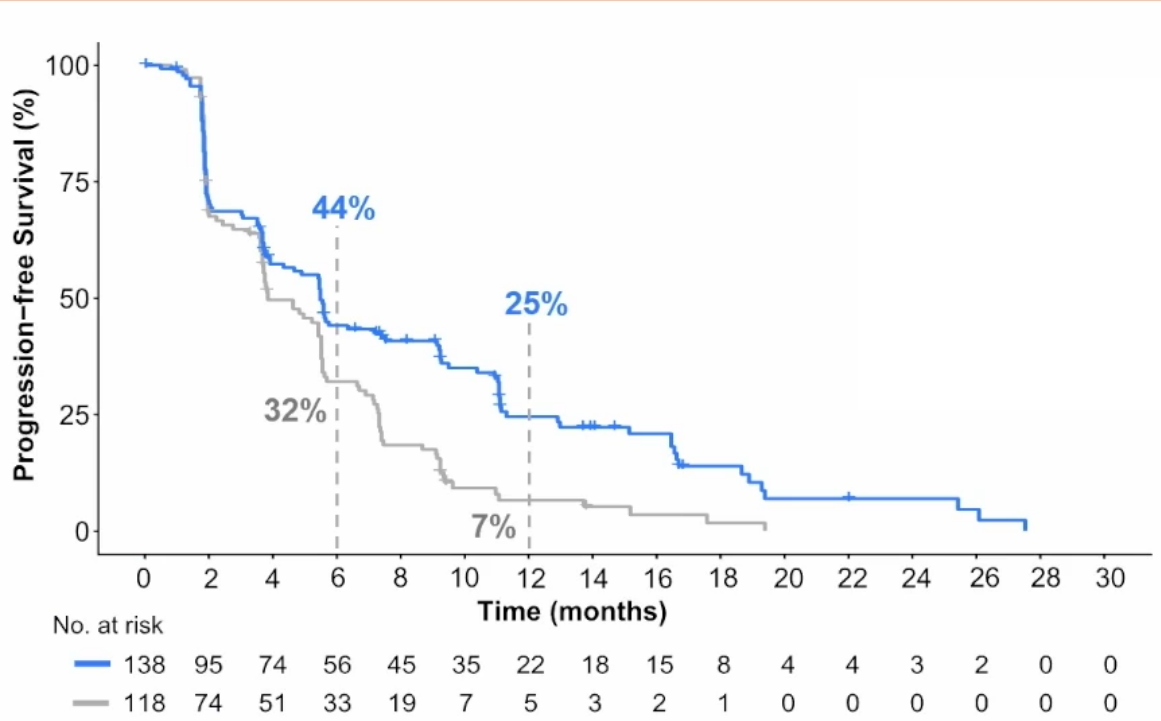
Key Secondary Endpoints
- OS, PFS by BICR, and ORR
- Safety

Exploratory Endpoints
- PFS and OS for C vs B in all[h] patients

ABC, advanced breast cancer; AI, aromatase inhibitor; BICR, blinded independent central review; CDK4/6i CDK4/6 inhibitor; ER, estrogen receptor; *ESR1*m, *ESR1* mutation; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QD, once daily; SOC ET, standard of care endocrine therapy. Patients were enrolled from October 2021 to November 2023 across 195 sites in 22 countries. [a] A GnRH agonist was required in men and premenopausal women; [b] Enrollment into Arm C started with Protocol Amendment A (at which point 122 patients had been randomized across Arms A and B); [c] East Asia vs United States/European Union vs others; [d] Investigator's choice; [e] Labeled dose; [f] Scans every 8 weeks for the first 12 months, then every 12 weeks; [g] *ESR1*m status was centrally determined in baseline plasma by the Guardant 360 ctDNA assay and OncoCompass Plus assay (Burning Rock Biotech) for patients from China; [h] Analysis conducted in all concurrently randomized patients.

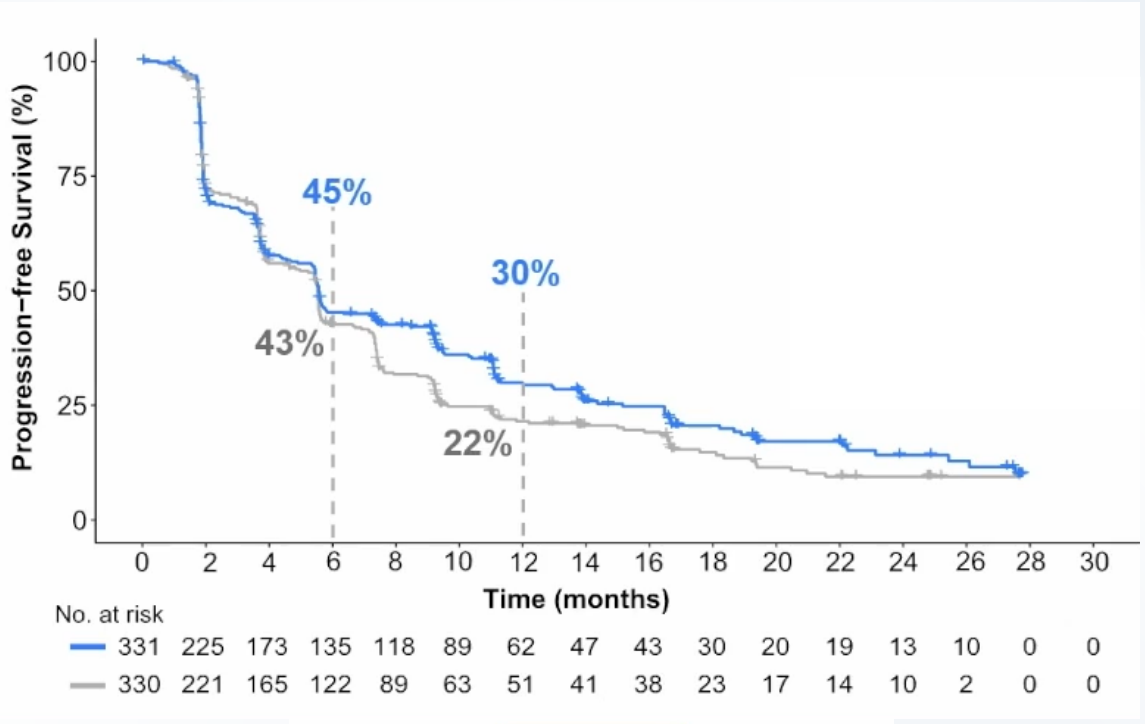
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Primary Endpoint: Imlunestrant vs SOC ET Investigator-assessed PFS in Patients with *ESR1*m



	Imlunestrant n=138	SOC ET n=118
No. of events	109	102
Median (95% CI); Months	**5.5** (3.9-7.4)	**3.8** (3.7-5.5)
HR (95% CI)	**0.62 (0.46-0.82)**[a] *p*-value<0.001	

Primary Endpoint: Imlunestrant vs SOC ET Investigator-assessed PFS in All Patients



	Imlunestrant n=331	SOC ET n=330
No. of events	237	253
Median (95% CI); Months	**5.6** (5.3-7.3)	**5.5** (4.6-5.6)
HR (95% CI)	**0.87 (0.72-1.04)** *p*-value 0.12	

Prespecified Critical HR < 0.84[a]

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PHASE 3 oral SERD studies

	Elacestrant	Imlunestrant	Vepdegestrant
Study name	EMERALD	EMBER-3	VERITAC-2
Total n	477	834	634
Post-CDK	100%	60%	100%
Prior SERD	30.4%	0%	0%
Prior chemo	22%	0%	0%
ESR1mut PFS	3.8 mo elacestrant vs 1.9 mo SOC	5.5 mo imlunestrant vs 3.8 mo SOC ET	5.1 mo vepdeg vs 3.1 mo SOC ET
Hazard Ratio	0.55	0.62	0.57
G3/4 AEs	27% elacestrant vs 20.5 % SOC	17.1% imlunestrant vs 20.7% SOC	23% vepdegestrant vs 18% SOC
Dose reductions	3.0% elacestrant vs NA SOC	2.4% imlunestrant vs NA SOC	2% vepdegestrant vs NA SOC
Dose discontinuations	6.3% elacestrant vs 4.4% SOC	4.3% imlunestrant vs 1.2% SOC	3% vepdegestrant vs 1% SOC

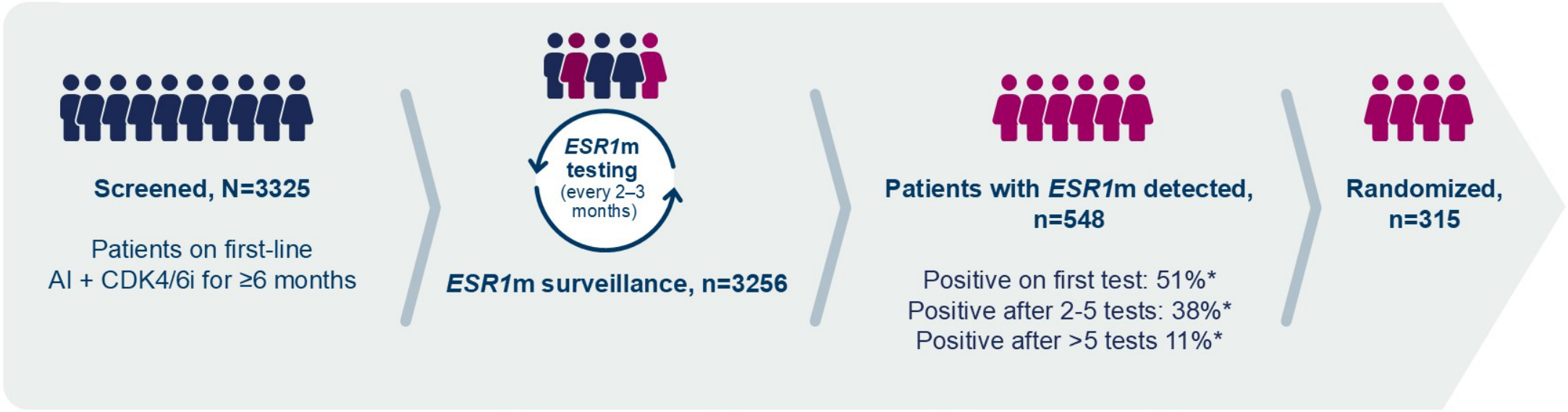
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Should we change first line therapy based on molecular progression (*ESR1mut)* prior to radiographic/ clinical progression?

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*ESR1*m surveillance during first-line AI+CDK4/6i

SERENA-6



Patients tested for *ESR1*m in ctDNA with Guardant360 CDx every 2–3 months at time of routine staging scans

Patients ongoing in surveillance when screening closed, n=1949

Discontinued (n=233) due to:

- Screen failure (n=200)
  - Concurrent disease progression (n=53)
  - Patient not meeting other eligibility criteria (n=48)
  - Reason not provided (n=99)
- Withdrew consent, lost to follow-up or unknown (n=33)

An estimate of the proportion of patients with emerging *ESR1*m during the study period is 42%, calculated from the 548 patients with a positive test/(the number of patients tested for *ESR1*m [n=3256] minus the number of patients that were still ongoing in surveillance when screening closed [n=1949]).

