

Integrating New Advances into Community Oncology Practice

CME/MOC, NCPD and ACPE Accredited

**Saturday, October 17, 2026
7:15 AM – 12:00 PM ET**



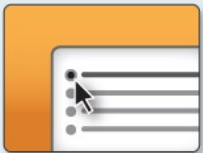
Welcome FCS Members!

Clinicians in the Meeting Room

Networked iPads are available.



Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.



Answer Survey Questions: Complete the premeeting survey.



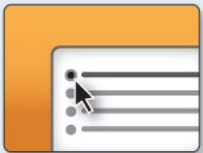
Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

Clinicians Attending via Zoom



Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.



Answer Survey Questions: Complete the premeeting surveys.



Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.



Get CME/ACPE/NCPD Credit: A credit link will be provided in the chat room at the conclusion of the program.

This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

Where We Are, Where We're Headed: Bispecific Antibodies in the Management of Follicular Lymphoma

A CME/MOC-Accredited Live Webinar

Thursday, October 22, 2026

5:00 PM – 6:00 PM ET

Faculty

Professor Chan Cheah, MBBS (Hons), DMSc
Matthew Matasar, MD

Moderator

Neil Love, MD

Second Opinion: A Case-Based Exploration of Clinical Investigator Best Practices Related to the Management of Breast Cancer

A CME Satellite Symposium Series at the San Antonio Breast Cancer Conference

HER2-Positive Breast Cancer

Tuesday, December 8, 2026

7:00 PM – 9:00 PM CT

Localized HR-Positive Breast Cancer

Thursday, December 10, 2026

7:00 PM – 9:00 PM CT

PI3K/AKT/mTOR Inhibitors for HR-Positive Breast Cancer

Tuesday, December 8, 2026

7:00 PM – 9:00 PM CT

Oral SERDs for HR-Positive Breast Cancer

Thursday, December 10, 2026

7:00 PM – 9:00 PM CT

Triple-Negative Breast Cancer

Wednesday, December 9, 2026

7:00 PM – 9:00 PM CT

A Friday Satellite Symposium Series Preceding the 68th ASH Annual Meeting in New Orleans

Friday, December 11, 2026

Acute Myeloid Leukemia

7:30 AM – 9:30 AM CT

Myelofibrosis

3:15 PM – 5:15 PM CT

Chronic Lymphocytic Leukemia

7:30 AM – 9:30 AM CT

**BCMA ADCs and Bispecific
Antibodies for Multiple Myeloma**

7:00 PM – 9:00 PM CT

Non-Hodgkin Lymphoma

11:30 AM – 1:30 PM CT

**Novel Therapies for
Non-Hodgkin Lymphoma**

7:00 PM – 9:00 PM CT

Multiple Myeloma

11:30 AM – 1:30 PM CT

Grand Rounds

CME/MOC-Accredited Interactive Series

Regional Activities

Four Series

**Squamous Cell
Carcinoma of the
Head and Neck**

**Gastroesophageal
Cancers**

**Hormone-Sensitive
Prostate Cancer**

**HER2-Positive
Breast Cancer**

**Host a 1-hour session at your institution:
Email Meetings@ResearchToPractice.com
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Save The Date

Sixth Annual National General Medical Oncology Summit

***A Multitumor CME/MOC, NCPD- and ACPE-Accredited
Educational Conference Developed in Partnership with
Florida Cancer Specialists & Research Institute***

Friday to Sunday, April 23 to 25, 2027

The Ritz-Carlton Orlando, Grande Lakes | Orlando, Florida

Moderated by Neil Love, MD

Solid Tumors

Scan to view video and slides from
5 recent programs held during the
2026 ASCO® Annual Meeting

EGFR-Mutated Non-Small Cell Lung Cancer



Sarah B Goldberg, MD
Jonathan Goldman, MD
Joel W Neal, MD, PhD
Antonio Passaro, MD, PhD
Jacob Sands, MD



Small Cell Lung Cancer



Anne Chiang, MD, PhD
Apar Kishor Ganti, MD
Luis Paz-Ares, MD, PhD
Misty Dawn Shields, MD, PhD

Colorectal Cancer



Tanios Bekaii-Saab, MD • Stacey A Cohen, MD •
Arvind Dasari, MD

Gastroesophageal Cancers



Yelena Y Janjigian, MD • Manish A Shah, MD •
Eric Van Cutsem, MD, PhD

Prostate Cancer



Wassim Abida, MD, PhD • Rahul Aggarwal, MD •
Emmanuel S Antonarakis, MD •
Karim Fizazi, MD, PhD • Rana R McKay, MD

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RECENT ADVANCES IN CANCER CARE

Access 4 free NCPD activities from our educational programs presented during the 2026 ONS Congress.

NCPD/ILNA Accredited

6 Contact or Pharmacotherapeutic Hours Available

Antibody-Drug Conjugates



Courtney Arn, CNP
Jamie Carroll, APRN
Edward Garon, MD
Heather McArthur, MD
Kathleen Moore, MD

Ovarian Cancer



Bradley Monk, MD
David O'Malley, MD
Kathryn Schlenker, WHNP-BC
Jaclyn Shaver, APRN



Prostate Cancer



Michael Lai, ARNP
Scott Tagawa, MD
Stacy Walker, FNP-BC
Evan Yu, MD

Endometrial Cancer



Dana Chase, MD
Sarah Karpen, PA-C
Jaclyn Shaver, APRN
Alejandro Rauh-Hain, MD



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Consulting General Medical Oncologists



Susmitha Apuri, MD

Florida Cancer Specialists & Research Institute
Inverness and Lecanto, Florida



Mamta Choksi, MD

Florida Cancer Specialists & Research Institute
Trinity, Florida



Sunil Gandhi, MD

Florida Cancer Specialists & Research Institute
Lecanto, Florida



Shaachi Gupta, MD, MPH

Florida Cancer Specialists & Research Institute
West Palm Beach, Florida



Maen Hussein, MD

Florida Cancer Specialists & Research Institute
The Villages, Florida



Renjitha Ignatius, MD

Florida Cancer Specialists & Research Institute
Sun City Center, Florida



Shachar Peles, MD

Florida Cancer Specialists & Research Institute
Lake Worth, Florida



Syed F Zafar, MD

Florida Cancer Specialists & Research Institute
Fort Myers, Florida



Dr Peles

“I walk into one room ... it’s a man with prostate cancer. The next patient has myeloma, and the next patient has lung cancer, and then maybe I’m seeing a patient with ITP.

Oncology is just exploding — accelerating as we go along. It’s a challenge to keep up with all the details and really helpful for us to have input from docs who focus on one area and can really tease out the nuances. Figuring out how to do that efficiently and obtain that input is critical for patient care.”

Select ESMO 2026 Abstracts

Presidential

Abstract LBA1

INTerpath-001: Phase 3 study of the mRNA-based individualized neoantigen therapy (INT) *intismeran* autogene (*intismeran*) plus *pembrolizumab* (*pembro*) vs *pembro* alone for adjuvant treatment of resected stage IIB-IV melanoma (MEL)
Georgina V Long

Abstract LBA2

Perioperative *durvalumab* with or without *tremelimumab* plus neoadjuvant *enfortumab vedotin* in muscle-invasive bladder cancer: Results from the phase 3 VOLGA trial
Thomas B Powles

Abstract LBA3

***Tarlatamab* plus *durvalumab* (*durva*) vs *durva* as 1L maintenance (1LM) therapy following *durva*, *platinum*, and *etoposide* (1L *durva* + EP) in extensive-stage small cell lung cancer (ES-SCLC): Primary analysis of the phase 3 DeLLphi-305 trial**
Jacob Sands

Select ESMO 2026 Abstracts

Presidential

Abstract LBA4

Darolutamide with androgen deprivation therapy (ADT) and definitive or salvage locoregional radiation therapy (RT) for localised, very high-risk prostate cancer: Interim analysis of an international, placebo-controlled, randomised phase 3 trial (DASL-HiCaP; ANZUP1801)
Tamim Niazi

Abstract LBA5

Krascendo 1: Efficacy and safety of **divarasib (diva)** vs **sotorasib (soto)** or **adagrasib (ada)** in previously treated locally advanced or metastatic KRAS G12C-mutated NSCLC
Ferdinandos Skoulidis

Abstract LBA7

CLARITY-Gastric 01 (CG-01): A phase 3 study of **sonesitug vedotin (Sone-Ve)** in second or later-line (2L+) advanced or metastatic claudin 18.2 (CLDN18.2) positive gastroesophageal carcinoma (GEC)
Rui-Hua Xu

Select ESMO 2026 Abstracts

Presidential

Abstract LBA8

Ivonescimab plus chemotherapy versus **durvalumab** plus chemotherapy as first-line treatment for advanced biliary tract cancer: A randomized, controlled, double-blinded, phase 3 trial (HARMONi-GI1)
Jian Zhou (Shanghai, China)

Abstract LBA11

Sacituzumab tirumotecan in previously treated advanced or recurrent endometrial cancer: Results from the phase 3 TroFuse-005/ENGOT-en23/GOG-3095 study
Domenica Lorusso

Abstract LBA12

KEYNOTE-C93/GOG-3064/ENGOT-en15: Phase 3, randomized, open-label study of first-line (1L) **pembrolizumab** (**pembro**) vs **carboplatin** (C) + **paclitaxel** (P) in mismatch repair-deficient (dMMR) advanced or recurrent endometrial carcinoma (a/rEC)
Brian M Slomovitz

Agenda

Module 1 — Breast Cancer: *Drs Geyer, Lustberg, Nanda and Wander*

Module 2 — Prostate Cancer: *Drs Agarwal and Antonarakis*

Module 3 — Multiple Myeloma: *Drs Lonial and Richardson*

Agenda

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Module 2 — Prostate Cancer: *Drs Agarwal and Antonarakis*

Module 3 — Multiple Myeloma: *Drs Lonial and Richardson*

Breast Cancer



Charles E Geyer Jr, MD

Professor of Medicine
University of Pittsburgh School of Medicine
Division Chief, Malignant Hematology and
Medical Oncology
UPMC Hillman Cancer Center
Chief Scientific Officer, NSABP Foundation
Associate Group Chair, NRG Oncology
Pittsburgh, Pennsylvania



Rita Nanda, MD

Director, Breast Oncology
Associate Professor of Medicine
Section of Hematology/Oncology
The University of Chicago
Chicago, Illinois



Maryam Lustberg, MD, MPH

Professor of Internal Medicine (Medical Oncology)
Director, Center for Breast Cancer
Chief, Breast Medical Oncology
Yale School of Medicine
New Haven, Connecticut



Seth Wander, MD, PhD

Director of Precision Medicine
Termeer Center for Targeted Therapies
Director of Translational Research
Breast Oncology Program
Massachusetts General Hospital
Assistant Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Agenda

Introduction: ESMO 2026; Recent FDA Approvals

ER-Positive Breast Cancer

HER2-Positive Breast Cancer

Triple-Negative Breast Cancer

Agenda

Introduction: ESMO 2026; Recent FDA Approvals

ER-Positive Breast Cancer

HER2-Positive Breast Cancer

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Select ESMO 2026 Abstracts

Breast Cancer

Abstract LBA17

HER2-PET imaging to predict **trastuzumab deruxtecan (T-DXd)** efficacy in advanced breast cancer: The phase II PREDICT-HER trial.
Juan Jin et al.

Abstract LBA23

Final results of TALENT: A neoadjuvant trial of **T-DXd** with or without **anastrozole**, or in sequence with chemotherapy for HER2-low, HR+ early-stage breast cancer.
Sara Hurvitz et al.

Abstract LBA25

Adjuvant **ribociclib (RIB)** + nonsteroidal aromatase inhibitor (NSAI) in patients (pts) with HR+/HER2- early breast cancer (EBC): NATALEE 6-y overall survival (OS) and efficacy outcomes.
Dennis Slamon et al.

Abstract LBA28

Compression therapy using normal-sized surgical gloves for prevention of **paclitaxel**-induced peripheral neuropathy in breast cancer: Results from the multicenter randomized AIUR trial.
Young-Joon Kang et al.

Select ESMO 2026 Abstracts

Breast Cancer

Abstract LBA49

A DESTINY-Breast09 (DB-)09 analysis of **trastuzumab deruxtecan (T-DXd)** + **pertuzumab (P)** vs **taxane + trastuzumab + pertuzumab (THP)** for patients (pts) with HER2+ advanced/metastatic breast cancer (a/mBC) and baseline (BL) brain metastases (BM).
Cristina Saura Manich et al.

Abstract LBA51

Results from KEYNOTE-B49: A phase 3, randomized, double-blind study of **pembrolizumab (Pembro)** vs placebo (Pbo) plus chemotherapy (CT) in participants (pts) with HR+/HER2- advanced breast cancer (ABC).
Hope Rugo et al.

Abstract LBA96

First-line (1L) **datopotamab deruxtecan (Dato-DXd)** vs chemotherapy in patients (pts) with locally recurrent inoperable or metastatic triple-negative breast cancer (mTNBC) for whom immunotherapy was not an option: Exploratory analysis of pts with brain metastases in TROPION-Breast02.
Rebecca Dent et al.

Abstract 1RO

Overall survival from the Phase 3 postMONARCH trial of **abemaciclib + fulvestrant** vs placebo + **fulvestrant** for HR+, HER2- advanced breast cancer following progression on a prior CDK4/6 inhibitor + endocrine therapy.
Kevin Kalinsky et al.

Select ESMO 2026 Abstracts

Breast Cancer

Abstract 4RO

Target switching with conserved-payload novel ADCs in patients with metastatic breast cancer following prior ADC therapy (SWITCH): A prospective, open-label, phase 2 platform trial.
Xiyu Liu et al.

Abstract 540RO

Ultrasensitive monitoring of early ctDNA dynamics during neoadjuvant treatment in early-stage triple-negative breast cancer: Pre-interim results from the B-STRONGER-I study.
Carlos Barcenas et al.

Recent FDA Approvals

FDA APPROVAL
October 7, 2026

Tucatinib with **trastuzumab** and **pertuzumab** for the maintenance treatment of HER2-positive breast cancer

FDA APPROVAL
September 18,
2026

Imlunestrant in combination with **abemaciclib** for ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer

FDA APPROVAL
September 4,
2026

Accelerated approval for **camizestrant** with a **CDK4/6 inhibitor** for ESR1-mutated HR-positive, HER2-negative locally advanced or metastatic breast cancer

FDA APPROVAL
July 14, 2026

Gedatolisib with **fulvestrant**, with or without **palbociclib**, for HR-positive, HER2-negative locally advanced or metastatic breast cancer

Recent FDA Approvals (Continued)

FDA APPROVAL
June 24, 2026

Palbociclib with **trastuzumab**, with or without **pertuzumab**, and endocrine therapy for maintenance treatment of HR-positive, HER2-positive metastatic breast cancer

FDA APPROVAL
June 24, 2026

Sacituzumab govitecan-hziy as monotherapy and in combination with **pembrolizumab** for first-line treatment of unresectable or metastatic triple-negative breast cancer

FDA APPROVAL
May 22, 2026

Datopotamab deruxtecan for first-line treatment of unresectable or metastatic triple-negative breast cancer

FDA APPROVAL
May 15, 2026

Fam-trastuzumab deruxtecan-nxki for 2 indications in HER2-positive early-stage breast cancer

Recent FDA Approvals (Continued)

FDA APPROVAL
May 1, 2026

Vepdegestrant for ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer

Agenda

Introduction: ESMO 2026; Recent FDA Approvals

ER-Positive Breast Cancer

- CDK4/6 Inhibitors and Oral SERDs in the Adjuvant Setting – *Dr Geyer*
- Novel Approaches to First-Line Treatment of ER-Positive, HER2-Negative Metastatic Breast Cancer (mBC); PROTACs – *Dr Lustberg*
- Oral SERDs in the Metastatic Setting – *Dr Wander*
- Relapsed/Refractory HR-Positive mBC: PI3K/AKT/mTOR Pathway Inhibitors – *Dr Nanda*

HER2-Positive Breast Cancer

Triple-Negative Breast Cancer

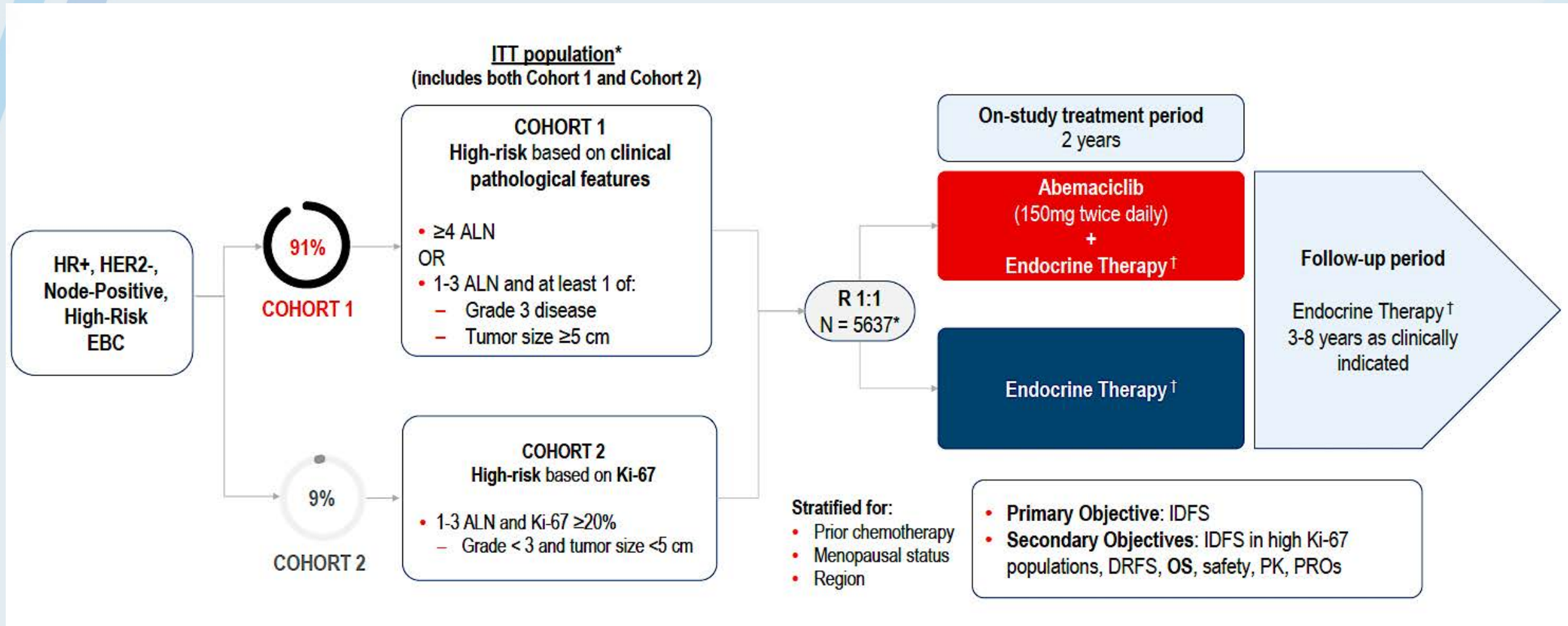
CKD4/6 Inhibitors and Oral SERDs in the Adjuvant Setting

Dr Geyer

Select Datasets

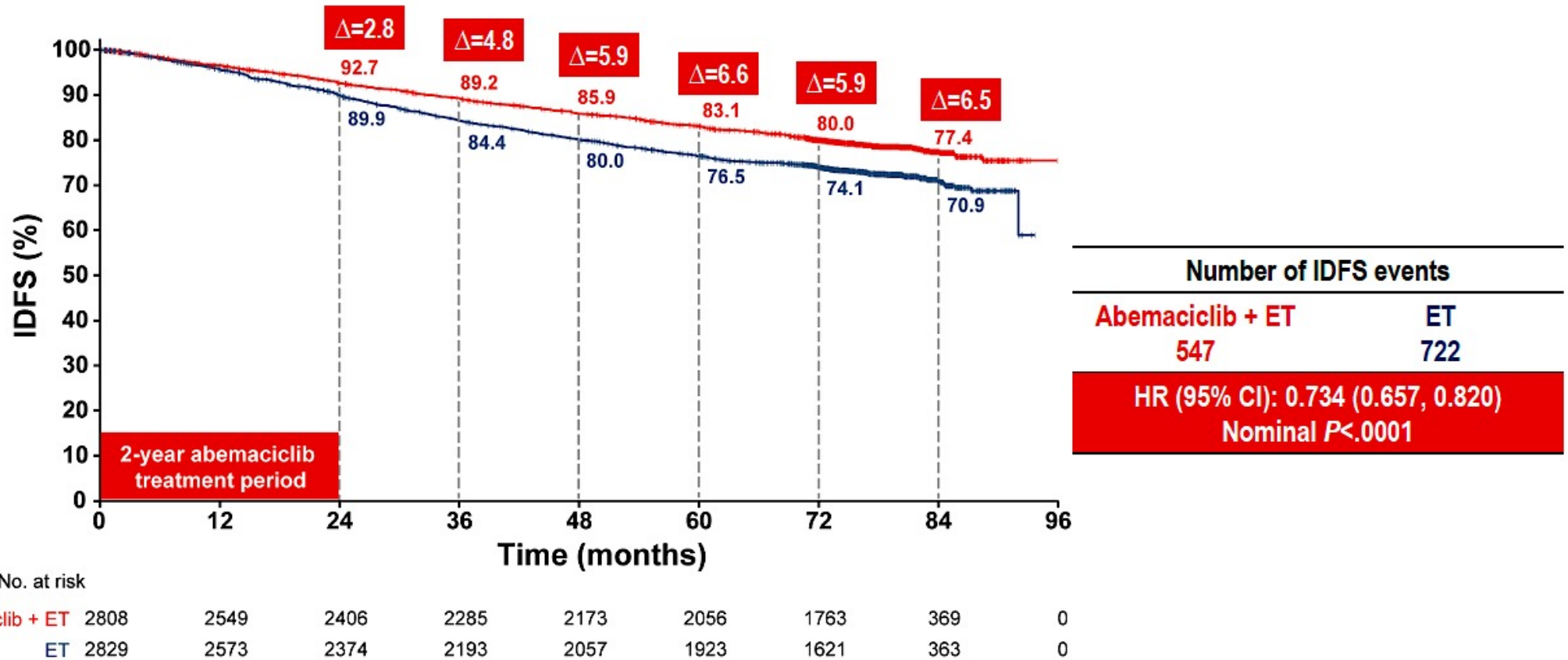
- Johnston S et al. Overall survival with abemaciclib in early breast cancer. *Ann Oncol* 2026;37(2):155-65.
- Mayer EL et al. TRADE: A phase II trial to assess the tolerability of abemaciclib dose escalation in early-stage HR-positive/HER2-negative breast cancer. *Ann Oncol* 2026;37(1):117-24.
- Crown J et al. Adjuvant ribociclib plus nonsteroidal aromatase inhibitor therapy in patients with HR-positive/HER2-negative early breast cancer: 5-year follow-up of NATALEE efficacy outcomes and updated overall survival. *ESMO Open* 2025;10(11):105858.
- Bardia A et al. Giredestrant vs standard-of-care endocrine therapy as adjuvant treatment for patients with estrogen receptor-positive, HER2-negative early breast cancer: Results from the global Phase III lidERA Breast Cancer trial. San Antonio Breast Cancer Symposium 2025;Abstract GS1-10.
- Schmid P et al. Efficacy and safety of giredestrant in patients with estrogen receptor-positive, HER2-negative early breast cancer in the phase III lidERA BC clinical trial: Results by menopausal status. ASCO 2026;Abstract 502.

monarchE Study Design



EBC = early breast cancer; ALN = axillary lymph nodes

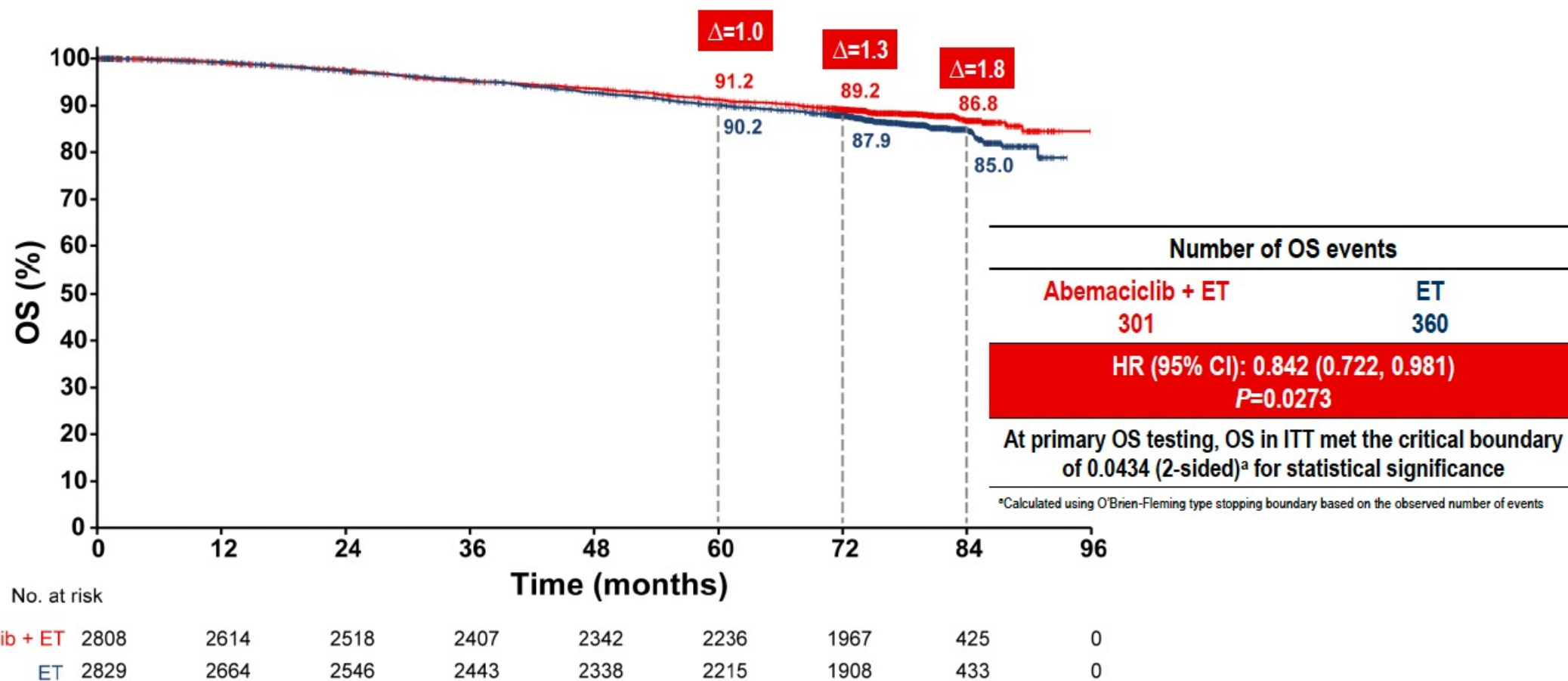
monarchE: Invasive Disease-Free Survival (IDFS) Outcomes



Abemaciclib + ET reduced the risk of IDFS events by 26.6% compared to ET alone

ET = endocrine therapy

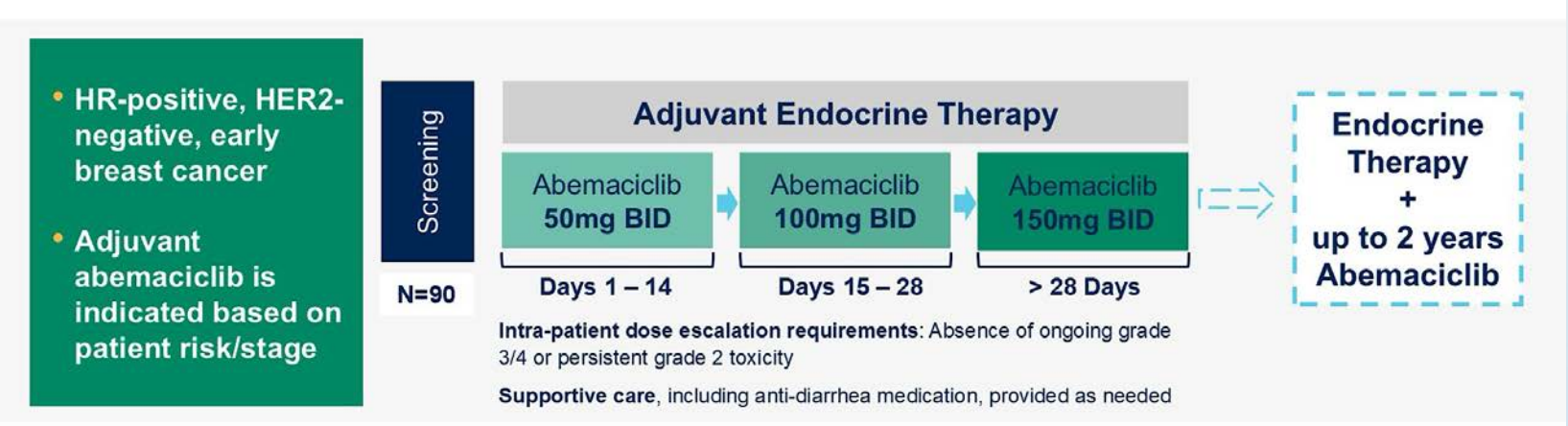
monarchE: Overall Survival (OS) Outcomes



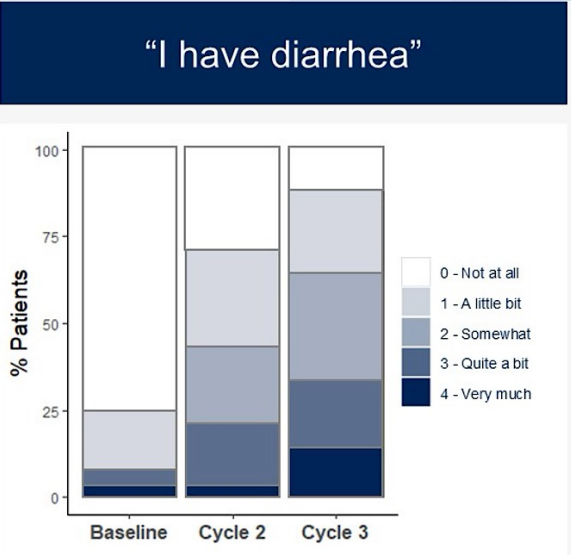
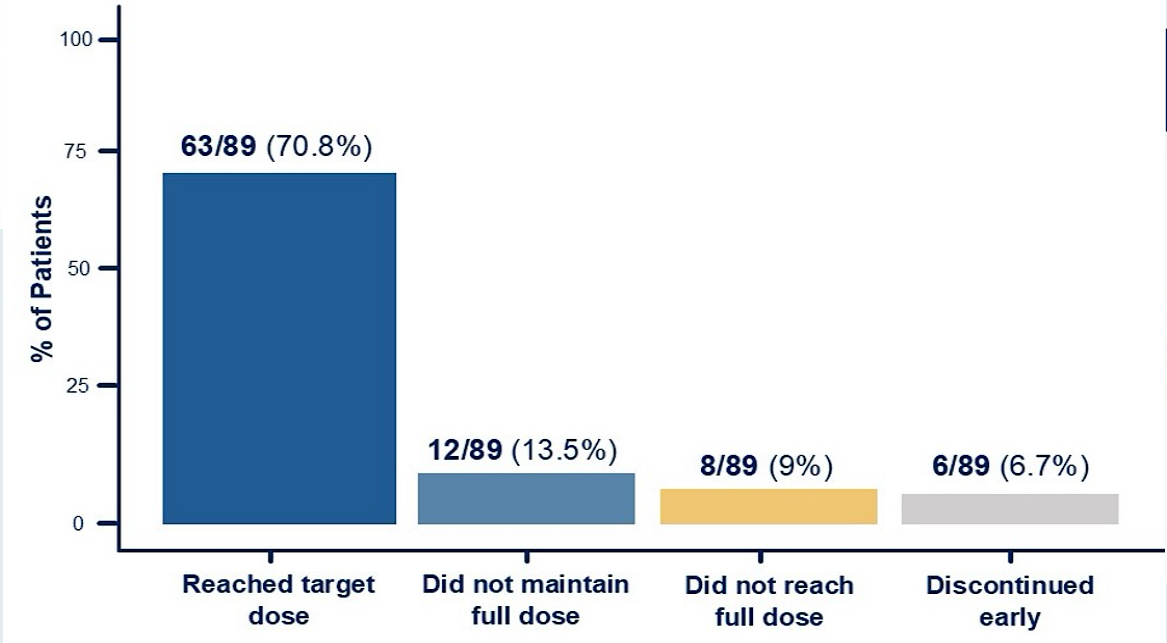
At a median follow-up of 6.3 years, abemaciclib + ET reduced the risk of death by 15.8% compared to ET alone

TRADE Trial: Abemaciclib Dose Escalation

Patient disposition in monarchE		
Outcome in monarchE	By 12 weeks	Overall at 2 years
Discontinued abemaciclib for any reason	10%	30.6%
Discontinued for adverse events	7%	18.5%
Required abemaciclib dose reduction	27%	43.4%



Primary endpoint: composite AE rate (discontinuation of adjuvant abemaciclib for any reason and/or need to dose reduce by 12 weeks of therapy)



NATALEE Study Design

Adult patients with stage II and III HR+/HER2- EBC

- Prior ET allowed up to 12 months
- **Anatomical stage IIA^a**
 - N0 with:
 - Grade 2 and evidence of high risk:
 - Ki-67 $\geq 20\%$
 - Oncotype DX Breast Recurrence Score ≥ 26 or
 - High risk via genomic risk profiling
 - Grade 3
 - N1
- **Anatomical stage IIB^a**
 - N0 or N1
- **Anatomical stage III**
 - N0, N1, N2, or N3

R
1:1

RIB

400 mg/day
3 weeks on/1 week off for 3 y

+

NSAI

Letrozole or anastrozole^b for ≥ 5 y
+ goserelin in men and premenopausal women

NSAI

Letrozole or anastrozole^b for ≥ 5 y
+ goserelin in men and premenopausal women

Primary End Point

iDFS using STEEP criteria

Secondary End Points

- RFS, DDFS, OS
- PROs
- Safety and tolerability
- PK

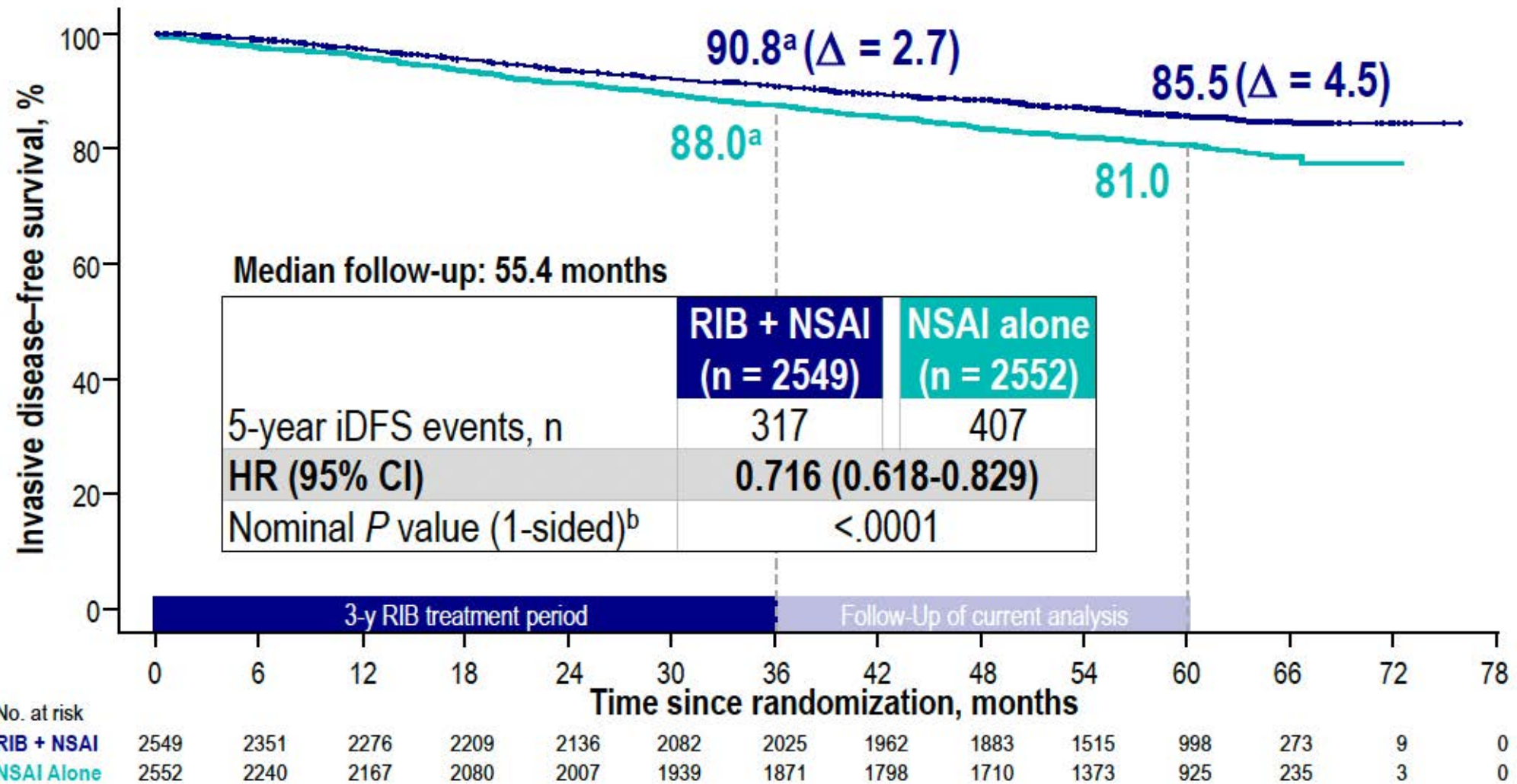
Exploratory End Points

- DRFS
- Gene expression and alterations in tumor ctDNA/ctRNA samples

Efficacy outcomes for the 5-year analysis were estimated by the Kaplan-Meier method, and results are descriptive. The Cox proportional hazards model was used to estimate the HRs and 95% CIs.

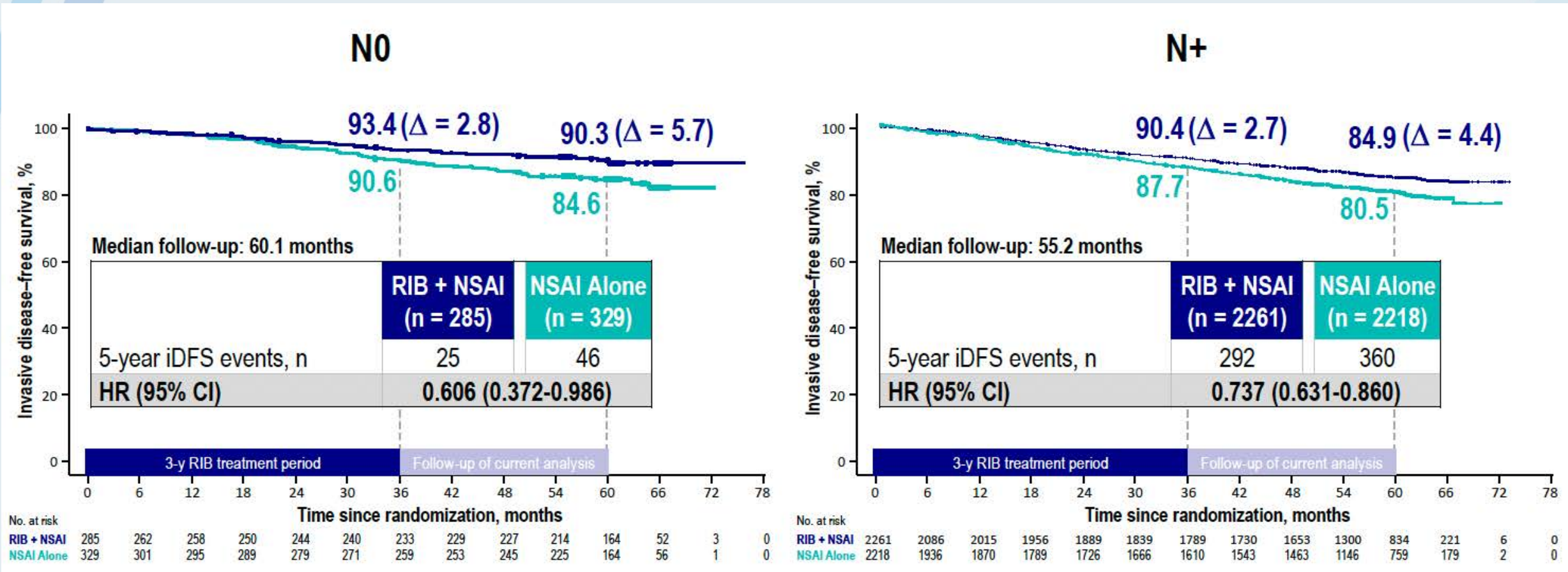
RIB = ribociclib; NSAI = nonsteroidal aromatase inhibitor

NATALEE: IDFS Outcomes

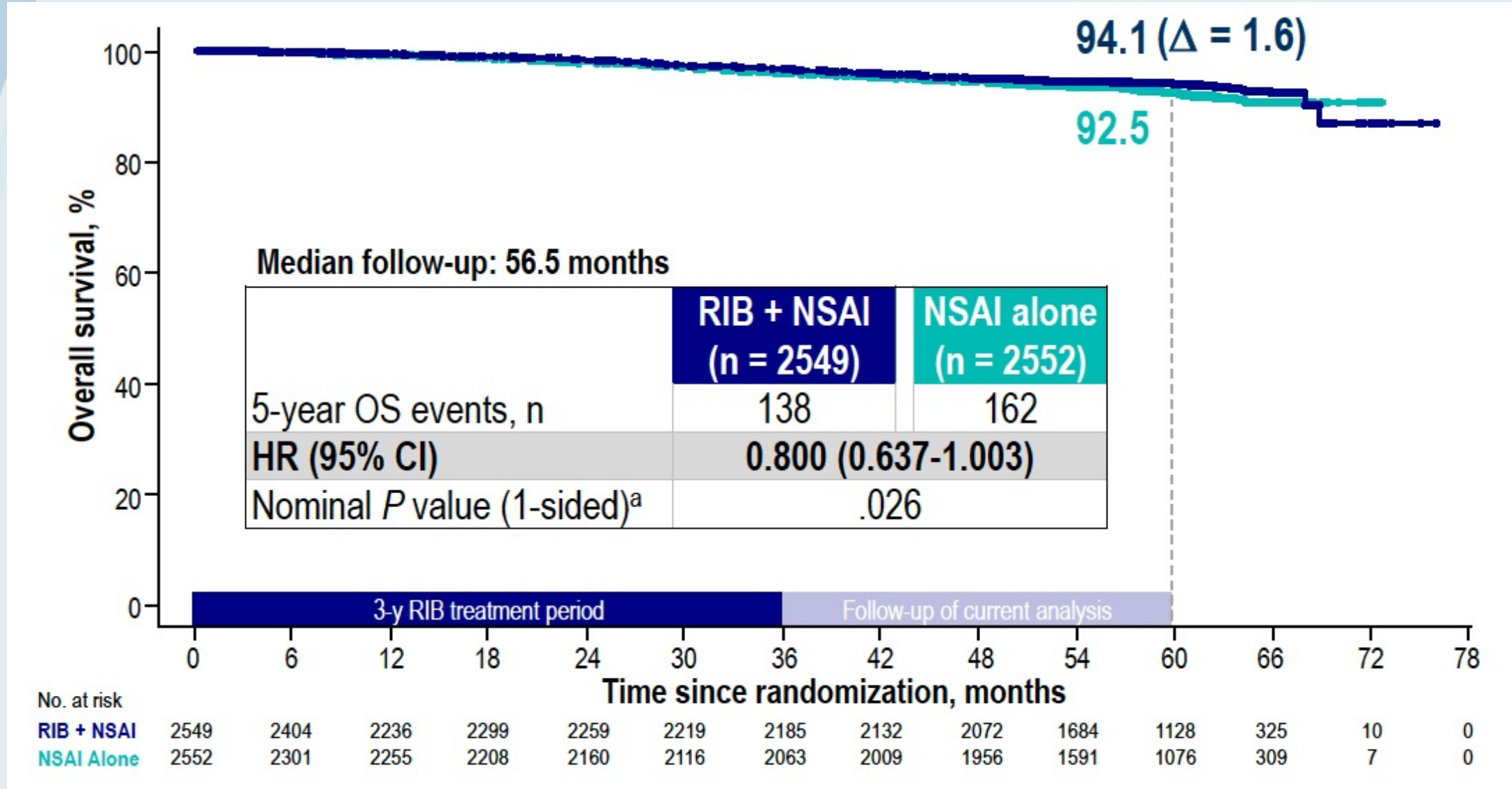


RIB = ribociclib; NSAI = nonsteroidal aromatase inhibitor

NATALEE: IDFS by Nodal Status



NATALEE: OS Outcomes



IdERA Breast Cancer Study Design

Key eligibility criteria

- Participants with ER+, HER2-negative early breast cancer
- Stage I–III disease (anatomical)
 - pN0 and pT > 1 cm with Grade 3, or Ki67 ≥ 20%, or high score on genomic assay,* or pT4N0
 - Node-positive
- Pre- or post-menopausal†
- Breast cancer surgery within 12 months
- (Neo)adjuvant chemotherapy if indicated

Stratification factors

- Risk: Medium-‡ vs high-risk§ Stage I–III breast cancer
- Region: USA/Canada/Western Europe vs Asia–Pacific vs RoW
- Previous chemotherapy: No vs yes
- Menopausal status: Pre-menopausal vs post-menopausal

N = 4170

R
1:1

At least 5-year treatment duration

Giredestrant (30 mg PO QD)

SOC ET

Tamoxifen/anastrozole/letrozole/exemestane

5-year follow-up

**Long-term
follow-up**

Primary endpoint

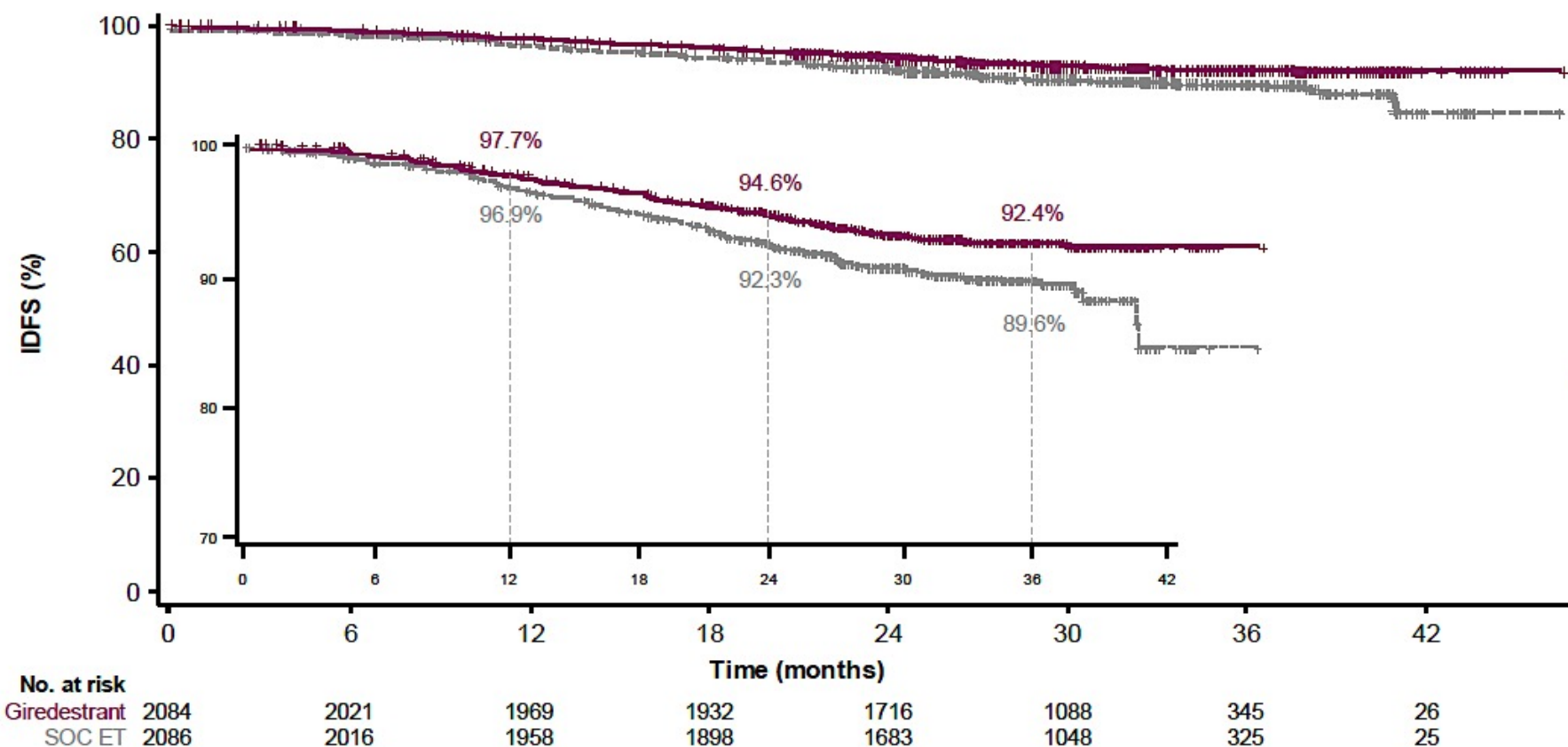
- IDFS (excluding second primary non-breast cancer)

Key secondary endpoints

- DFS, DRFI, IDFS (including second primary non-breast invasive cancer with exception of non-melanoma skin cancers and *in situ* carcinomas of any site), LRRFI, OS, safety

SOC = standard of care; ET = endocrine therapy; DRFI = distant recurrence-free interval; LRRFI = locoregional recurrence-free interval

IdERA Breast Cancer: IDFS Outcomes



	Giredestrant n = 2084	SOC ET n = 2086
Events, n (%)	140 (6.7)	196 (9.4)
Stratified HR (95% CI)	0.70 (0.57, 0.87); p = 0.0014*	

Exploratory analysis: IDFS by SOC ET

	Total, n	Stratified HR (95% CI)
AI	1745	0.73 (0.58, 0.92)
Tamoxifen	326	0.53 (0.35, 0.80)

0.3 0.8

Giredestrant better SOC ET better

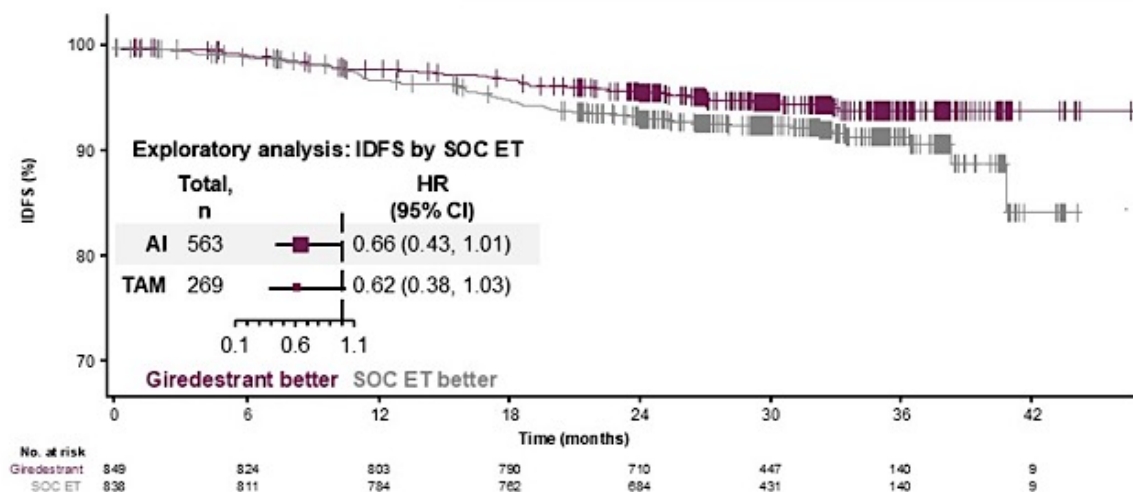
Median follow-up: 32.3 months

Statistically significant and clinically meaningful improvement in IDFS:
Giredestrant reduced the risk of invasive disease recurrence or death by 30% compared with SOC ET

IdERA Breast Cancer: IDFS by Menopausal Status

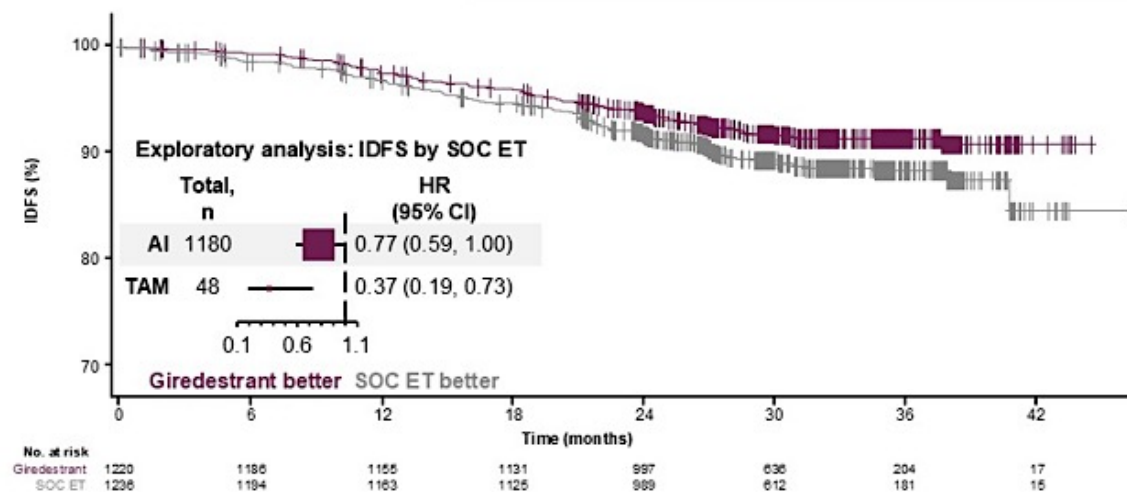
Pre-menopausal

	Giredestrant n = 849	SOC ET n = 838
Events, n (%)	44 (5.2)	66 (7.9)
3-year rate, %	94.0	91.5
HR (95% CI)	0.65 (0.44, 0.95)	



Post-menopausal

	Giredestrant n = 1220	SOC ET n = 1236
Events, n (%)	96 (7.9)	129 (10.4)
3-year rate, %	91.3	88.3
HR (95% CI)	0.74 (0.57, 0.96)	

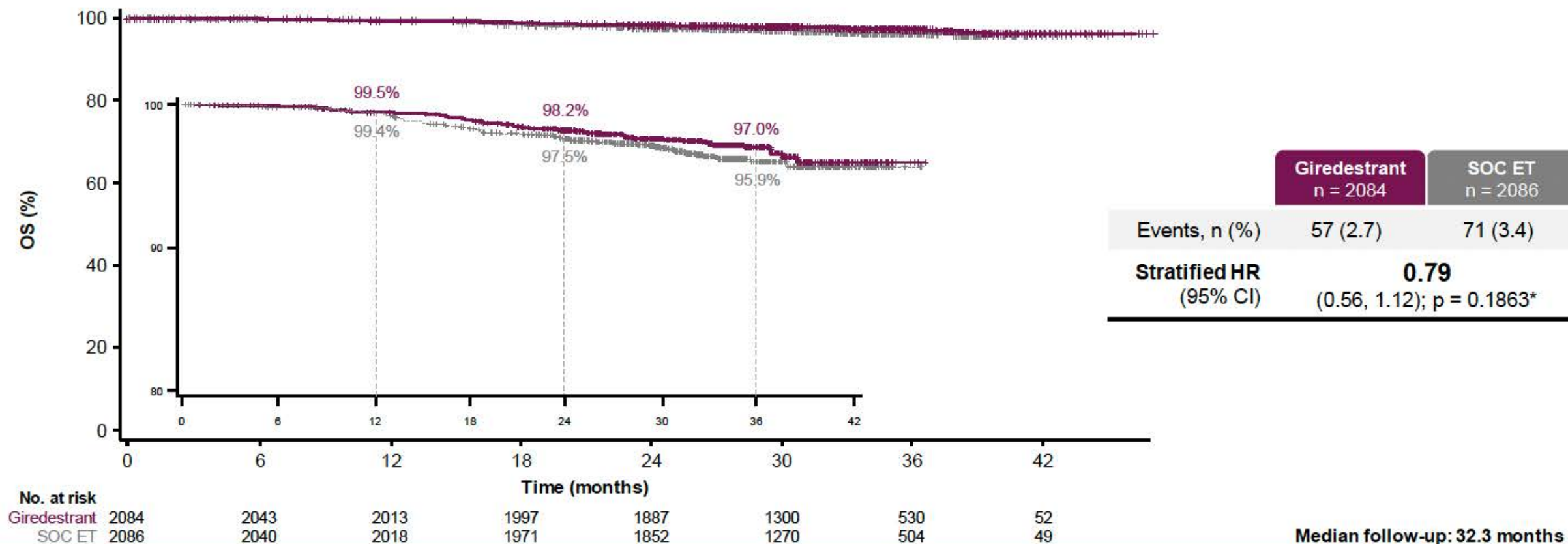


Giredestrant showed IDFS benefit and higher 3-year rates in both pre-menopausal and post-menopausal subgroups

Data cutoff: August 8, 2025. HR estimates are unstratified vs SOC ET.

AI, aromatase inhibitor; CI, confidence interval; ET, endocrine therapy; HR, hazard ratio; IDFS, invasive disease-free survival; SOC, standard-of-care; TAM, tamoxifen.

lidERA Breast Cancer: OS Outcomes



While OS data were immature, a clear positive trend was observed. OS testing will continue at future analyses

Select Ongoing Phase III Trials of Oral SERDs for HR-Positive, HER2-Negative Localized Breast Cancer

- Bardia A et al. ELEGANT: Elacestrant versus standard endocrine therapy (ET) in women and men with node-positive, estrogen receptor-positive (ER+), HER2-negative (HER2-), early breast cancer (eBC) with high risk of recurrence in a global, multicenter, randomized, open-label phase 3 study. ASCO 2025;Abstract TPS619.
- Dynamic marker-adjusted therapy comparing adjuvant elacestrant with standard endocrine treatment in genomically and/or clinically high-risk ER+/HER2- early breast cancer (ADAPTela). NCT072423352
- Ignatiadis M et al. EORTC-2129-BCG: Elacestrant for treating ER+/HER2- breast cancer patients with ctDNA relapse (TREAT ctDNA). ASCO 2025;Abstract TPS620.
- Jhaveri K et al. EMBER-4: A phase 3 adjuvant trial of imlunestrant vs standard endocrine therapy (ET) in patients with ER+, HER2- early breast cancer (EBC) with an increased risk of recurrence who have previously received 2 to 5 years of adjuvant ET. SABCS 2022;Abstract OT1-01-02.
- Hamilton EP et al. CAMBRIA-1 & CAMBRIA-2 phase III trials: Camizestrant versus standard endocrine therapy in ER+/HER2- early breast cancer. *Future Oncol* 2025;21(7):795-806.
- A phase IIIb, single-arm, open-label study evaluating adherence, tolerability, and patient reported outcomes (PRO) of giredestrant in patients with ER+/HER2- early breast cancer who are intolerant to adjuvant aromatase inhibitor therapy. NCT07541079

Faculty Discussion



Questions for the Faculty

- In general, do you follow the criteria outlined in the FDA approvals when selecting patients to receive a CDK4/6 inhibitor in the adjuvant setting?
- For patients who are eligible to receive either adjuvant abemaciclib or ribociclib, how do you select between the two agents?
- Do you employ a dose-escalation strategy with abemaciclib?
- If adjuvant giredestrant were to become available, for which specific patients would you recommend it, and what would be your clinical approach? Are other oral SERDs being investigated in the adjuvant setting?
- Regulatory and reimbursement issues aside, for a patient who is not tolerating an adjuvant AI, would you consider switching to giredestrant?

Novel Approaches to First-Line Treatment of ER-Positive, HER2-Negative mBC; PROTACs

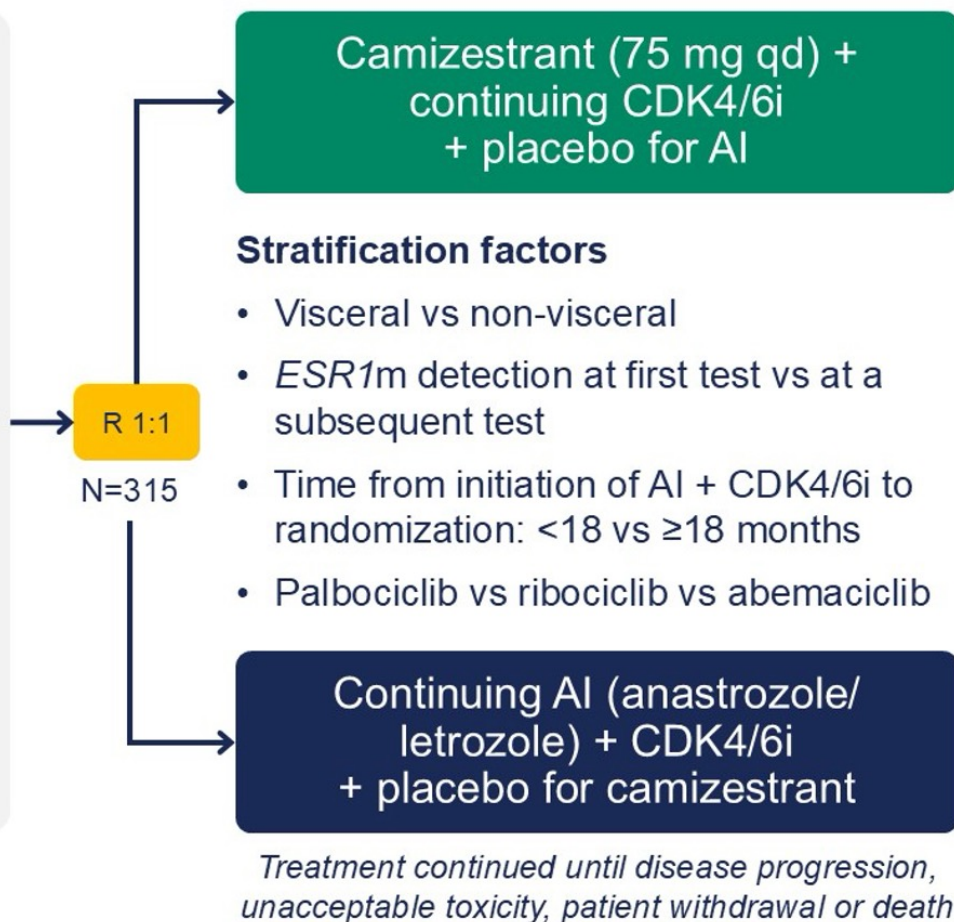
Dr Lustberg

Select Datasets

- Bidard FC et al. First-line camizestrant for emergent ESR1 mutations in advanced breast cancer: Final progression-free survival 2 from the phase III SERENA-6 trial. ASCO 2026;Abstract LBA1007.
- Jhaveri KL et al. Overall survival with inavolisib in *PIK3CA*-mutated advanced breast cancer. *N Engl J Med* 2025;393(2):151-61.
- Campone M et al. Vepdegestrant, a PROTAC estrogen receptor degrader, in advanced breast cancer. *N Engl J Med* 2025;393(6):556-68.

SERENA-6 Study Design

- 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
- *ESR1m* detected in ctDNA with no evidence of disease progression



Primary endpoint

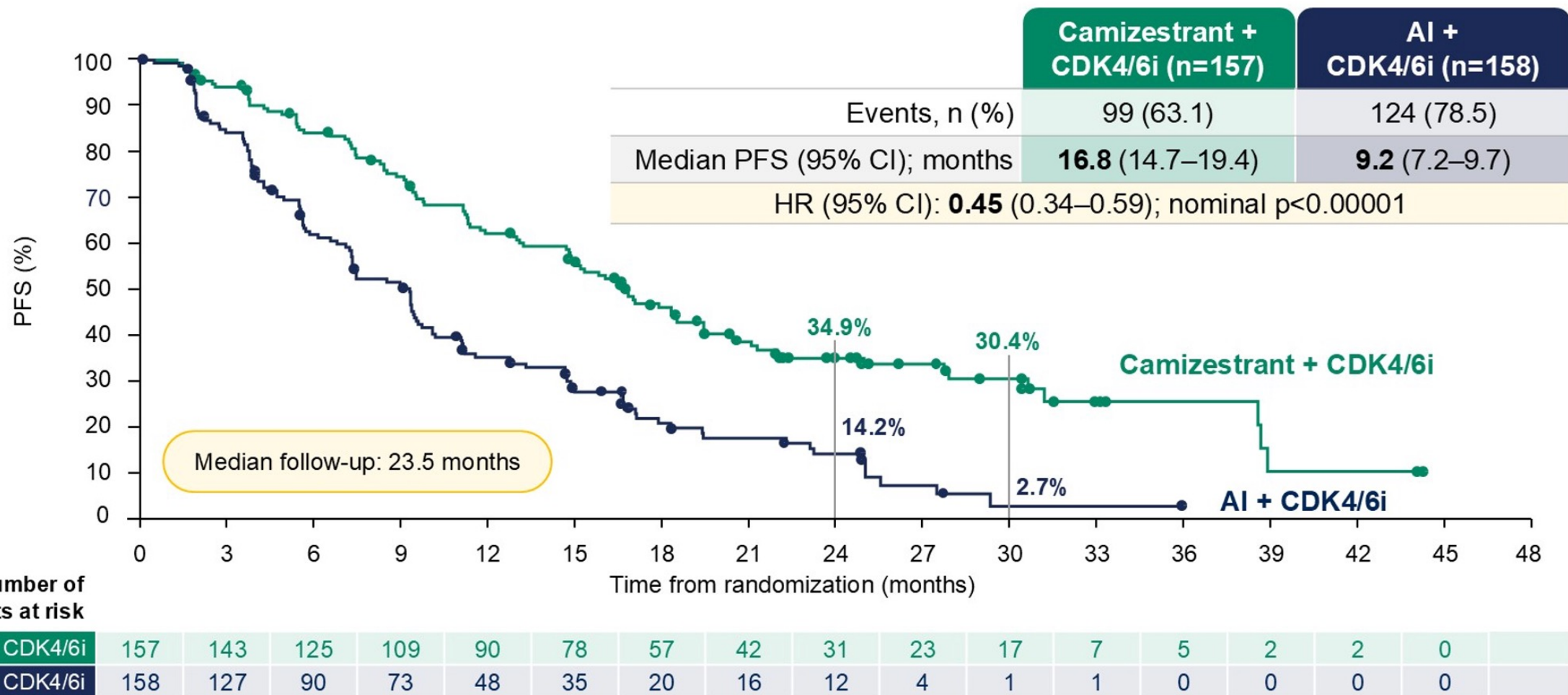
PFS by investigator assessment (RECIST v1.1)

Secondary endpoints

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

AI = aromatase inhibitor; CDK4/6i = CDK4/6 inhibitor; ctDNA = circulating tumor DNA

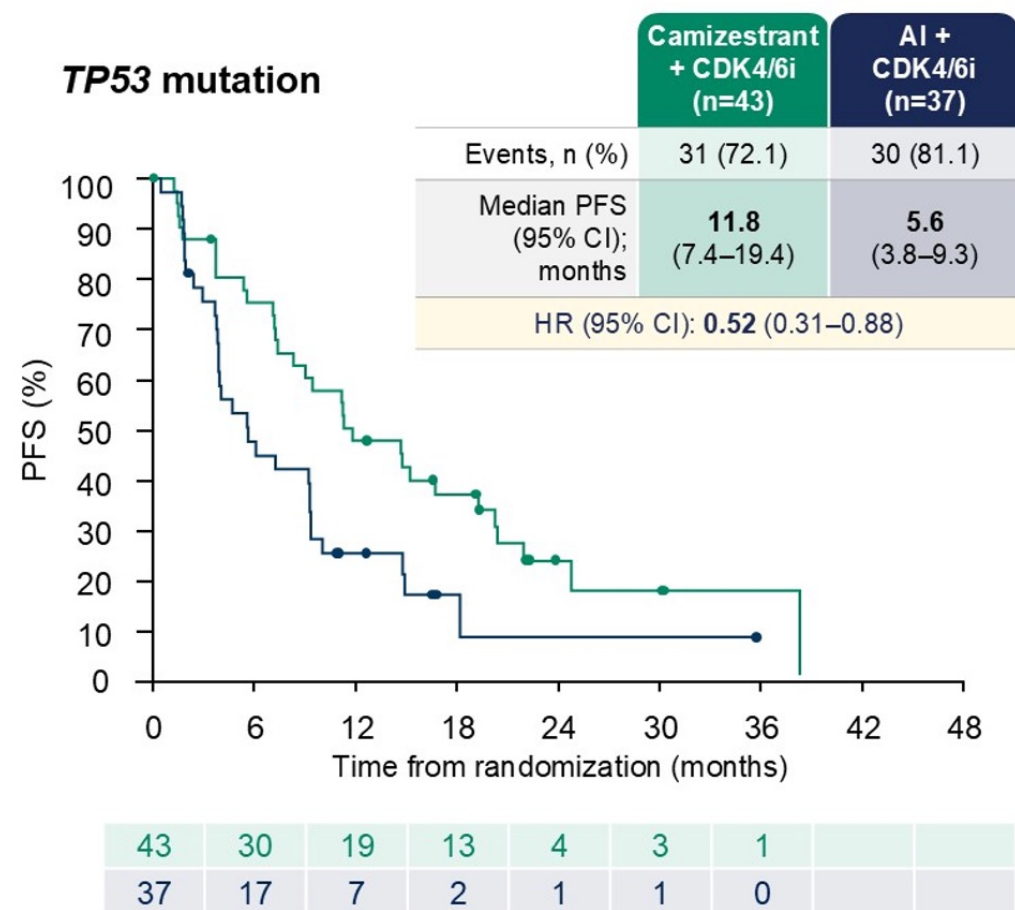
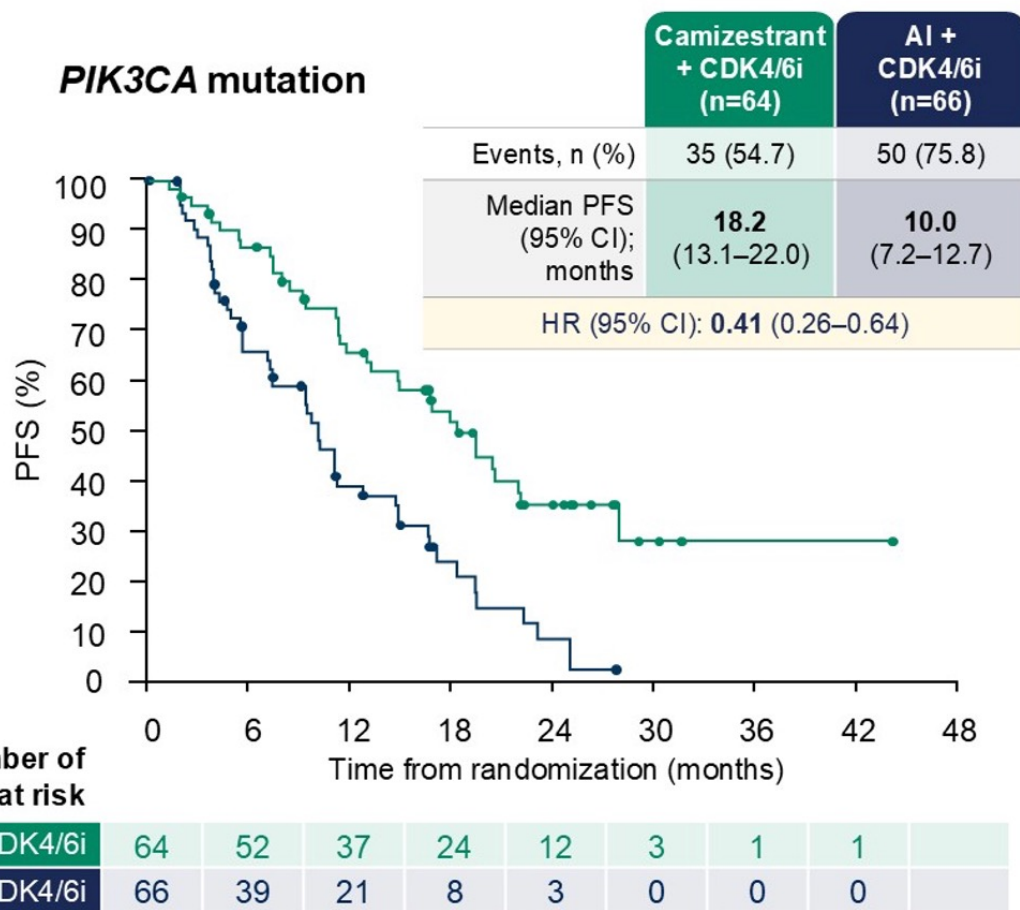
SERENA-6: Investigator-Assessed Progression-Free Survival (PFS)



DCO3 (Jan 02, 2026). At DCO3, 45 patients in the camizestrant + CDK4/6i arm and 12 patients in the AI + CDK4/6i arm were still receiving study treatments. The p value is based on the stratified log-rank test, stratified by disease site (visceral vs non-visceral), timing of ESR1m detected (first vs subsequent test), and time from initiation of AI + CDK4/6i to randomization (<18 months vs ≥18 months).

DCO3 = third data cutoff date

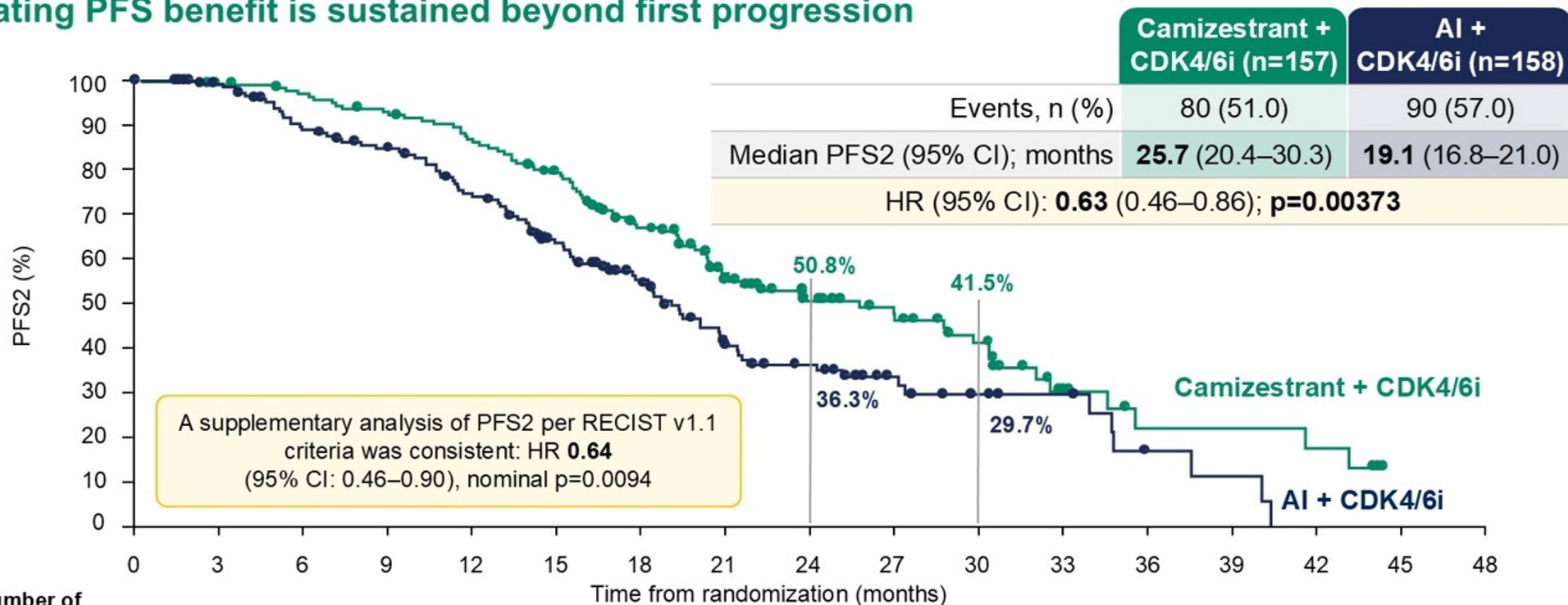
SERENA-6: PFS by Co-Mutation Status



DCO3 (Jan 02, 2026). PFS benefit was comparable in patients without a *PIK3CA* mutation (HR [95% CI]: **0.48** [95% CI: 0.34–0.68]) or a *TP53* mutation (**0.42** [0.30–0.58]).
PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase gene; *TP53*, tumor protein 53 gene.

SERENA-6: Final PFS2

Camizestrant + CDK4/6i significantly extended time to second progression or death, demonstrating PFS benefit is sustained beyond first progression

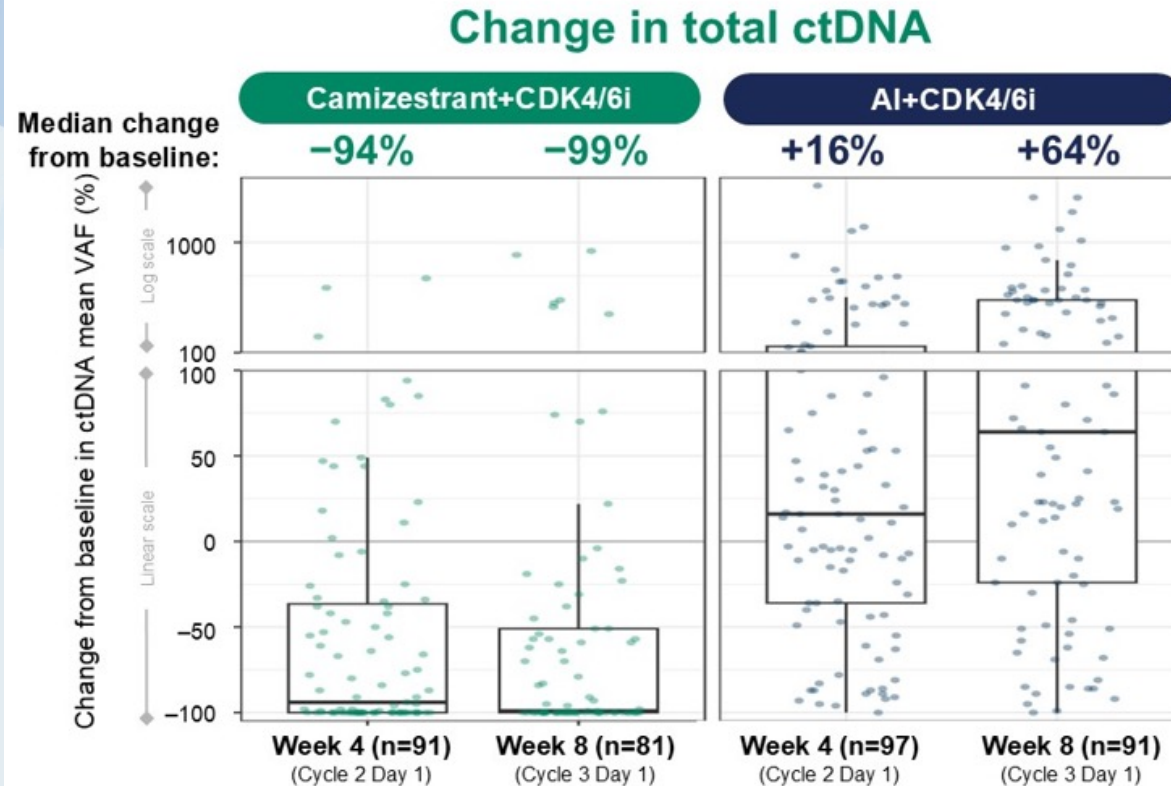


Number of patients at risk																	
Camizestrant + CDK4/6i	157	150	145	138	127	113	86	63	42	32	24	10	5	5	4	0	
AI + CDK4/6i	158	149	129	120	102	82	60	40	30	17	12	8	3	2	0	0	

DCO3 (Jan 02, 2026). PFS2, defined in a standard manner (assessed by the investigator according to local standard clinical practice) as the time from randomisation to the earliest of disease progression after first subsequent therapy or death in the primary analysis. The p value is based on the stratified log-rank test, stratified by disease site (visceral vs non-visceral), timing of ESR1m detected (first vs subsequent test), and time from initiation of AI+CDK4/6i to randomization (<18 months vs ≥18 months).