Number of tests to obtain a positive *ESR1*m test result based on n=521 patients who met all the eligibility criteria for the *ESR1m* surveillance step. Patients were screened for inclusion into the study from 264 sites in 23 countries.

Of the 3325 patients screened for inclusion, ctDNA from patient blood samples were tested for *ESR1*m using Guardant360CDx (Guardant Health, Redwood City, CA, US).

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SERENA-6 study design

Phase III, randomized, double-blind, placebo-controlled study (NCT04964934)

- Female/male patients with ER+/HER2– ABC*
- All patients that have received AI + CDK4/6i (palbociclib, ribociclib, or abemaciclib) as initial endocrine-based therapy for ABC for at least 6 months
- *ESR1*m detected in ctDNA with no evidence of disease progression

R 1:1

N=315

Camizestrant (75 mg qd) + continuing CDK4/6i + placebo for AI

Stratification factors

- Visceral vs non-visceral
- *ESR1*m detection at first test vs at a subsequent test
- Time from initiation of AI + CDK4/6i to randomization: <18 vs ≥18 months
- Palbociclib vs ribociclib vs abemaciclib

Continuing AI (anastrozole/ letrozole) + CDK4/6i + placebo for camizestrant

Treatment continued until disease progression, unacceptable toxicity, patient withdrawal or death

Primary endpoint

PFS by investigator assessment (RECIST v1.1)

Secondary endpoints

- PFS2**
- OS**
- Safety
- Patient-reported outcomes

*Pre- or perimenopausal women, and men received a luteinizing hormone–releasing hormone agonist per clinical guidelines. **Key secondary endpoint.
OS, overall survival; PFS2, second progression-free survival; qd, once daily dose; R, randomized; RECIST, response evaluation criteria in solid tumors.

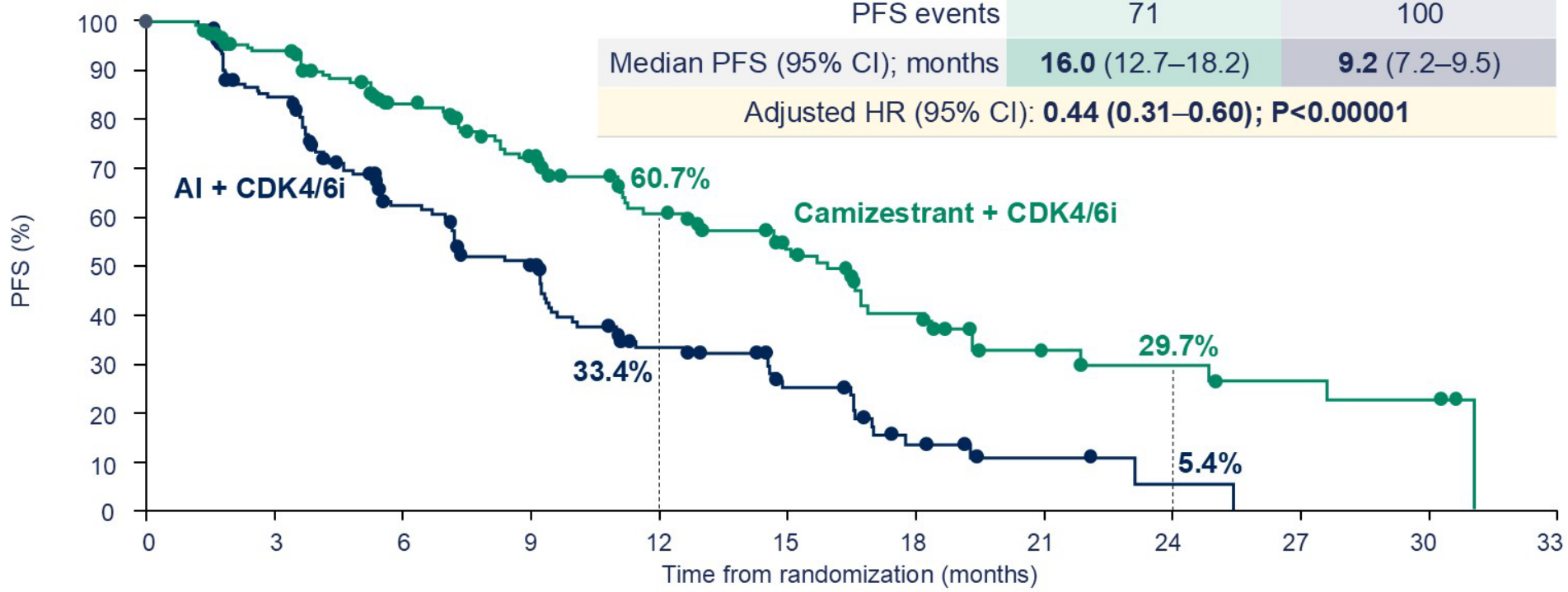
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Primary endpoint: Investigator-assessed PFS

SERENA-6

	Camizestrant + CDK4/6i (N=157)	AI + CDK4/6i (N=158)
PFS events	71	100
Median PFS (95% CI); months	**16.0** (12.7–18.2)	**9.2** (7.2–9.5)
Adjusted HR (95% CI): **0.44 (0.31–0.60); P<0.00001**		



Number of patients at risk

Camizestrant + CDK4/6i	157	138	105	82	55	41	26	11	9	7	6	0
AI + CDK4/6i	158	124	73	55	29	17	7	3	1	0	0	0

P-value crossed the threshold for significance (P=0.0001). PFS was defined per RECIST v1.1. HR was estimated using the Cox proportional hazard model adjusted for stratification factors.
CI, confidence interval; HR, hazard ratio.

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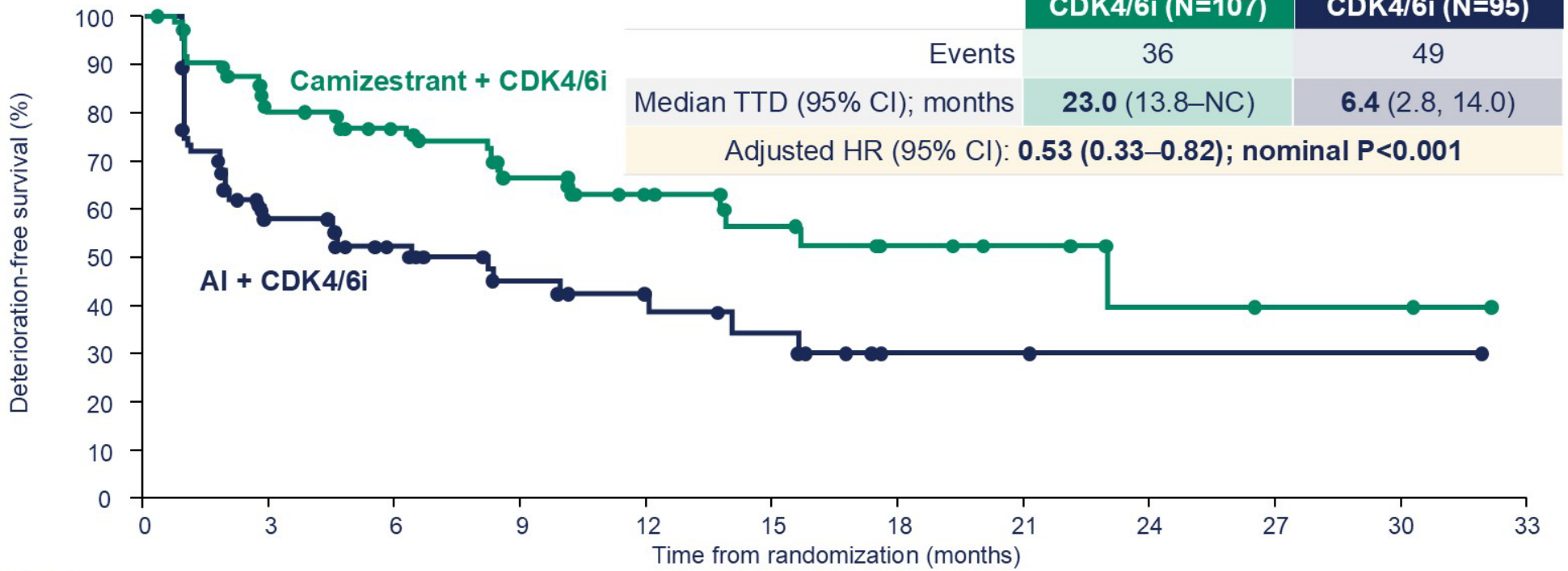
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Time to deterioration in global health status/quality of life

EORTC QLQ-C30

SERENA-6

	Camizestrant + CDK4/6i (N=107)	AI + CDK4/6i (N=95)
Events	36	49
Median TTD (95% CI); months	**23.0** (13.8–NC)	**6.4** (2.8, 14.0)
Adjusted HR (95% CI): **0.53 (0.33–0.82); nominal P<0.001**		



Number of patients at risk

Camizestrant + CDK4/6i	107	72	59	40	24	16	9	6	3	2	2	0
AI + CDK4/6i	95	42	26	16	11	8	2	2	1	1	1	0

- Camizestrant + CDK4/6i also delayed the time to deterioration in pain compared with AI + CDK4/6i

Assessments were conducted at baseline, weeks 4, 8 and 12 and then every 8 weeks until PFS2. Analysis conducted in patients with a baseline score and at least one post-baseline assessment. TTD in global health status/quality of life, an exploratory endpoint, was defined as the time from randomization to first deterioration that was confirmed at a subsequent timepoint measured using the European Organization for Research and Treatment of Cancer 30-item quality-of-life questionnaire (**EORTC QLQ-30**). Deterioration was defined as a decrease from baseline ≥16.6. HR was estimated using the Cox proportional hazard model stratified by time of *ESR1*m detection (one test vs more than one test), and time from initiation of AI + CDK4/6i to randomization (<18 months vs. ≥18 months). NC, not calculable; TTD, time-to-deterioration.