SERENA-6: Total ctDNA and OS Outcomes

Total ctDNA levels were substantially reduced on camizestrant + CDK4/6i
Median 99% reduction at Week 8; 51% of patients showed clearance of total ctDNA



Total ctDNA was **profoundly reduced** in the camizestrant + CDK4/6i arm vs the AI + CDK4/6i arm (Wilcoxon nominal $P < 0.00001$) at Week 4 and 8

Total ctDNA clearance by Guardant360*

Camizestrant + CDK4/6i

51.0%

n=50/98

AI + CDK4/6i

1.9%

n=2/108

In an exploratory analysis pooled across arms, total ctDNA clearance is associated with OS benefit (HR 0.39; 95% CI 0.19–0.73); consistent with other studies

Total ctDNA = mean VAF of probable tumor-specific somatic mutations (Guardant360). *Total ctDNA clearance at Week 4 and/or Week 8 in clearance-evaluable patients.

VAF = variant allele frequency

INAVO120 Study Design

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%**

Stratification factors:

- Visceral Disease (Yes vs. No)
- Endocrine Resistance (Primary vs. Secondary)[†]
- Region (North America/Western Europe; Asia; Other)

N=325

R
1:1

Enrolment period: December 2019 to September 2023

**Inavolisib (9 mg QD PO)
+ palbociclib (125 mg PO QD D1–D21)
+ fulvestrant (500 mg C1D1/15 and Q4W)****

**Placebo (PO QD)
+ palbociclib (125 mg PO QD D1–D21)
+ fulvestrant (500 mg C1D1/15 and Q4W)****

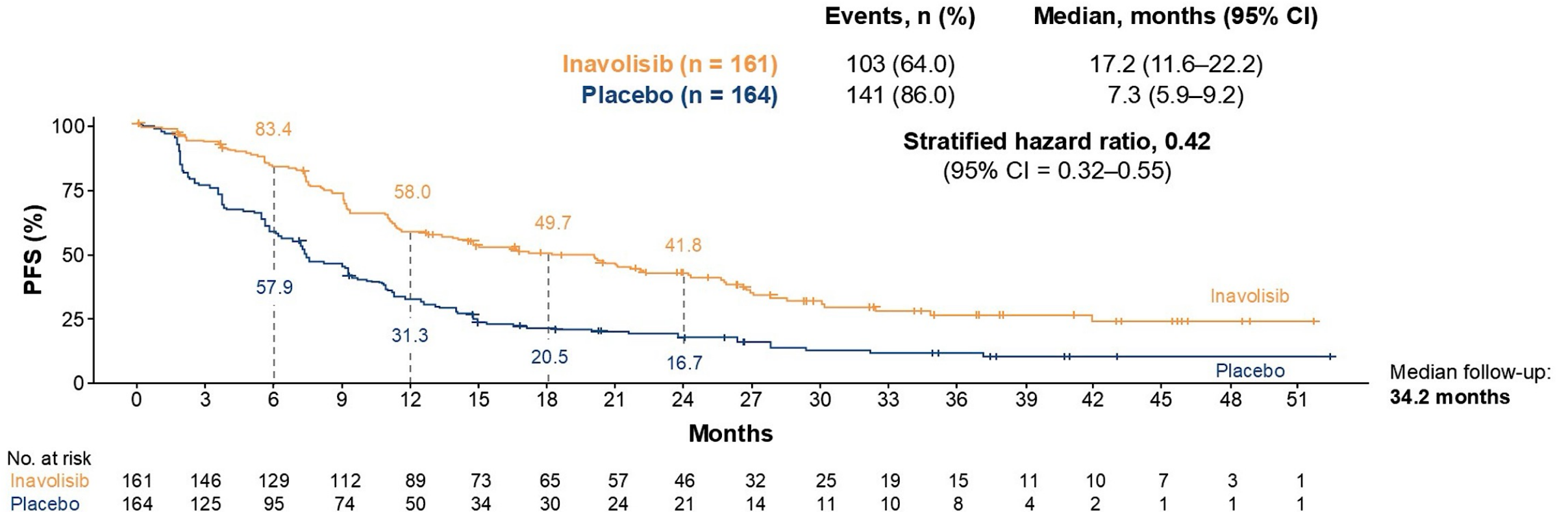
**Until PD
or toxicity**

**SURVIVAL
FOLLOW-UP**

Endpoints

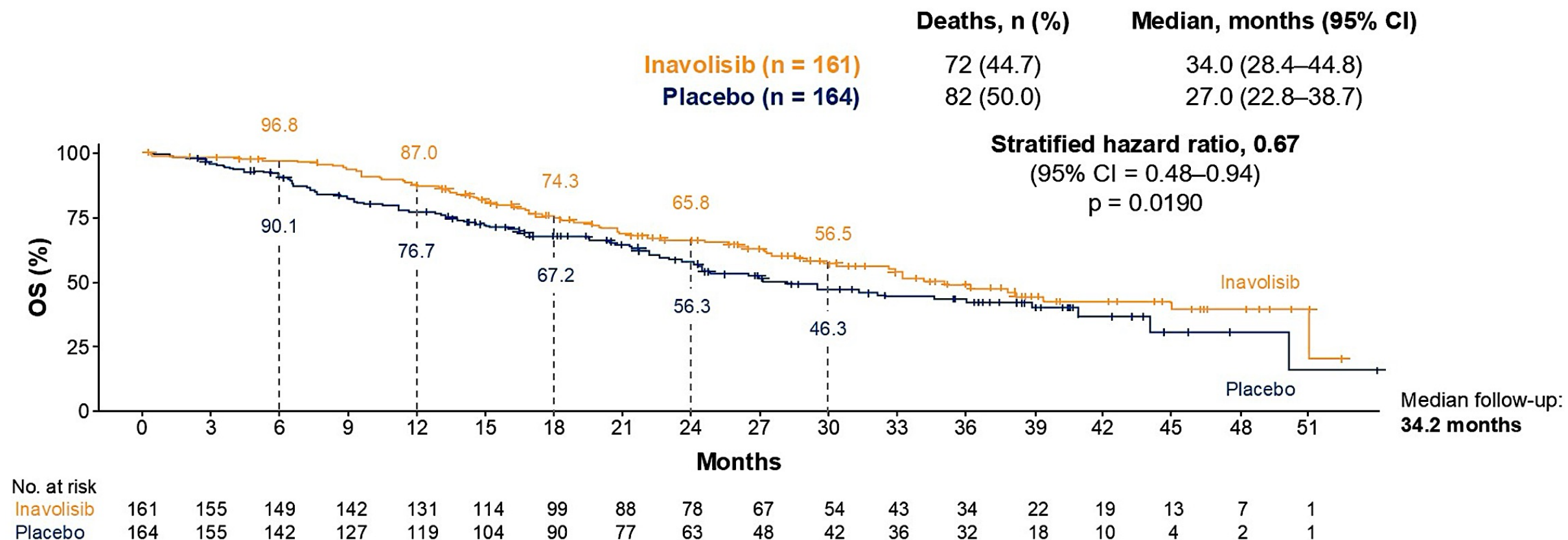
- Primary: PFS by Investigator
- Secondary: OS[‡], ORR, BOR, CBR, DOR, PROs

INAVO120: PFS Outcomes



The improvement in PFS was maintained during longer follow-up

INAVO120: Final OS



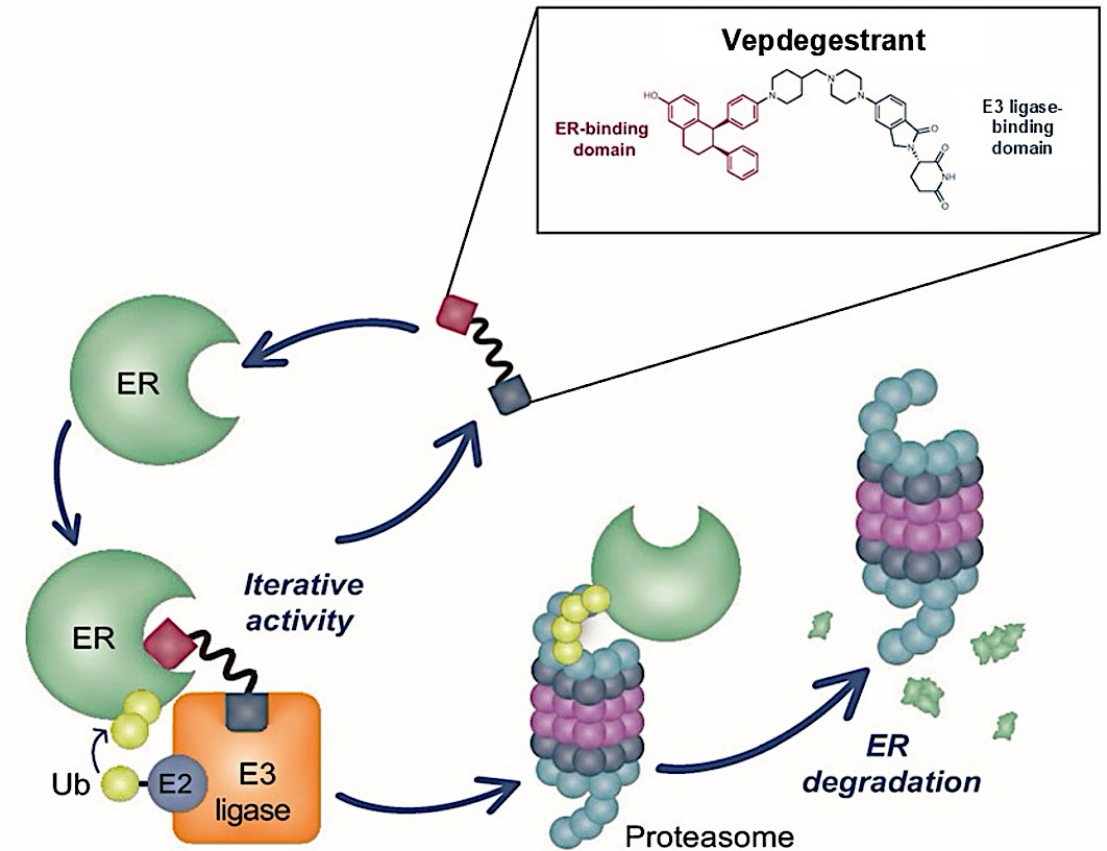
Improvement in median OS: 7 months. The prespecified boundary for statistical significance ($p < 0.0469$) was crossed

Select Ongoing Phase III Trials Evaluating PI3K/AKT/mTOR Pathway Inhibitors as First-Line Treatment

- Cortes J et al. INAVO123: Phase III study of first-line (1L) inavolisib/placebo + a CDK4/6 inhibitor + letrozole (INAVO/PBO + CDK4/6i + LET) in participants (pts) with PIK3CA-mutated (mut), hormone receptor-positive (HR+), HER2-negative (HER2-), endocrine-sensitive advanced breast cancer (aBC): ESMO Breast 2025;Abstract 408TiP
- Rugo H et al. CAPItello-292 Phase 3: An open-label, randomized study of capivasertib, fulvestrant, and investigator's choice of CDK4/6 inhibitor (palbociclib or ribociclib) in HR+/HER2– advanced breast cancer. SABCS 2023;Abstract PO2-19-10.
- Hurvitz S et al. A randomized, open-label, phase 3 study of fulvestrant and CDK4/6 inhibitors with or without gedatolisib as first-line treatment in patients with HR+/HER2- advanced breast cancer (VIKTORIA-2). AACR 2025;Abstract CT258.

Background and Vepdegestrant Mechanism of Action (MOA)

- There is no established consensus for treatment of ER+/HER2- advanced breast cancer after progression on first-line ET¹
- 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 cancer⁷



Vepdegestrant has a unique MOA that directly harnesses the ubiquitin-proteasome system to degrade ER⁸

IM = intramuscularly; WT = wild type

VERITAC-2 Study Design

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:

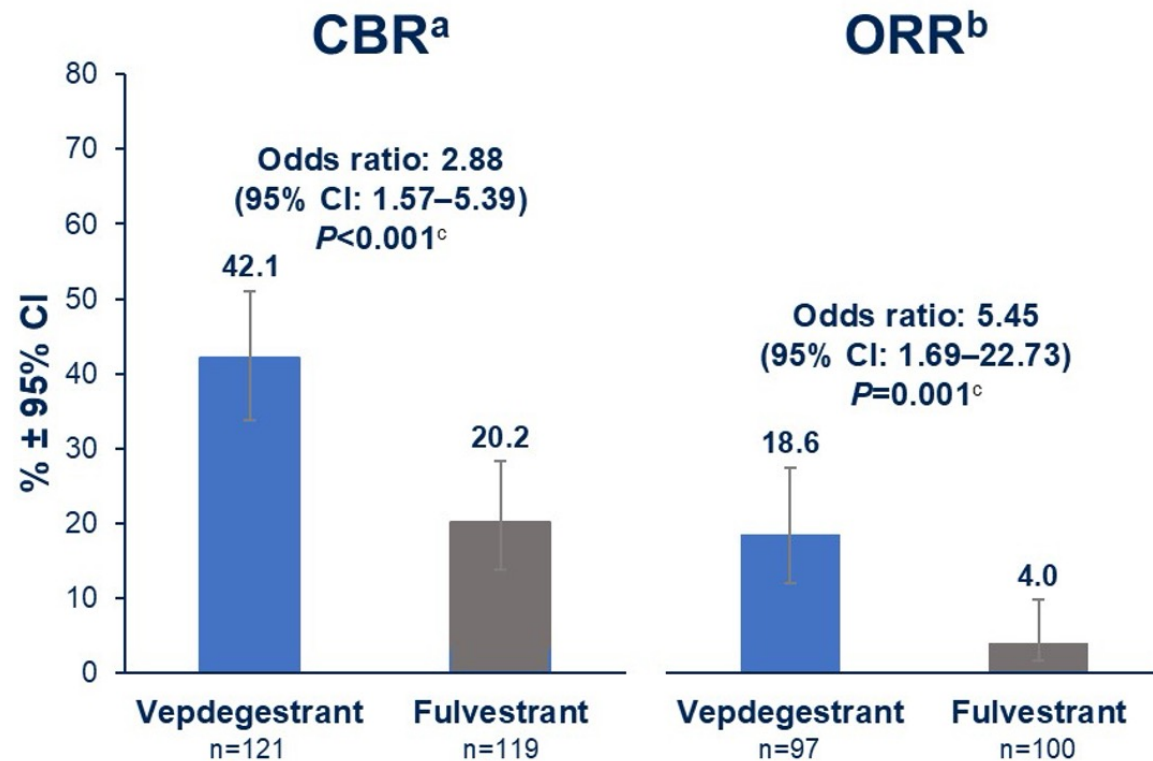
- PFS by BICR in
 - *ESR1*m population
 - All patients

Secondary Endpoints:

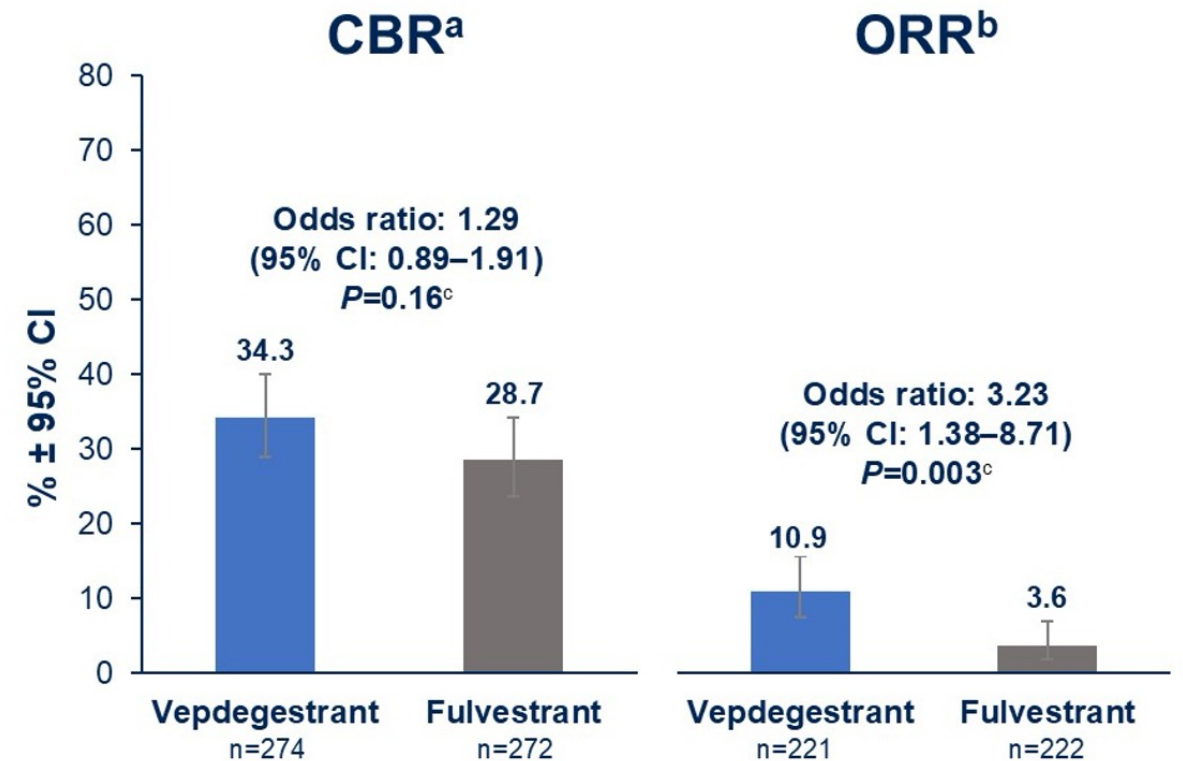
- OS (key secondary)
- CBR and ORR by BICR
- AEs

VERITAC-2: Clinical Benefit Rate (CBR) and Objective Response Rate (ORR)

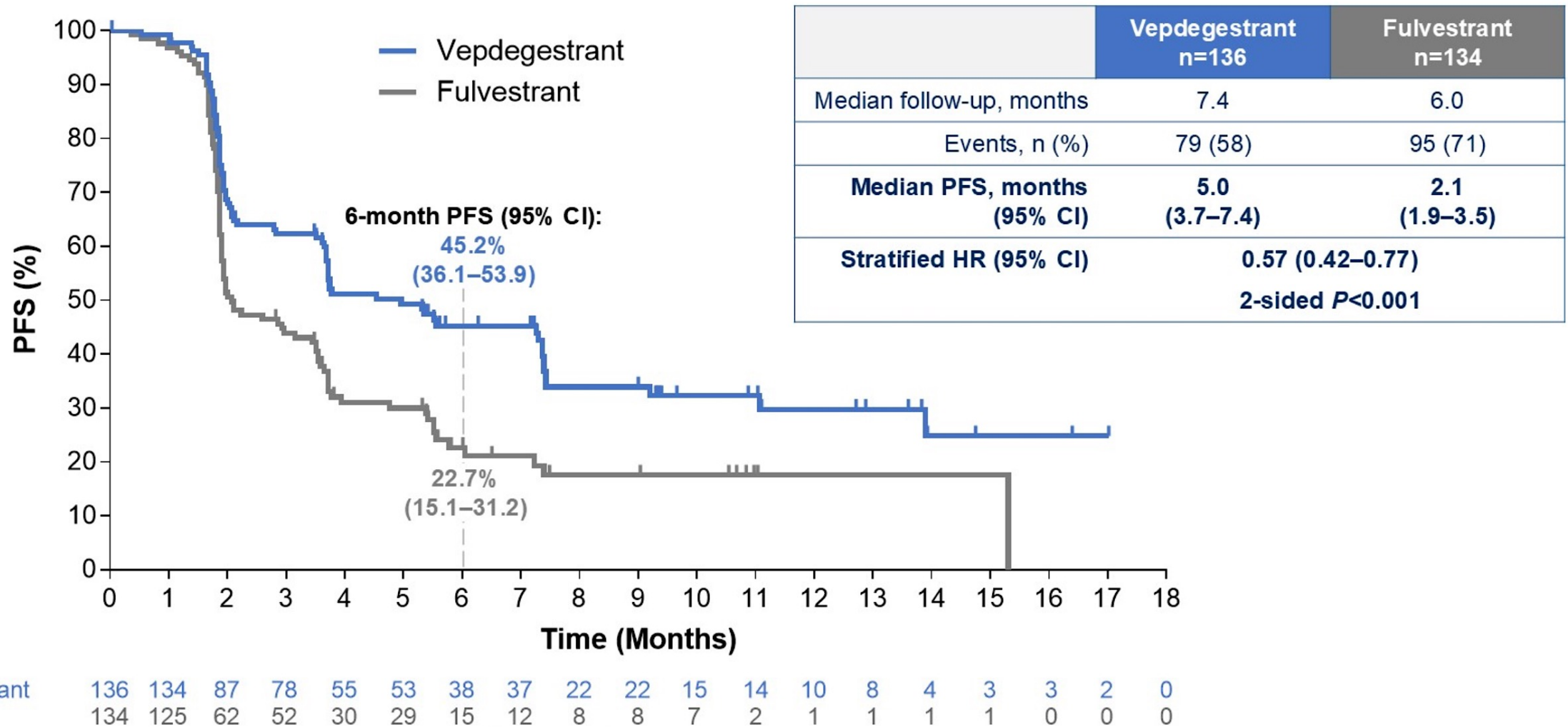
Patients With *ESR1m*



All Patients



VERITAC-2: PFS by BICR in the ESR1 Mutation Population



BICR = blinded independent central review

VERITAC-2: Safety Profile

Overview

	Vepdegestrant (n=312)	Fulvestrant (n=307)
TEAEs, %		
Any grade	87	81
Grade ≥3	23	18
Serious	10	9
Leading to treatment discontinuation	3	1
Leading to dose reduction	2	NA
TRAEs, %		
Any grade	57	40
Grade ≥3	8	3

QT prolongation

- TEAEs: vepdegestrant, 10%; fulvestrant, 1%
- A QT interval sub-study (n=88) confirmed a mild increase (11.1 ms) from baseline in mean QTcF, with upper 90% CI (13.7 ms) <20 ms,^f **indicating no large QT-prolonging effect**

TEAEs in >10% of Patients in Either Group

	Vepdegestrant (n = 312)		Fulvestrant (n = 307)	
TEAE, %	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Fatigue ^a	27	1	16	1
ALT increased ^b	14	1	10	1
AST increased ^b	14	1	10	3
Nausea	13	0	9	1
Anemia ^{b, c}	12	2	8	3
Neutropenia ^d	12	2 ^e	5	1 ^e
Back pain	11	1	7	<1
Arthralgia	11	1	11	0
Decreased appetite	11	<1	5	0

TEAEs = treatment-emergent adverse events

Faculty Discussion



Questions for the Faculty

- In what situations, if any, are you utilizing the SERENA-6 strategy?
- How would you approach ctDNA testing for consideration of the SERENA-6 strategy? How long after starting first-line AI + CDK4/6i do you start monitoring? How often do you test?
- What is the side effect profile of camizestrant?
- How do you counsel your patients who are about to receive camizestrant about potential ocular toxicity?



Dr Gupta

Questions for the Faculty

52-year-old woman with ER+, HER2-neg disease with recurrence during 4th year of adjuvant AI. PIK3CA mutation-positive, gPALB2 mutation.

Receiving the INAVO120 protocol of inavolisib/palbociclib/fulvestrant; she was having some mouth sores. We did prophylactically use dexamethasone oral rinse, but I dose reduced to 6 mg and that helped.

She's already on a GLP-1 agonist for weight loss, and she has good glucose control.

Questions

- Would the presence of a gPALB2 mutation affect your adjuvant treatment selection?
- How would you integrate a PARP inhibitor for this patient who is also PIK3CA mutation-positive? Which PARP inhibitor would you choose?



Dr Gupta

Questions for the Faculty (Continued)

Questions

- What are your criteria to use the INAVO120 triplet? What about patients with disease recurrence more than a year off an adjuvant aromatase inhibitor?
- What adverse effects have you observed with the triplet?
- Do you use the INAVO120 triplet for patients with well-controlled diabetes? If not well controlled, do you have them intensify diabetic treatment (GLP-1?) and then treat? Which HbA1c level is necessary to start inavolisib?
- How do you approach dose reduction?



Dr Gupta

Questions for the Faculty

64-year-old woman with ER+, HER2-neg bone-only metastatic disease who received PROTAC vepdegestrant on a clinical trial with good response and excellent tolerability for 4 years. Now with disease progression. PIK3CA and ESR1 mutations.

I switched her to capivasertib and fulvestrant, and she is doing well.

Questions

- When and for whom are you using vepdegestrant?
- What have you observed regarding the tolerability/toxicity profile of vepdegestrant?
- What would be a logical next endocrine treatment? Imlunestran alone or with abemaciclib?

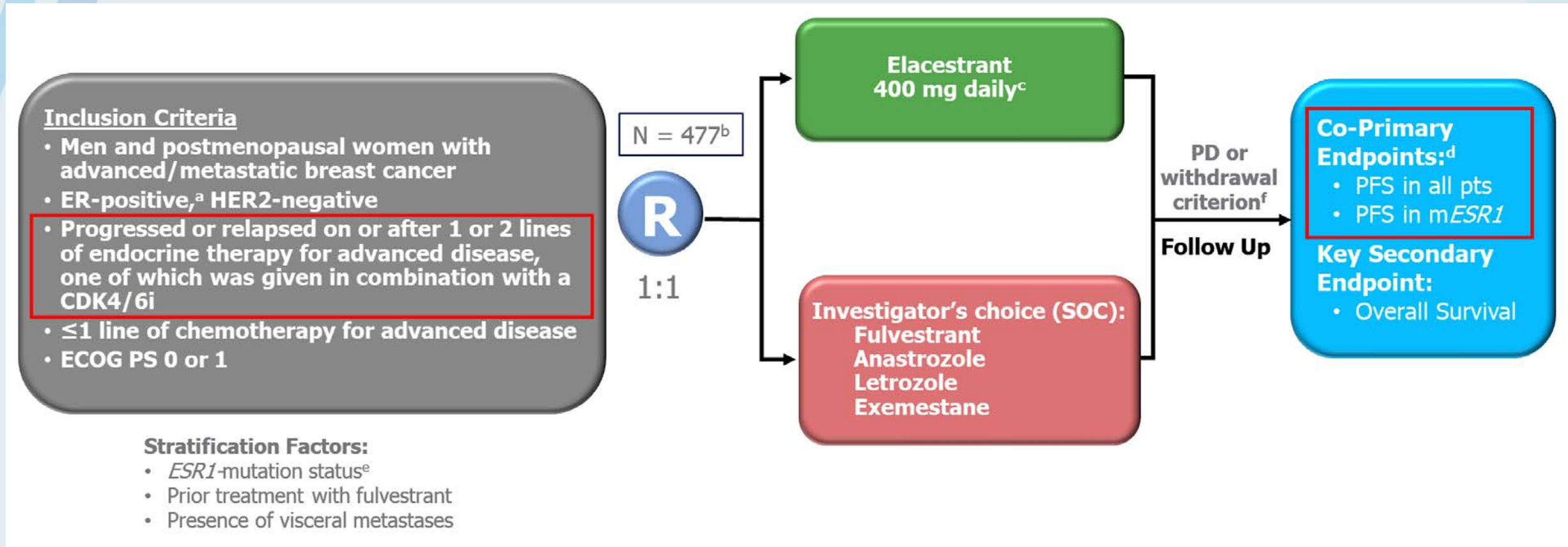
Oral SERDs in the Metastatic Setting

Dr Wander

Select Datasets

- Bidard FC et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: Results from the randomized phase III EMERALD trial. *J Clin Oncol* 2022;40(28):3246-56.
- Lloyd MR et al. Clinical and genomic factors associated with elacestrant outcomes in ESR1-mutant metastatic breast cancer. *Clin Cancer Res* 2026;32(1):169-78.
- Jhaveri KL et al. Imlunestrant with or without abemaciclib in advanced breast cancer: Updated efficacy results from the phase III EMBER-3 trial. *Ann Oncol* 2026;37(4):532-43.
- Mayer E et al. Giredestrant (GIRE), an oral selective oestrogen receptor (ER) antagonist and degrader, + everolimus (E) in patients (pts) with ER-positive, HER2-negative advanced breast cancer (ER+, HER2– aBC) previously treated with a CDK4/6 inhibitor (i): Primary results of the phase III evERA BC trial. ESMO 2025; Abstract LBA16.

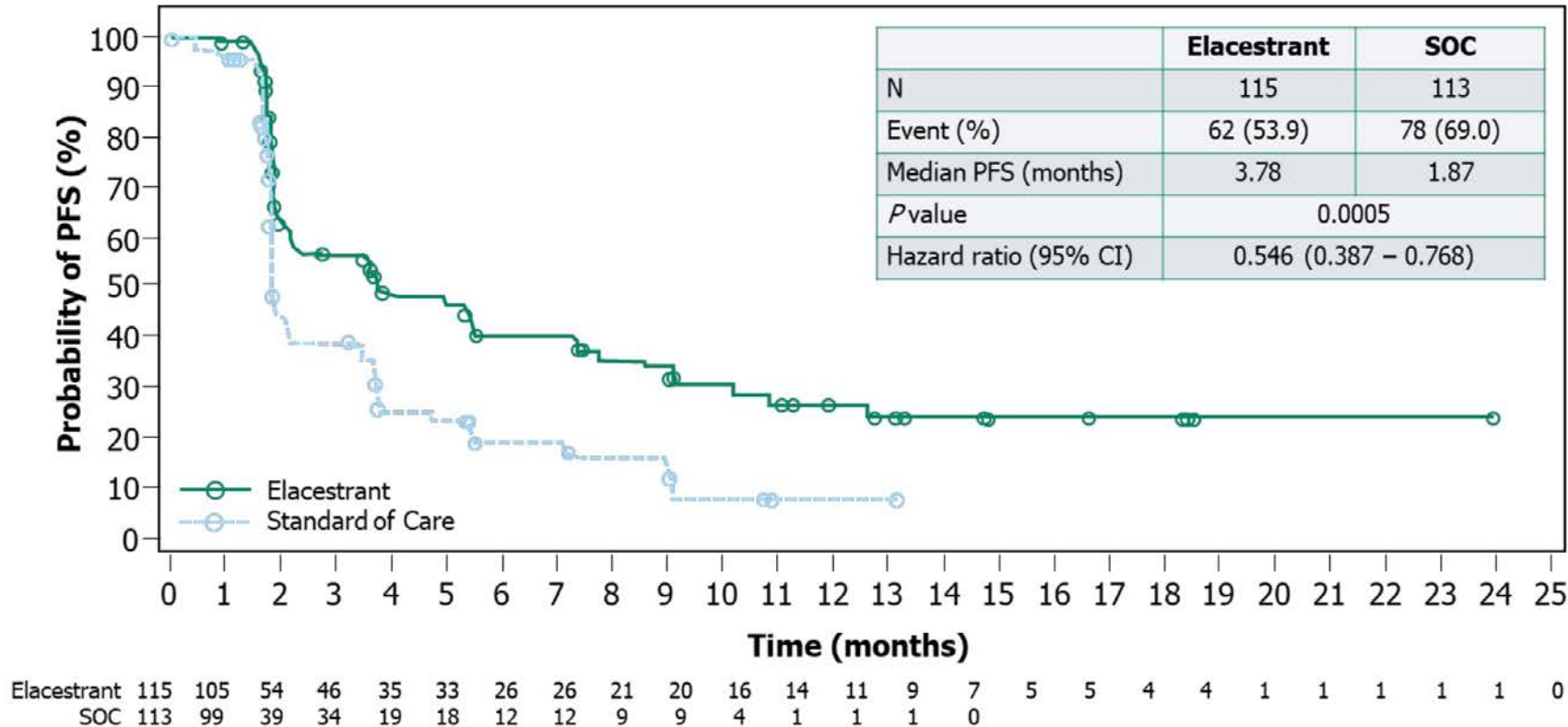
EMERALD Study Design



SOC = standard of care; PD = disease progression

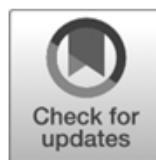
EMERALD: PFS for Patients with ESR1 Mutations (mESR1)

Patients With Tumors Harboring *mESR1*



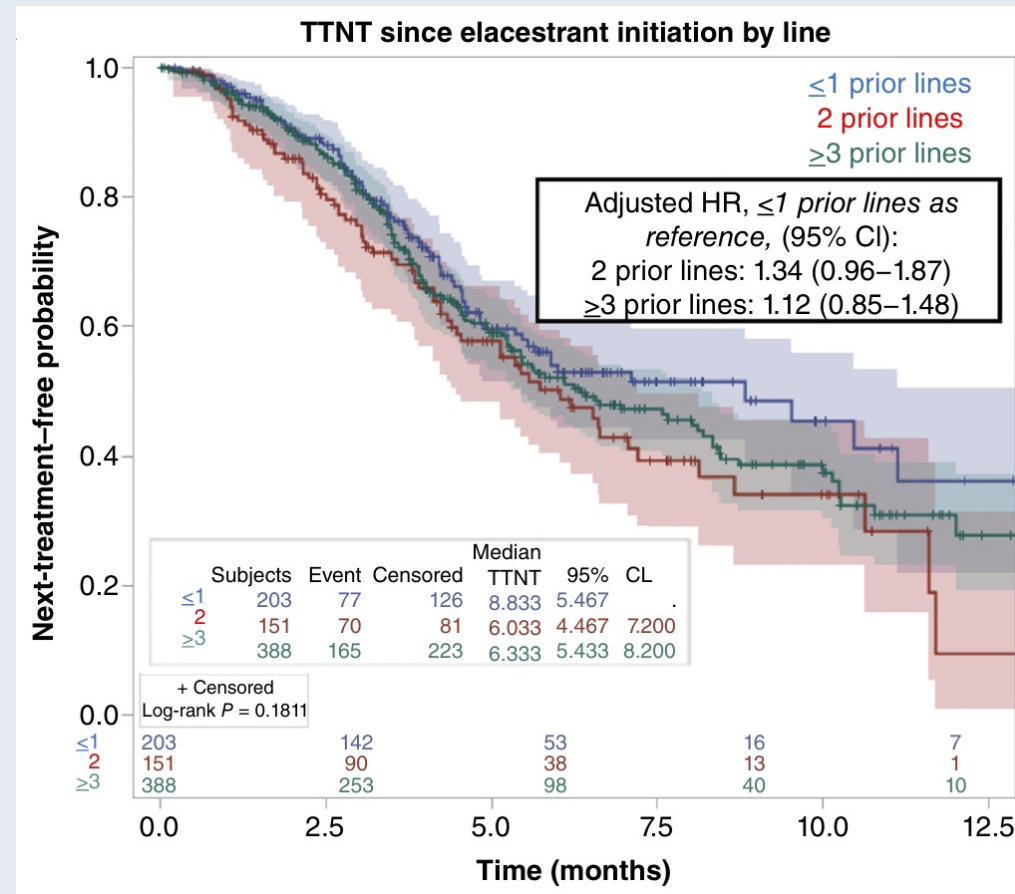
Elacestrant is associated with a 45% reduction in the risk of progression or death in patients harboring *mESR1*

Clinical and Genomic Factors Associated with Elacestrant Outcomes in *ESR1*-Mutant Metastatic Breast Cancer



Maxwell R. Lloyd¹, Caroline M. Weipert², Azka Ali³, Sheila R. Solomon², Jayati Saha², Marla D. Lipsyc-Sharf⁴, Erika P. Hamilton⁵, Kevin Kalinsky⁶, Adam M. Brufsky⁷, Aditya Bardia⁴, Nicole Zhang², and Seth A. Wander⁸

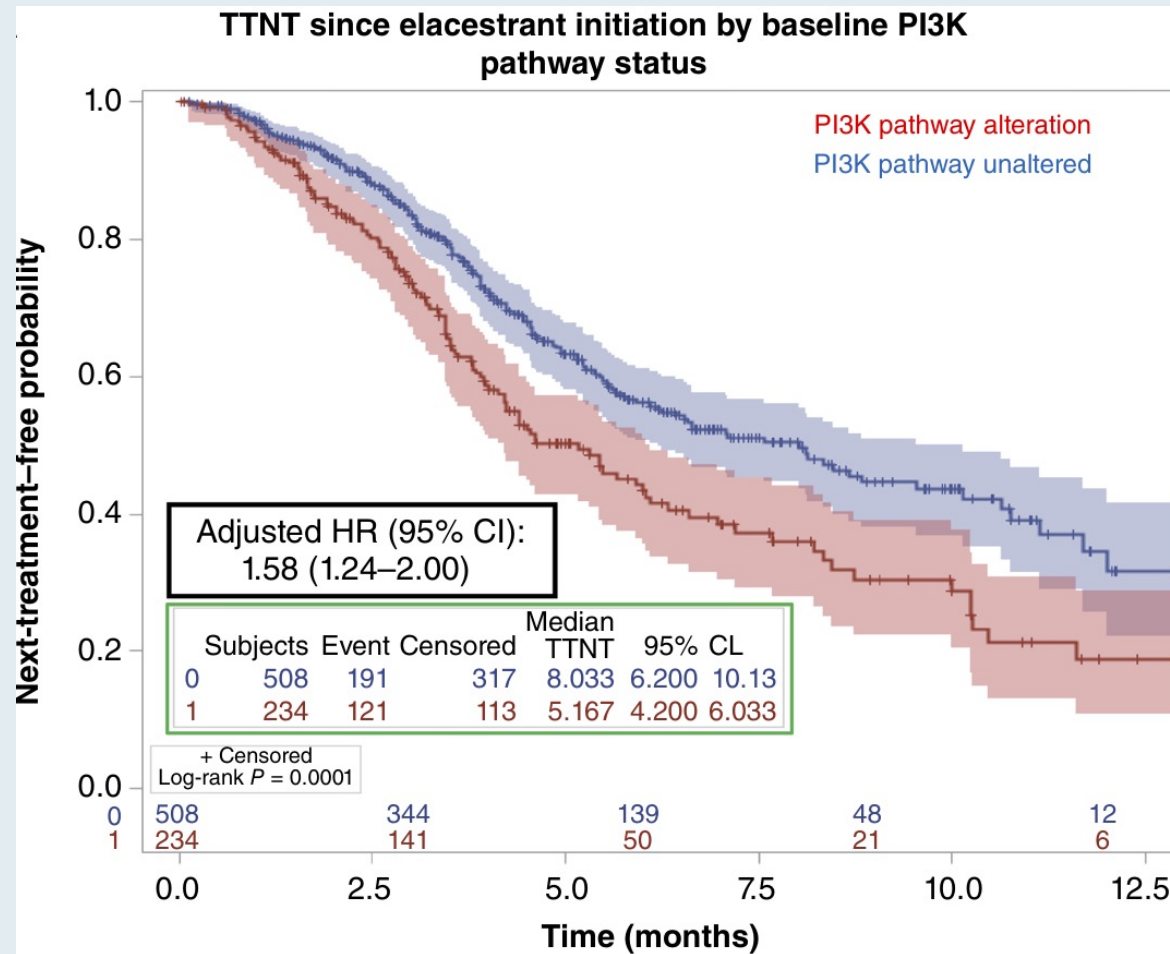
Real-World Time to Next Treatment (rwTTNT) Since Elacestrant Initiation by Line of Treatment



Patients treated in earlier lines (ie, 2L) seemed to have a longer rwTTNT.

Observational retrospective analyses are not intended for direct comparisons with clinical trials.