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Second progression-free survival (PFS2)

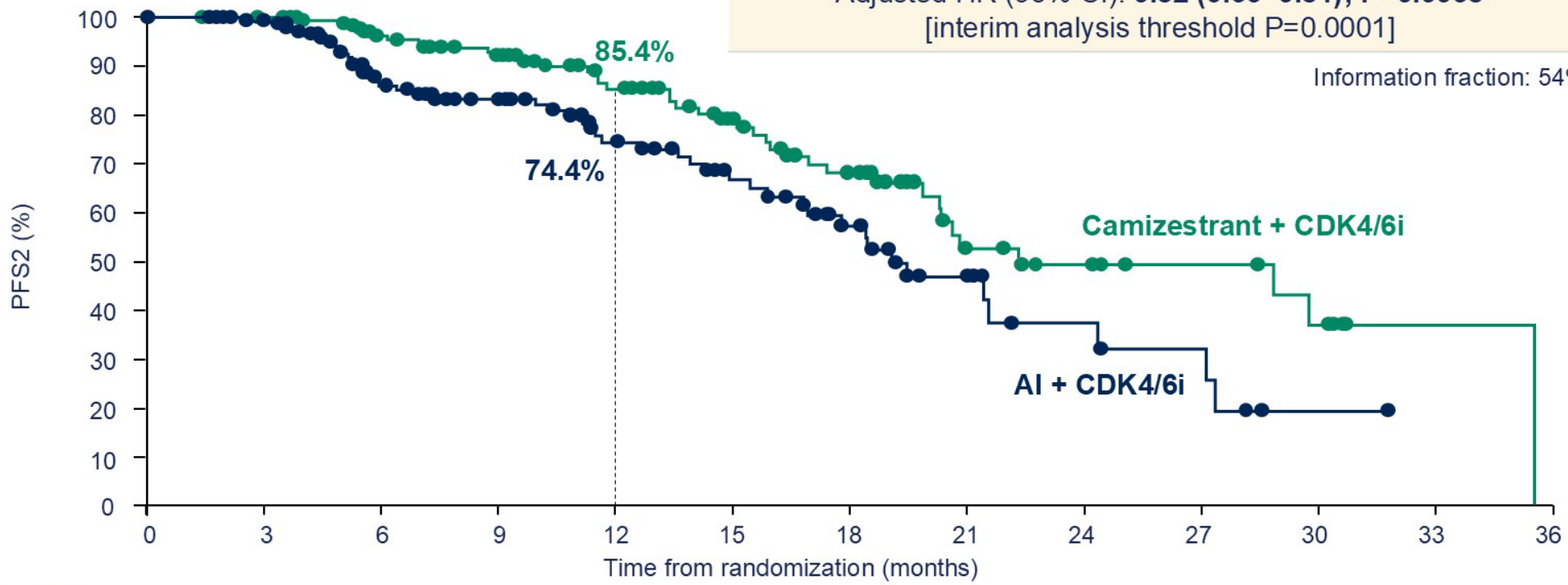
Key secondary endpoint

SERENA-6

	Camizestrant + CDK4/6i (N=157)	AI + CDK4/6i (N=158)
PFS2 events	38	47

Adjusted HR (95% CI): **0.52 (0.33–0.81); P=0.0038**
[interim analysis threshold P=0.0001]

Information fraction: 54%



Number of patients at risk

Camizestrant + CDK4/6i	157	146	120	103	74	55	39	17	12	9	6	1	0
AI + CDK4/6i	158	144	98	78	55	38	25	12	7	5	1	0	0

HR was estimated using the Cox proportional hazard model adjusted for stratification factors. Final PFS2 analysis will occur at 158 PFS2 events.

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SERENA 6 conclusions

Highly innovated study utilizing emerging biomarker to change therapy.

Limitations: Screening 3325 to find 315 patients. Is PFS-2 interpretable?

The control arm PFS was 9.2 months. Could ESR1 features or ESR1 VAF or VAF dynamics inform who benefits most from a switching strategy?

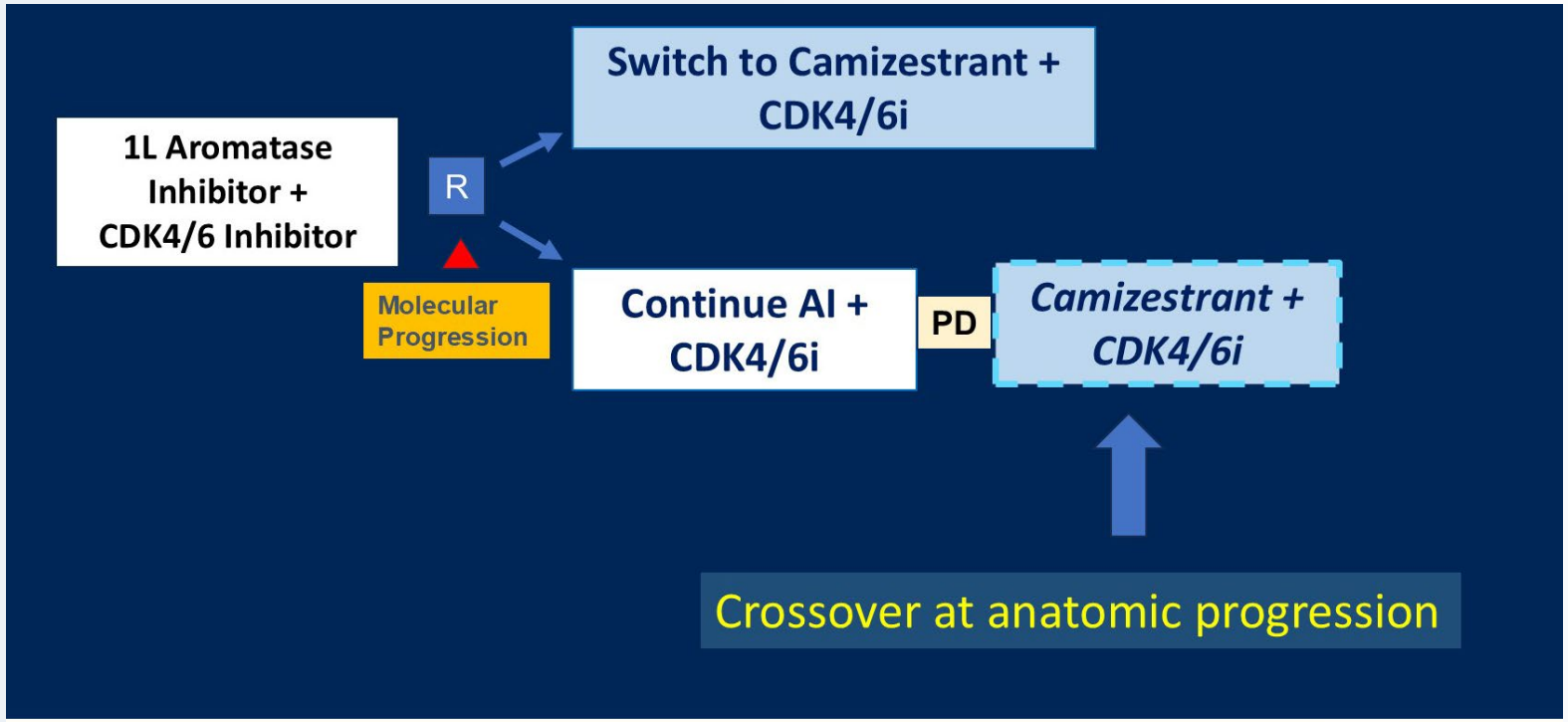


Table S6. Summary of Subsequent Anti-Cancer Regimen Contributing to Second Progression Free Survival

Subsequent regimen — no. (%)	Camizestrant+CDK4/6 inhibitor (n=57)	AI+CDK4/6 inhibitor (n=83)
Antibody-drug conjugate	**0**	**10 (12.0)**
Sacituzumab govitecan	0	1 (1.2)
Trastuzumab deruxtecan	0	8 (9.6)
Datopotamab deruxtecan	0	1 (1.2)
Chemotherapy	**26 (45.6)**	**19 (22.9)**
Anthracycline-based regimen	3 (5.3)	2 (2.4)
Pyrimidine-based regimen	15 (26.3)	11 (13.3)
Taxane-based regimen	11 (19.3)	7 (8.4)
Vinca alkaloids and analogues	1 (1.8)	0
Endocrine therapy + targeted therapy	**21 (36.8)**	**35 (42.2)**
Aromatase inhibitors + CDK4/6 inhibitor	4 (7.0)	4 (4.8)
Endocrine therapy + MTOR inhibitor	12 (21.1)	10 (12.0)
Fulvestrant + CDK4/6 inhibitor	3 (5.3)	9 (10.8)
Fulvestrant + PIK3CA or AKT inhibitor	2 (3.5)	8 (9.6)
Oral SERD + targeted therapy	0	4 (4.8)
Endocrine monotherapy	**14 (24.6)**	**23 (27.7)**
Anti-estrogens	1 (1.8)	1 (1.2)
Aromatase inhibitors	4 (7.0)	2 (2.4)
Fulvestrant	6 (10.5)	12 (14.5)
Oral SERD	0	8 (9.6)
Tamoxifen	3 (5.3)	0
Other†	**4 (7.0)**	**3 (3.6)**

Patients may have received more than one regimen. All categories reflect regimens containing the therapies without duplication. †Other includes poly (adp-ribose) polymerase inhibitors, bevacizumab, investigational agonist androgen receptor, abemaciclib monotherapy or pertuzumab.

AKT, protein kinase B; CDK4/6, cyclin-dependent kinase 4/6; MTOR, mechanistic target of rapamycin; PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha; SERD, selective estrogen receptor degrader.

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In patients with PIK3CA/AKT/PTEN pathway alterations:

Updated data on frontline triplet therapy (INAVO-120) and new 2L phase 3 data on ipatasertib (FINER)

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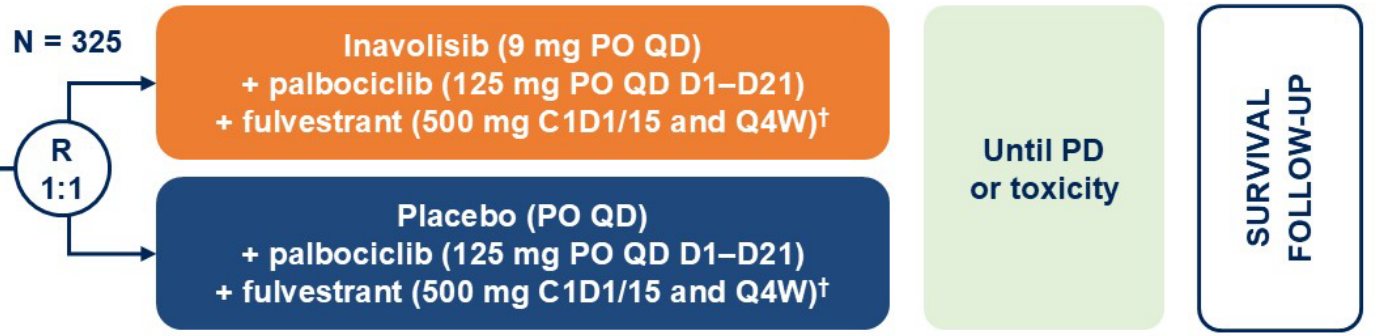
INAVO120: A Phase III, randomized, double-blind, placebo-controlled study[1,2]

Key eligibility criteria

Enrichment of patients with poor prognosis:

- ***PIK3CA*-mutated, HR+, HER2– aBC** by central ctDNA* or local tissue/ctDNA test
- **Measurable disease**
- **Progression during/within 12 months of adjuvant ET completion**
- **No prior therapy for aBC**
- **Fasting glucose <126 mg/dL and HbA_{1c} <6.0%**

Enrollment period: January 2020 to September 2023



Stratification factors:

- Visceral disease (yes vs. no)
- Endocrine resistance (primary vs. secondary)‡
- Region (North America/Western Europe vs. Asia vs. Other)

- Primary endpoint: Investigator-assessed PFS
- Secondary endpoints included: OS; investigator-assessed ORR, BOR, CBR, and DoR; PROs