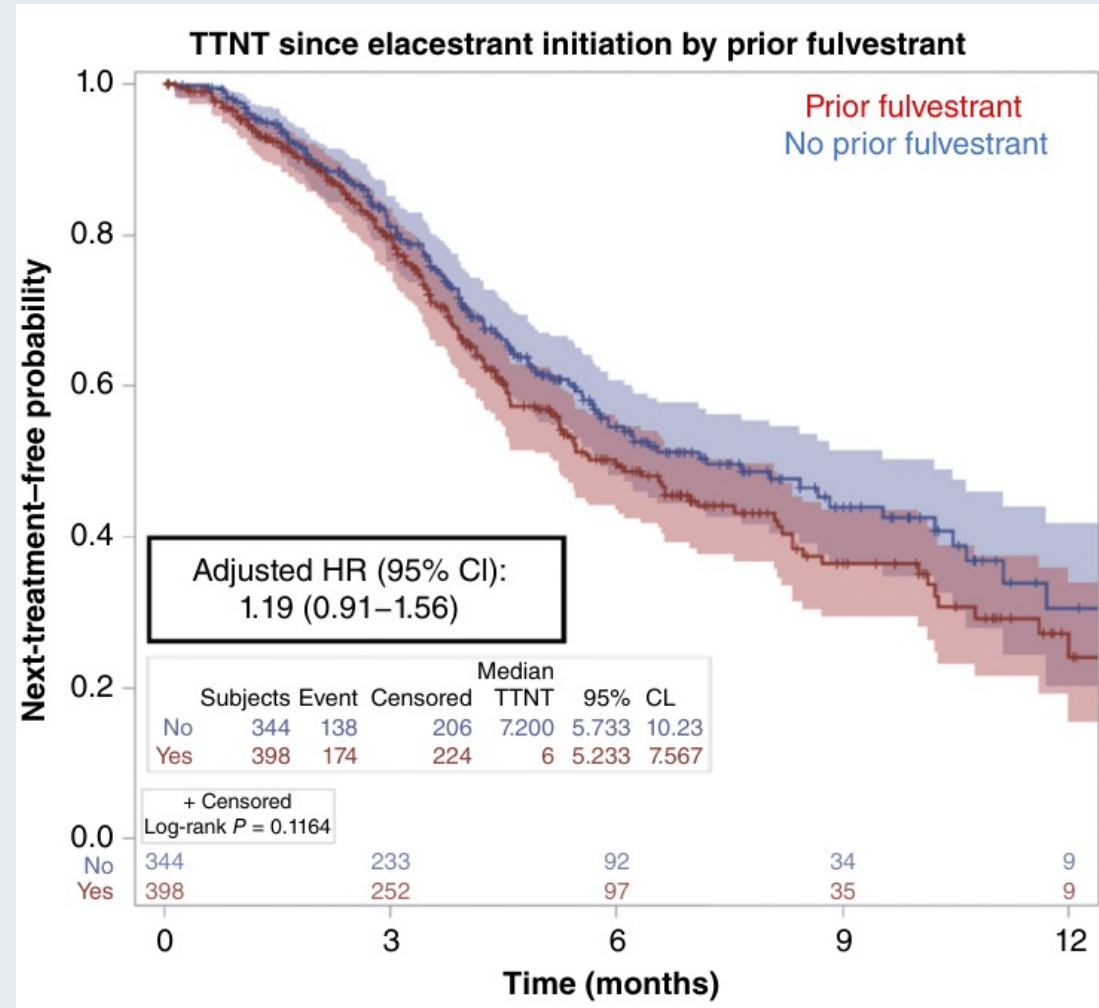
rwTTNT Since Elacestrant Initiation by Baseline PI3K Pathway Status



Patients without oncogenic PI3K pathway alterations showed to have a longer rwTTNT (8.0 mo vs 5.2 mo) compared to those having an alteration in this pathway.

Observational retrospective analyses are not intended for direct comparisons with clinical trials.

rwTTNT Since Elacestrant Initiation by Prior Fulvestrant



Patients without prior fulvestrant versus those with previous fulvestrant exposure trended toward better rwTTNT on elacestrant.

Observational retrospective analyses are not intended for direct comparisons with clinical trials.

Lloyd MR et al. *Clin Cancer Res* 2026;32(1):169-78.

Content courtesy of Joyce O'Shaughnessy, MD

EMBER-3 Study Design

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

**Imlunestrant
400 mg QD**

A

**SOC ET^{d,e}
Fulvestrant or
Exemestane**

B

**Imlunestrant
400 mg QD +
abemaciclib^e**

C^b

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

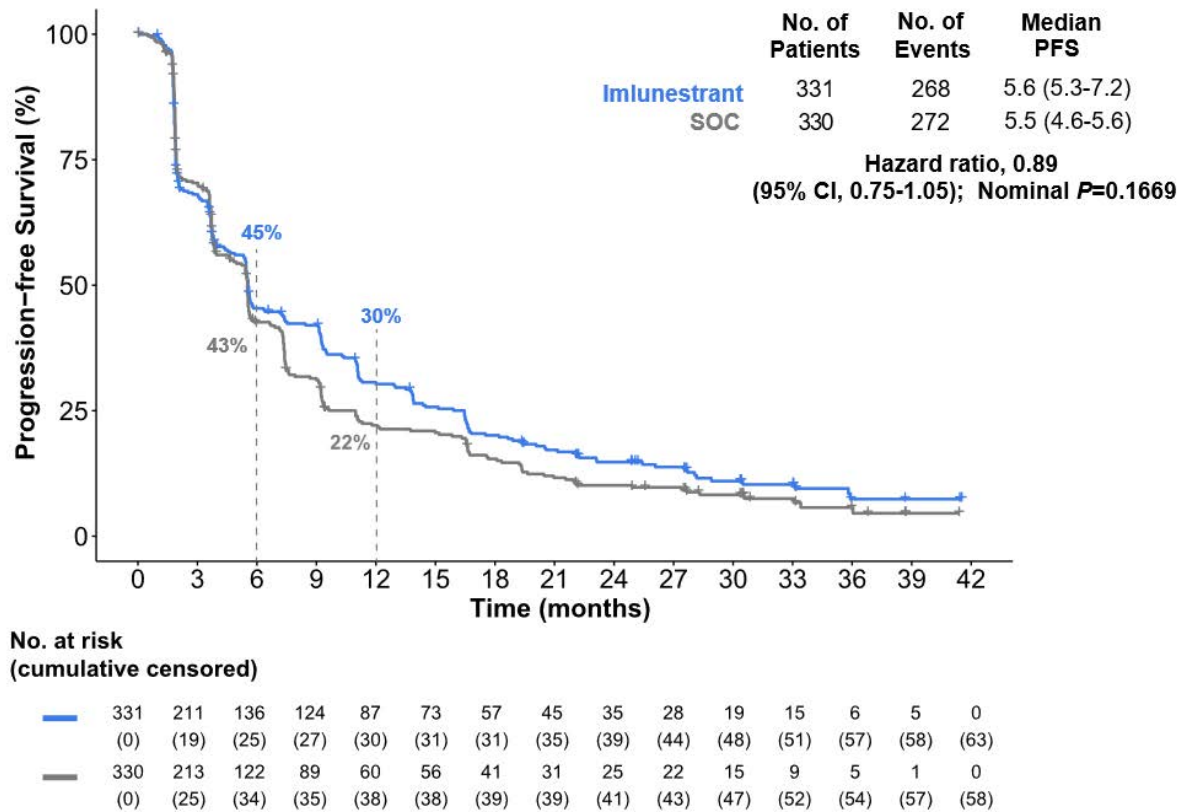
Exploratory Endpoints

- PFS and OS for C vs B in all^h patients

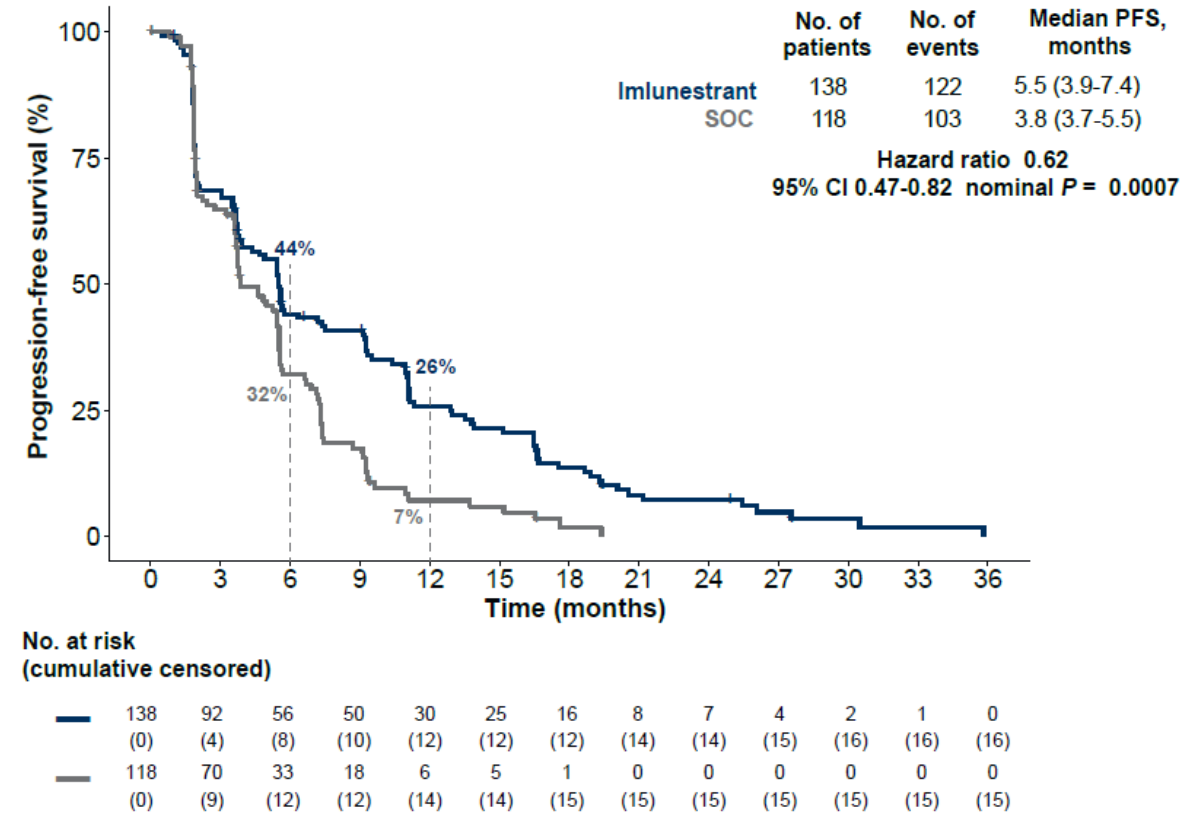
ABC, advanced breast cancer; AI, aromatase inhibitor; BICR, blinded independent central review; CDK4/6i CDK4/6 inhibitor; ER, estrogen receptor; *ESR1*m, *ESR1* mutation; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QD, once daily; SOC ET, standard of care endocrine 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 for patients from China; ^h Analysis conducted in all concurrently randomized patients.

EMBER-3: PFS with Imlunestrant Monotherapy

All Patients

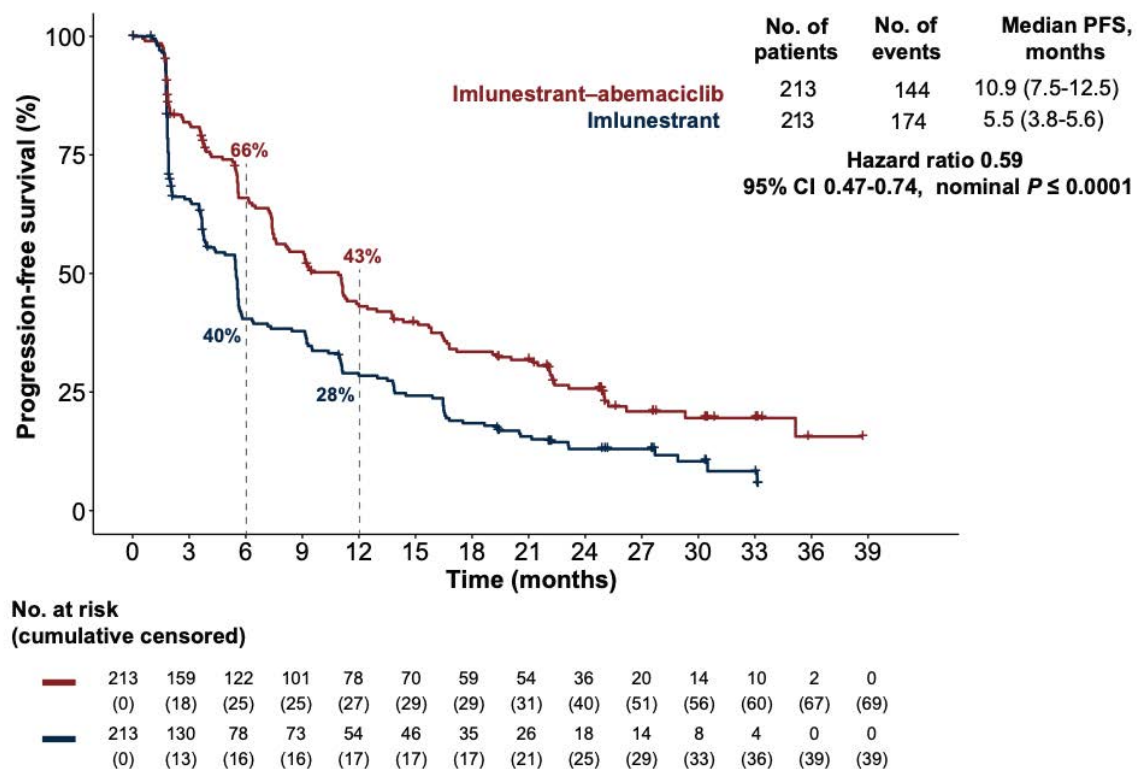


Patients with ESR1m

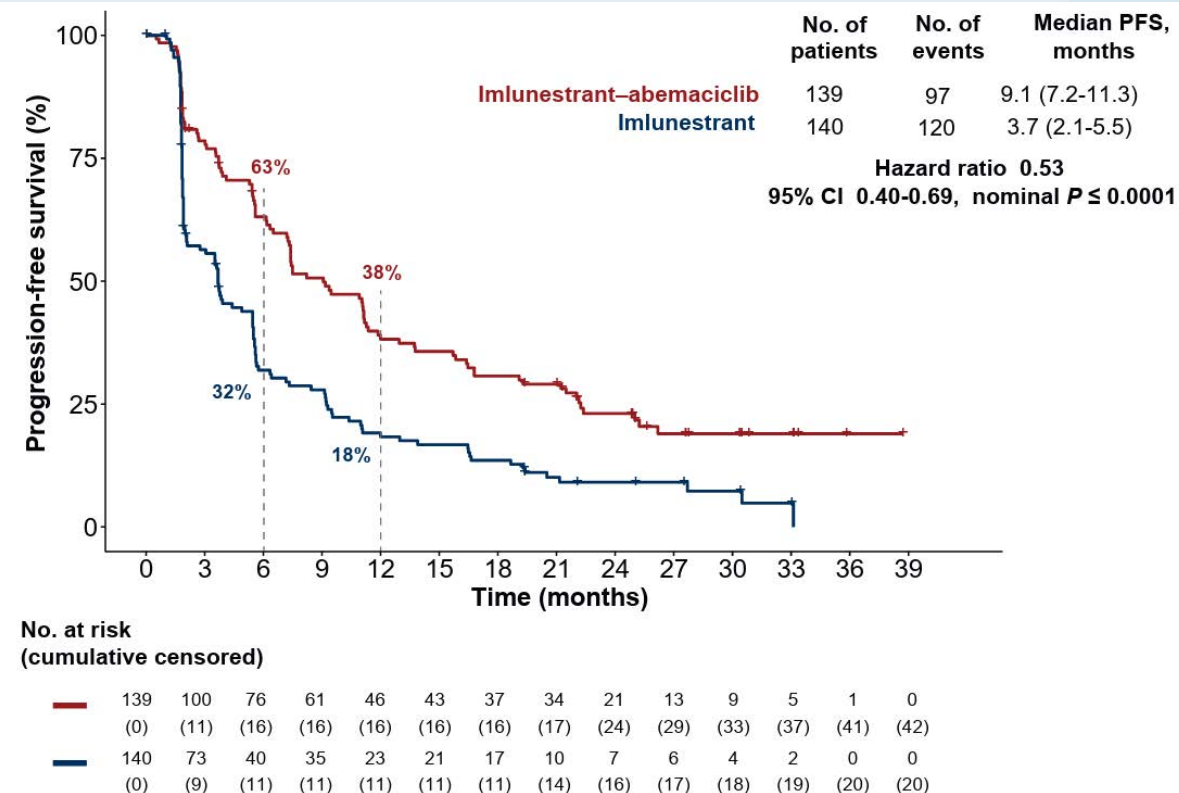


EMBER-3: PFS with Imlunestrant and Abemaciclib

All patients

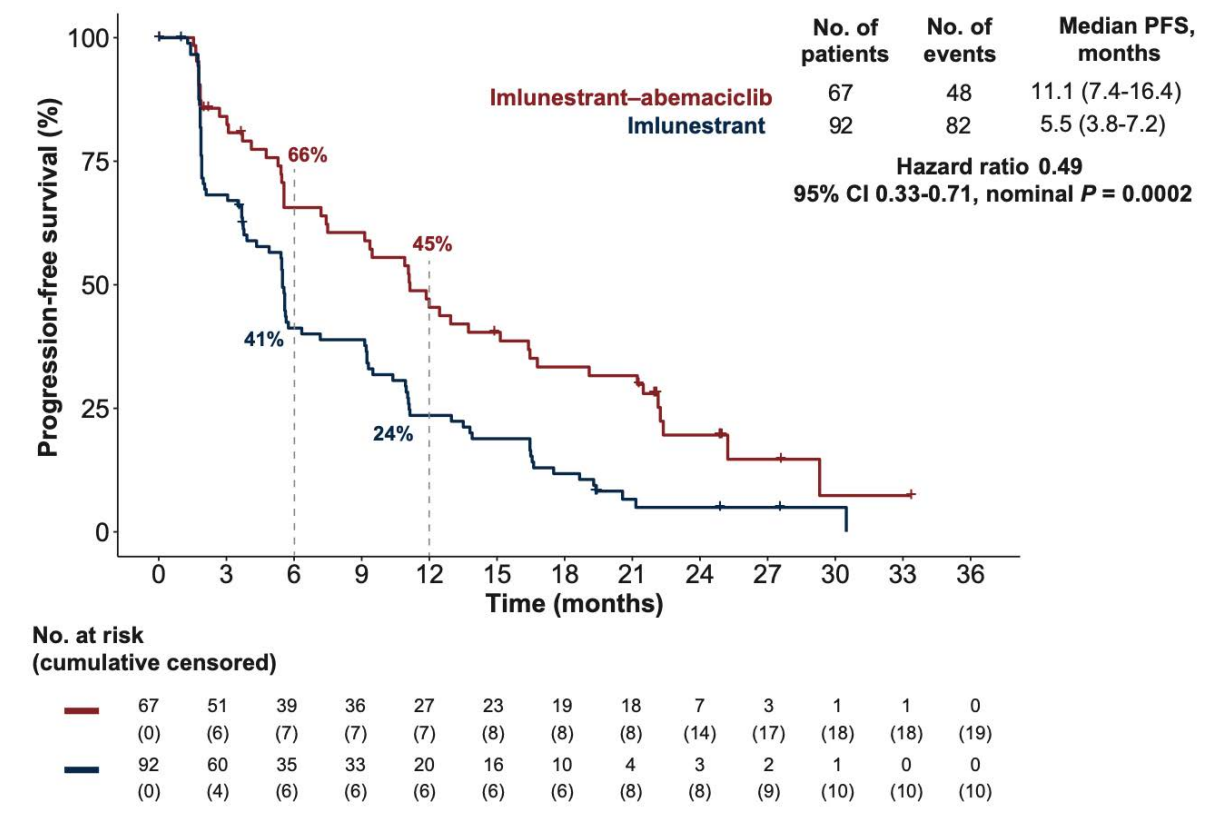


Patients who previously received a CDK4/6i

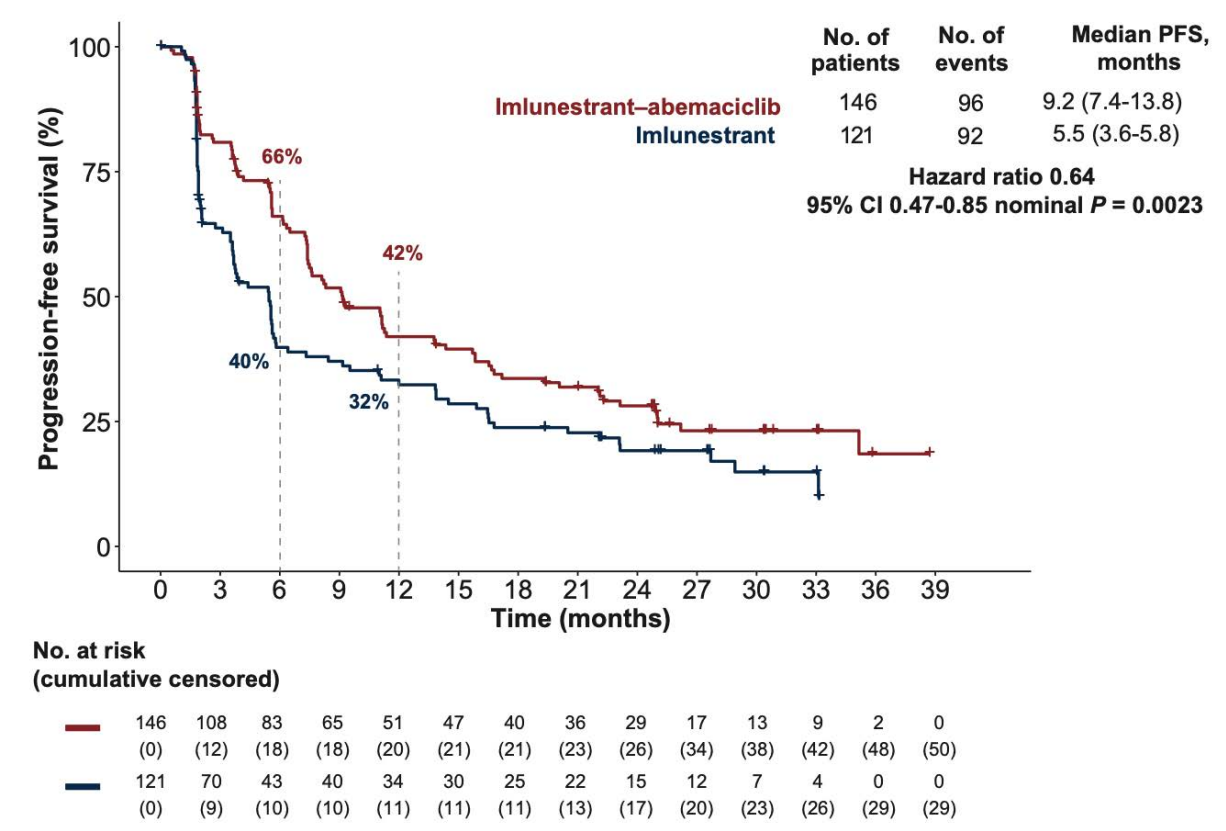


EMBER-3: PFS with Imlunestrant and Abemaciclib by ESR1 Mutation Status

With ESR1 mutation

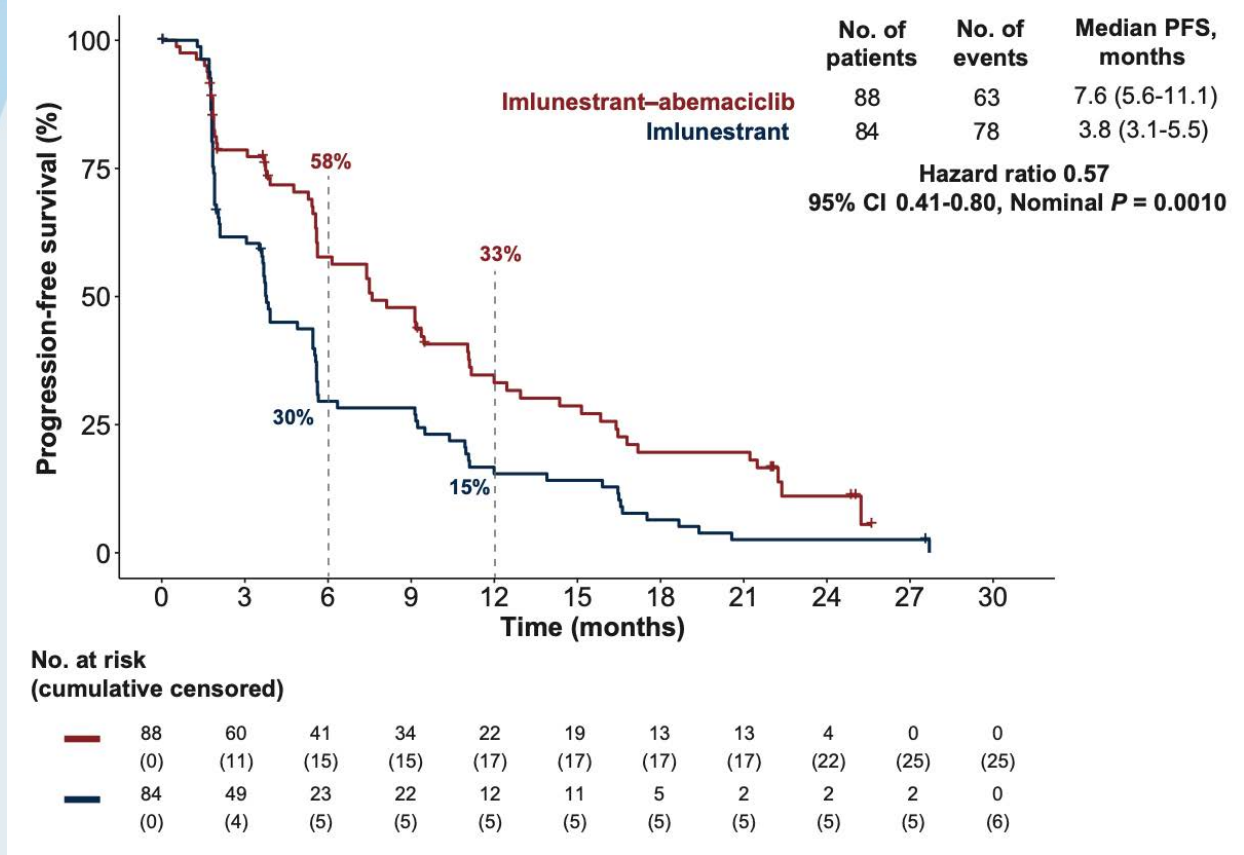


Without ESR1 mutation

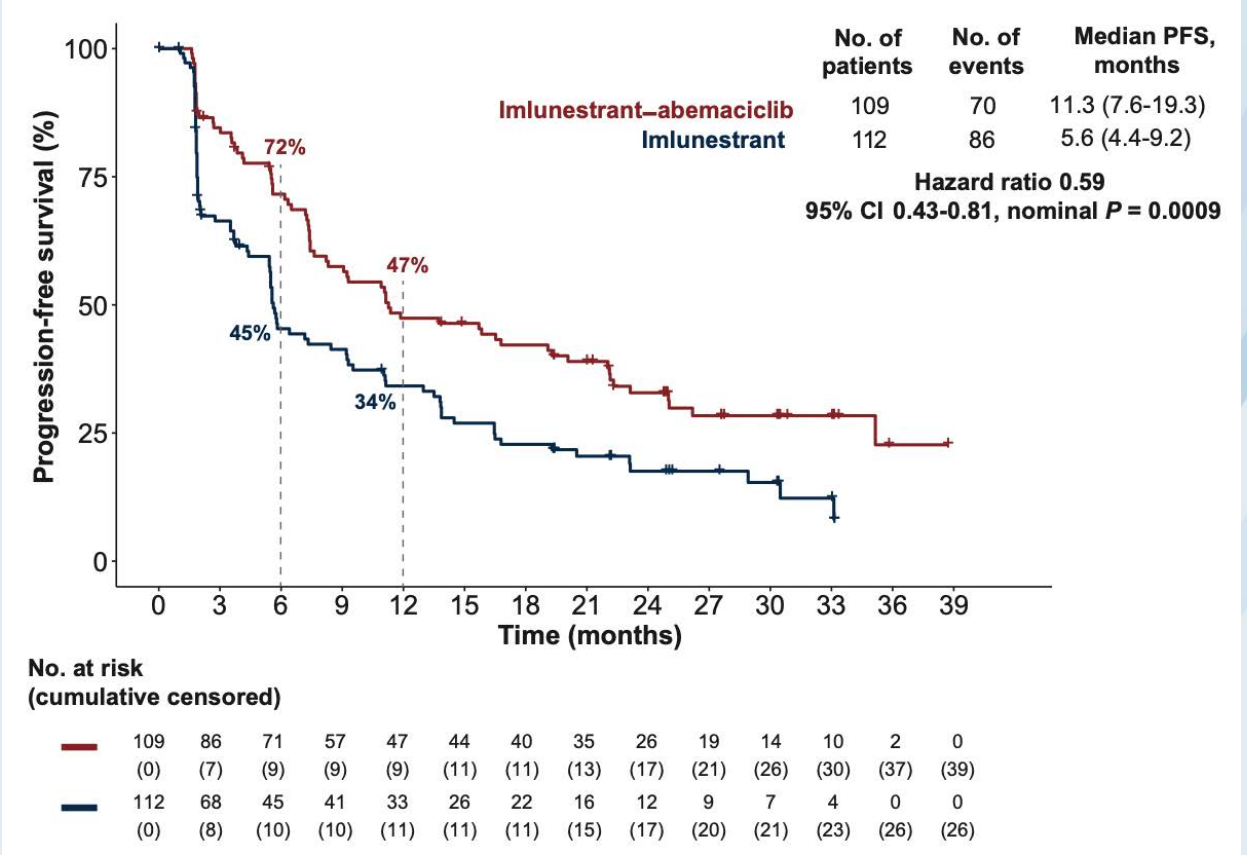


EMBER-3: PFS with Imlunestrant and Abemaciclib by PI3K Mutation Status

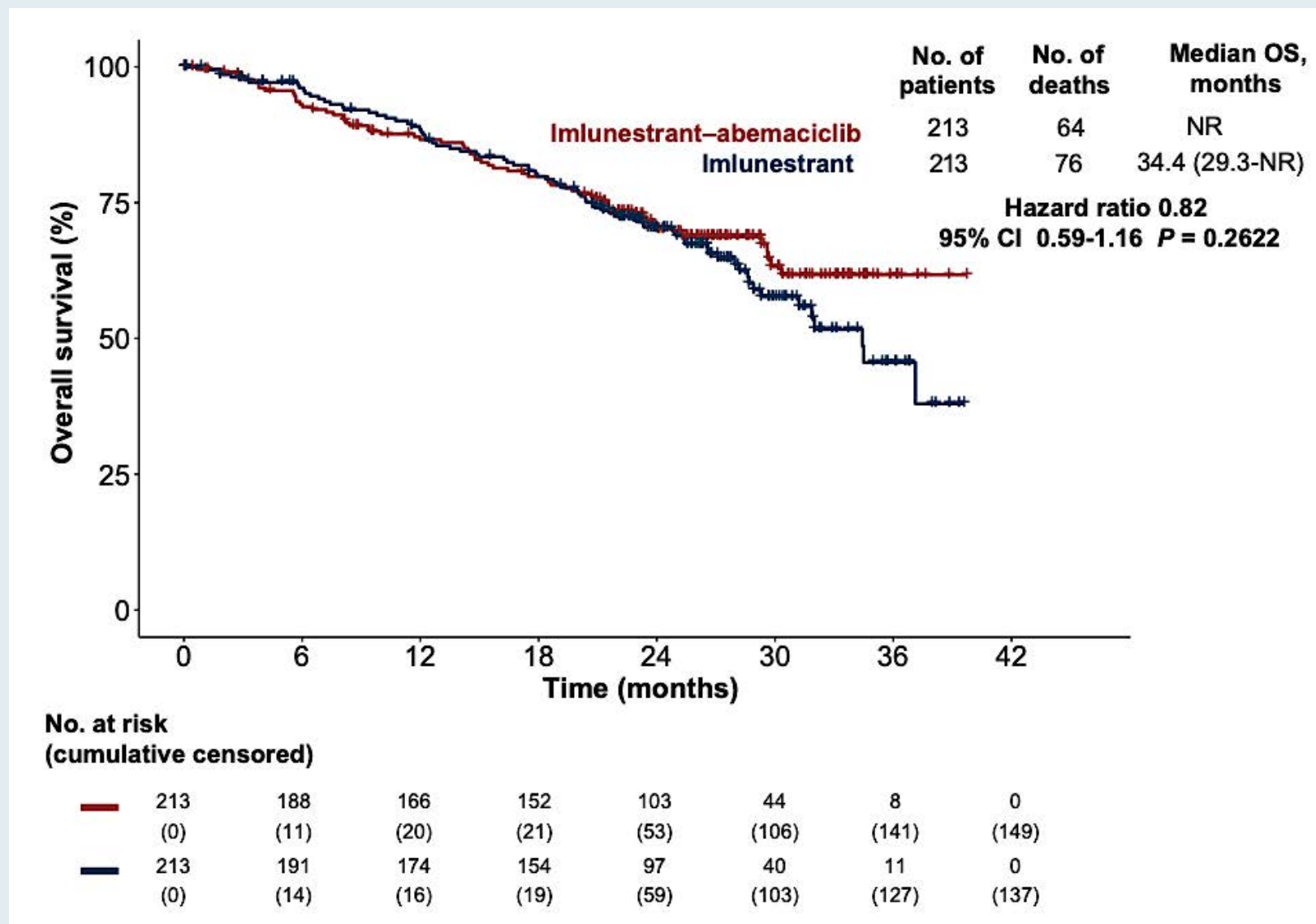
With PI3K pathway mutation



Without PI3K pathway mutation



EMBER-3: OS with Imlunestrant and Abemaciclib for All Patients



evERA Study Design

Key eligibility criteria*

- ER+, HER2– aBC (1–3L of therapy)
- ≤ 2 prior lines of ET in the aBC setting
- PD or relapse during/post-CDK4/6i + ET
- No prior chemotherapy in the aBC setting
- Measurable disease per RECIST v1.1 or evaluable bone metastases

N = 373*

R
1:1

Enrolment period: August 2022 to October 2024

Giredestrant (30 mg) + everolimus (10 mg)[†]

SOC ET[‡] + everolimus (10 mg)[†]

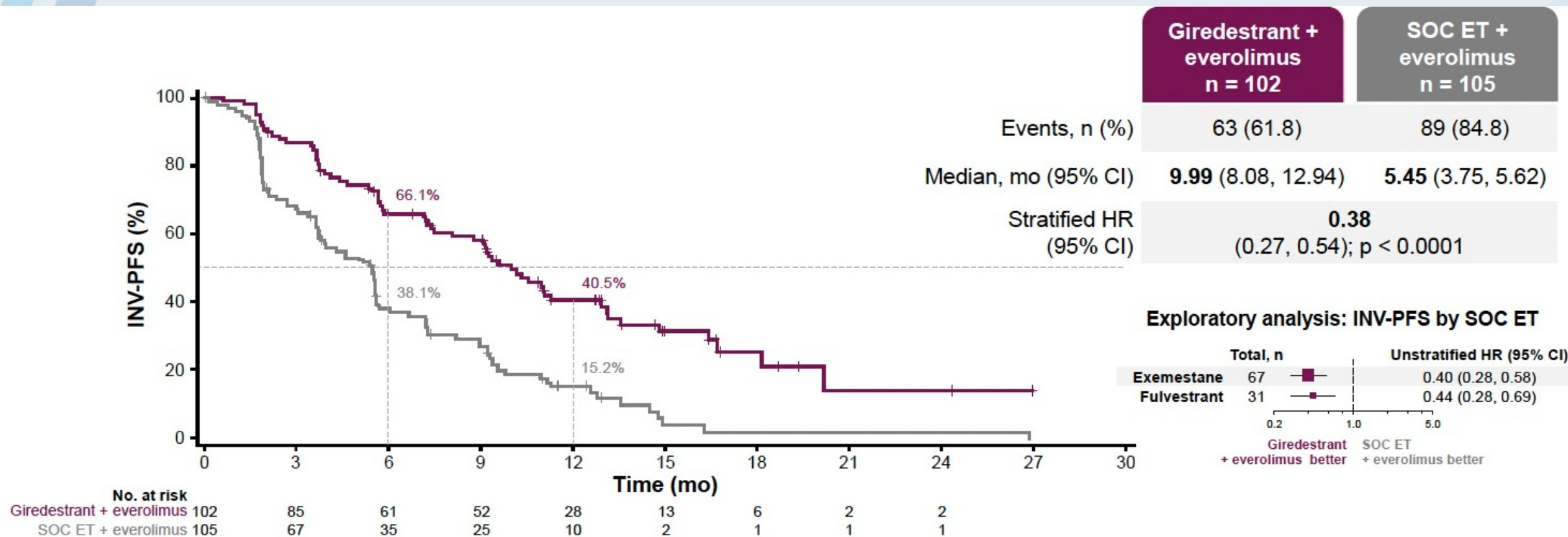
[‡]Exemestane/fulvestrant/tamoxifen

**Until PD
or
unacceptable
toxicity**

[†] Dexamethasone mouthwash prophylaxis and treatment was strongly recommended per SWISH trial protocol¹

PD = disease progression

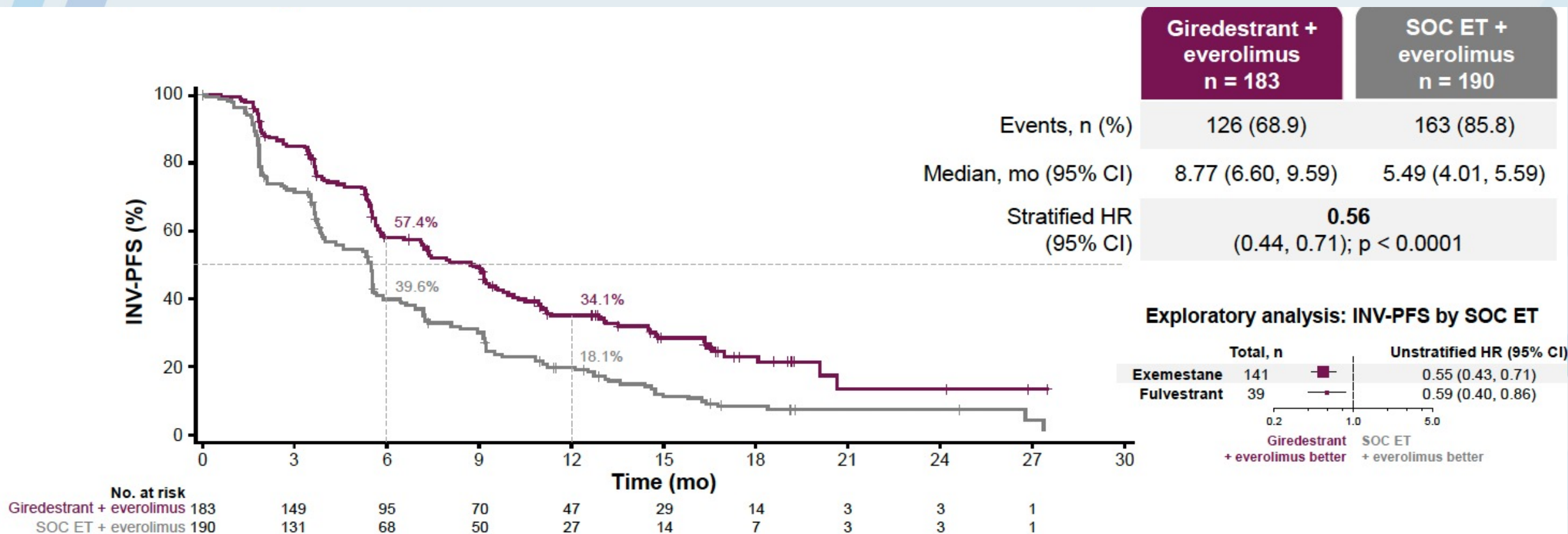
evERA: PFS in the ESR1 Mutation (ESR1m) Population



Combination therapy with giredestrant + everolimus led to a clinically meaningful 62% reduction in the risk of progression or death in patients with *ESR1m*

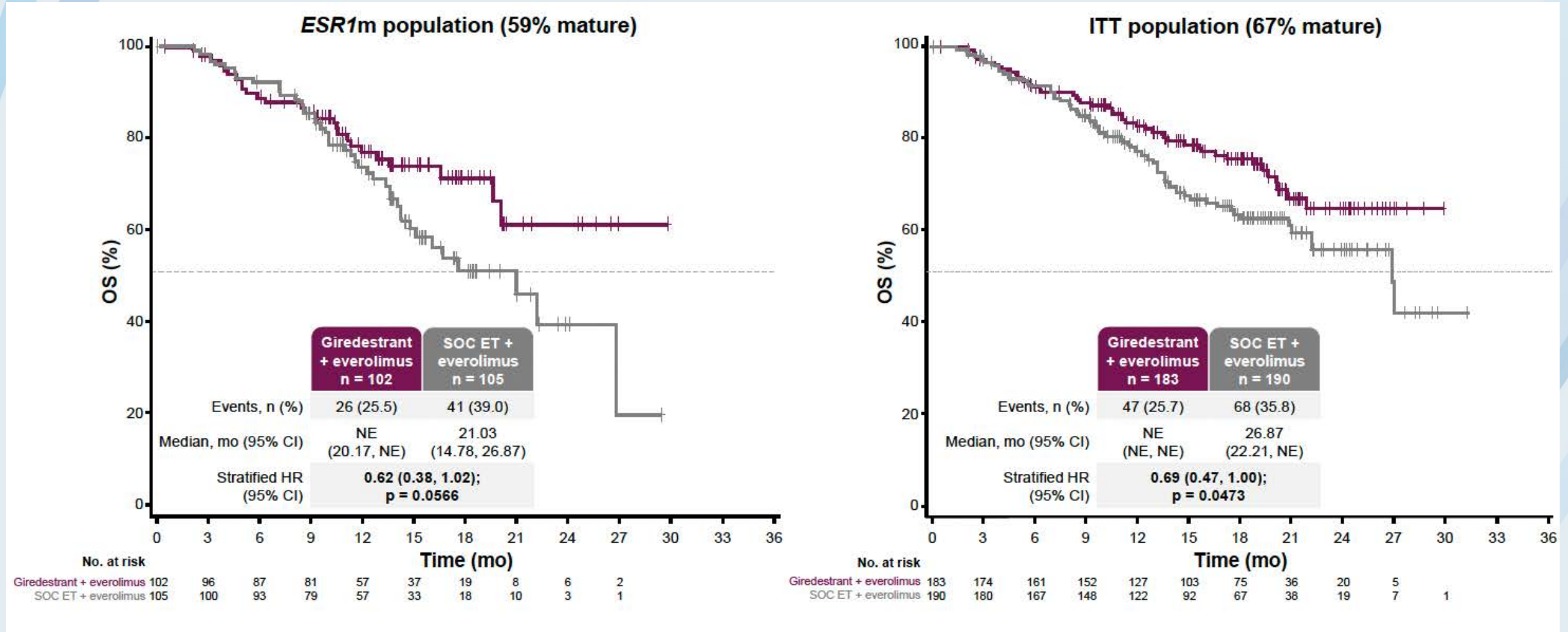
INV-PFS = investigator-assessed progression-free survival

evERA: PFS in the Intent-to-Treat (ITT) Population



Combination therapy with giredestrant + everolimus led to a clinically meaningful 44% reduction in the risk of progression or death in patients in the ITT population

evERA: Interim OS in the ESR1m and ITT Populations



Faculty Discussion



Dr Hussein

Questions for the Faculty

A woman in her early 70s with asymptomatic bone-only ER+, HER2-low (1+) metastatic disease with progression after 2 years of palbociclib/anastrozole. Liquid biopsy reveals ESR1 and PIK3CA mutations.