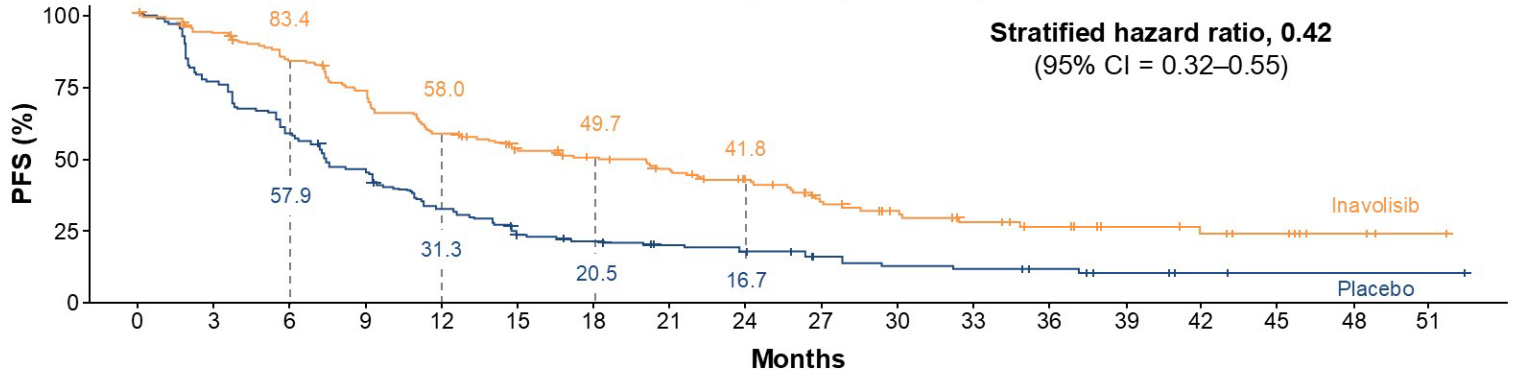
ClinicalTrials.gov number, NCT04191499.
Adapted from Jhaveri KJ, *et al.* SABCS 2023 (Abstract GS03-13). * Central testing for *PIK3CA* mutations was done on ctDNA using FoundationOne®Liquid (Foundation Medicine, Inc.). In China, the central ctDNA test was the PredicineCARE NGS assay (Huidu); † Pre-menopausal women received ovarian suppression; ‡ Defined per 4th European School of Oncology (ESO)–European Society for Medical Oncology (ESMO) International Consensus Guidelines for Advanced Breast Cancer.[3]
Primary: Relapse while on the first 2 years of adjuvant ET; secondary: Relapse while on adjuvant ET after at least 2 years or relapse within 12 months of completing adjuvant ET.
aBC, advanced breast cancer; BOR, best overall response; C, cycle; CBR, clinical benefit rate; ctDNA, circulating tumor DNA; D, day; DoR, duration of response; ET, endocrine therapy; HbA_{1c}, glycated hemoglobin; HER2–, HER2-negative; HR+, hormone receptor-positive; NGS, next-generation sequencing; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PO, by mouth; PRO, patient-reported outcome; Q4W, every 4 weeks; QD, daily; R, randomization.
1. Turner NC, *et al. N Engl J Med* 2024; **391:**1584–1596; 2. Jhaveri KJ, *et al.* SABCS 2023 (Abstract GS03-13); 3. Cardoso F, *et al. Ann Oncol* 2018; **29:**1634–1657.

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INAVO120 updated PFS

	Events, n (%)	Median, months (95% CI)
Inavolisib (n = 161)	103 (64.0)	17.2 (11.6–22.2)
Placebo (n = 164)	141 (86.0)	7.3 (5.9–9.2)

Stratified hazard ratio, 0.42
(95% CI = 0.32–0.55)



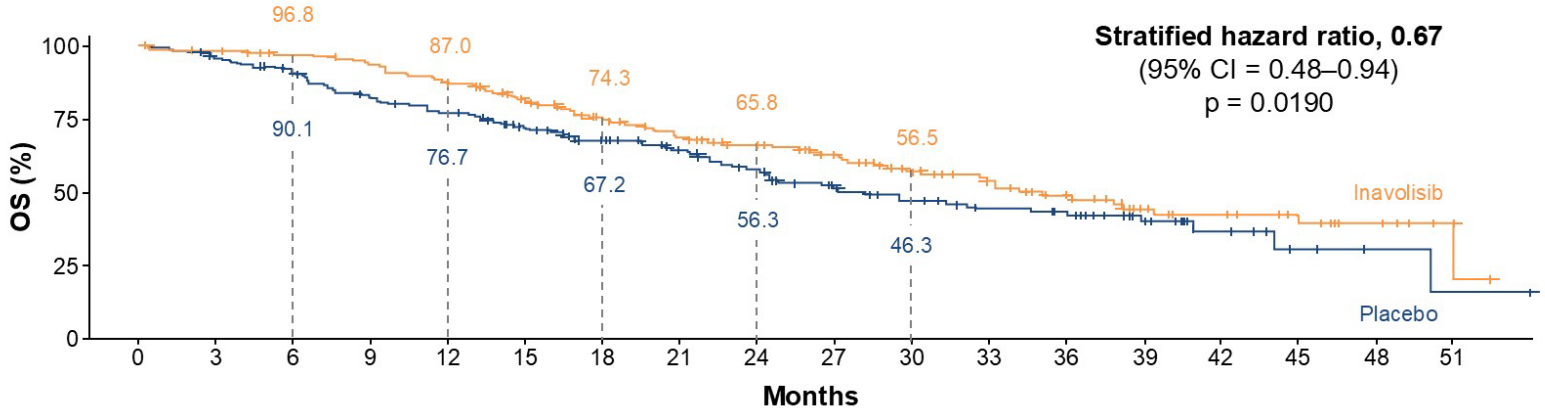
Median follow-up:
34.2 months

No. at risk																		
Inavolisib	161	146	129	112	89	73	65	57	46	32	25	19	15	11	10	7	3	1
Placebo	164	125	95	74	50	34	30	24	21	14	11	10	8	4	2	1	1	1

INAVO120 key secondary endpoint: OS

	Deaths, n (%)	Median, months (95% CI)
Inavolisib (n = 161)	72 (44.7)	34.0 (28.4–44.8)
Placebo (n = 164)	82 (50.0)	27.0 (22.8–38.7)

Stratified hazard ratio, 0.67
(95% CI = 0.48–0.94)
p = 0.0190



Median follow-up:
34.2 months

No. at risk																		
Inavolisib	161	155	149	142	131	114	99	88	78	67	54	43	34	22	19	13	7	1
Placebo	164	155	142	127	119	104	90	77	63	48	42	36	32	18	10	4	2	1

CCTG MA.40/FINER Trial Design

Study population:

- Stage IV ER+/HER-2 negative breast cancer
- Prior line of systemic treatment with CDK 4/6i and AI
- ECOG PS 0–1
- Measurable or evaluable disease

CDK 4/6i and AI progression → randomization ≦ 4 weeks

cfDNA for Stratification
(FoundationOne®Liquid CDx)

N=250

R
1:1

Ipatasertib + Fulvestrant
400 mg PO day 1-21

Stratification
- *PIK3CA/PTEN/AKT* altered vs wild type/unknown
- Primary versus secondary endocrine resistance

Placebo + Fulvestrant
Placebo PO day 1-21

Primary endpoint
- PFS by RECIST v1.1 in intent to treat (ITT) population

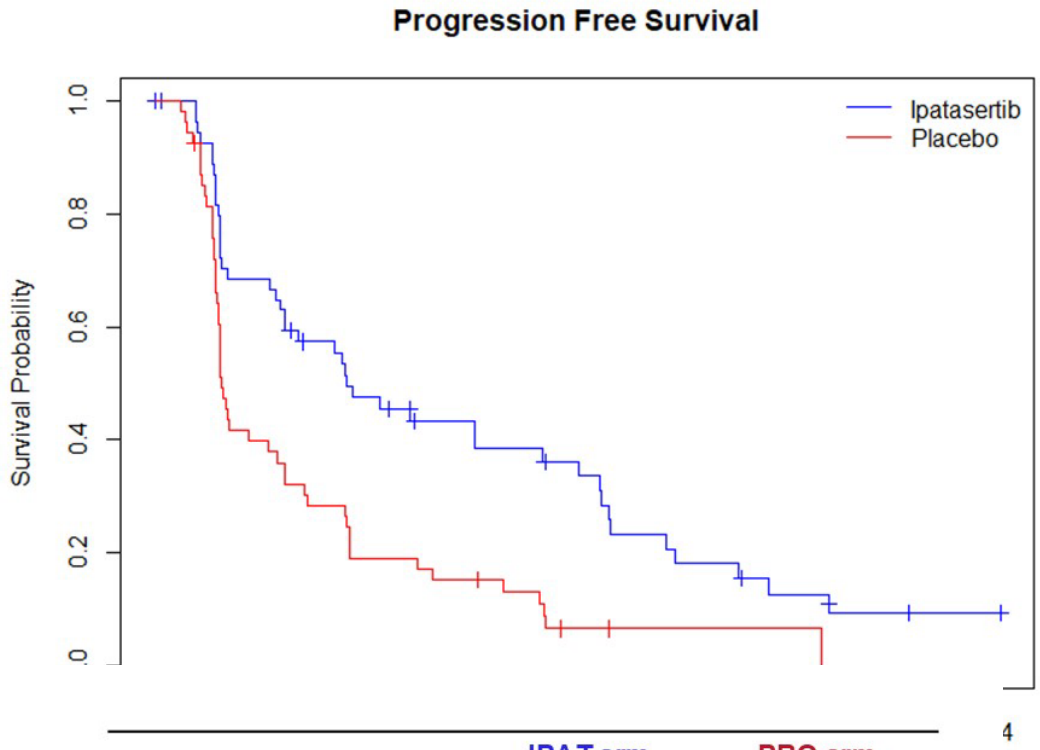
Key secondary endpoints
- PFS
  - by BICR in ITT
  - in AKT pathway altered cohort
- OS
- AEs
- QoL
- Health Economics
- Correlative

Today, we will present the final PFS analysis from ITT and biomarker altered cohort

Fulvestrant 500 mg IM days 1 and 14 and 28 then q28 days

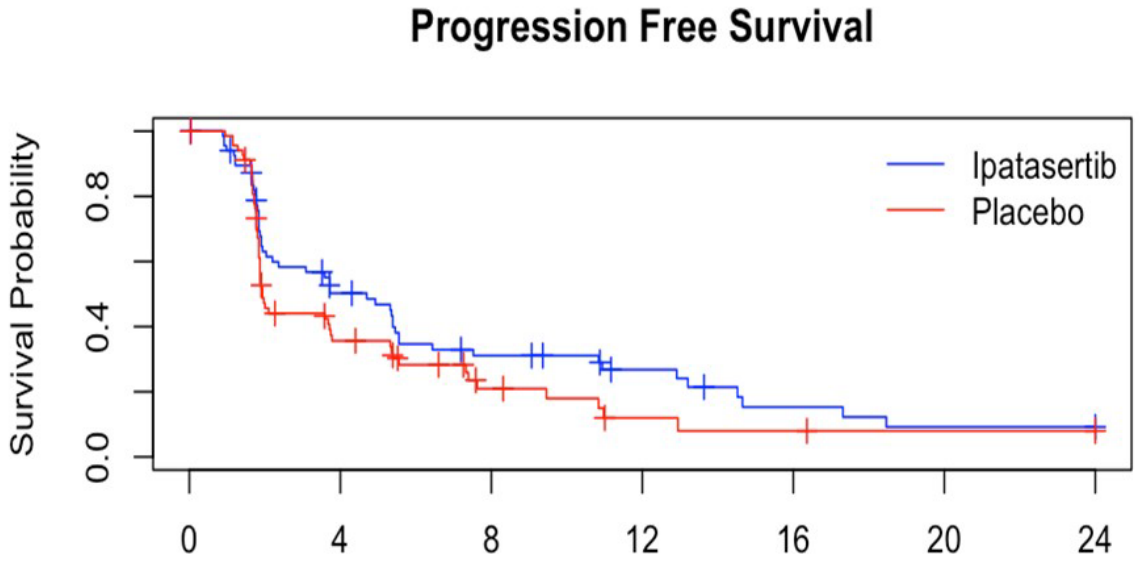
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PFS in AKT pathway altered cohort