Questions

- How do you care for patients with both mutations? Would you have given her capivasertib? I chose elacestrant because you don't need fulvestrant injections as with capi and I have seen very few adverse effects — occasionally abdominal discomfort, nausea, maybe fatigue, but no serious issues. With capivasertib I worry about the blood sugar and other side effects, but I wasn't sure.
- Now that imlunestrant/abemaciclib is available, when would you opt for it over oral SERD monotherapy?
- Do you think giredestrant plus everolimus will have a future role? For which patients would you consider this combination?



Dr Hussein

Questions for the Faculty (Continued)

She did well on elacestrant for 18 months but then had disease progression but not with liver metastases. She's still in good shape, with mild bone aches.

Questions

- How would you treat this patient?
- I recently started her on T-DXd, and she tolerated the first 2 doses very well. What exact antiemetic strategy do you use with T-DXd, and how often do you do pulmonary imaging?
- Can we come back to capivasertib in the future ?

Relapsed/Refractory HR-Positive mBC: PI3K/AKT/mTOR Pathway Inhibitors

Dr Nanda

Select Datasets

- Turner NC et al. Capivasertib in hormone receptor-positive advanced breast cancer. *N Engl J Med* 2023;388(22):2058-70.
- Rugo HS et al. Capivasertib (C) and fulvestrant (F) for patients (pts) with HR+/HER2-advanced breast cancer (ABC): Final overall survival (OS) results from the phase III CAPItello-291 trial. ESMO Breast 2026;Abstract 4170.
- Hurvitz SA et al. VIKTORIA-1 trial of gedatolisib plus fulvestrant with or without palbociclib in hormone receptor-positive/HER2-/PIK3CA wild-type advanced breast cancer. *J Clin Oncol* 2026;44(12):1108-19.
- Hurvitz SA et al. A randomized, open-label, phase 3 study of gedatolisib + fulvestrant ± palbociclib vs standard of care in HR+/HER2-/PIK3CA-mutant (MT) advanced breast cancer (VIKTORIA-1 Study 2). ASCO 2026;Abstract LBA1008.

CAPitello-291 Study Design

Patients with HR+/HER2– ABC

- Men and pre-/post-menopausal women
- Recurrence while on or <12 months from end of adjuvant AI, or progression while on prior AI for ABC
- ≤2 lines of prior endocrine therapy for ABC
- ≤1 line of chemotherapy for ABC
- Prior CDK4/6 inhibitors allowed (at least 51% required)
- No prior SERD, mTOR inhibitor, PI3K inhibitor, or AKT inhibitor
- HbA1c <8.0% (63.9 mmol/mol) and diabetes not requiring insulin allowed
- FFPE tumor sample from the primary/recurrent cancer available for retrospective central molecular testing

R1:1
(N=708)

Capivasertib

400 mg twice daily,
4 days on, 3 days off

Fulvestrant

500 mg: cycle 1, days 1 &
15; then every 4 weeks

Stratification factors:

- Liver metastases (yes/no)
- Prior CDK4/6 inhibitor (yes/no)
- Region*

Placebo

Twice daily,
4 days on, 3 days off

Fulvestrant

500 mg: cycle 1, days 1 &
15; then every 4 weeks

Dual primary endpoints

PFS by investigator assessment

- Overall
- AKT pathway-altered tumors (≥1 qualifying *PIK3CA*, *AKT1*, or *PTEN* alteration)

Key secondary endpoints

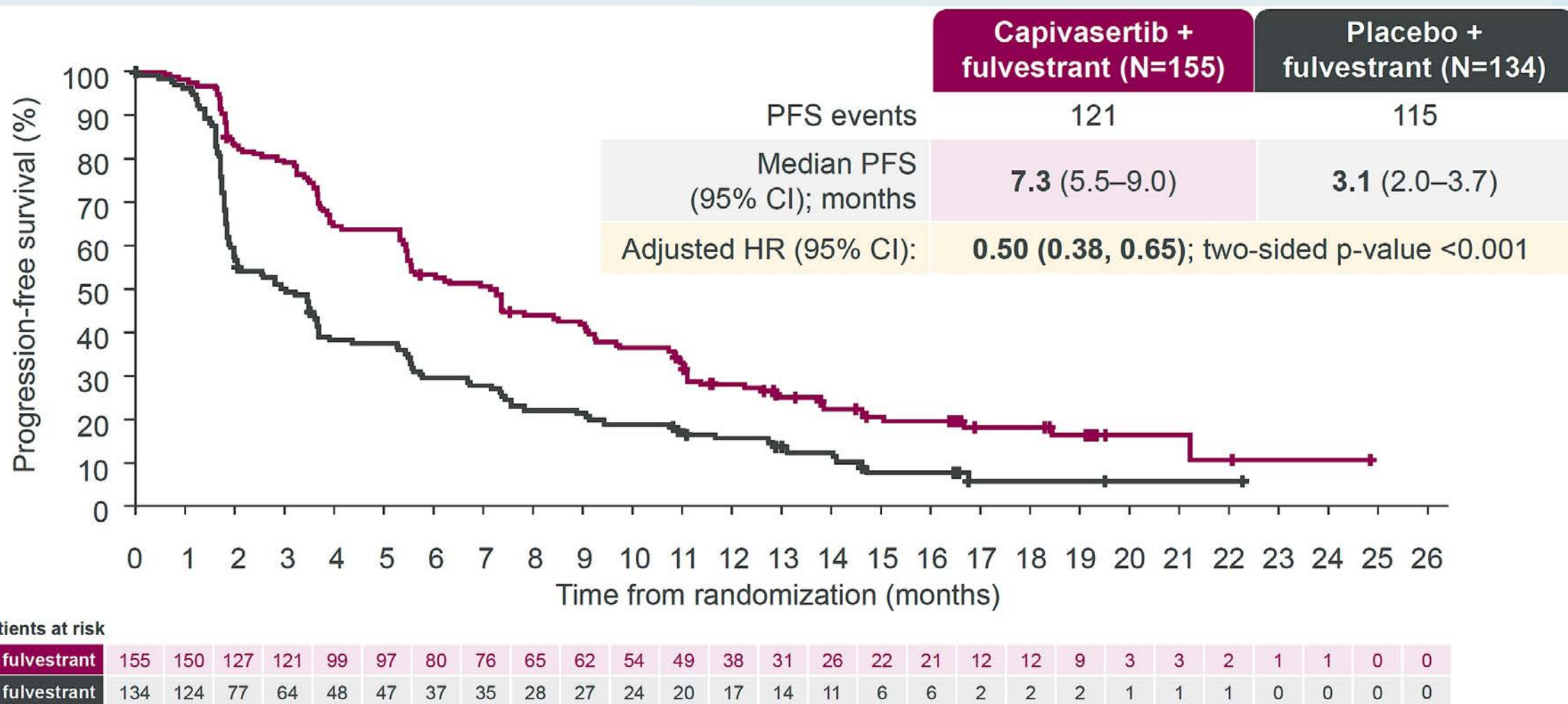
Overall survival

- Overall
- AKT pathway-altered tumors

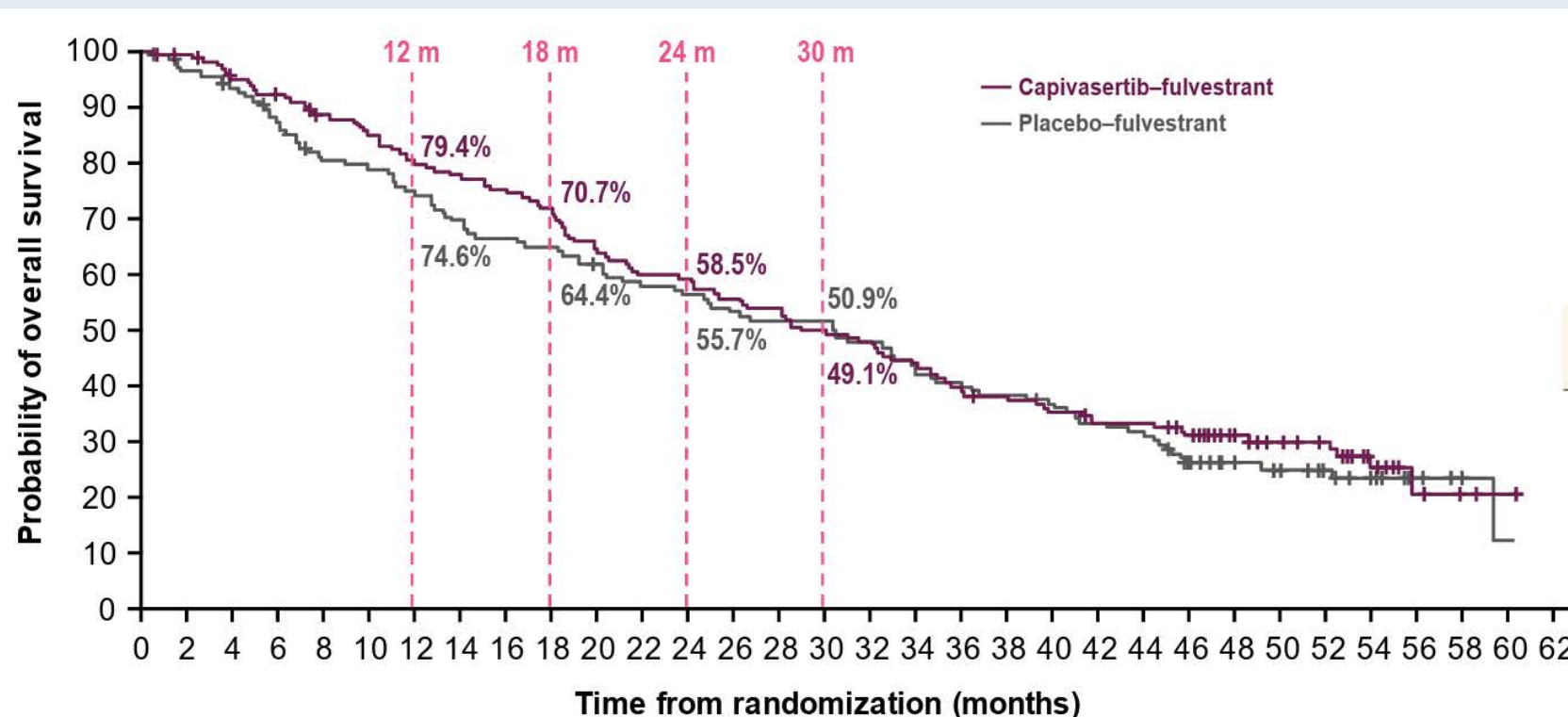
Objective response rate

- Overall
- AKT pathway-altered tumors

CAPitello-291: PFS in the AKT Pathway-Altered Population



CAPitello-291: Final OS in the AKT Pathway-Altered Population



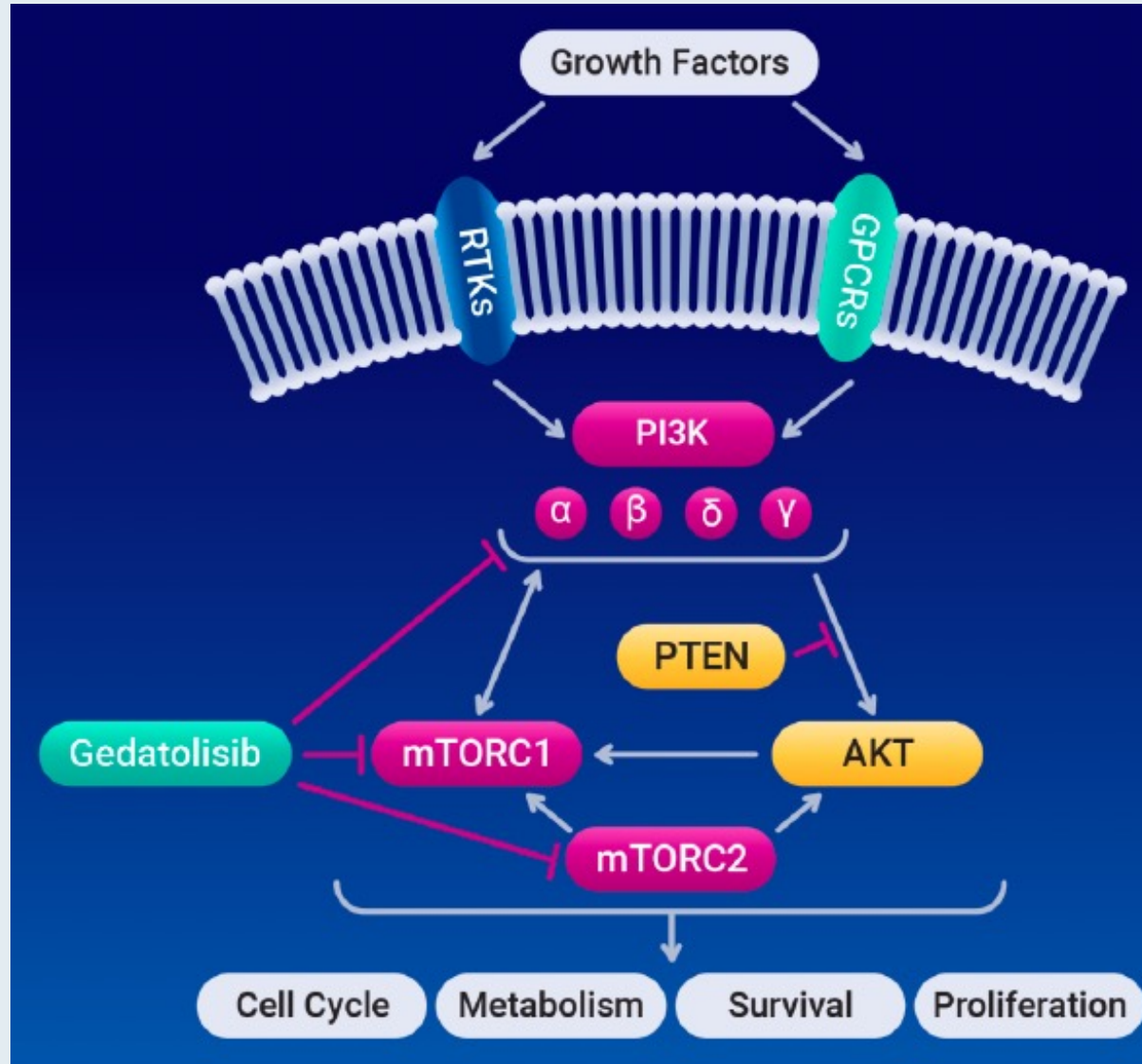
	Capivasertib -fulvestrant (N=155)	Placebo -fulvestrant (N=134)
OS events, n (%)	109 (70.3)	98 (73.1)
Median OS, months	28.5	30.4
Hazard ratio (95% CI): 0.83 (0.63–1.10); p=0.201		

Number of patients at risk

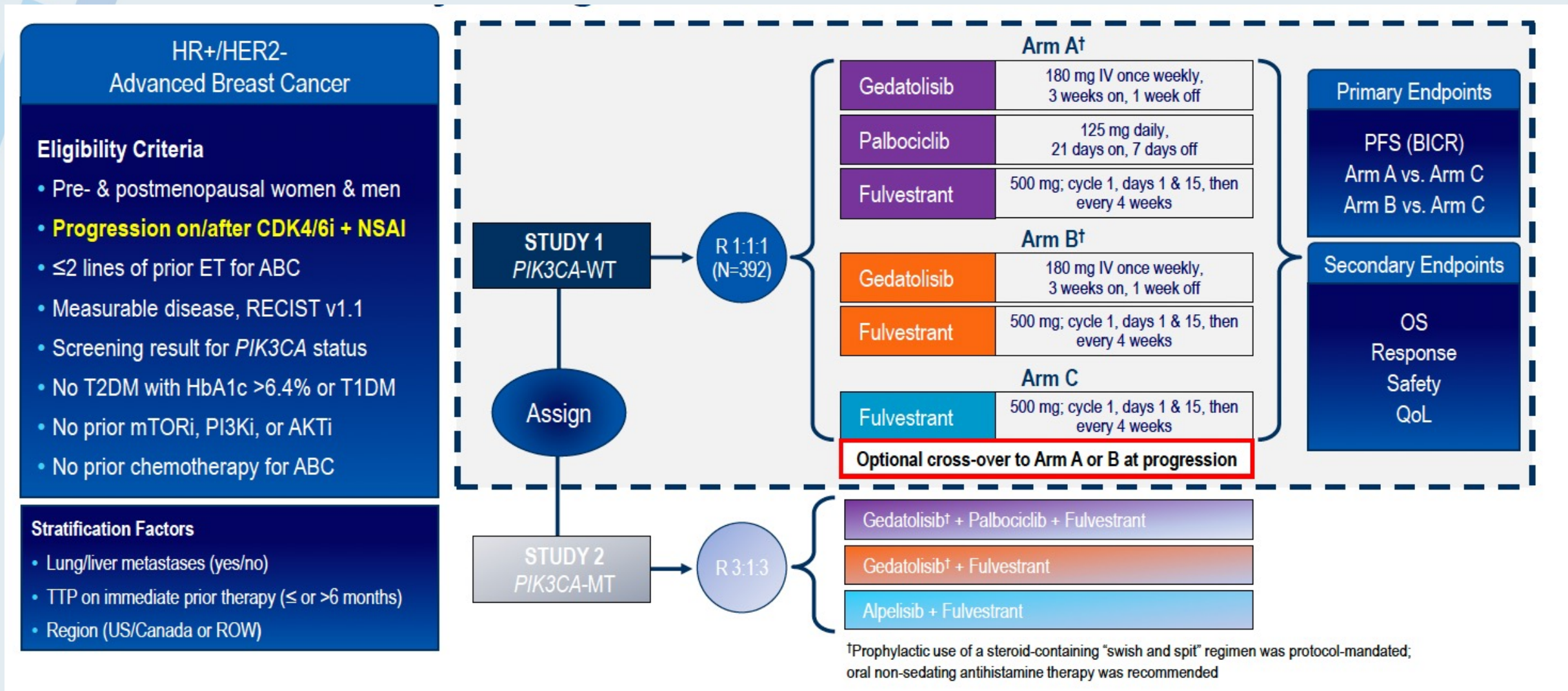
Capivasertib-fulvestrant	155	153	144	139	131	126	118	115	111	105	94	88	87	82	79	73	70	64	57	54	50	46	46	41	33	26	21	13	4	2	1	0
Placebo-fulvestrant	134	127	122	113	102	100	95	88	84	82	77	72	70	66	64	64	59	52	49	47	44	40	38	27	21	18	14	10	5	2	1	0

Final DCO: 16 June 2025. Data maturity: 71.6%.

Gedatolisib: A PI3K/AKT/mTOR Pathway Inhibitor

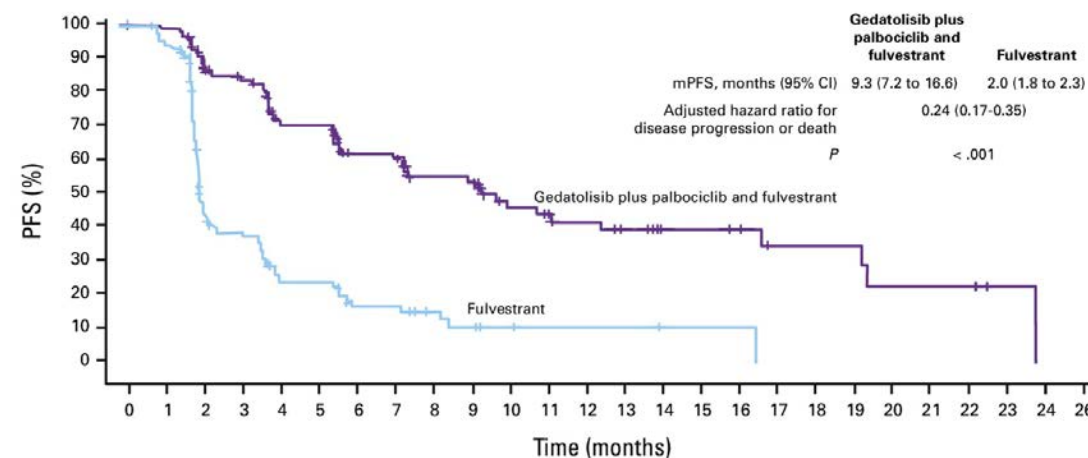
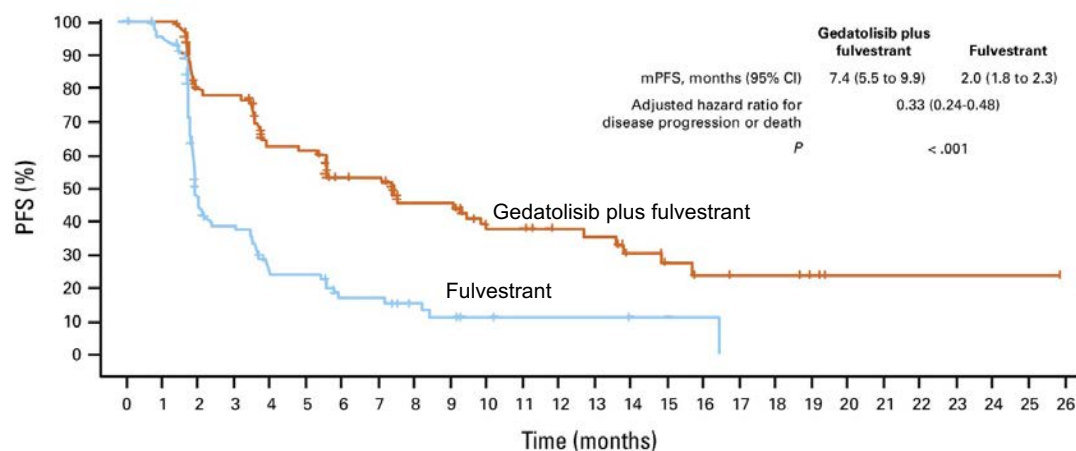


VIKTORIA-1 Study 1: A Phase III Trial of Gedatolisib for PIK3CA Wild-Type mBC



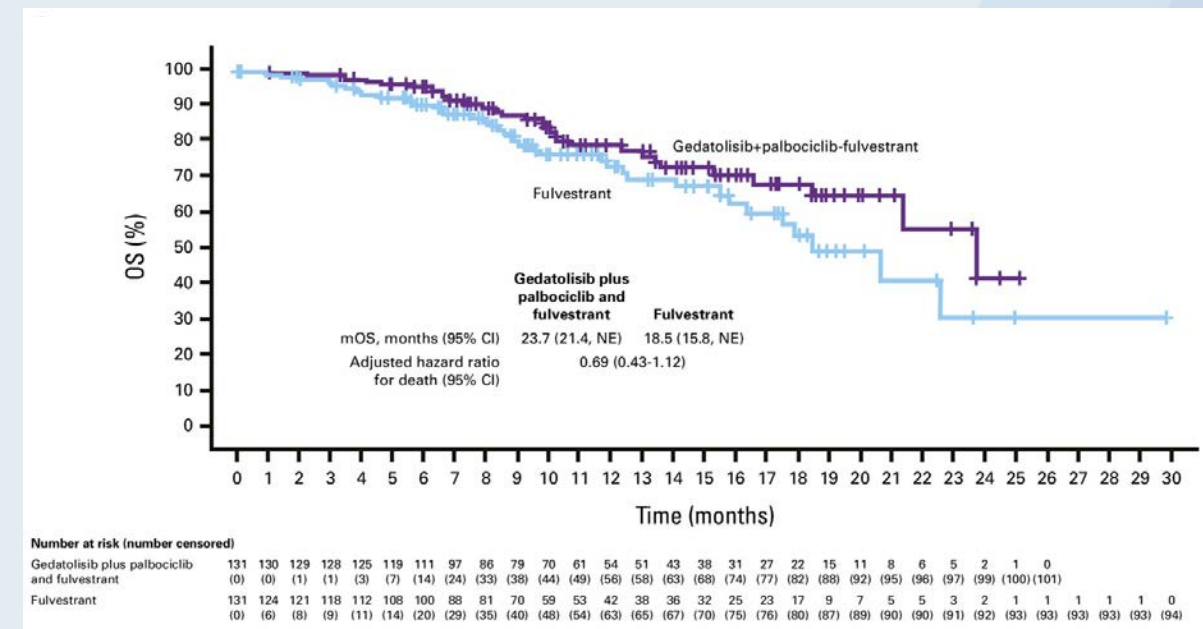
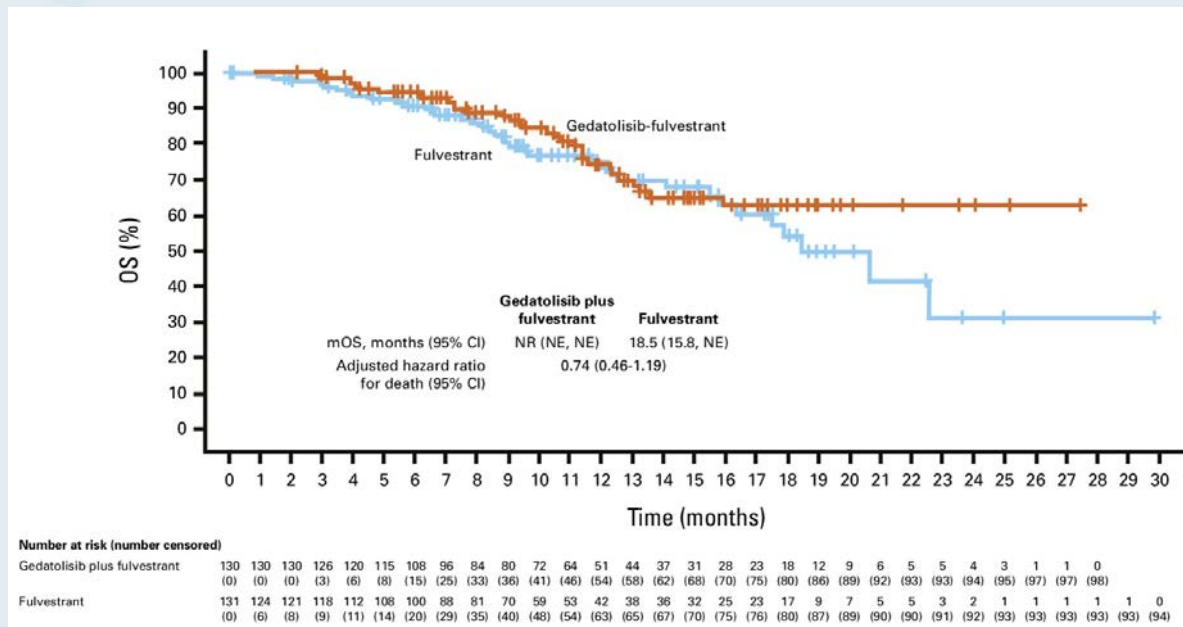
VIKTORIA-1 Study 1: PFS

	Gedatolisib and fulvestrant	Fulvestrant	Gedatolisib, palbociclib and fulvestrant	Fulvestrant
Median PFS, months (95% CI)	7.4 (5.5 to 9.9)	2.0 (1.8 to 2.3)	9.3 (7.2 to 16.6)	2.0 (1.8 to 2.3)
Adjusted HR	0.33 (0.24-0.48)		0.24 (0.17-0.35)	
p-value	<0.001		<0.001	



VIKTORIA-1 Study 1: OS

	Gedatolisib and fulvestrant	Fulvestrant	Gedatolisib, palbociclib and fulvestrant	Fulvestrant
Median OS, months (95% CI)	NR (NE, NE)	18.5 (15.8, NE)	23.7 (21.4, NE)	18.5 (15.8, NE)
Adjusted HR	0.74 (0.46-1.19)		0.69 (0.43-1.12)	



NR = not reached; NE = not estimable

VIKTORIA-1 Study 2: A Phase III Trial of Gedatolisib for PIK3CA-Mutant mBC

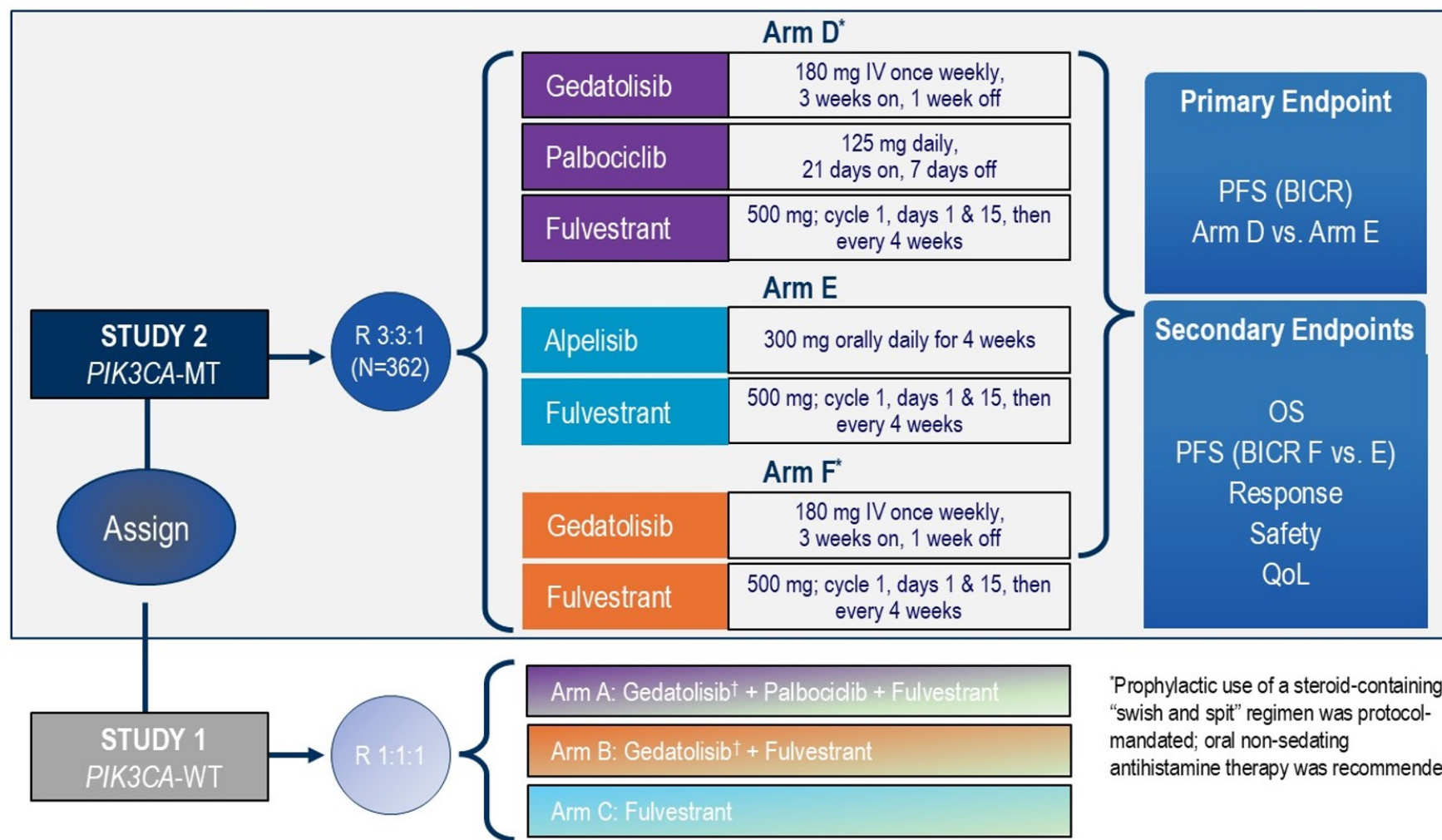
HR+/HER2- Advanced Breast Cancer

Eligibility Criteria

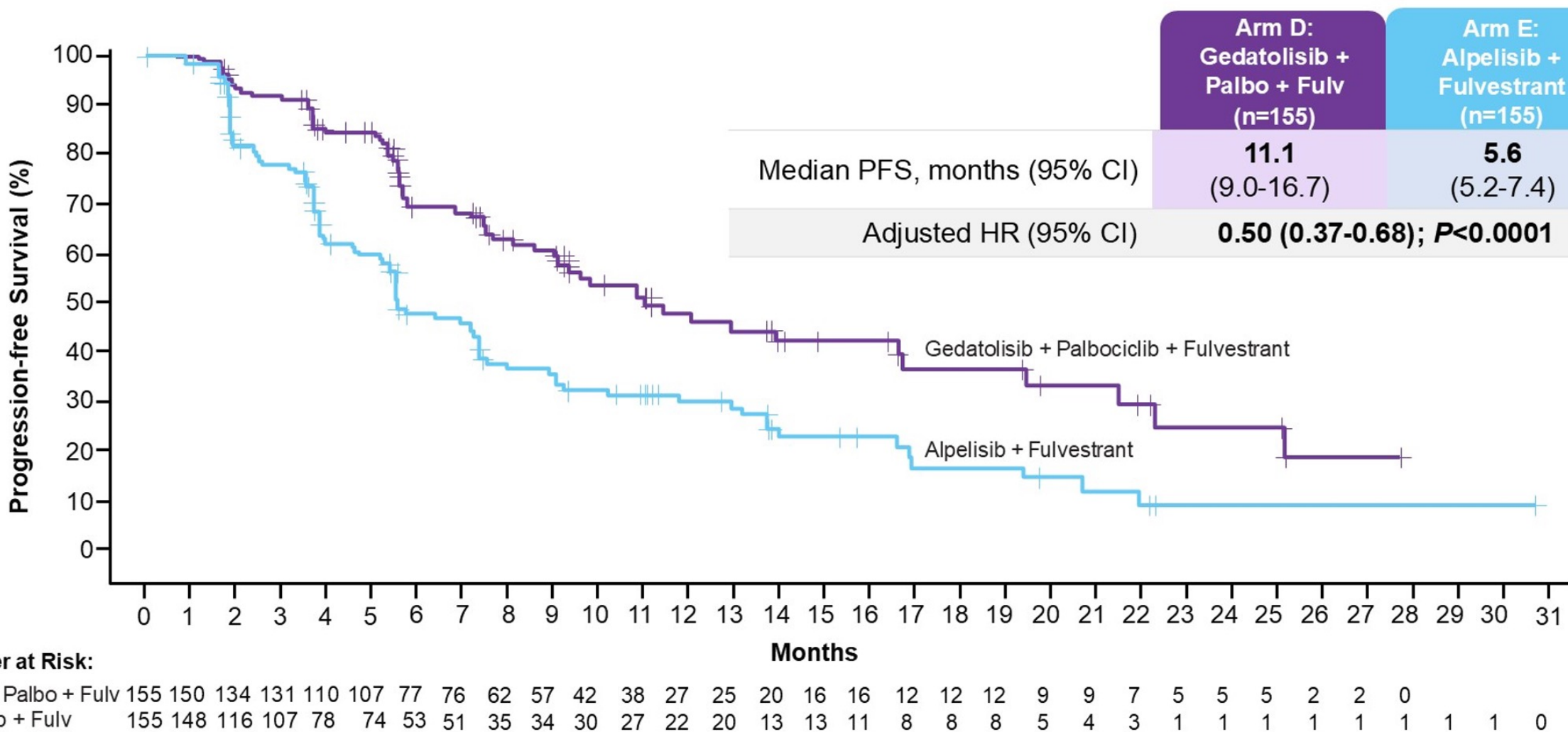
- Pre- & postmenopausal women & men
- Progression on/after CDK4/6i + NSAI
- ≤2 lines of prior ET for ABC
- Measurable disease, RECIST v1.1
- Screening result for *PIK3CA* status
- No T2DM with HbA1c >6.4% or T1DM
- No prior mTORi, PI3Ki, or AKTi
- No prior chemotherapy for ABC

Stratification Factors

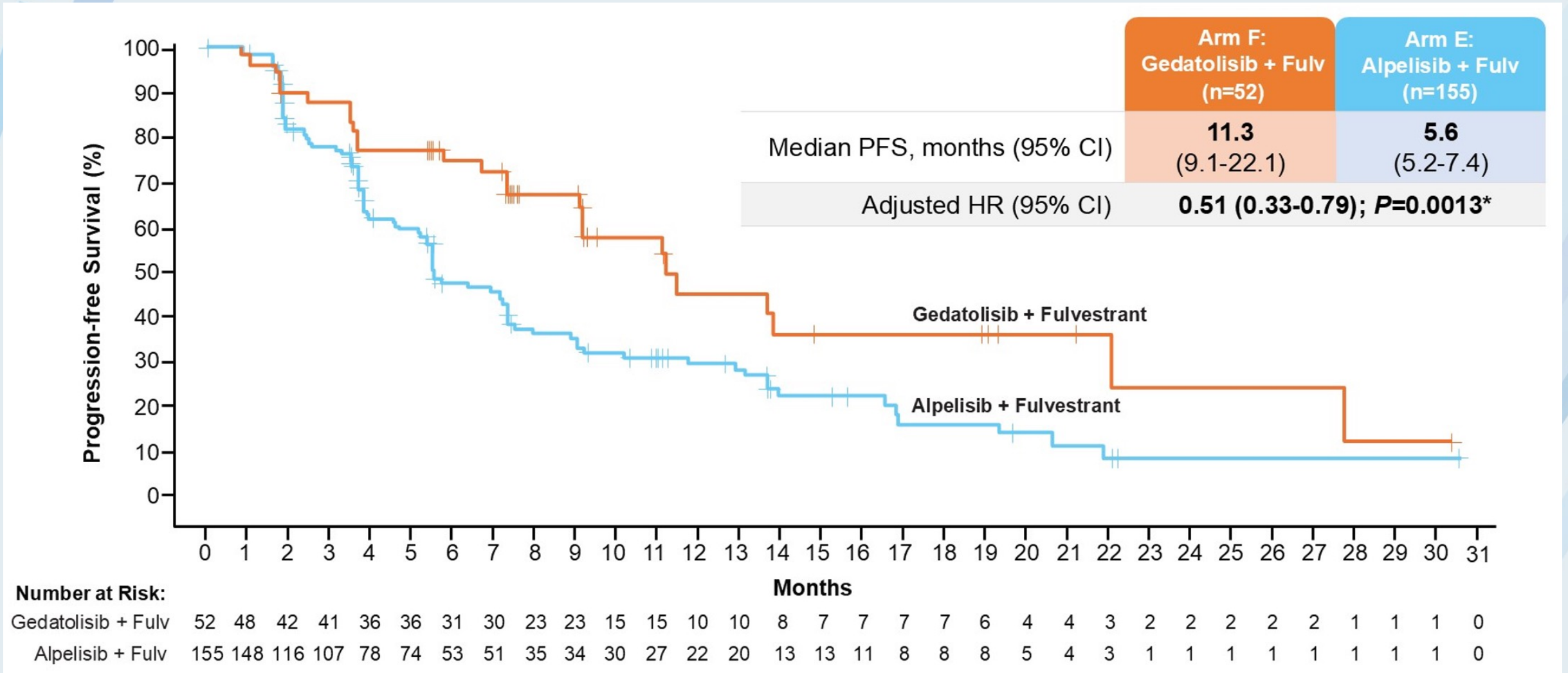
- Lung/liver metastases (yes/no)
- TTP on immediate prior therapy (≤ or >6 months)
- Region (US/Canada or ROW)



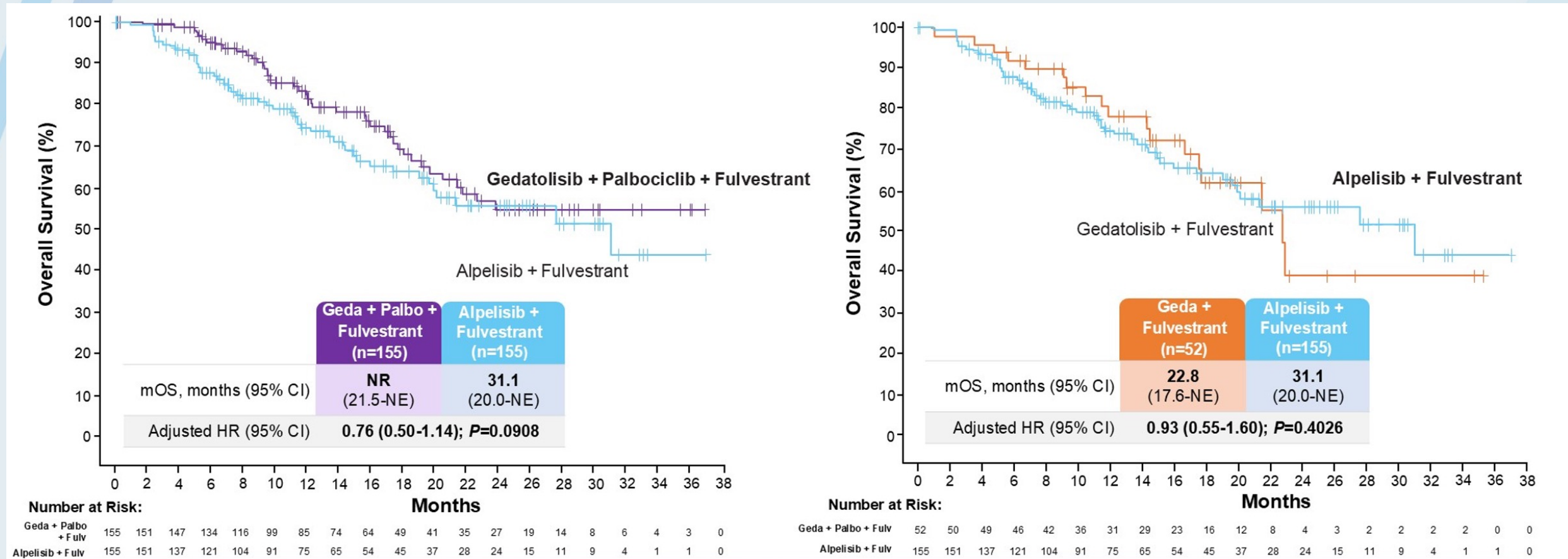
VIKTORIA-1 Study 2: Gedatolisib/Palbociclib/Fulvestrant Triplet – PFS



VIKTORIA-1 Study 2: Gedatolisib/Fulvestrant Doublet – PFS



VIKTORIA-1 Study 2: Interim OS



Key Toxicity Experience Across PI3K/AKT/mTOR Pathway Inhibitors

	SOLAR-1		INAVO120		CAPItello-291		VIKTORIA-1	
	Alpelisib		Inavolisib		Capivasertib		Gedatolisib	
	All Grades	Grade 3+	All Grades	Grade 3+	All Grades	Grade 3+	All Grades	Grade 3+
Hyperglycemia	63.7%	36.6%	58.6%	5.6%	16.3%	2.3%	9.2%	2.3%
Diarrhea	57.7%	6.7%	48.1%	3.7%	72.4%	9.3%	16.9%	1.5%
Mucositis	24.6%	2.5%	51.2%	5.6%	14.6%	2.0%	69.2%	19.2%
Rash	35.6%	9.9%	25.3%	0.0%	38.0%	12.1%	27.7%	4.6%

Inclusion A1c <6.4%

Inclusion A1c <6%

Inclusion A1c <8%

Inclusion A1c <6.4%

Courtesy of Seth Wander, MD, PhD

Andre F et al. *NEJM* 2019; Turner NC et al. *NEJM* 2024; Turner NC et al. *NEJM* 2023; Hurvitz SA et al. ESMO 2025.