	IPAT arm n=57	PBO arm n=54
Median follow-up: 15.2 months		
Median PFS (95% CI), months	5.45 (3.55-11.01)	1.91 (1.77-3.48)
HR (95% CI)	0.47 (0.31-0.72)	
***P*-value (2-sided)**	0.0005	

PFS in non-AKT altered cohort (exploratory analyses)



	IPAT arm n=68	PBO arm n=71
Median follow-up: 15.2 months		
Median PFS (95% CI), months	4.70 (2.04, 5.55)	1.94 (1.84, 3.75)
HR (95% CI)	0.75 (0.51-1.11)	

Benefit of PIK3CA/AKT/mTOR targeted therapy in the post-CDK4/6i setting (second line)

	Alpelisib	Capivasertib	Ipatasertib	Everolimus
Study name	BYLieve[1]	Capitello-291[2]	FINER[4]	ALCINA[3]
N	127	194	111	57
Biomarker selection	PIK3CA	PIK3CA/AKT/PTEN	PIK3CA/AKT/PTEN	None
Study design	Prospective, nonrandomized	Prospective, randomized	Prospective, randomized	Prospective, nonrandomized
mPFS	7.2 months	5.5 months	5.5 months	6.8 months
mPFS (control arm)	------	2.6 months (fulvestrant)	1.9 months (fulvestrant)	------

1. Rugo, Lancet 2021 2. Turner, NEJM 2023. 3. Vasseur, Oncogene 2024. 4. Chia, ASCO 2025.

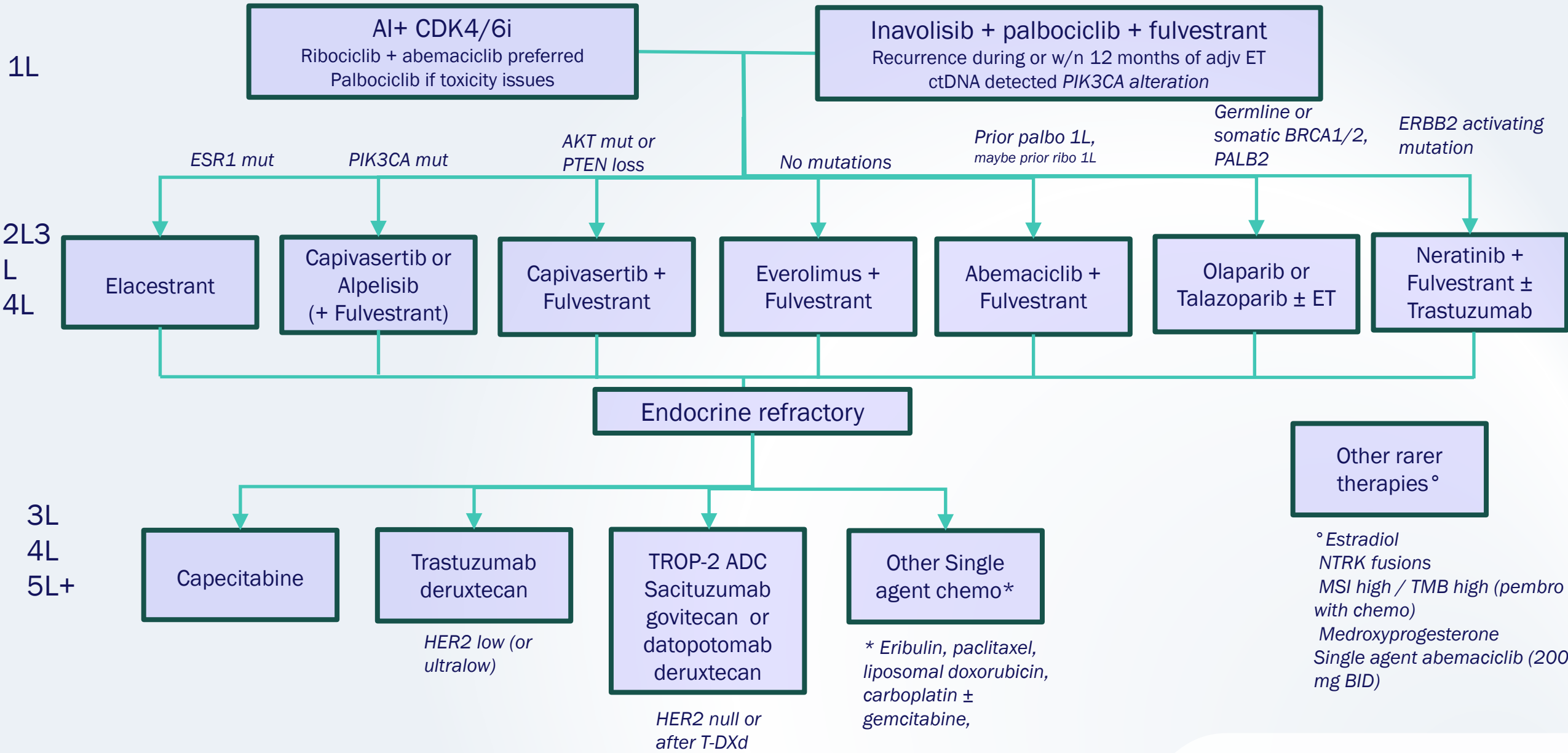
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AE profiles of PIK3CA/AKT targeted therapy

	Alpelisib	Inavolisib	Capivasertib	Ipatasertib
Study name	Solar-1[1]	INAVO-120[1]	Capitello-291[2]	FINER[4]
N	571	325	805	724
Dose interruptions	74% alpelisib 32.2% placebo	72.5% Inavolisib 40.5% placebo	34.9% Capivasertib 10.3% placebo	NR
Dose reductions	63.9% alpelisib 8.8% placebo	14.9% Inavolisib 3.9% placebo	19.7% Capivasertib 1.7% placebo	NR
Dose discontinuations due to AEs	25% alpelisib 4% placebo	6.8% Inavolisib 0.8% placebo	13% Capivasertib 2.3% placebo	6.5% Ipatasertib 0.8% placebo
AES of interest				
Hyperglycemia	63.7% any grade 34.6% G3/4	63.4% any grade 6.8% G3/4	16.3% any grade 2.3% G3/G4	43.6% any grade 0% G3/G4
Rash	35.6% any grade 9.9% G3/4	26.7% any grade 0% G3/4	22.0% any grade 5.4% G3/G4	25% any grade 1% G3/G4
Diarrhea	57.7% any grade 6.7% G3/G4	52.2% any grade 3.7% G3/G4	72.4% any grade 9.3% G3/G4	87.1% any grade 16.1% G3/G4
Stomatitis	24.6% any grade 2.5% G3/G4	55.3% any grade 5.6% G3/G4	14.6% any grade 2.0% G3/G4	16.1% any grade 0% G3/G4

1. Andre, NEJM 2019 2 Jhaveri, NEJM 2025 3. Turner, NEJM 2023. 4. Chia ASCO 2025

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HER2 Positive Breast Cancer

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Key updates in 2025 for HER2 PositiveBreast Cancer

Early Stage:

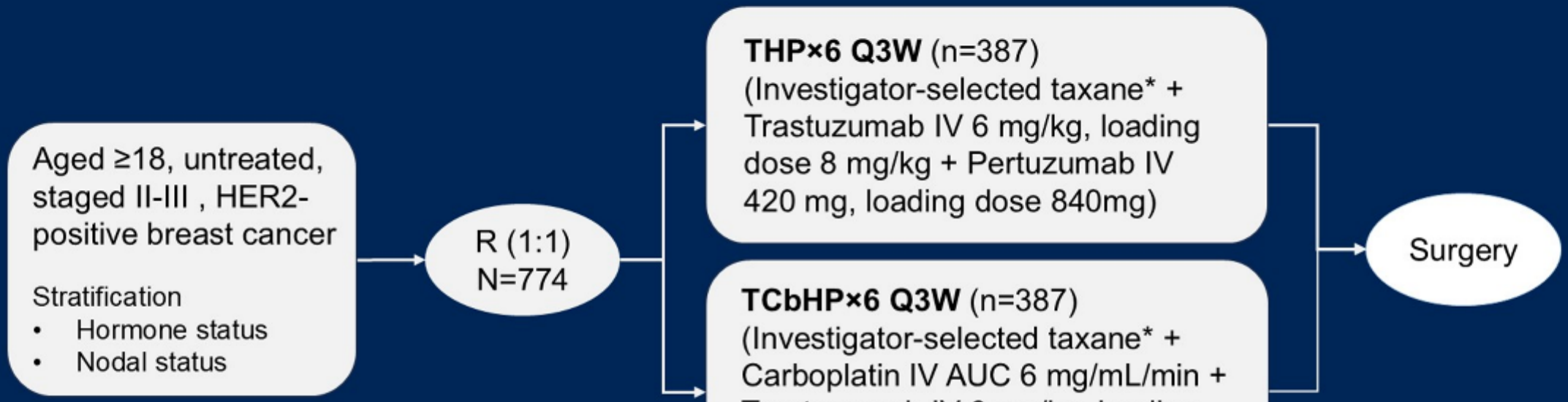
neoCARP: de-escalated neoadjuvant THP vs TCHP

Advanced / Metastatic:

- DESTINY-Breast09/I moving T-DXd into the first line setting
- MINI trial: Chemotherapy free 1L therapy - Ribociclib with Trastuzumab + ET

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neoCARHP Study Design (NCT04858529)



- Primary endpoint: pCR (ypT0/is ypN0)
- Secondary endpoints: Safety, clinical response during neoadjuvant therapy, EFS, DFS, OS

* Docetaxel, Paclitaxel or Nab-paclitaxel

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Pathologic Complete Response
No different by adding carboplatin

Trial	pCR Overall	pCR in ER-positive	pCR in ER-negative
neoCARHP-TCHPx6	66%	59%	78%
neoCARHP-THPx6	64%	56%	78%

Safety:

- Increased grade 3/4 adverse events in TCHP arm: neutropenia (16.4% vs 6.8%), febrile neutropenia (2.6% vs. 1.3%), thrombocytopenia (4.2% vs. 0.3%), anemia (6.6% vs. 2.1%)

- Higher all grade nausea, vomiting, increased creatinine

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Conclusions

- THP provided non-inferior pCR and improved tolerability compared with TCbHP, while keeping the patient-friendly 3-weekly dosing schedule.

- Omitting carboplatin could be an efficacious de-escalated neoadjuvant strategy in the presence of dual HER2 blockade for patients with HER2-positive early breast cancer.

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Take Home Message

- Can we omit carboplatin from standard neoadjuvant THP?
  - Yes, with these caveats
    - Only one-quarter of patients had stage III disease; would still use TCHP in stage III unless long term outcomes are similar
    - Insufficient evidence to support q3 weekly nab-paclitaxel or q3 weekly paclitaxel. Would recommend qweekly paclitaxel or q3 weekly docetaxel
  - Await EFS, DFS, OS data
  - Await biomarker data – can we better select pts who may benefit from carboplatin?

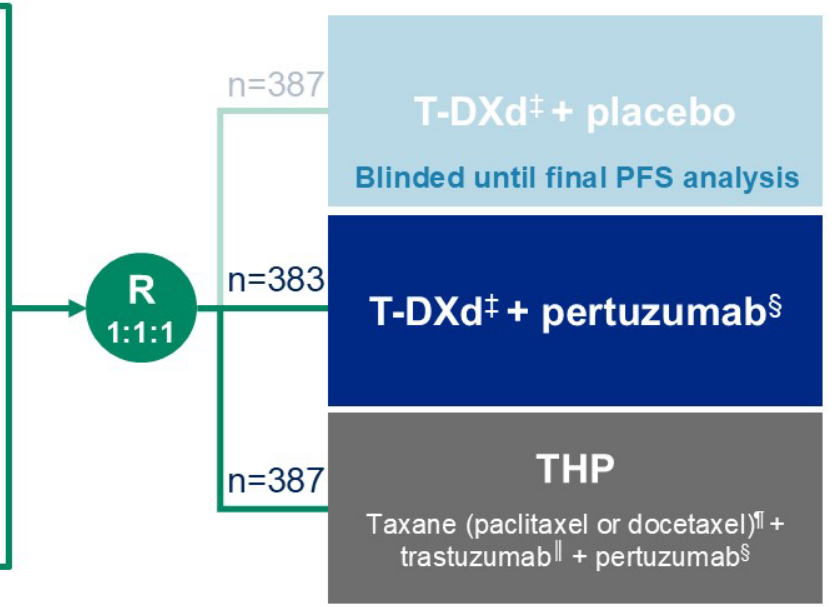
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DESTINY-Breast09 study design

A randomized, multicenter, open-label,* Phase 3 study (NCT04784715)

Eligibility criteria

- HER2+ a/mBC
- Asymptomatic/inactive brain mets allowed
- DFI >6 mo from last chemotherapy or HER2-targeted therapy in neoadjuvant/adjuvant setting
- One prior line of ET for mBC permitted
- **No other prior systemic treatment for mBC†**



Endpoints

Primary

- PFS (BICR)

Key secondary

- OS

Secondary

- PFS (INV)
- ORR (BICR/INV)
- DOR (BICR/INV)
- PFS2 (INV)
- Safety and tolerability

Stratification factors

- De-novo vs recurrent mBC
- HR+ or HR−
- *PIK3CA*m (detected vs non-detected)

At this planned interim analysis (DCO Feb 26, 2025), results are reported for the T-DXd + P and THP arms

*Open label for THP arm. Double blinded for pertuzumab in experimental arms; †HER2-targeted therapy or chemotherapy; ‡5.4 mg/kg Q3W; §840 mg loading dose, then 420 mg Q3W; ¶paclitaxel 80 mg/m² QW or 175 mg/m² Q3W, or docetaxel 75 mg/m² Q3W for a minimum of six cycles or until intolerable toxicity; ‖8 mg/kg loading dose, then 6 mg/kg Q3W

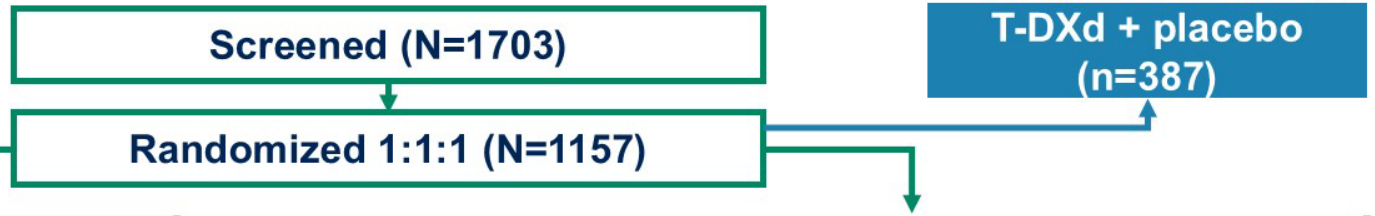
a/mBC, advanced/metastatic breast cancer; BICR, blinded independent central review; DCO, data cutoff; DFI, disease-free interval; DOR, duration of response; HER2, human epidermal growth factor receptor 2; HER2+, HER2-positive; HR+/−, hormone receptor–positive/–negative; INV, investigator; mBC, metastatic breast cancer; mets, metastases; mo, months; ORR, objective response rate; OS, overall survival; P, pertuzumab; PFS, progression-free survival; PFS2, second progression-free survival; *PIK3CA*m, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha mutation; Q3W, every 3 weeks; QW, once every week; R, randomization; T-DXd, trastuzumab deruxtecan

NCT04784715. Updated. May 6, 2025. Available from: https://clinicaltrials.gov/study/NCT04784715 (Accessed May 29, 2025)

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Patient disposition



Discontinuation reasons, %*	T-DXd + P (n=383) Treated (n=380; 99.2%)	THP (n=387) Treated (n=383; 99.0%)‡	
	Discontinued **T-DXd** (59.7%)*†	Discontinued **taxane** (96.3%)*	Discontinued **trastuzumab** (66.6%)*
PD	21.3	18.8	52.5
AE	20.8	25.8	3.4
Patient decision	11.1	7.3	5.7
Protocol deviation	0.3	0.3	0.3
Lost to follow up	–	0.5	0.5
Other	2.4	43.6§	3.7
Death	3.9	–	0.5

- In the T-DXd + P arm, **8.7% (n=33/380)** of patients switched to trastuzumab (+ P) after discontinuation of T-DXd for reasons other than PD
- Concurrent ET use was **13.5% (T-DXd + P)** vs **38.3% (THP)** among patients with HR+ disease¶

At DCO, 39.6% (n=302) of patients remained on **any treatment**: 45.8% (n=174) T-DXd + P vs 33.4% (n=128) THP*

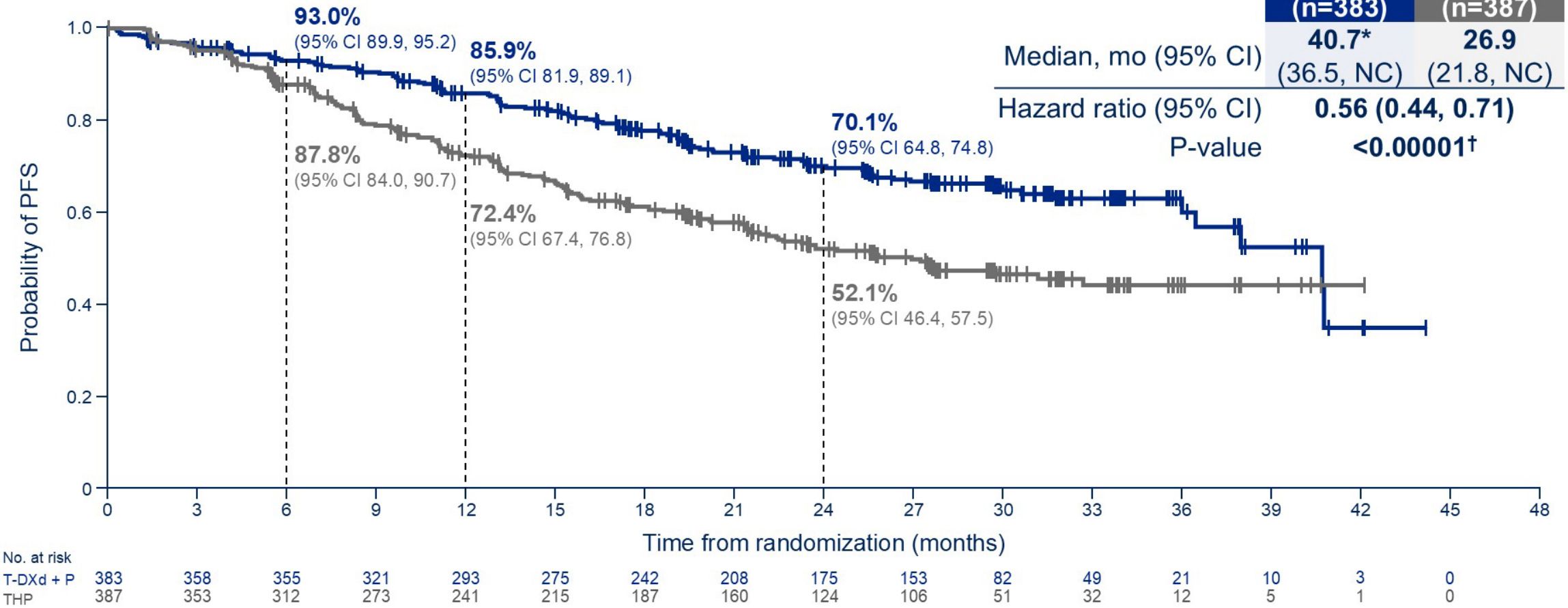
Median duration of follow up: 29.2 months

Pertuzumab could not be continued as a single agent without T-DXd or trastuzumab. THP was administered as per institutional standards
*Percentages are based on the patients who started treatment; †54.2% of patients discontinued all treatments; ‡64.6% (n=250) of patients were assigned to docetaxel, and 34.4% (n=133) were assigned to paclitaxel; §>50% of patients completed the minimum of six cycles of taxane per protocol; ¶patients with HR+ disease could receive ET after six cycles of T-DXd or discontinuation of taxane
AE, adverse event; DCO, data cutoff; ET, endocrine therapy; HR+, hormone receptor–positive; P, pertuzumab; PD, progressive disease; PFS, progression-free survival; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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PFS (BICR): primary endpoint

	T-DXd + P (n=383)	THP (n=387)
Median, mo (95% CI)	40.7* (36.5, NC)	26.9 (21.8, NC)
Hazard ratio (95% CI)	0.56 (0.44, 0.71)	
P-value	<0.00001†	



No. at risk

T-DXd + P	383	358	355	321	293	275	242	208	175	153	82	49	21	10	3	0
THP	387	353	312	273	241	215	187	160	124	106	51	32	12	5	1	0

Statistically significant and clinically meaningful PFS benefit with T-DXd + P (median Δ 13.8 mo)

*Median PFS estimate for T-DXd + P is likely to change at updated analysis; †stratified log-rank test. A P-value of <0.00043 was required for interim analysis superiority
BICR, blinded independent central review; CI, confidence interval; mo, months; (m)PFS, (median) progression-free survival; NC, not calculable; P, pertuzumab; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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Take Home points

- T-DXd + P demonstrates significant improvement in PFS compared to THP (40.7mo vs 26.9mo)
- 44% reduction in risk of death or progression (HR = 0.56)
- Almost 2x CR rate with T-DXd + P (15.1% vs 8.5%)
- OS is trending towards T-DXd + P