Faculty Discussion



Dr Hussein

Questions for the Faculty

82-year-old woman with PIK3CA-mutant mBC with bone and liver metastases. Was on ribociclib/letrozole for 3 years and on disease progression received capivasertib with good response and tolerance, very different from what we saw with alpelisib. She had no issues with hyperglycemia.

Questions

- How do you decide between second-line endocrine treatment and an ADC? How do you factor in the amount of time on prior endocrine treatment?
- Do you use capivasertib for patients with well-controlled diabetes? If not well controlled, do you have them intensify diabetic treatment (GLP-1?) and then treat? Which HbA1c level is necessary to start capivasertib?
- How do you approach dose reduction?
- For which patients are you considering gedatolisib in combination with fulvestrant and palbociclib? Are there patients for whom you would omit the palbociclib?
- How is gedatolisib tolerated relative to other PI3K/AKT/mTOR Inhibitors?



Dr Choksi

Questions for the Faculty

62-year-old woman with recurrent ER+, HER2-negative mBC in the bones and lymph nodes s/p adjuvant chemotherapy and CDK4/6 inhibitor/AI, just received cycle 6 of datopotamab deruxtecan with partial response on CT scan and good tolerance. Tumor-related symptoms like not feeling well, asthenia and fatigue have improved on the treatment.

Questions

- How do you decide between datopotamab deruxtecan and sacituzumab govitecan for ER-positive disease?
- Where does T-DXd fit in for HER2-low disease?
- Do TROP2-targeted agents work in the CNS?

Agenda

Introduction: ESMO 2026; Recent FDA Approvals

ER-Positive Breast Cancer

HER2-Positive Breast Cancer

- HER2-Positive Localized BC: Trastuzumab deruxtecan and neratinib – *Dr Geyer*
- HER2-Positive Metastatic BC: First-Line Treatment and Maintenance Therapy – *Dr Wander*

Triple-Negative Breast Cancer

HER2-Positive Localized Breast Cancer: Trastuzumab Deruxtecan and Neratinib

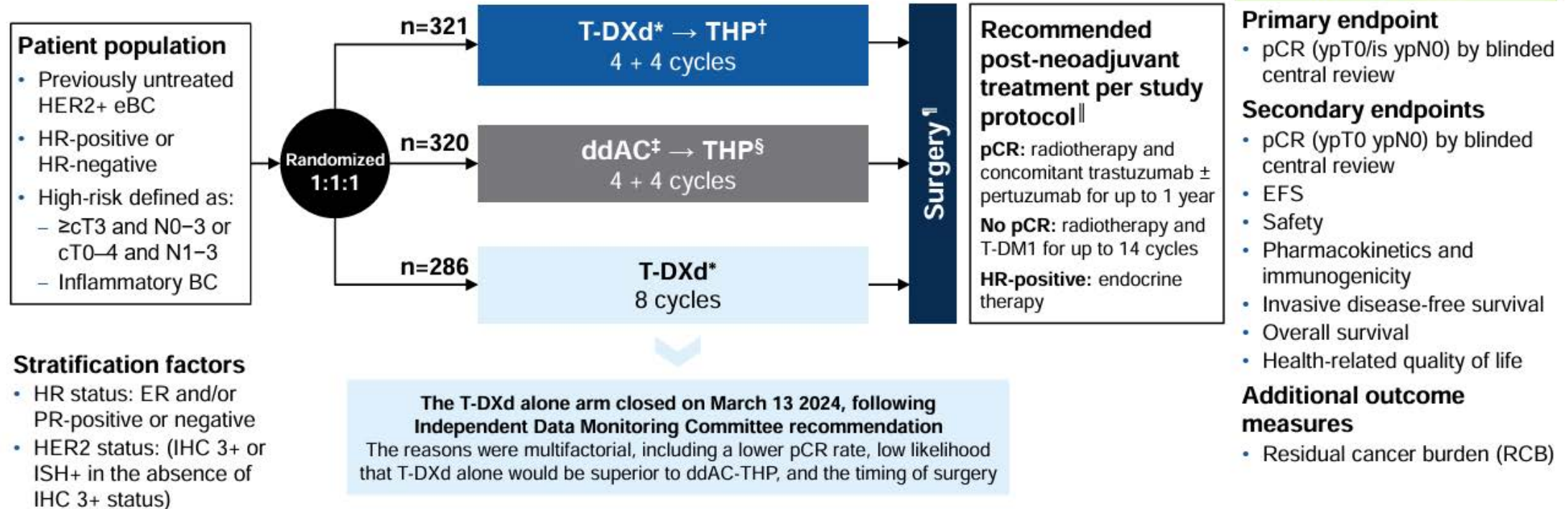
Dr Geyer

Select Datasets

- Harbeck N et al. Neoadjuvant trastuzumab deruxtecan alone or followed by paclitaxel, trastuzumab, and pertuzumab for high-risk HER2-positive early breast cancer (DESTINY-Breast11): A randomized, open-label, multicentre, phase III trial. *Ann Oncol* 2026;37:166-79.
- Pusztai L et al. Residual cancer burden (RCB) following neoadjuvant treatment with trastuzumab deruxtecan (T-DXd) followed by paclitaxel + trastuzumab + pertuzumab (THP) vs dose-dense doxorubicin + cyclophosphamide followed by THP in high-risk, HER2+ early-stage breast cancer. ESMO Breast 2026;Abstract LBA1.
- Loibl S et al. Trastuzumab deruxtecan in residual HER2-positive early breast cancer. *New Engl J Med* 2026;394:845-57.
- Untch M et al. Secondary safety analysis of trastuzumab deruxtecan (T-DXd) vs trastuzumab emtansine (T-DM1) in DESTINY-Breast05: Clinical and demographic risk factors of interstitial lung disease and radiation pneumonitis. ASCO 2026;Abstract 516.
- Luftner D et al. Extended adjuvant neratinib in HER2+/HR+ early breast cancer in clinical routine – Final results from the multinational, prospective, observational study ELEANOR. ESMO 2025;Abstract 299P.

Phase III DESTINY-Breast11 Study Design

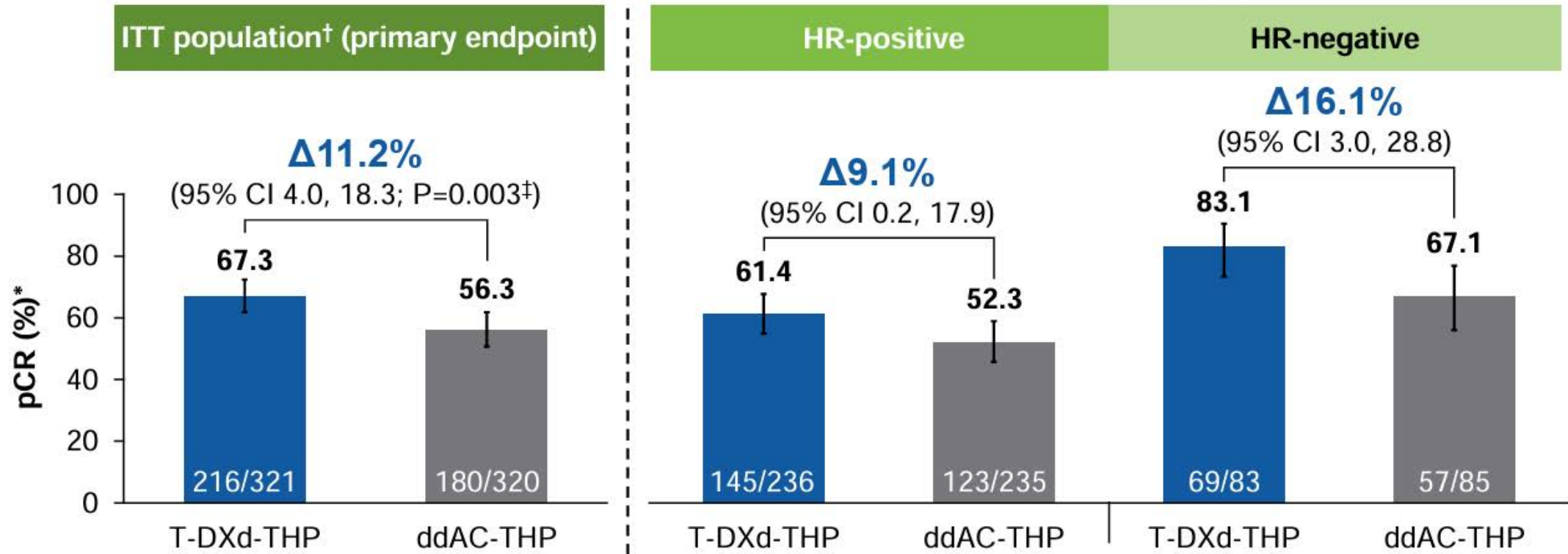
A randomized, global, multicenter, open-label, Phase 3 study (NCT05113251)



High-resolution computed tomography chest scans were performed every 6 weeks during treatment; if ILD/pneumonitis was suspected while receiving T-DXd, treatment was interrupted and a full investigation completed. Echocardiograms or multigated acquisition scans were performed during screening (<28 days prior to randomization), during treatment (<3 days before Cycle 5), and at end of treatment to assess left ventricular ejection fraction. *5.4 mg/kg Q3W; †paclitaxel (80 mg/m² QW) + trastuzumab (6 mg/kg Q3W) + pertuzumab (840 mg loading dose followed by 420 mg Q3W); ‡doxorubicin (60 mg/m² Q2W) + cyclophosphamide (600 mg/m² Q2W); §paclitaxel (80 mg/m² QW) + trastuzumab (8 mg/kg loading dose followed by 6 mg/kg Q3W) + pertuzumab (840 mg loading dose followed by 420 mg Q3W); ||the recommended window for surgery was 3–6 weeks following administration of the last dose of neoadjuvant study treatment; ||administered as part of the patient's SOC at the investigator's discretion. cT, clinical tumor stage; ER, estrogen receptor; IHC, immunohistochemistry; ILD, interstitial lung disease; ISH+, in situ hybridization-positive; N, nodal stage; PR, progesterone receptor; QXW, every X weeks; T-DM1, trastuzumab emtansine; ypT0/is ypN0, absence of invasive cancer in the breast and axillary nodes; ypT0 ypN0, absence of invasive and in-situ cancer in the breast and axillary nodes

T-DXd = trastuzumab deruxtecan

Phase III DESTINY-Breast11: Pathologic Complete Response (pCR) (ypT0/is ypN0)

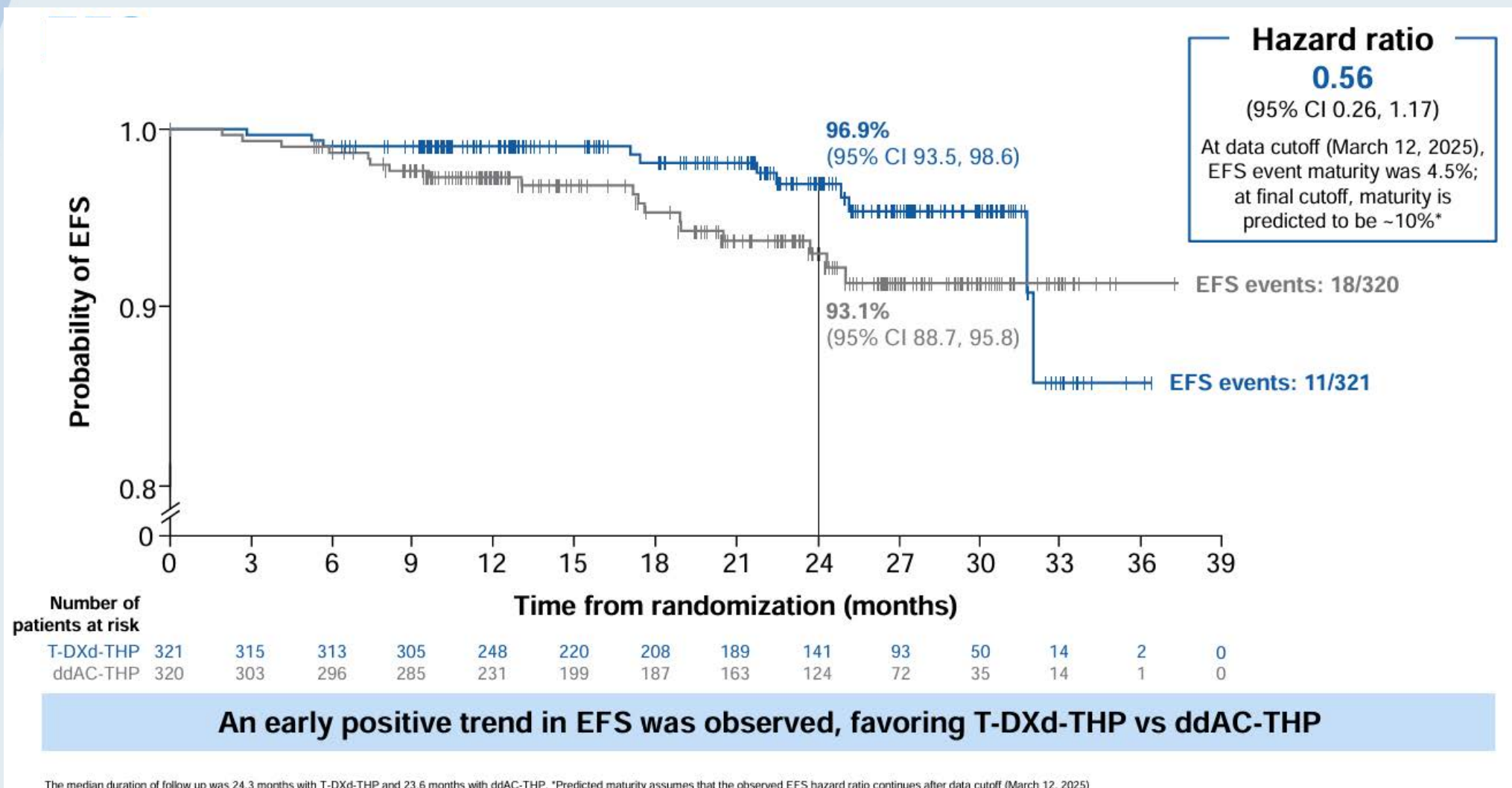


Neoadjuvant T-DXd-THP demonstrated a statistically significant and clinically meaningful improvement in pCR vs ddAC-THP

Improvement was observed in both the HR-positive and HR-negative subgroups

For the ITT population, treatment effects were estimated by the difference in pCR with 95% CIs and P-values based on the stratified Miettinen and Nurminen's method, with strata weighting by sample size (ie Mantel-Haenszel weights). Patients with no valid records regarding pCR status for any reason were considered to be non-responders (including but not limited to withdrawal from the study, progression of disease or death before surgery, lack of surgical specimen, or defined as not evaluable by the central pathologist). Subgroup analyses were unstratified. *By blinded central review; †pCR responders were defined as patients who only received randomized study treatment (at least one dose) and had pCR; ‡two-sided P-value crossed the 0.03 prespecified boundary. ITT, intent-to-treat

Phase III DESTINY-Breast11 Event-Free Survival (EFS)



Phase III DESTINY-Breast05 Study Design

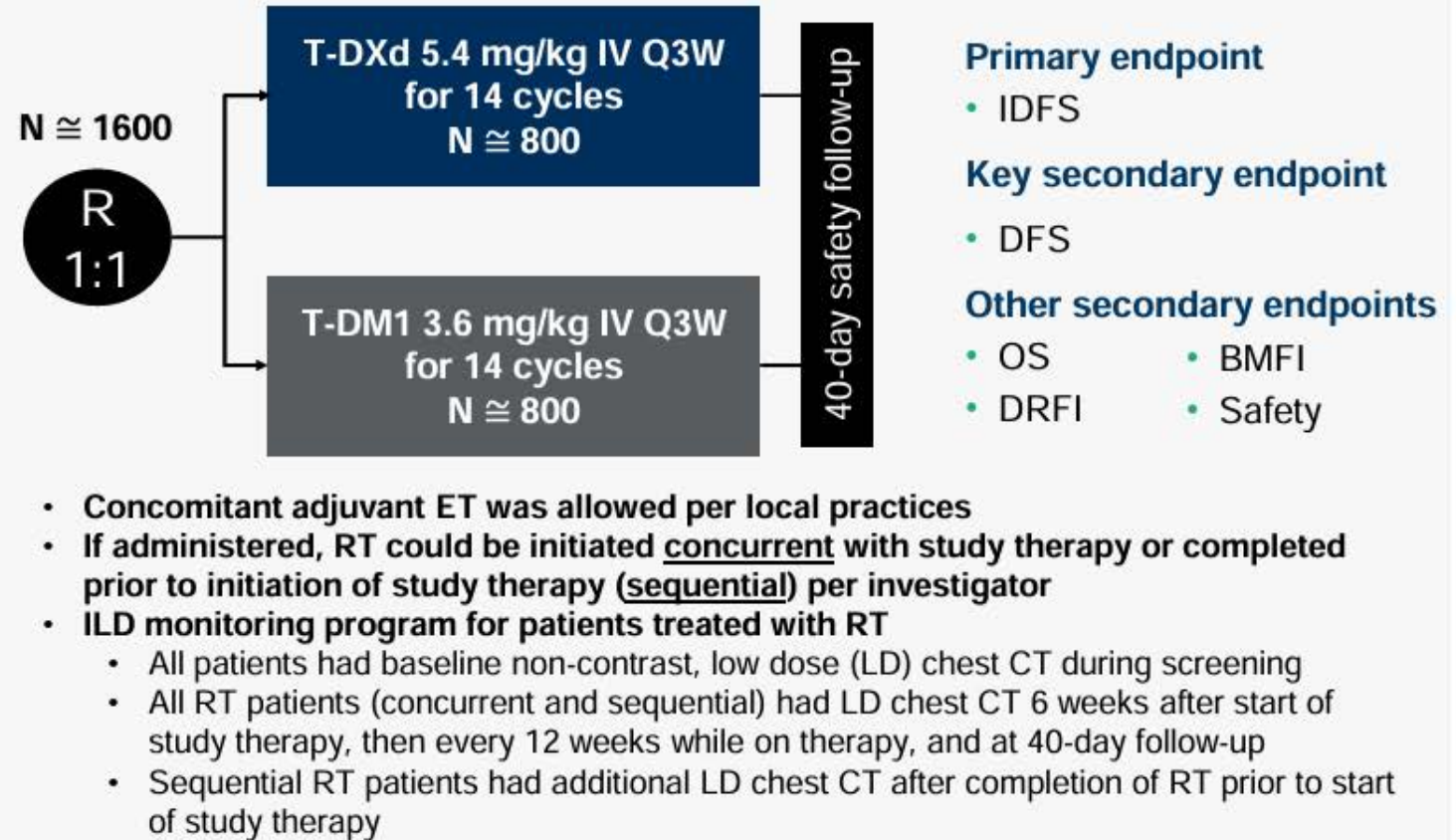
A global, multicenter, randomized, open-label, phase 3 trial (NCT04622319)

Key Eligibility Criteria

- Residual invasive disease in the breast and/or axillary lymph nodes after neoadjuvant chemotherapy with HER2-directed therapy (NAT)^a
- High-risk defined as presentation prior to NAT with:
 - Inoperable eBC (cT4,N0-3,M0 or cT1-3,N2-3,M0) OR
 - Operable eBC (cT1-3,N0-1,M0) with axillary node-positive disease (ypN1-3) after NAT
- Centrally confirmed HER2+ (IHC 3+ or ISH+) eBC
- ECOG PS 0 or 1

Stratification factors

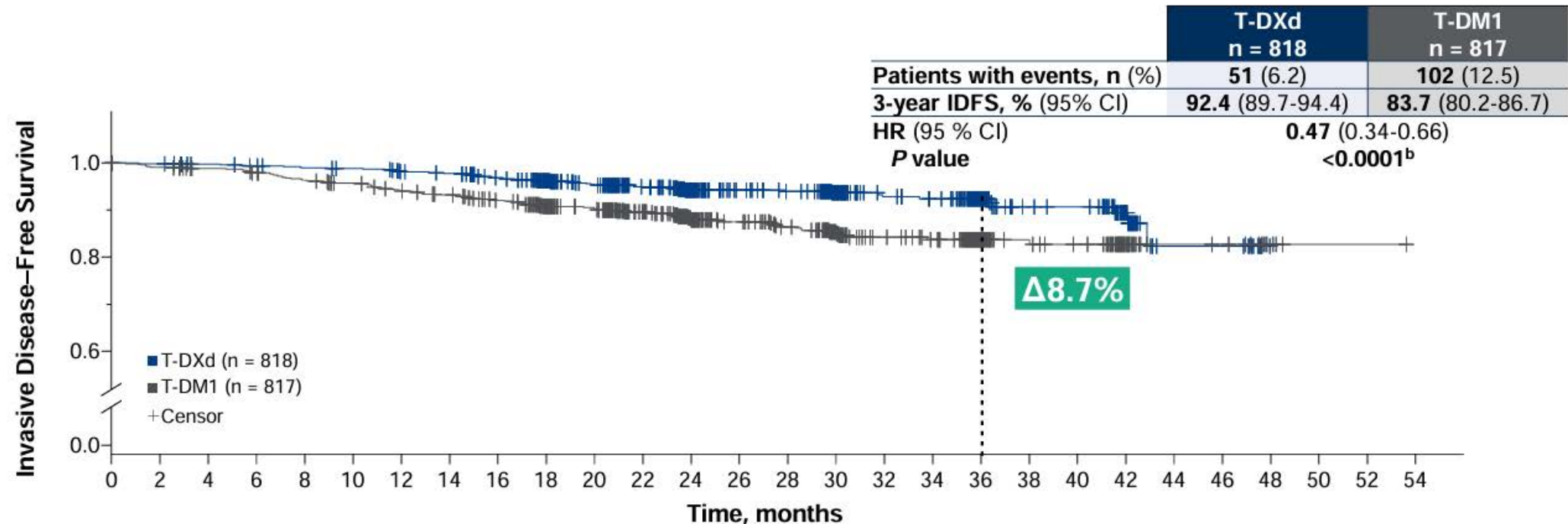
- Extent of disease at presentation (inoperable, operable)
- HER2-targeted NAT (single, dual)
- Hormone receptor status (positive, negative)
- Post-NAT pathologic nodal status (positive, negative)



BMFI, brain metastasis-free interval; CT, computed tomography; eBC, early breast cancer; DCO, data cutoff; DFS, disease-free survival; DRFI, distant recurrence-free interval; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; IDFS, invasive disease-free survival; IHC, immunohistochemistry; ILD, interstitial lung disease; ISH, in situ hybridization; IV, intravenous; NAT, neoadjuvant therapy; OS, overall survival; Q3W, every 3 weeks; R, randomization; RT, radiotherapy; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan.

^aNAT is defined as ≥16 weeks' NAT with ≥9 weeks trastuzumab ± pertuzumab and ≥9 weeks taxane-based chemotherapy.

Phase III DESTINY-Breast05: IDFS



Number at Risk:

T-DXd	818	788	781	776	771	768	758	753	731	684	634	544	440	380	370	275	218	212	129	92	90	46	14	14	0	0	0	0
T-DM1	817	781	769	760	745	734	719	708	687	632	599	527	417	355	337	233	186	177	120	84	79	38	14	13	4	1	1	0

53% reduction in the risk of invasive disease recurrence or death for T-DXd compared with T-DM1

HR, hazard ratio; IDFS, invasive disease-free survival; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan.

Efficacy stopping boundary, $P = 0.0183$.

^aIDFS is defined as the time from randomization until the date of first occurrence of one of the following events: recurrence of ipsilateral invasive breast tumor, recurrence of ipsilateral locoregional invasive breast cancer, contralateral invasive breast cancer, a distant disease recurrence, or death from any cause. ^bTwo-sided P value from stratified log-rank test. Hazard ratio and 95% CI from stratified Cox proportional hazards model with stratification factor of operative status at disease presentation.

ELEANOR: A Multinational, Prospective, Observational Study of Extended-Adjuvant Neratinib for HR-Positive, HER2-Positive Breast Cancer

Adherence to neratinib treatment (primary endpoint)

- Adherence to neratinib treatment was assessed as:
 - Proportion of compliant days, (i.e., the proportion of days within the treatment period with neratinib intake as planned by the physician)
 - Rate of adherent patients (i.e., the rate of patients with $\geq 75\%$ of compliant days within the treatment period)
- Adherence rate to neratinib treatment was 96.8% (see **Table 3**).

Table 3: Adherence to neratinib treatment [CS]

	CS, N=279
Median proportion of compliant days, % (IQR)	100.0 (98.6–100.0)
Rate of adherent patients, n (%), [95% CI]	270 (96.8), [94.0–98.5]

Compliant day: intake of at least one tablet of neratinib on days with planned neratinib administration *or* no intake of neratinib on days without planned neratinib administration.

CI, confidence interval; CS, compliance set; IQR, interquartile range.

ELEANOR: A Multinational, Prospective, Observational Study of Extended-Adjuvant Neratinib for HR-Positive, HER2-Positive Breast Cancer

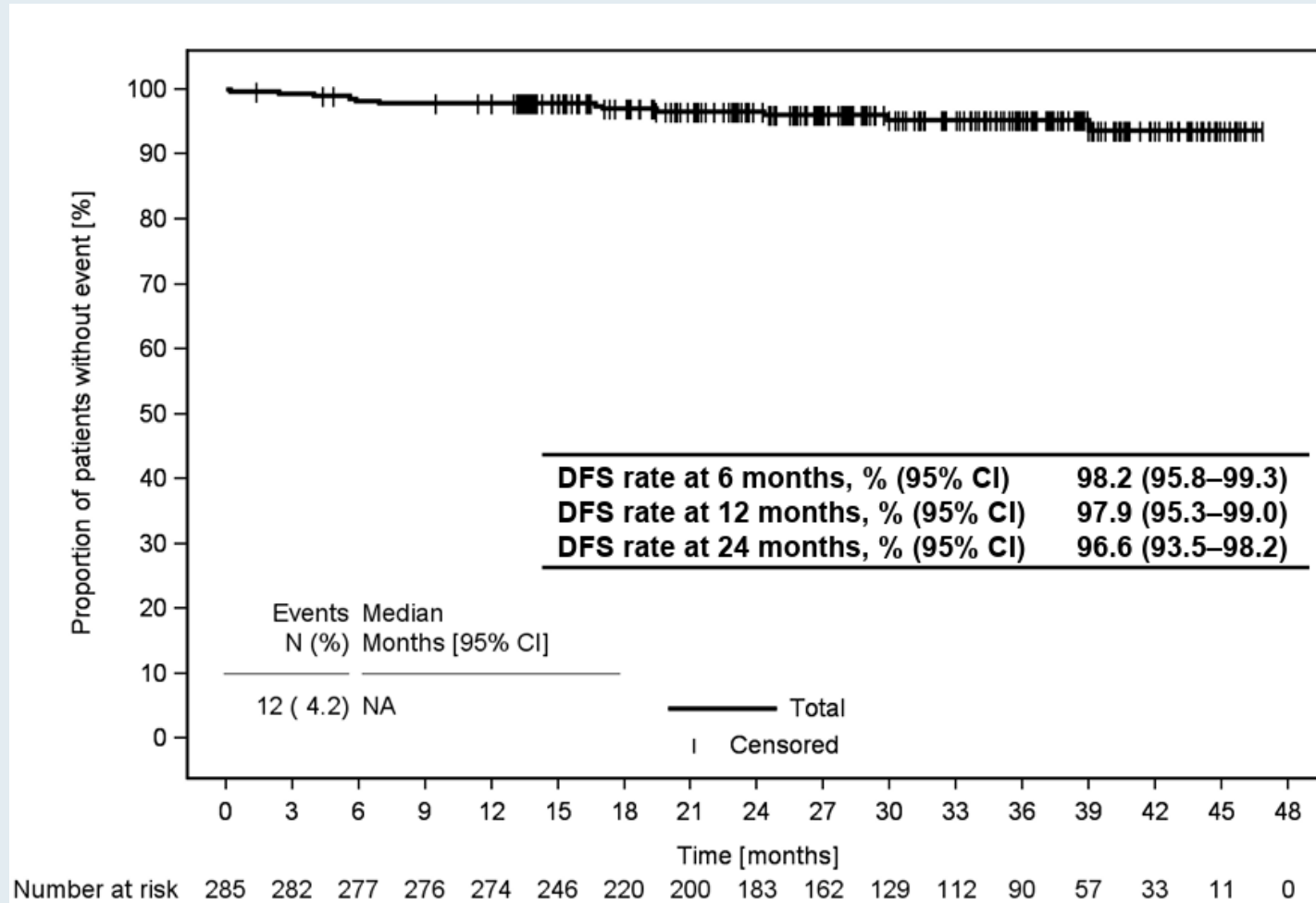


Figure 3: Disease-free survival (DFS) [MAS].

MAS = main analysis set

ELEANOR: A Multinational, Prospective, Observational Study of Extended-Adjuvant Neratinib for HR-Positive, HER2-Positive Breast Cancer

Table 5: Safety [SAF]^a

n (%)	SAF, N=287
TEAEs^b, any grade	272 (94.8)
• Grade $\geq 3^c$	78 (27.2)
• Serious TEAEs	21 (7.3)
• Leading to discontinuation of neratinib	74 (25.8)
TEAEs in $\geq 10\%$ of pts, any grade	
• Diarrhea	247 (86.1)
• Nausea	68 (23.7)
• Fatigue	66 (23.0)
• Abdominal pain upper	29 (10.1)
Diarrhea by worst grade	
• Grade 1	103 (35.9)
• Grade 2	85 (29.6)
• Grade 3	57 (19.9)
• Grade 4	2 (0.7)
• Grade ≥ 3 by worst grade and by starting dose	59 (20.6)
• Neratinib starting dose <240 mg/day, N=127	19 (15.0)
• Neratinib starting dose =240 mg/day, N=160	40 (25.0)
• Leading to treatment	185 (64.5)

^a Data are retrieved from the AE form; ^b TEAE, treatment emergent adverse event; ^c No fatal TEAEs were reported.

SAF, safety analysis set.

Faculty Discussion



Dr Apuri

Questions for the Faculty

42-year-old woman with localized HER2-positive breast cancer with residual disease in the breast and 1 node after neoadjuvant TCHP. Receiving T-DXd post-op. Doing well after dose reduction for extreme fatigue, myalgias and rash.

Questions

- Criteria to use neoadjuvant T-DXd? What about postneoadjuvant T-DXd? What about patients who have received neoadjuvant T-DXd and have residual disease?
- Quality of life, side effects and dose reduction with T-DXd?
- In which situations are you using postadjuvant neratinib? Are you using a dose-escalation approach? Do you use pre-emptive loperamide?

HER2-Positive Metastatic Breast Cancer: First-Line Treatment and Maintenance Therapy

Dr Wander

Select Datasets

- Tolaney SM et al. Trastuzumab deruxtecan plus pertuzumab for HER2-positive metastatic breast cancer. *N Engl J Med* 2026;394;551-62.
- Loibl S et al. Trastuzumab deruxtecan (T-DXd) + pertuzumab vs taxane + trastuzumab + pertuzumab (THP) for patients with HER2+ advanced/metastatic breast cancer: Additional analyses of DESTINY-Breast09 in key subgroups of interest. ESMO 2025;Abstract LBA18.
- Park YH et al. A DESTINY-Breast09 analysis of treatment duration and clinical outcomes by best response to trastuzumab deruxtecan (T-DXd) + pertuzumab (P). ASCO 2026;Abstract 1021.
- Harbeck N et al. Trastuzumab deruxtecan in HER2-positive advanced breast cancer with or without brain metastases: A phase 3b/4 trial. *Nat Med* 2024;30:3717-27.
- Dieras V et al. HER2CLIMB-05: A phase III study of tucatinib versus placebo in combination with trastuzumab and pertuzumab as first-line maintenance therapy for HER2+ metastatic breast cancer. *J Clin Oncol* 2026;44:1597-607.
- Metzger O et al. Palbociclib for hormone-receptor-positive, HER2-positive advanced breast cancer. *N Engl J Med* 2026;394:451-62.
- Metzger O et al. Central nervous system outcomes from the phase III PATINA trial (AFT-38). SABCS 2025;Abstract RF4-01.

Phase III DESTINY-Breast09 Study Design

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[†]**

Stratification factors

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

R
1:1:1

n=387

T-DXd[‡] + placebo

n=383

T-DXd[‡] + pertuzumab[§]

n=387

THP

Taxane (paclitaxel or docetaxel)[¶] +
trastuzumab^{||} + pertuzumab[§]

Endpoints

Primary

- PFS (BICR)

Key secondary

- OS

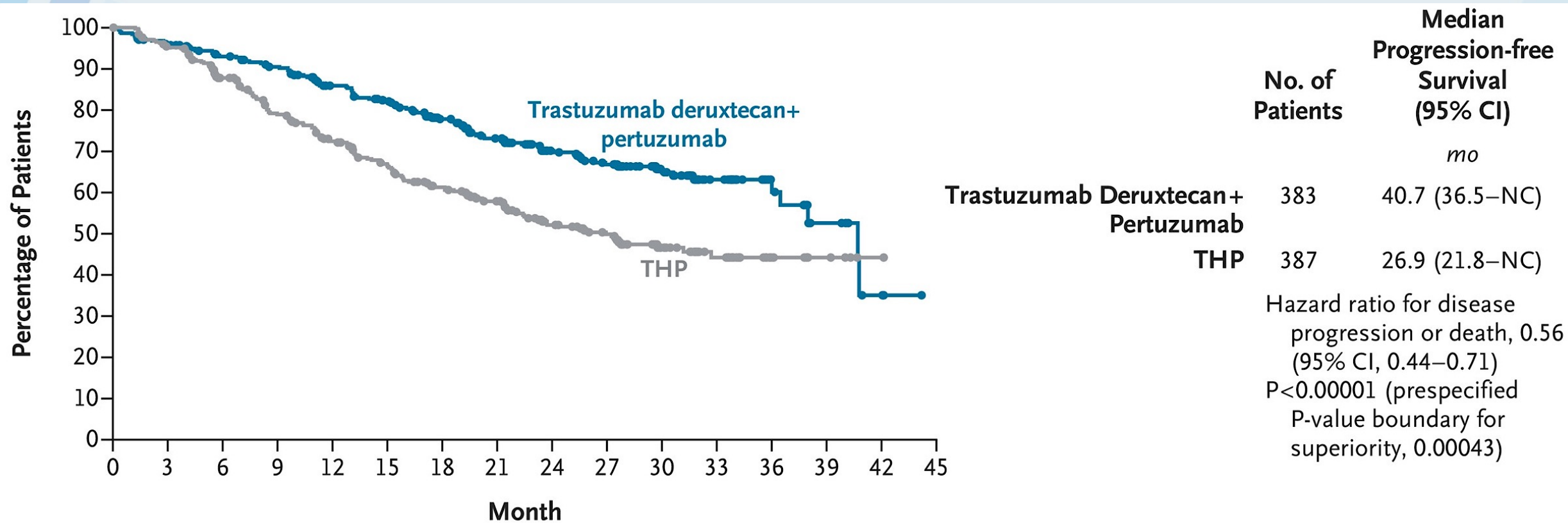
Secondary

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

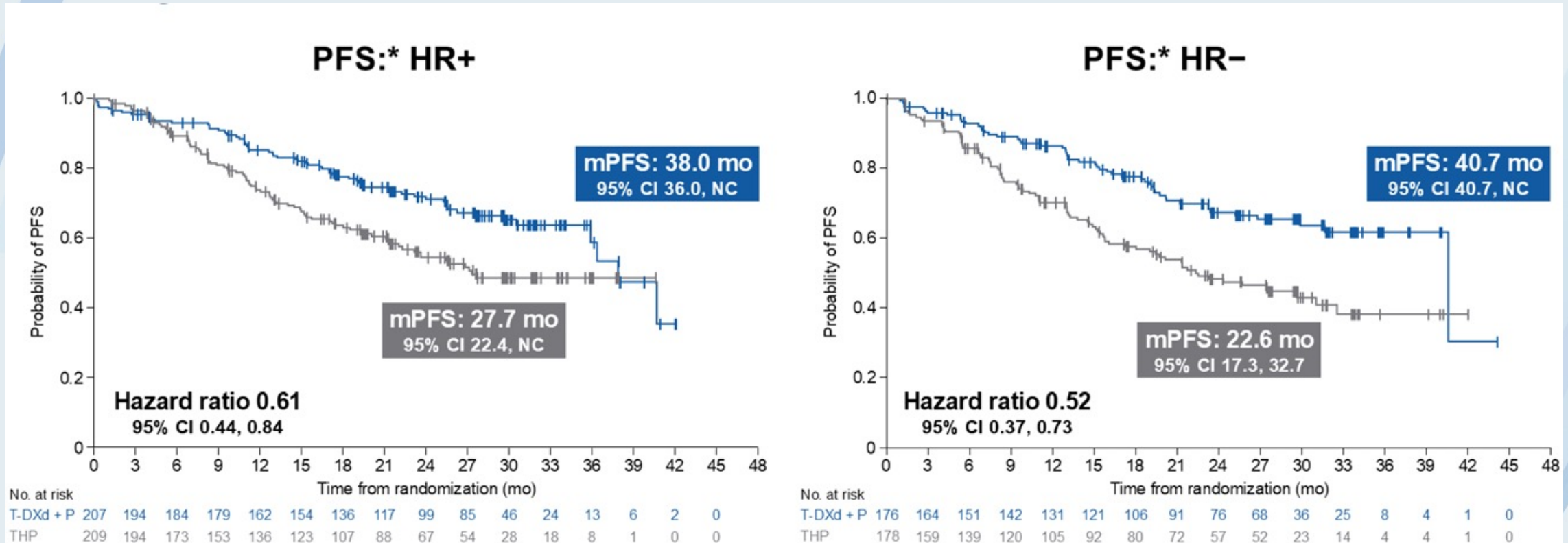
- If T-DXd was discontinued due to AEs (except Grade >2 ILD), patients could switch to trastuzumab^{**}
- Concurrent use of ET (AI or tamoxifen) was allowed for those with HR+ disease after six cycles of T-DXd or discontinuation of taxane in THP arm

*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; ^{**}without loading dose
AE, adverse event; AI, aromatase inhibitor; a/mBC, advanced/metastatic breast cancer; BICR, blinded independent central review; DFI, disease-free interval; DOR, duration of response; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HER2+, HER2-positive; HR+/-, hormone receptor-positive/-negative; ILD, interstitial lung disease; INV, investigator; mets, metastases; mo, months; ORR, objective response rate; OS, overall survival; 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)

Phase III DESTINY-Breast09: PFS by Blinded Independent Central Review



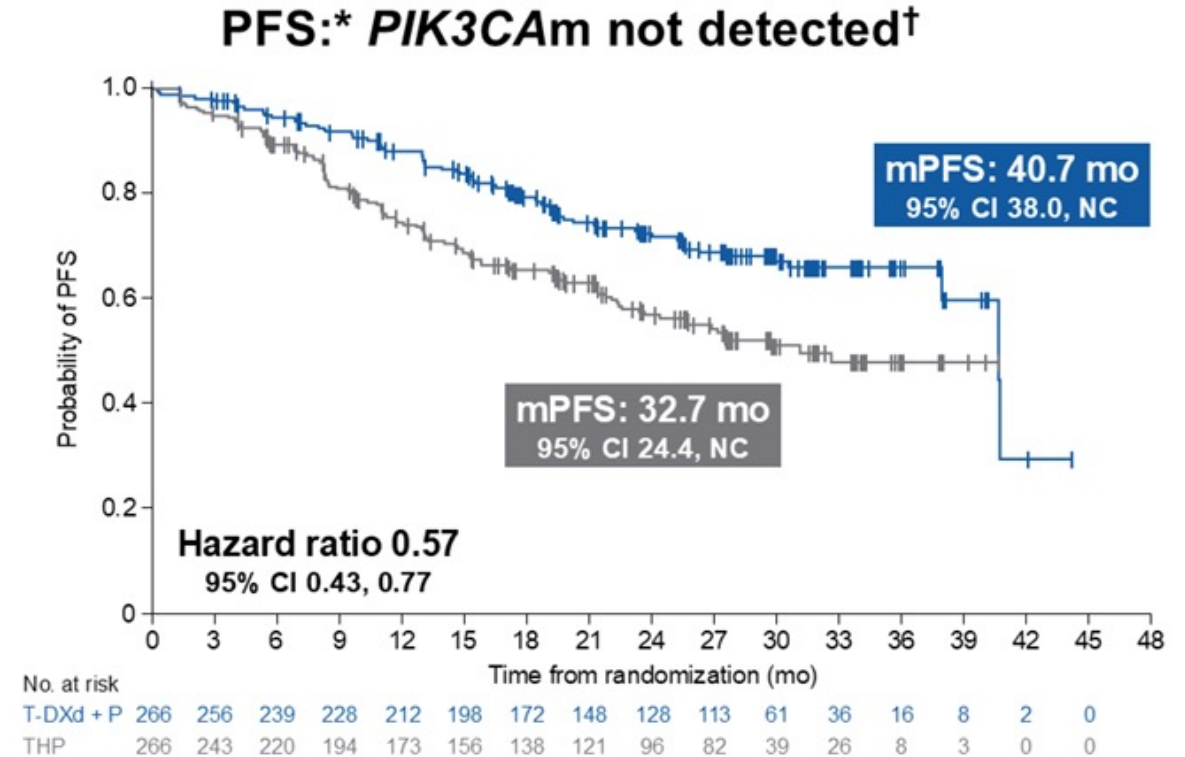
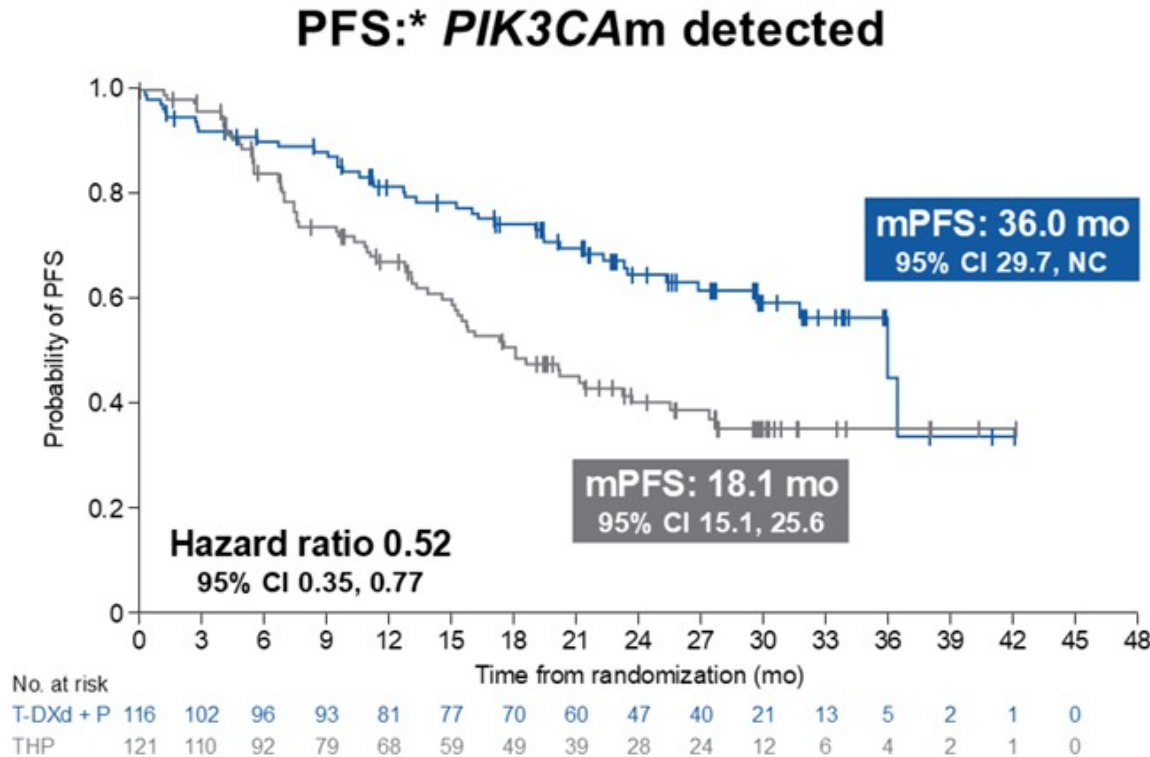
Phase III DESTINY-Breast09 Subgroup Analysis: PFS by HR Status



Patients with HR+ disease could receive concurrent ET after six cycles of T-DXd or discontinuation of taxane, which occurred in **13.5% (T-DXd + P)** versus **38.3% (THP)** of patients

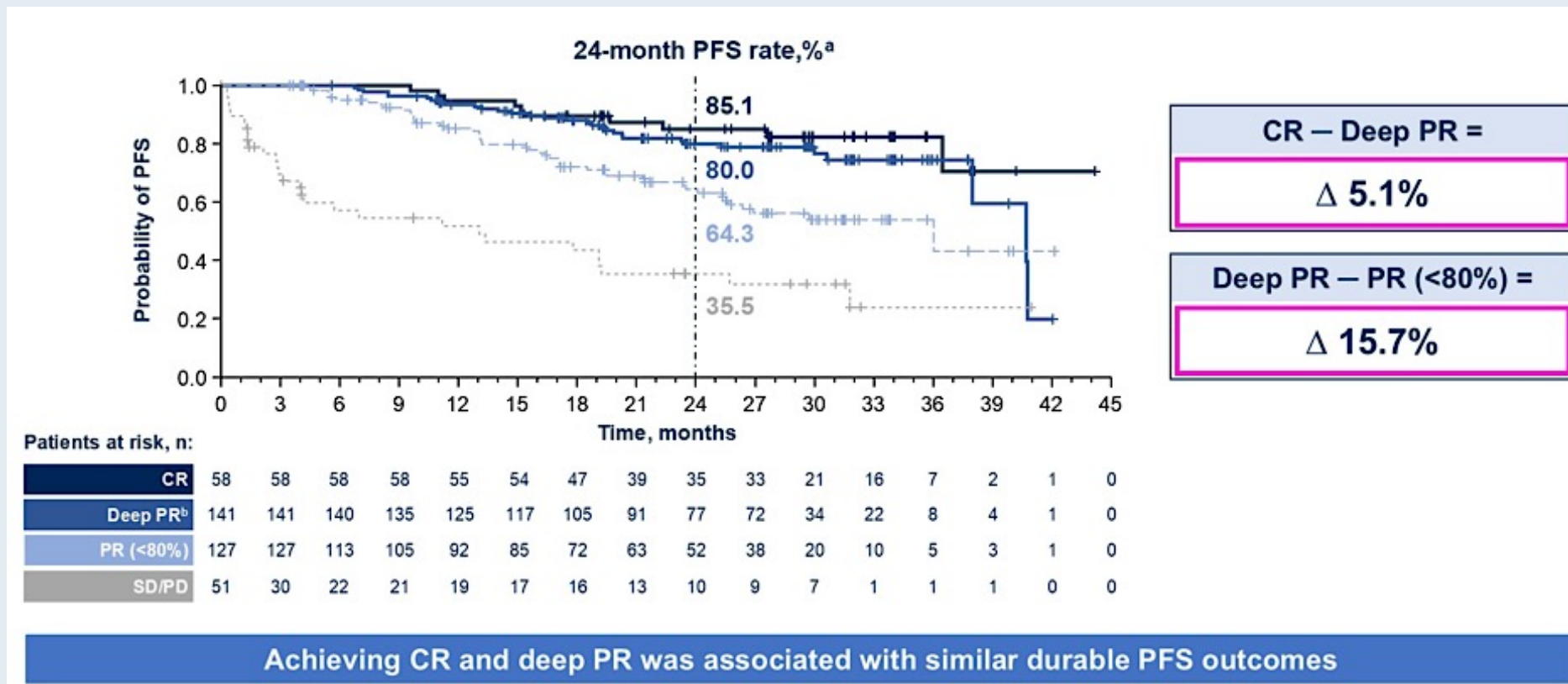
T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of HR status

Phase III DESTINY-Breast09 Subgroup Analysis: PFS by PIK3CA Mutation Status



T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of *PIK3CA*m status

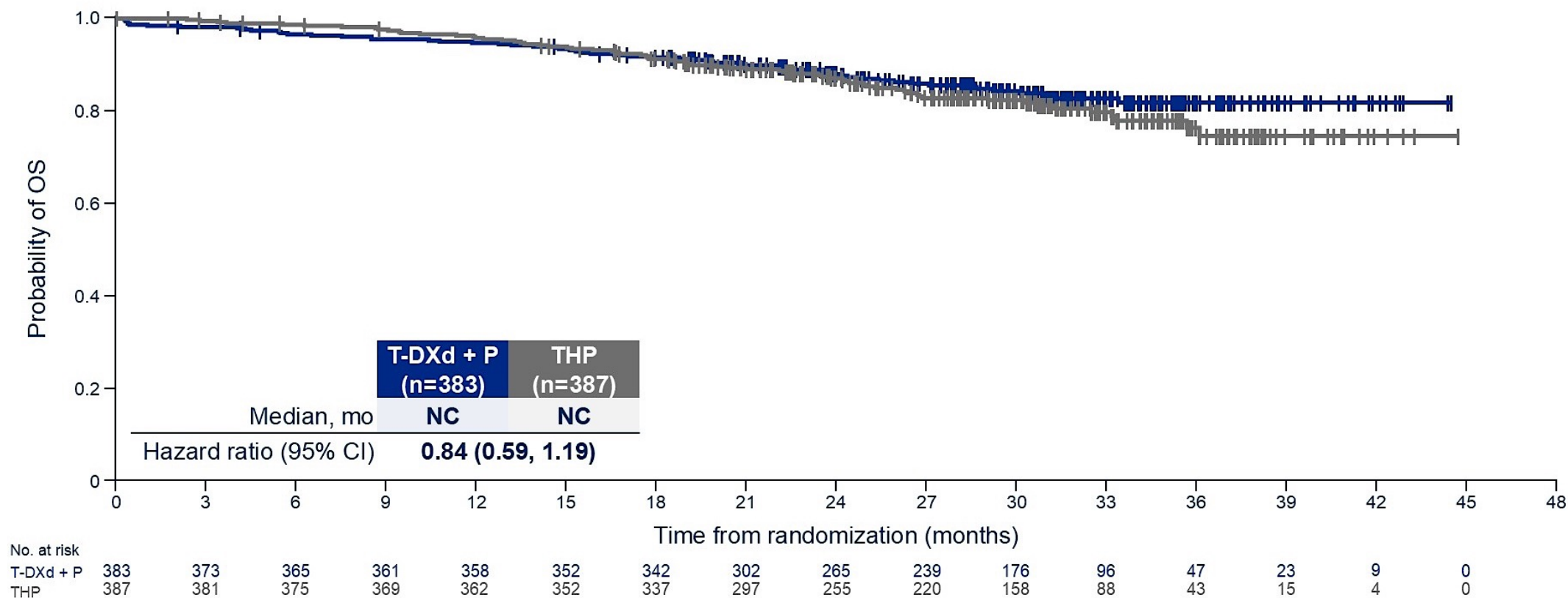
DESTINY-Breast09 Exploratory Analysis: PFS with T-DXd and Pertuzumab by Best Response



	T-DXd + pertuzumab	THP
Median time to deep PR mo (95% CI)	9.6 (6.8-11.0)	8.2 (6.8-9.6)

CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease

Phase III DESTINY-Breast09: Overall Survival at 16% Maturity

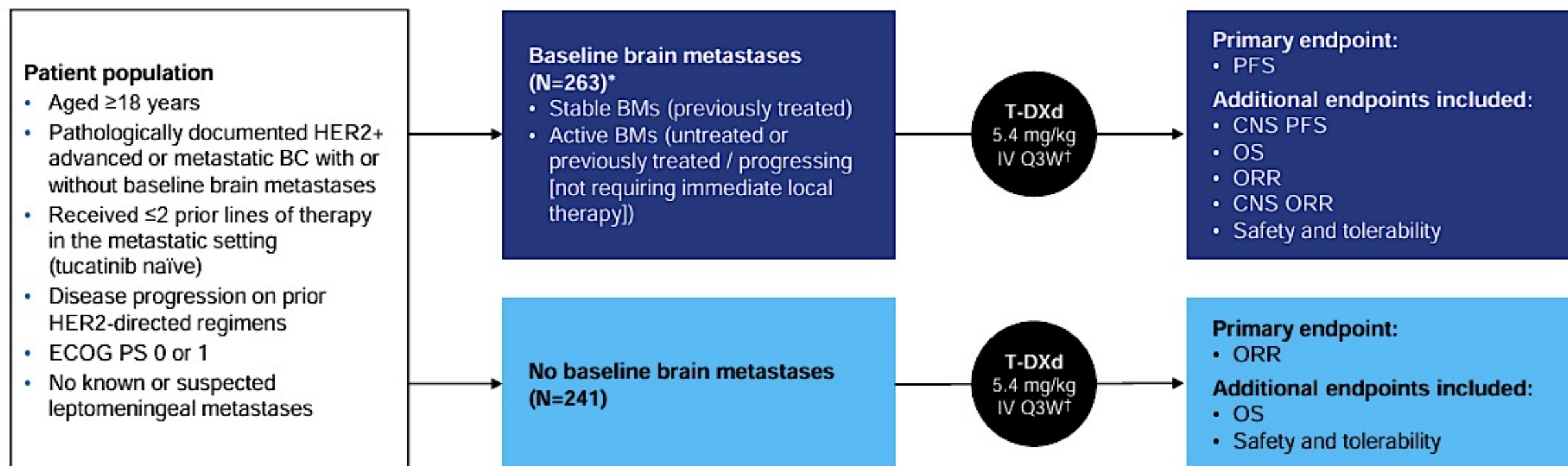


Early OS data suggest a positive trend favoring T-DXd + P over THP

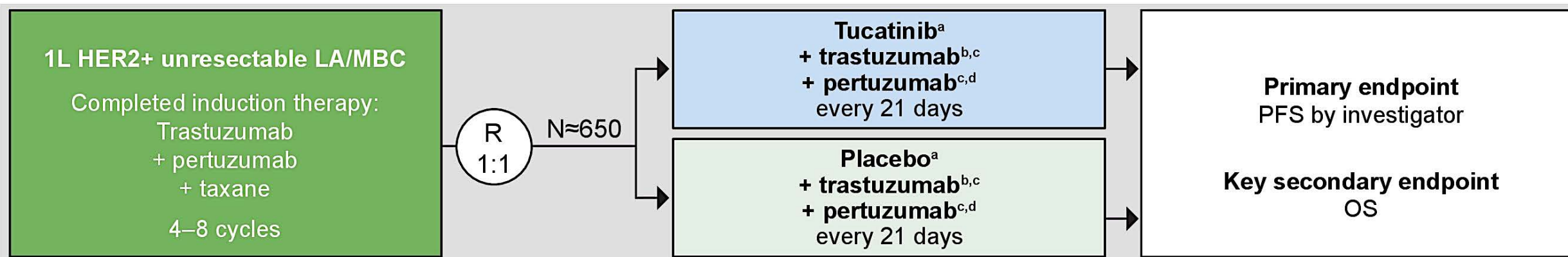
CI, confidence interval; OS, overall survival; NC, not calculable; P, pertuzumab; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

Phase IIIb/IV DESTINY-Breast12 Study Design

Phase 3b/4, multicenter, single-arm, two-cohort, open-label study of T-DXd in previously treated HER2+ mBC with and without brain metastases (BMs); the largest prospective study of T-DXd in patients with stable or active BMs



Phase III HER2CLIMB-05 Study Design



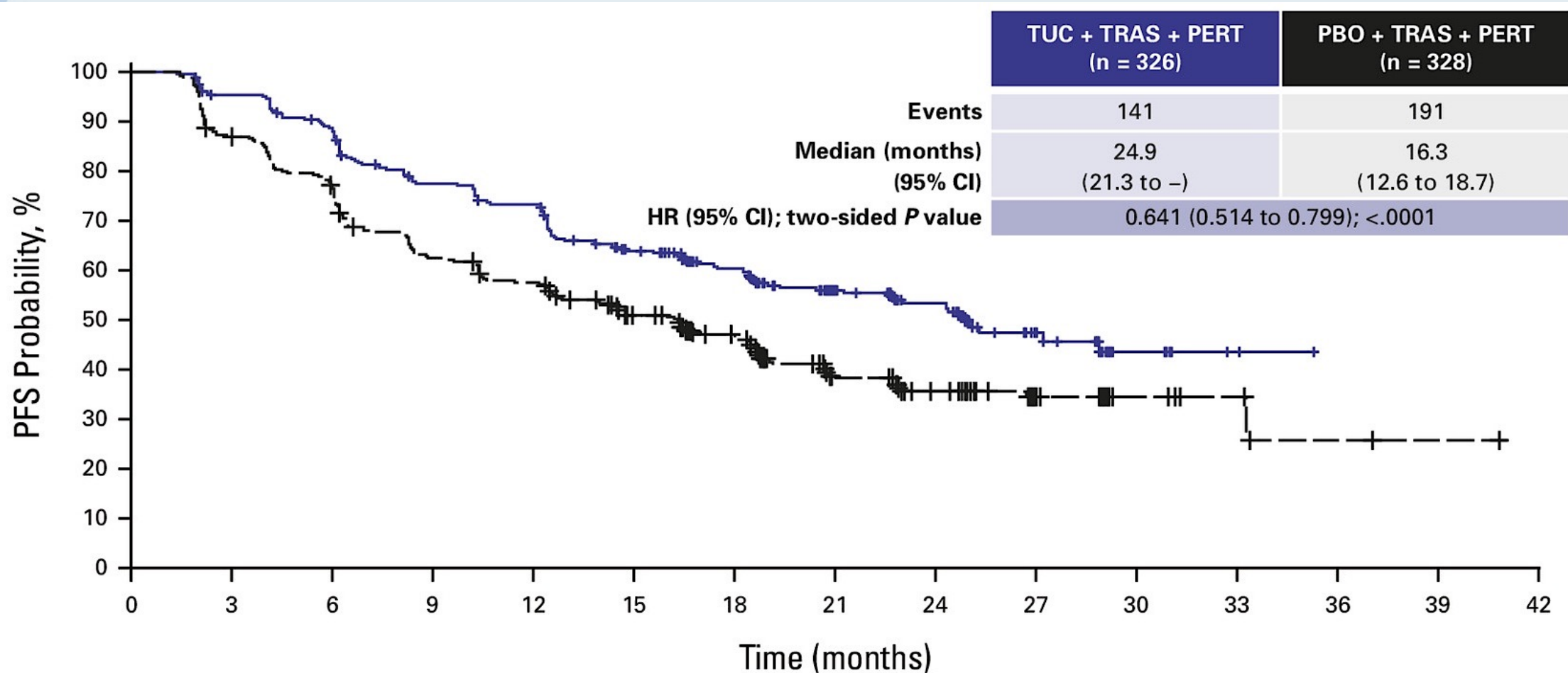
Randomization will be stratified by diagnosis (de novo vs recurrent MBC), hormone receptor status (positive vs negative), and presence or history of BMs (yes vs no).

Patients are permitted to receive up to 2 cycles of carboplatin during the start of induction therapy in combination with trastuzumab, pertuzumab, and taxane.

^aTucatinib/placebo 300 mg will be administered PO from Cycle 1 Day 1 onward, BID on each day of study treatment. ^bIV trastuzumab will be given at a dose of 6 mg/kg once every 21 days. Alternatively, trastuzumab may be administered as an SC dose, at a fixed dose of 600 mg once every 21 days. SC trastuzumab does not require a loading dose. ^cA fixed dose of trastuzumab + pertuzumab (600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase) can be administered every 21 days by SC administration, in lieu of trastuzumab and pertuzumab administered IV individually. ^dPertuzumab 420 mg will be administered every 21 days intravenously over 30-60 minutes.

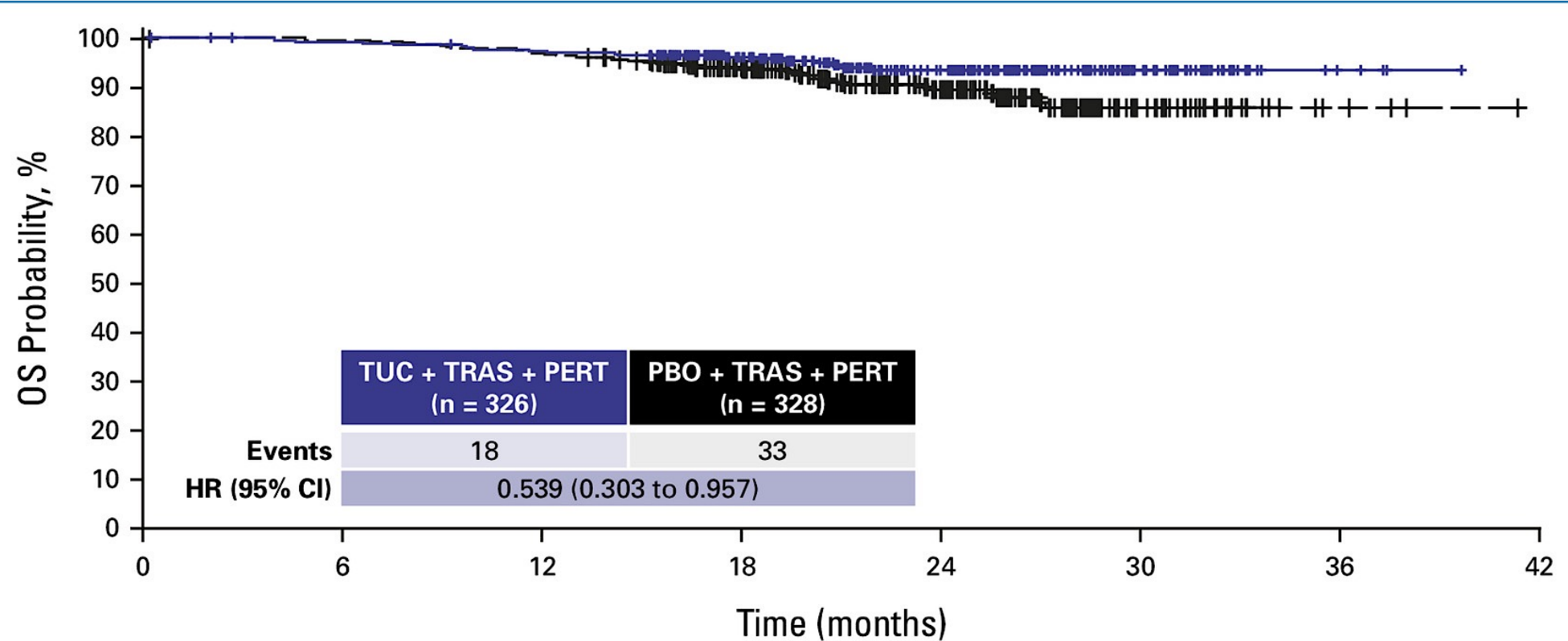
1L = first line; LA = locally advanced; MBC = metastatic breast cancer

Phase III HER2CLIMB-05: Investigator-Assessed PFS in the ITT Population



TUC = tucatinib; TRAS = trastuzumab; PERT = pertuzumab; PBO = placebo

Phase III HER2CLIMB-05: Investigator-Assessed OS in the ITT Population

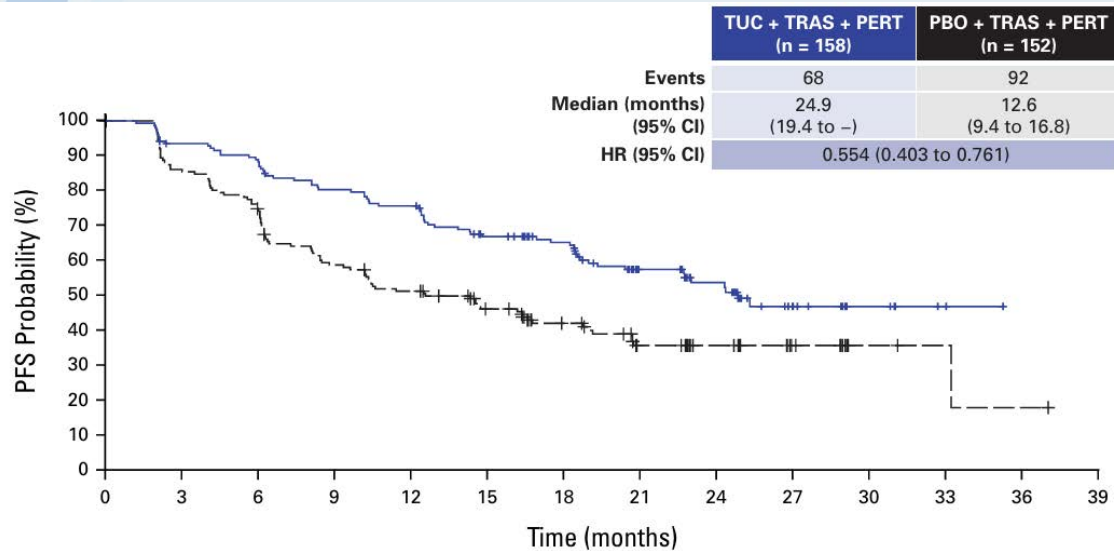


TUC + TRAS + PERT

No. at risk	326	321	314	255	152	43	4	0
No. censored	0	3	4	59	156	265	304	308
PBO + TRAS + PERT								
No. at risk	328	326	317	249	151	41	4	0
No. censored	0	1	1	60	148	254	291	295

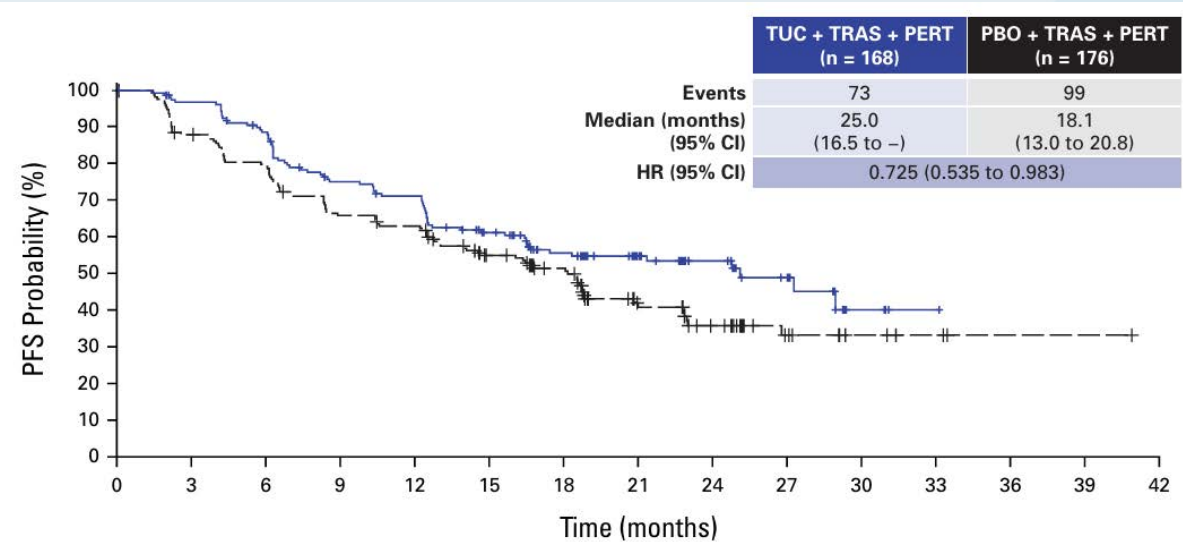
Phase III HER2CLIMB-05: Investigator-Assessed PFS by HR Status

HR-negative



TUC + TRAS + PERT														
No. at risk	158	142	135	121	114	94	79	52	38	16	6	2	0	0
No. censored	0	6	6	7	7	14	27	45	56	74	84	88	90	90
PBO + TRAS + PERT														
No. at risk	152	130	112	87	75	61	43	30	21	12	3	2	1	0
No. censored	0	1	2	3	4	11	24	31	40	49	58	59	59	60

HR-positive



TUC + TRAS + PERT																
No. at risk	168	154	139	115	108	84	64	43	29	15	4	1	0	0	0	0
No. censored	0	9	11	14	15	24	37	57	70	82	91	94	95	95	95	95
PBO + TRAS + PERT																
No. at risk	176	153	137	113	107	81	66	35	25	12	6	4	1	1	0	0
No. censored	0	2	3	4	5	18	28	47	53	65	71	73	76	76	77	77

Phase III PATINA Study Design

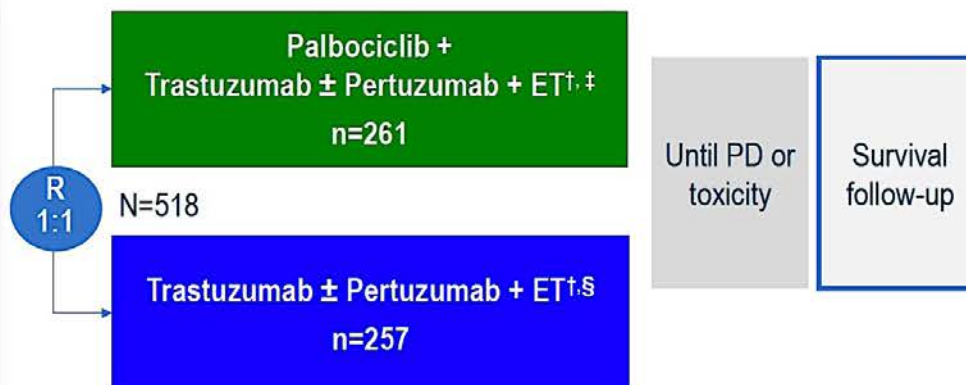
Objective: To evaluate the addition of palbociclib to anti-HER2 and ET for patients with HR+/HER2+ breast cancer

REGISTRATION

- Histologically confirmed HR+/HER2+ aBC
- No prior treatment in the advanced setting beyond induction treatment
- 6–8 cycles of treatment, including trastuzumab ± pertuzumab and taxane/vinorelbine

KEY ELIGIBILITY CRITERIA

- Completion of induction chemotherapy and no evidence of disease progression (ie, CR, PR, or SD)



Primary Outcome

- Investigator-assessed PFS

Secondary Outcomes

- OS
- 3- and 5- year survival probabilities
- ORR / DOR / CBR
- Safety
- **PRO**
- Incidence of CNS mets

Stratification Factors

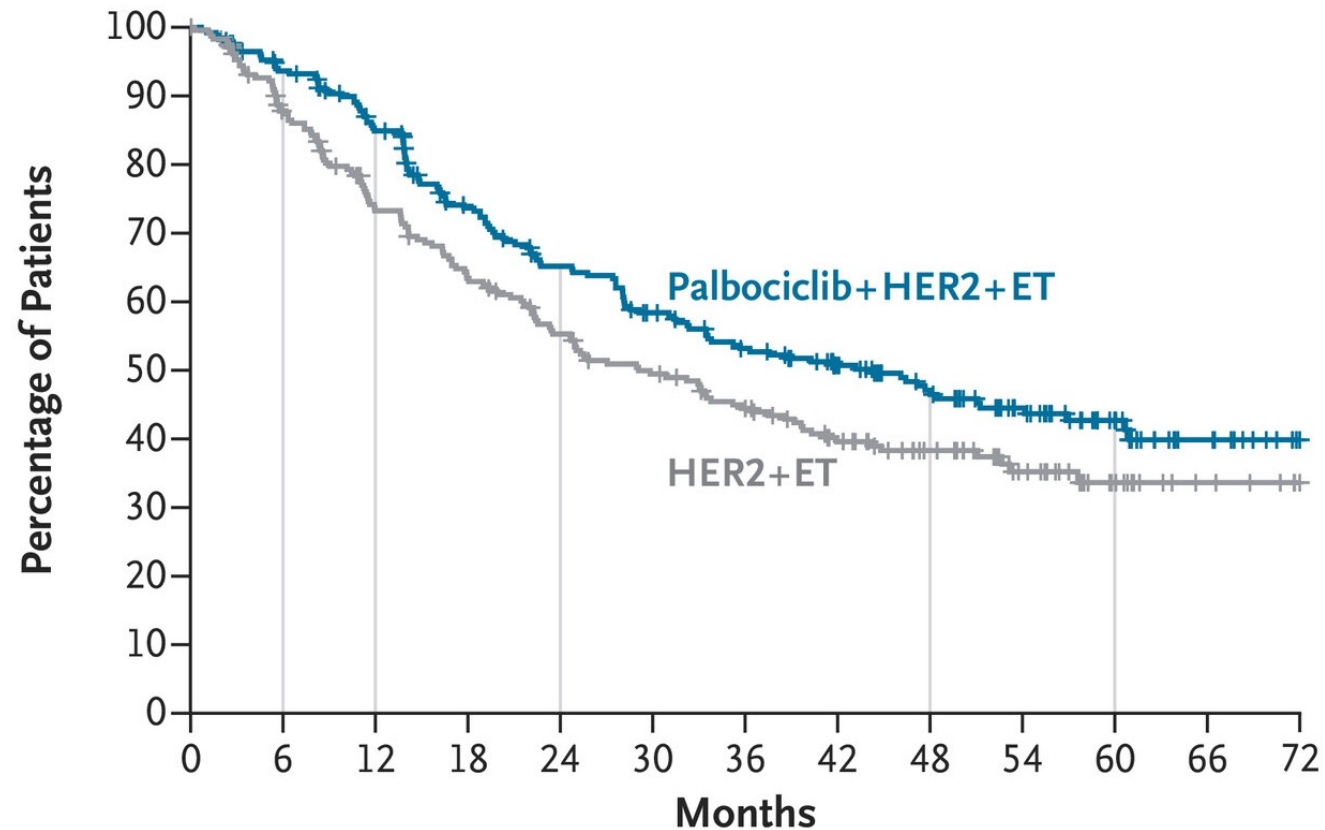
- Pertuzumab use (yes vs no)
 - The non-pertuzumab option is limited to up to 20% of the population
- Prior anti-HER2 therapy in the (neo)adjuvant setting (yes vs no, including de novo)[¶]
- Response to induction therapy (CR or PR vs SD) by investigator assessment^{||}
- Type of ET (fulvestrant vs aromatase inhibitor)

Data cutoff for final PFS analysis: October 15, 2024.

*Study enrollment period was June 2017 until 2021 across the United States, France, Germany, Italy, Portugal, Spain, Australia, and New Zealand. DSMB recommendation to release study data occurred on December 2, 2024. †Trastuzumab and pertuzumab were administered per SOC. ET options included an aromatase inhibitor or fulvestrant. ‡All patients included in the primary and secondary analyses. §Nine patients withdrew before starting treatment and were not included in the safety analysis. All patients were included in the ITT analysis. ||Factors used in stratified analyses. CBR, clinical benefit rate; CNS, central nervous system; CR=complete response; DOR, duration of response; DSMB=Data and Safety Monitoring Board; ET=endocrine therapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; mBC, metastatic breast cancer; mets, metastases; OS, overall survival; ORR, objective response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; PRO, patient-reported outcome; R, randomization; SD, stable disease; SOC, standard of care.

References: 1. <https://clinicaltrials.gov/study/NCT02947685>. Accessed September 11, 2025; 2. Metzger O, et al. SABCS 2024. Presentation GS2-12.

Phase III PATINA: PFS in the ITT Population



	No. of Events/Total No. of Patients	Median Progression-free Survival (95% CI) <i>mo</i>
Palbociclib+HER2+ET	127/261	44.3 (32.4–56.8)
HER2+ET	135/257	29.1 (23.3–38.6)
Hazard ratio for disease progression or death, 0.75 (95% CI, 0.59–0.96)		
Two-sided unstratified P=0.02 by log-rank test		

HER2 = anti-HER2 therapy

PATINA: Cumulative Incidence of CNS Disease Progression or Death Among Patients without CNS Metastases at Baseline

	Palbociclib + anti-HER2 + ET (n = 250)	Anti-HER2 + ET (n = 248)
CNS PFS event (n)	35	48
Death	3	1
CNS progression	32	47
Cumulative risk of CNS progression or death (%)		
12 months	4.6%	6.9%
24 months	9.7%	15.7%
36 months	13.0%	19.2%

Faculty Discussion



Dr Choksi

Questions for the Faculty

This 68-year-old woman presented with a palpable breast lump and had some financial and insurance restrictions in the beginning, so it took months before she could have medical care and evaluation. Her disease was ER-positive, HER2-positive, and by the time we saw her she had a positive lymph node in the axilla, but also disease in the bones. She received taxane-based chemotherapy with trastuzumab and pertuzumab and is about to finish chemotherapy and start maintenance.