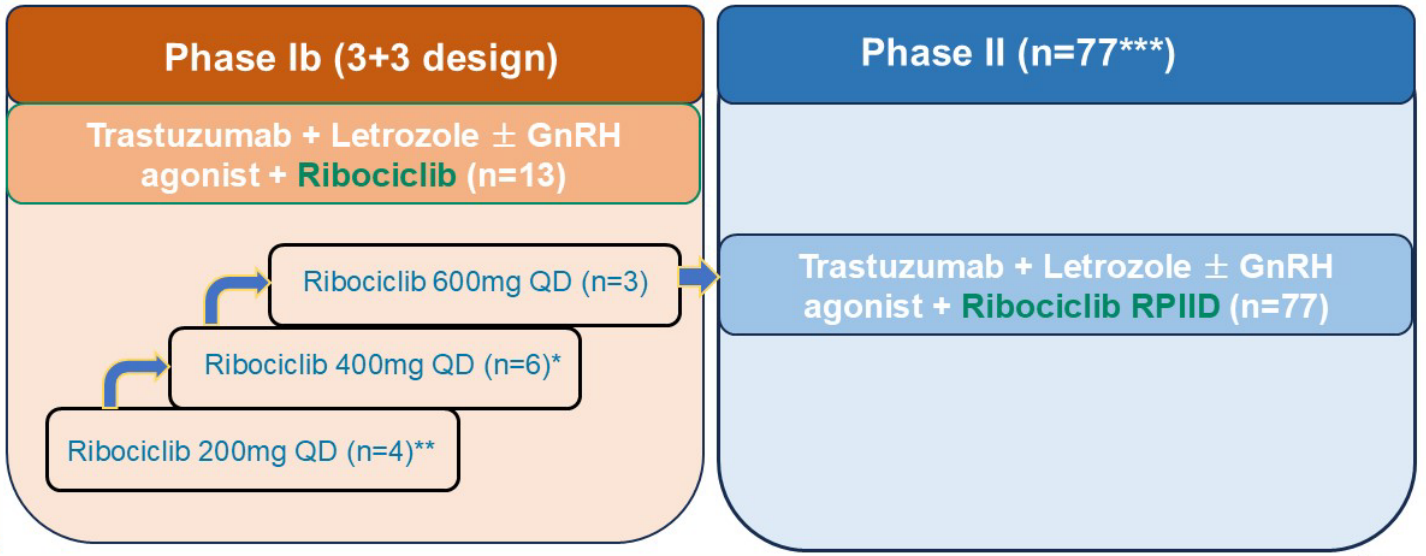
- Different study population
  - Access to pertuzumab and/or TDM-1 adjuvant
  - Access to T-DXd in 2+ line setting
- Toxicity with T-DXd + P is >>>> maintenance THP
- Better biomarkers or clinical features for identifying who benefits is critical.
- DEMETHER trial - Is induction + Maintenance strategy sufficient?

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Study Design

KEY ELIGIBILITY CRITERIA

- Metastatic Breast Cancer
- HR+/HER2+
- Pre- or Postmenopause
- No prior systemic Tx for MBC
- Previous (neo) adjuvant trastuzumab or ET is not allowed unless
  - DFI > 12 mo from last Trastuzumab
  - Adjuvant ET > 2 years
- Stable CNS metastasis allowed
- Baseline LVEF within normal range

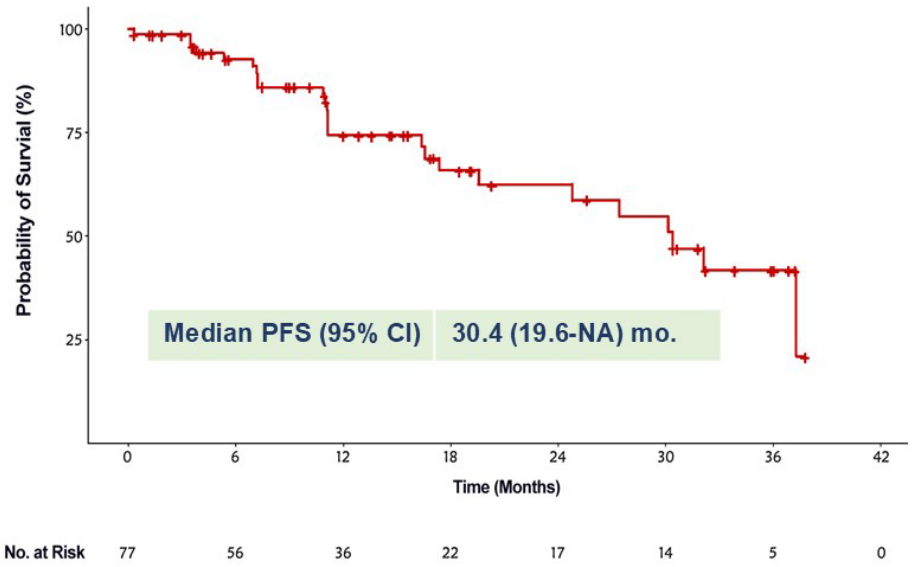


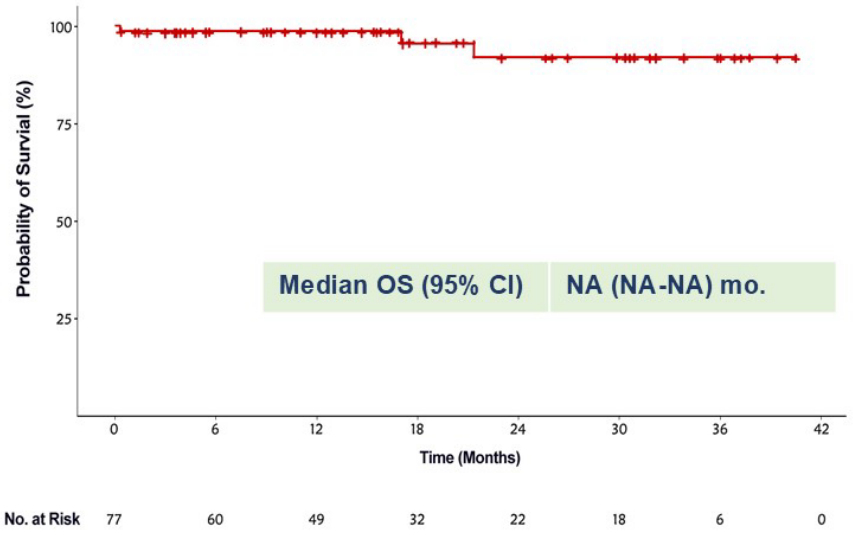
- Primary Endpoint
  - Phase Ib: Determination of RPIID
  - Phase II: PFS
- Key Secondary Endpoints
  - OS, ORR, DOR, and safety
- PAM50 testing was assessed to see correlations between intrinsic subtype and treatment efficacy (n=77).

- Trastuzumab was administered at 8mg/kg as a loading dose, followed by 6mg/kg every 3 weeks. Letrozole was administered at 2.5mg once daily (QD). Ribociclib was administered on a schedule of 3 weeks on, 1 week off.
- * A dose-limiting toxicity (G3 ALT elevation) was observed in 400mg cohort. ** One death from aortic aneurysm was reported, precluding DLT assessment.
- *** H0 8 months, H1 12 months, 80% power and a two-sided alpha of 0.05, accounting for a 20% dropout rate. This corresponds to a 33% reduction in hazard ratio.
- TAnDEM trial showed PFS of 5.8 months (95% CI, 4.6-8.3 months) with 1st line trastuzumab plus anastrozole in HER2+HR+ MBC..

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PFS and OS in phase II population (n=77)





Median follow up (95% CI) of 15.8 (12.9-19.1) months

No difference by PAM50 molecular subtypes

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Conclusion

Important to consider targeted and/or endocrine therapy in the treatment of HR+/HER2+ MBC

MINI - 1L Ribociclib + Trastuzumab and endocrine therapy is a safe and effective chemo free option (supported by many other trials DETECT V, ASPIRE, and PATINA (maintenance)

PERTAIN (no CDK 4/6i) showed 20.6mo PFS benefit in AI+HP compared to 15.8mo in AI+H

How do we put this into context if DB09 moves up to 1L therapy?

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Triple Negative Breast Cancer

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Key updates in 2025 for Triple Negative Breast Cancer

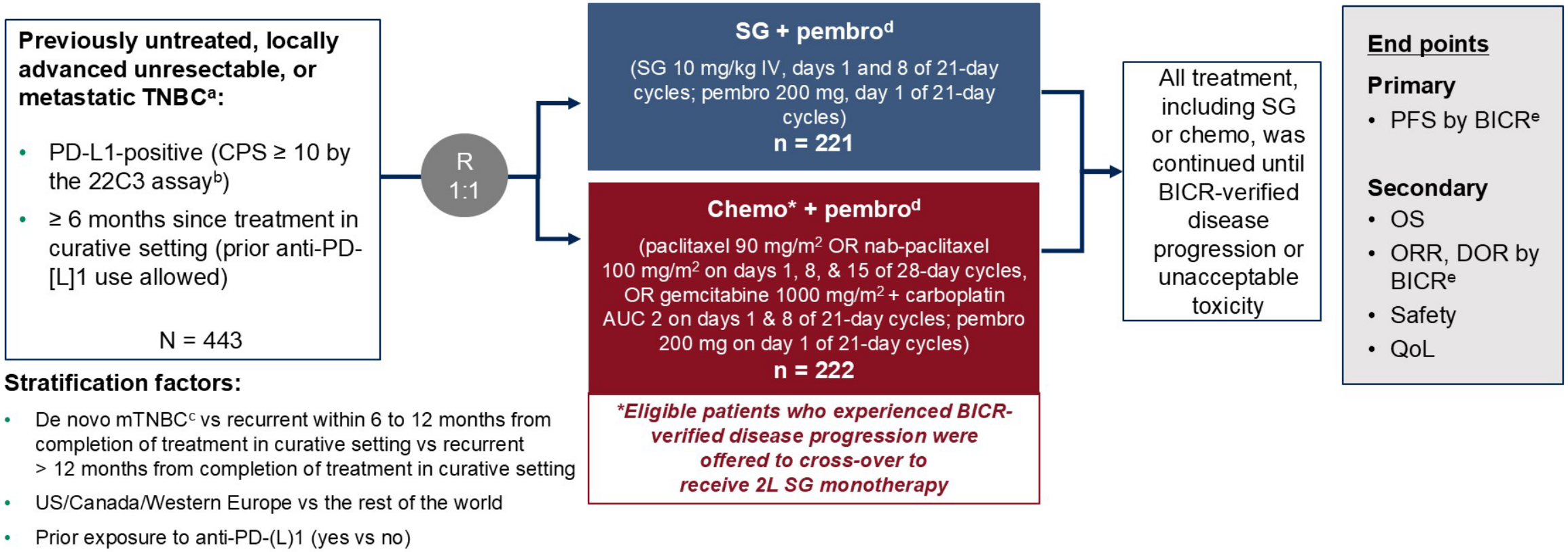
Early Stage:

Advanced / Metastatic:

- ASCENT-04: Moving Sacituzumab-Govetican to 1L setting in mTNBC

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ASCENT-04/KEYNOTE-D19 Study Design



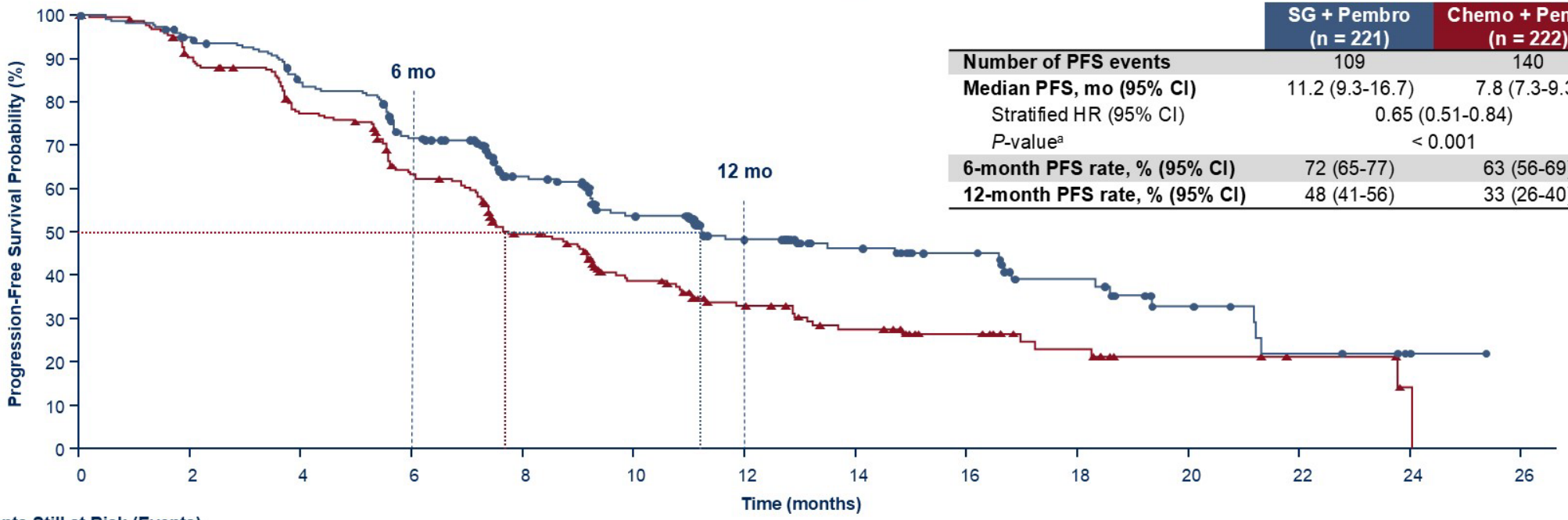
Stratification factors:

- De novo mTNBC[c] vs recurrent within 6 to 12 months from completion of treatment in curative setting vs recurrent > 12 months from completion of treatment in curative setting
- US/Canada/Western Europe vs the rest of the world
- Prior exposure to anti-PD-(L)1 (yes vs no)

ClinicalTrials.gov identifier: NCT05382286.
[a]TNBC status determined according to standard American Society of Clinical Oncology-College of American Pathologists criteria. [b]Dako, Agilent Technologies. [c]Up to 35% de novo mTNBC. [d]Pembro was administered for a maximum of 35 cycles. [e]Per RECIST v1.1.
AUC, area under the curve; BICR, blinded independent central review; chemo, chemotherapy; CPS, combined positive score; DOR, duration of response; IV, intravenously; ORR, objective response rate; OS, overall survival; PD-L1, programmed cell death ligand 1; pembro, pembrolizumab; PFS, progression-free survival; QoL, quality of life; R, randomized; RECIST v1.1; Response Evaluation Criteria in Solid Tumors, version 1.1; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; TTR, time-to-response.

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Progression-Free Survival by BICR



	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Number of PFS events	109	140
Median PFS, mo (95% CI)	11.2 (9.3-16.7)	7.8 (7.3-9.3)
Stratified HR (95% CI)	0.65 (0.51-0.84)	
P-value[a]	< 0.001	
6-month PFS rate, % (95% CI)	72 (65-77)	63 (56-69)
12-month PFS rate, % (95% CI)	48 (41-56)	33 (26-40)

No. of Patients Still at Risk (Events)

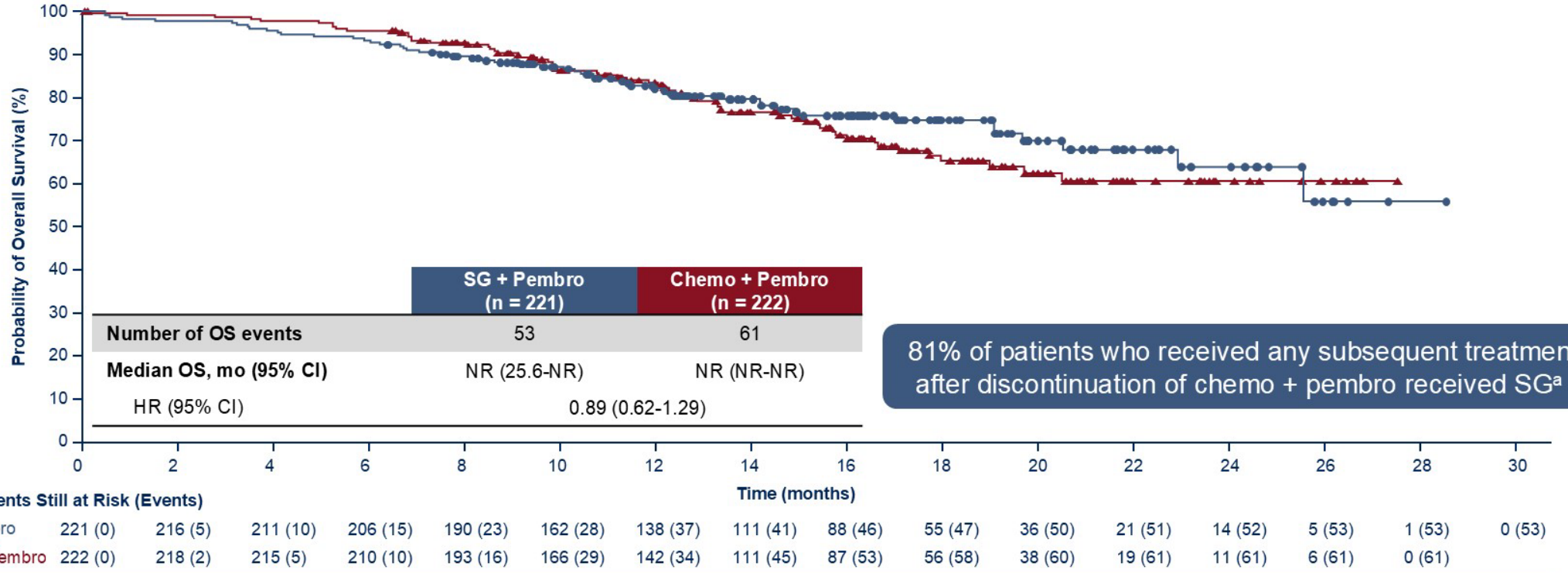
SG + Pembro	221 (0)	202 (11)	174 (33)	142 (59)	105 (75)	78 (89)	58 (96)	42 (98)	34 (99)	22 (103)	11 (106)	6 (109)	2 (109)	0 (109)
Chemo + Pembro	222 (0)	191 (21)	159 (48)	123 (76)	88 (102)	59 (120)	40 (128)	29 (134)	21 (135)	13 (137)	7 (138)	4 (138)	1 (139)	0 (140)

SG + pembro demonstrated statistically significant and clinically meaningful improvement in PFS vs chemo + pembro by BICR analysis, with a 35% reduction in risk of disease progression or death

Data cutoff date: March 3, 2025.
[a]Two-sided *P*-value from stratified log-rank test.
BICR, blinded independent central review; chemo, chemotherapy; HR, hazard ratio; PFS, progression-free survival; pembro, pembrolizumab; SG, sacituzumab govitecan.

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Descriptive Overall Survival at Primary Analysis



	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Number of OS events	53	61
Median OS, mo (95% CI)	NR (25.6-NR)	NR (NR-NR)
HR (95% CI)	0.89 (0.62-1.29)	

81% of patients who received any subsequent treatment after discontinuation of chemo + pembro received SG[a]

No. of Patients Still at Risk (Events)																
SG + Pembro	221 (0)	216 (5)	211 (10)	206 (15)	190 (23)	162 (28)	138 (37)	111 (41)	88 (46)	55 (47)	36 (50)	21 (51)	14 (52)	5 (53)	1 (53)	0 (53)
Chemo + Pembro	222 (0)	218 (2)	215 (5)	210 (10)	193 (16)	166 (29)	142 (34)	111 (45)	87 (53)	56 (58)	38 (60)	19 (61)	11 (61)	6 (61)	0 (61)	

OS data were immature (maturity rate, 26%), however, a positive trend in improvement was observed for SG + pembro vs chemo + pembro

Data cutoff date: March 3, 2025. Median follow-up was 14.0 months (range, 0.1-28.6).
[a]Of the 96 patients who received SG monotherapy as subsequent anticancer therapy, 77 received it as part of the protocol-specified crossover after meeting all crossover eligibility criteria, including BICR-verification of disease progression; the remaining 19 patients received subsequent SG monotherapy as commercial supply.
2L, second line; chemo, chemotherapy; HR, hazard ratio; pembro, pembrolizumab; NR, not reached; OS, overall survival; SG, sacituzumab govitecan.

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Conclusions

- ASCENT-04/KEYNOTE-D19 is the first randomized, phase 3 study to evaluate the efficacy and safety of an ADC/checkpoint inhibitor combination for first-line treatment of patients with PD-L1+[a] mTNBC
- SG + pembro led to a statistically significant and clinically meaningful improvement in PFS vs chemo + pembro (median 11.2 vs 7.8 months; HR, 0.65; 95% CI, 0.51-0.84; *P* < 0.001)
  - PFS benefit was observed across prespecified subgroups
- OS data are immature, but an early trend in improvement was observed
- ORR was higher (including an increased complete response rate), and responses were more durable with SG + pembro vs chemo + pembro
- The safety profile of SG + pembro was consistent with the established profiles of either agent; no additive toxicity was observed

Results from ASCENT-04/KEYNOTE-D19 support the use of SG + pembro as a potential new standard of care for patients with previously untreated, PD-L1+, locally advanced unresectable or metastatic TNBC

Data cutoff date: March 3, 2025
[a]CPS ≥ 10 per IHC 22C3 assay (Dako, Agilent Technologies).
ADC, antibody drug conjugate; chemo, chemotherapy; CPS, combined positive score; DOR, duration of response; HR, hazard ratio; IHC, immunohistochemistry; mTNBC; metastatic triple-negative breast cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed cell death ligand 1; pembro, pembrolizumab; PFS, progression-free survival; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer.

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Overall conclusions

- Many new treatment options
- Challenging to put new treatment options into context/practice without trials having an appropriate standard comparator arm or allowing for crossover
- DB09 and ASCENT04 are likely to change practice, we but need more data.
- Biomarkers - subgroup of patients to escalate vs de-escalate therapy in
- Is an “induction + maintenance” strategy equivalent to continuous?
- PROs and long term AE and follow up data is important

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Thank you!



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