Questions

- What are your criteria to use T-DXd in the first line? How long do you give it? How do you approach maintenance?
- For “triple-positive” disease do you use maintenance endocrine treatment including a CDK4/6 inhibitor (palbociclib)?
- Are you using tucatinib maintenance in patients with ER-negative, HER2-positive disease?

Agenda

Introduction: ESMO 2026; Recent FDA Approvals

ER-Positive Breast Cancer

HER2-Positive Breast Cancer

Triple-Negative Breast Cancer

- Localized TNBC – *Dr Lustberg*
- Metastatic TNBC: First-Line Treatment with TROP2-Directed ADCs – *Dr Nanda*

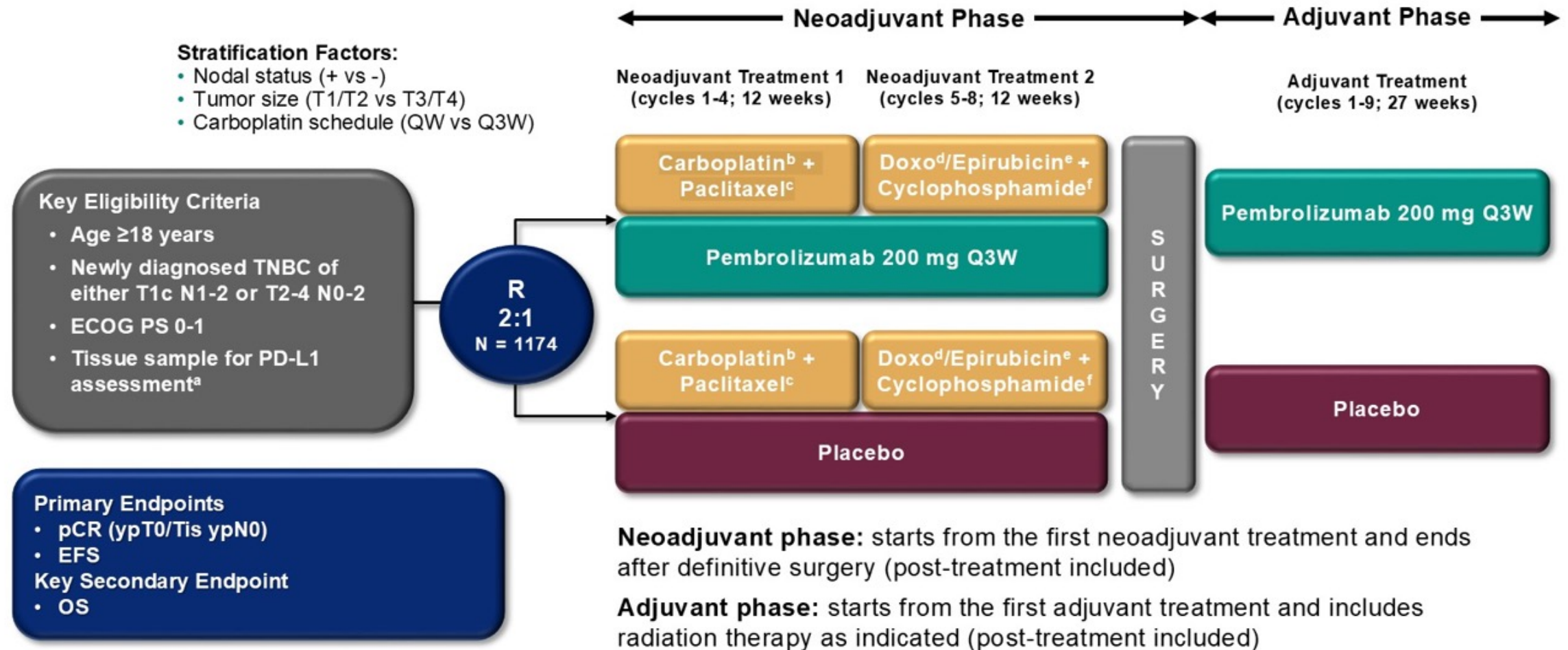
Localized TNBC

Dr Lustberg

Select Datasets

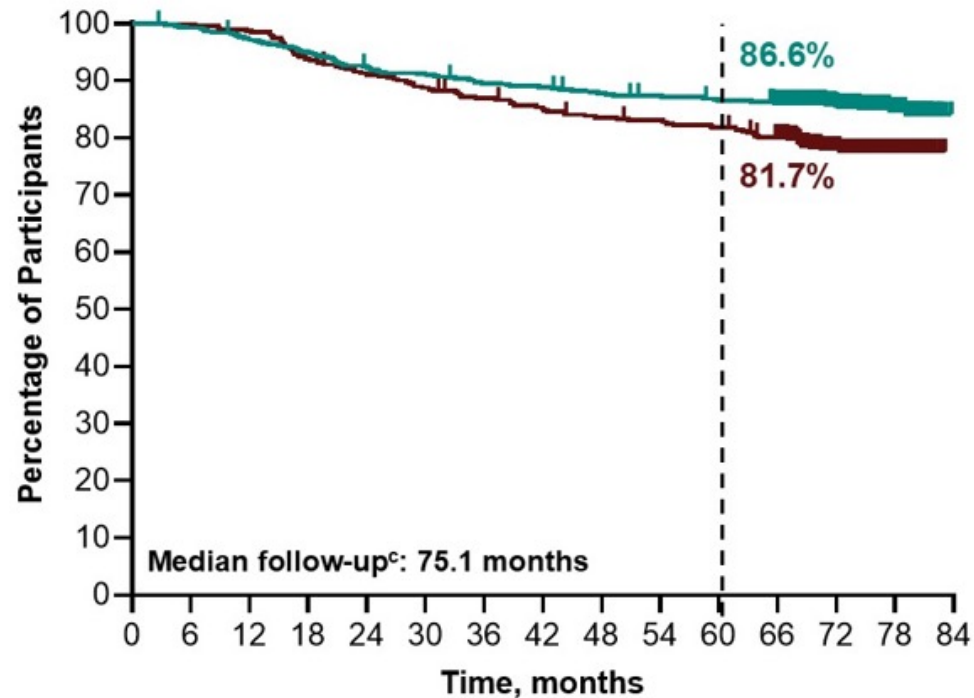
- Schmid P et al. Neoadjuvant pembrolizumab or placebo plus chemotherapy followed by adjuvant pembrolizumab or placebo for high-risk early-stage TNBC: Final analysis results from the phase 3 KEYNOTE-522 study. ASCO 2026;Abstract 507.
- Garber JE et al. Sustained benefit of adjuvant olaparib in women with germline BRCA1- and BRCA2-associated high-risk HER2-negative early breast cancer: Updated results from the OlympiA phase III trial. *Ann Oncol* 2026;[Online ahead of print].

Phase III KEYNOTE-522 Study Design



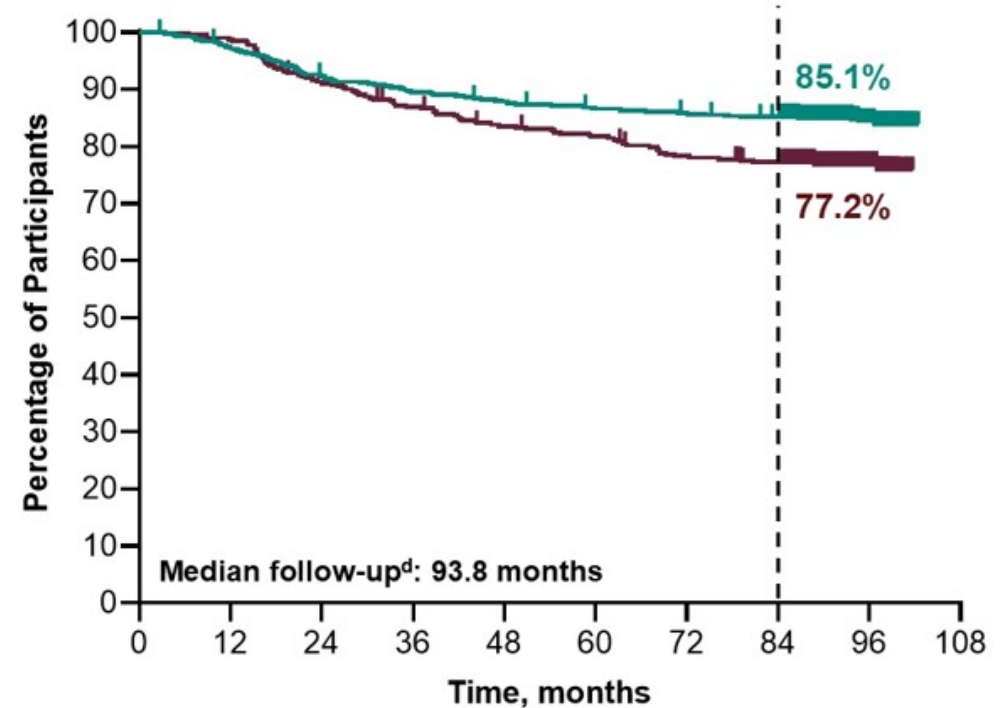
Phase III KEYNOTE-522 Study: Overall Survival

IA7	Events	HR (95% CI)	P-value
Pembro + Chemo/Pembro	14.7%	0.66 ^a (0.50-0.87)	0.00150 ^b
Placebo + Chemo/Placebo	21.8%		



No. at risk														
784	777	760	742	720	712	698	693	683	677	670	656	448	176	0
390	389	385	366	354	345	336	328	321	318	313	300	199	82	0

FA	Events	HR (95% CI)
Pembro + Chemo/Pembro	15.3%	0.64 ^a (0.49-0.85)
Placebo + Chemo/Placebo	23.1%	



No. at risk													
784	760	720	699	685	673	666	658	202	0				
390	385	354	336	321	313	298	290	97	0				



Contents lists available at ScienceDirect

The Breast

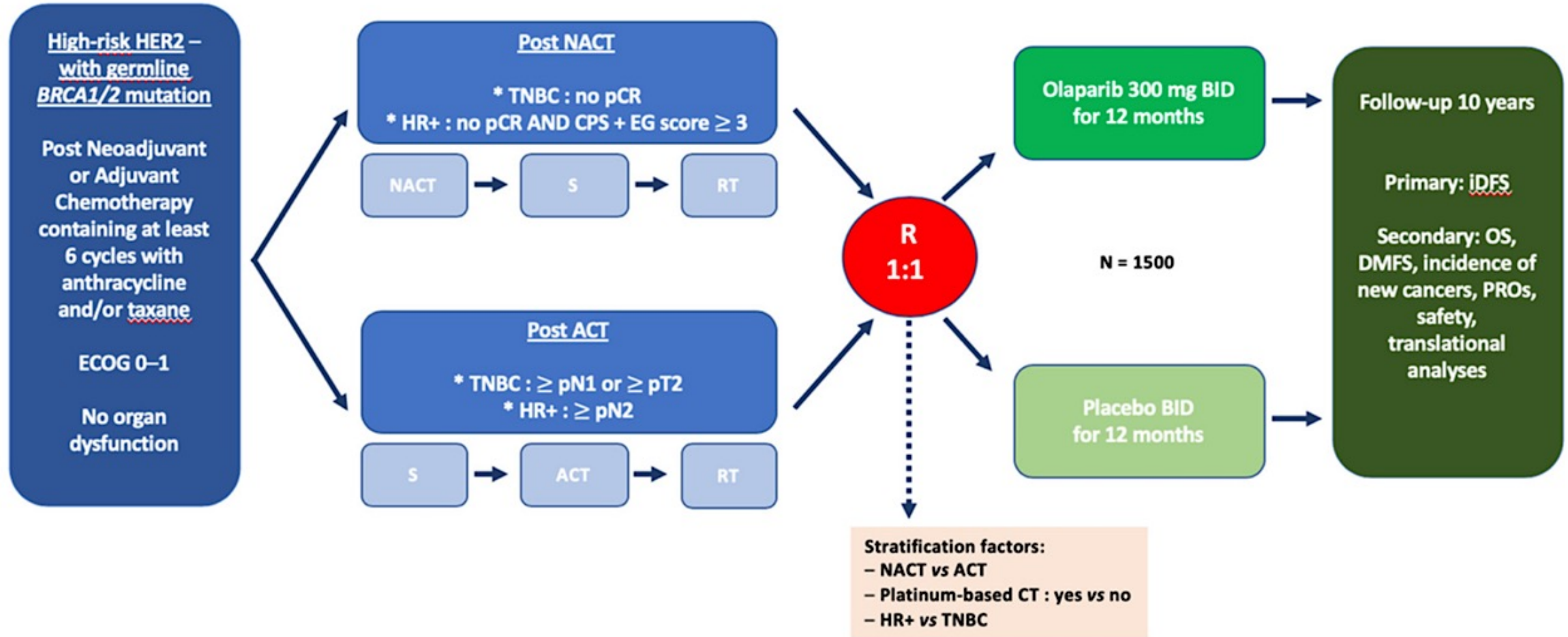
journal homepage: www.journals.elsevier.com/the-breast



Pembrolizumab plus chemotherapy followed by pembrolizumab in participants in Asia with early triple-negative breast cancer: An updated subgroup analysis of the KEYNOTE-522 randomized clinical trial

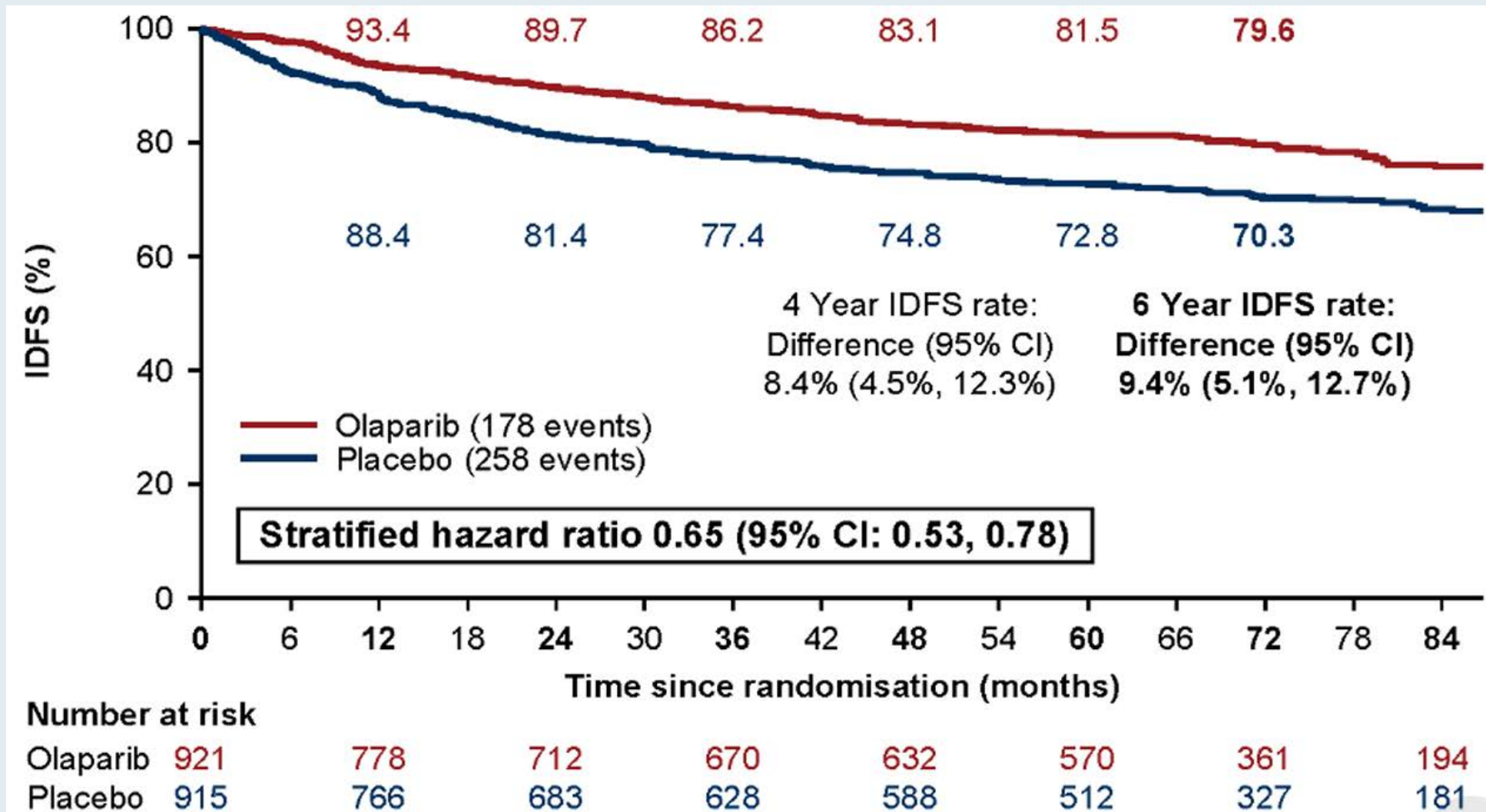
Yeon Hee Park^{a,*} , Rina Hui^{b,1}, Seock-Ah Im^c, Jin-Hee Ahn^d, Chiun-Sheng Huang^e, Min Hwan Kim^f, Shin-Cheh Chen^g, Hirofumi Mukai^h, Masato Takahashiⁱ, Hiroji Iwata^j, Javier Cortés^{k,l,m}, Heather McArthurⁿ, Lajos Pusztai^o, Sherko Kümmel^{p,q}, Carsten Denkert^r, Joyce O'Shaughnessy^s, Nadia Harbeck^t, Peter A. Fasching^u, Michael Untch^v, Fatima Cardoso^w, Liyi Jia^x, Francisco Beca^x, Jaime Mejia^x, Rebecca Dent^{y,z}, Peter Schmid^{aa}

Phase III OlympiA Study Design

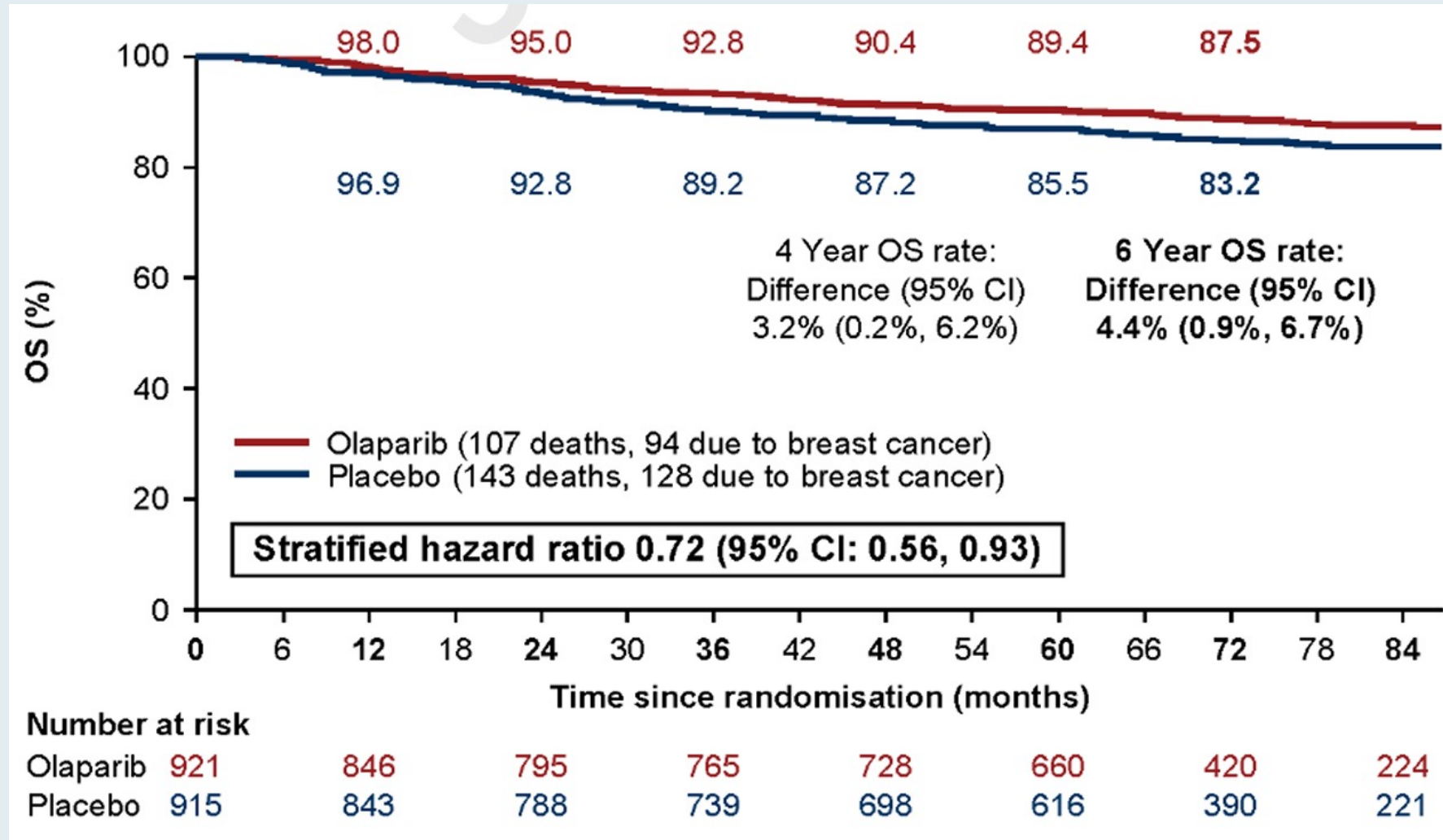


NACT = neoadjuvant chemotherapy; CPS + EG = clinical and pathological stage and estrogen receptor and nuclear grade; ACT = adjuvant chemotherapy

Phase III OlympiA: Invasive Disease-Free Survival (IDFS)



Phase III OlympiA: OS



Localized TNBC: Select Ongoing Antibody-Drug Conjugate (ADC) Trials

Sacituzumab Govitecan

- Tolaney SM et al. OptimICE-RD: Sacituzumab govitecan + pembrolizumab vs pembrolizumab ($\pm$ capecitabine) for residual triple-negative breast cancer. *Future Oncol* 2024;20:2343-55.
- Tolaney SM et al. ASCENT-05/OptimICE-RD (AFT-65): Phase 3, randomized, open-label study of adjuvant sacituzumab govitecan (SG) + pembrolizumab (pembro) vs pembro $\pm$ capecitabine (cape) in patients (pts) with triple-negative breast cancer (TNBC) and residual disease after neoadjuvant therapy (NAT) and surgery. ASCO 2023;Abstract TPS619.
- Schmid P et al. Neoadjuvant sacituzumab govitecan versus sacituzumab govitecan plus pembrolizumab in low-risk, triple-negative early breast cancer: WSG-ADAPT-TN-III. *Ann Oncol* 2025; 36(Suppl 2):376-7.
- ADAPT-TN-IV: Neoadjuvant dynamic marker-adjusted personalized therapy comparing sacituzumab govitecan + pembrolizumab vs SoC chemotherapy in clinical stage II-III, triple-negative early breast cancer. NCT07178730.

Localized TNBC: Select Ongoing ADC Trials (Continued)

Datopotamab Deruxtecan

- Loibl S et al. TROPION-Breast04: Phase (ph) III study of neoadjuvant (neoadj) datopotamab deruxtecan (Dato-DXd) + durvalumab (D) followed by adjuvant (adj) D vs standard of care (SoC) in treatment-naïve, triple-negative (TN) and HR-low/HER2-breast cancer. ESMO Breast 2024;Abstract 159TiP.
- Bardia A et al. TROPION-Breast03: A randomized phase III global trial of datopotamab deruxtecan $\pm$ durvalumab in patients with triple-negative breast cancer and residual invasive disease at surgical resection after neoadjuvant therapy. *Ther Adv Med Oncol* 2024;16:17588359241248336.

Localized TNBC: Select Ongoing ADC Trials (Continued)

Sacituzumab Tirumotecan

- McArthur HL et al. TroFuse-012: A phase 3, randomized study of adjuvant sacituzumab tirumotecan plus pembrolizumab vs treatment of physician's choice in participants with triple-negative breast cancer who received neoadjuvant therapy and did not achieve a pathological complete response at surgery. SABCS 2025;Abstract PS5-12-22.
- Harbeck N et al. TroFuse-032: A phase 3, randomized study of pembrolizumab plus sacituzumab tirumotecan or chemotherapy followed by pembrolizumab plus chemotherapy for early-stage triple-negative breast cancer or hormone receptor-low-positive (HR-low+)/human epidermal growth factor receptor 2-negative (HER2-) breast cancer. SABCS 2025;Abstract PS5-12-25.

Faculty Discussion



Dr Ignatius

Questions for the Faculty

60-year-old woman with a long history of lupus, mainly with cutaneous effects but not on current treatment. Presented with localized Stage T2N1 TNBC: left breast mass, multiple hypermetabolic left axillary nodes. Her rheumatologist cleared her for IO treatment, and she received the KEYNOTE-522 regimen. She had an excellent response but with some residual disease: 2.5 mm with only scattered tumor cells in the nodes (ypT1 pN1a). No evidence of any lupus flare-up, but while receiving adjuvant pembrolizumab she developed hyponatremia and adrenal insufficiency requiring hydrocortisone replacement. Pembrolizumab was discontinued. She is being followed with no evidence of recurrence.

Questions

- Is there a role for ctDNA surveillance for a patient like this or for any patient with breast cancer?
- Do you discontinue IO for patients with adrenal insufficiency?
- What is the spectrum of autoimmune toxicity that you've observed in the neoadjuvant setting with the KEYNOTE-522 regimen?

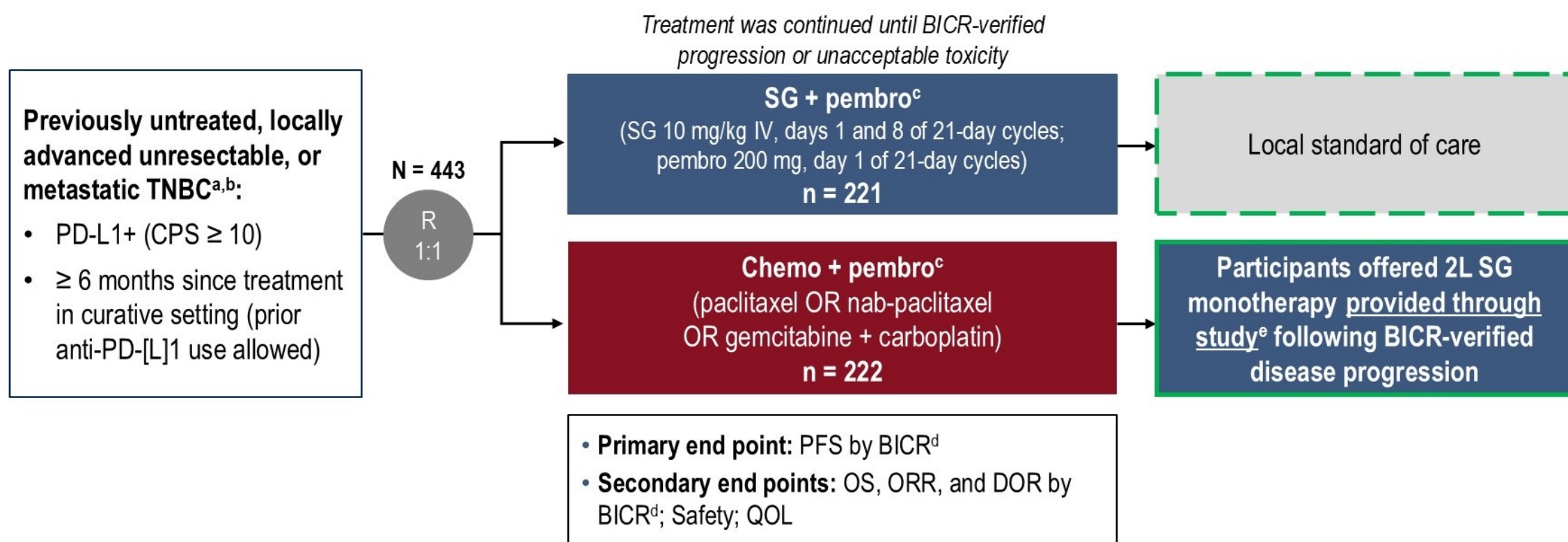
Metastatic TNBC First-Line Treatment: TROP2-Directed ADCs

Dr Nanda

Select Datasets

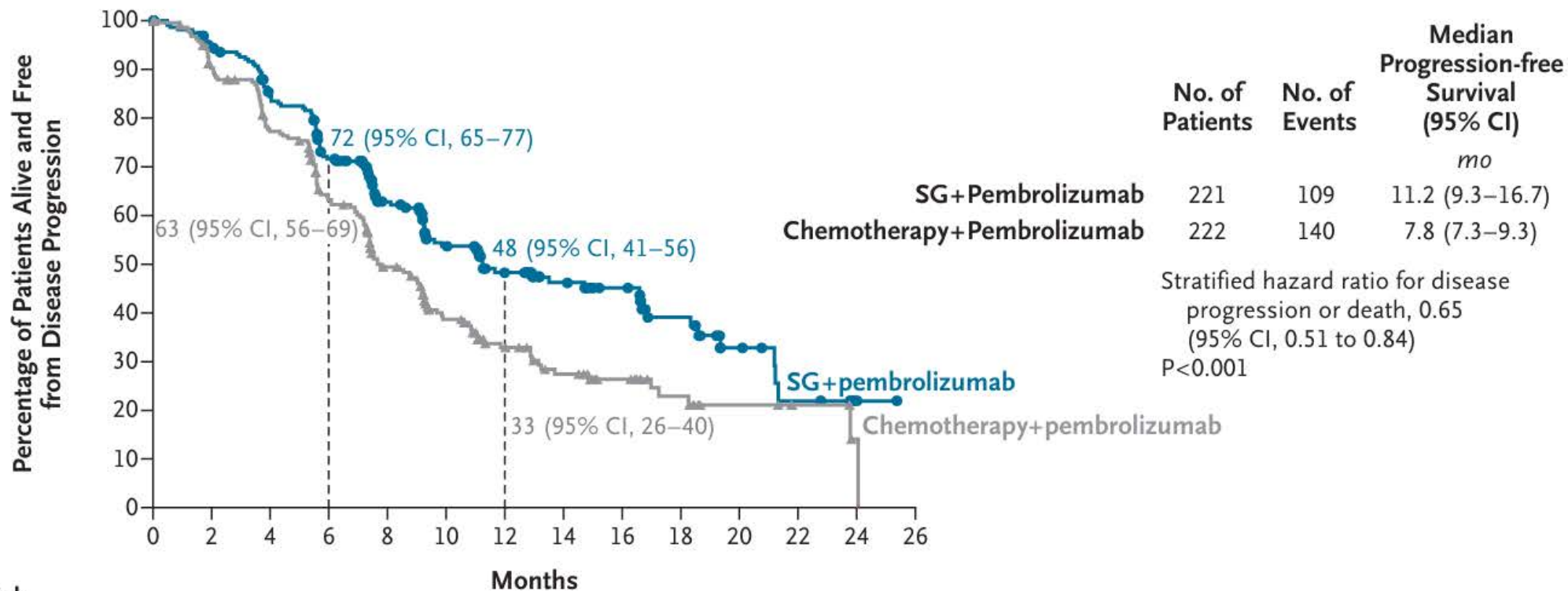
- Tolaney SM et al. Sacituzumab govitecan plus pembrolizumab for advanced triple-negative breast cancer. *N Engl J Med* 2026;394:354-66.
- Cortés J et al. Sacituzumab govitecan in untreated, advanced triple-negative breast cancer. *N Engl J Med* 2025;393(19):1912-25.
- Dent R et al. Datopotamab deruxtecan in patients with untreated, advanced triple-negative breast cancer (TROPION-Breast02): A randomized, open-label, international, phase III trial. *Ann Oncol* 2026;37(8):1066-80.

Phase III ASCENT-04 Study Design



CPS = combined positive score; SG = sacituzumab govitecan; pembro = pembrolizumab

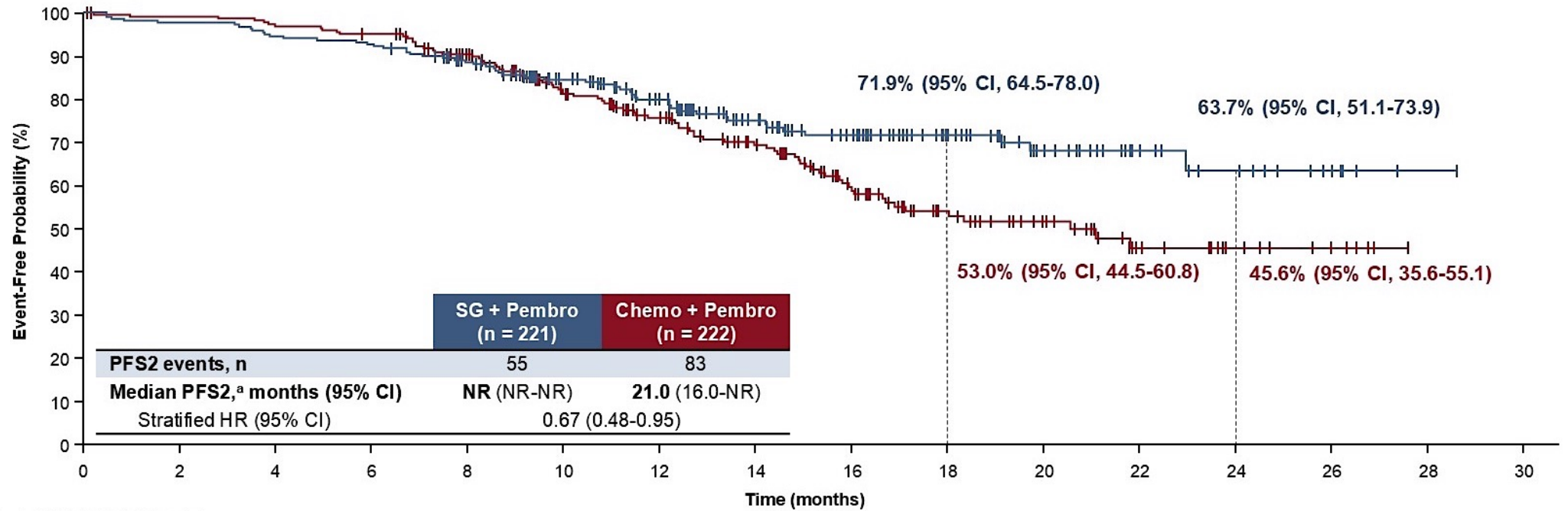
Phase III ASCENT-04/KEYNOTE-D19 Study: PFS



No. at Risk (no. of events)

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

Phase III ASCENT-04: PFS After Next Line of Treatment (PFS2)



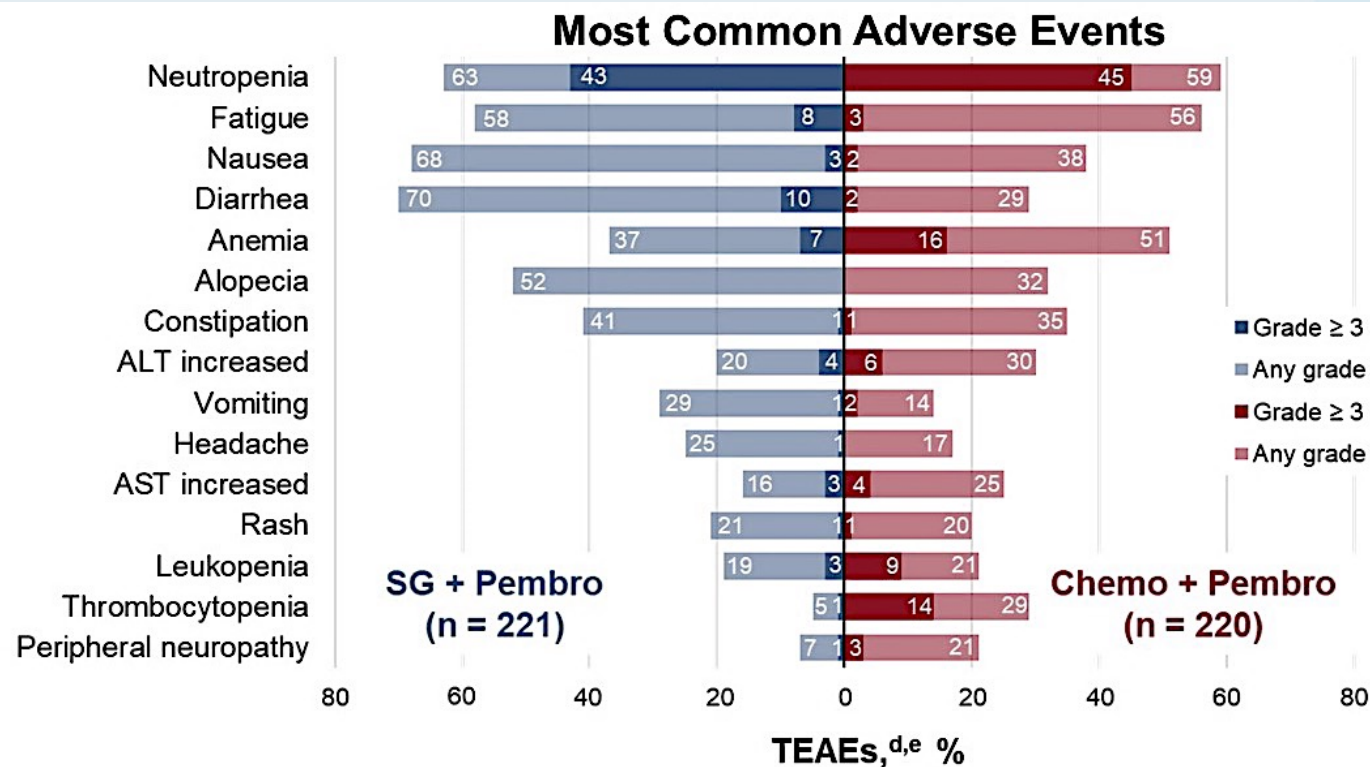
No. of Patients Still at Risk (Events)

SG + pembro	221 (0)	216 (5)	209 (12)	205 (16)	186 (25)	154 (33)	128 (41)	97 (48)	76 (52)	48 (52)	31 (54)	17 (54)	12 (55)	5 (55)	1 (55)	0 (55)
Chemo + pembro	222 (0)	218 (2)	213 (7)	208 (11)	186 (21)	154 (39)	129 (49)	101 (59)	70 (74)	46 (79)	32 (80)	16 (83)	10 (83)	5 (83)	0 (83)	

PFS2 was longer in the SG + pembro group compared with the chemo + pembro group despite the high rate of crossover in the chemo + pembro group, with a 33% reduction in risk of a PFS2 event with SG + pembro

Phase III ASCENT-04: Safety Summary

n (%)	SG + Pembro (n = 221)	Chemo + Pembro (n = 220)
Any TEAE	220 (> 99)	219 (> 99)
Grade ≥ 3	158 (71)	154 (70)
Treatment-emergent SAE	84 (38)	68 (31)
Treatment-related	61 (28)	42 (19)
TEAEs leading to treatment discontinuation^a	26 (12)	68 (31)
TEAEs leading to dose interruption	171 (77)	162 (74)
TEAEs leading to dose reduction	78 (35)	96 (44)
TEAEs leading to death^c	7 (3)	6 (3)
Treatment-related	3 (1)	1 (< 1)



The AEs observed were consistent with the known profiles of both SG and pembro, with no new safety concerns

SAE = serious adverse event

Phase III ASCENT-03 Study Design

Patients with previously untreated, locally advanced inoperable or metastatic TNBC^a:

- Not candidates for PD-(L)1 inhibitors:
 - PD-L1 negative^b tumors (CPS < 10)
 - PD-L1 positive^b tumors (CPS ≥ 10) and previously treated with a PD-(L)1 inhibitor in curative setting
 - Ineligible for a PD-(L)1 inhibitor due to a comorbidity
- ≥ 6 months since treatment in curative setting
- Previously treated, stable CNS metastases were allowed

N = 558

R
1:1

Treatment was continued until BICR-verified progression or unacceptable toxicity

Sacituzumab govitecan

10 mg/kg IV
(days 1 and 8 of 21-day cycles)
n = 279

Chemotherapy

Paclitaxel 90 mg/m² OR nab-Paclitaxel 100 mg/m²
(days 1, 8, and 15 of 28-day cycles) OR
Gemcitabine 1000 mg/m² + Carboplatin AUC2
(days 1 and 8 of 21-day cycles)
n = 279

End points

Primary

- PFS by BICR^d

Secondary

- OS
- ORR, DOR, TTR by BICR^d
- Safety
- QOL

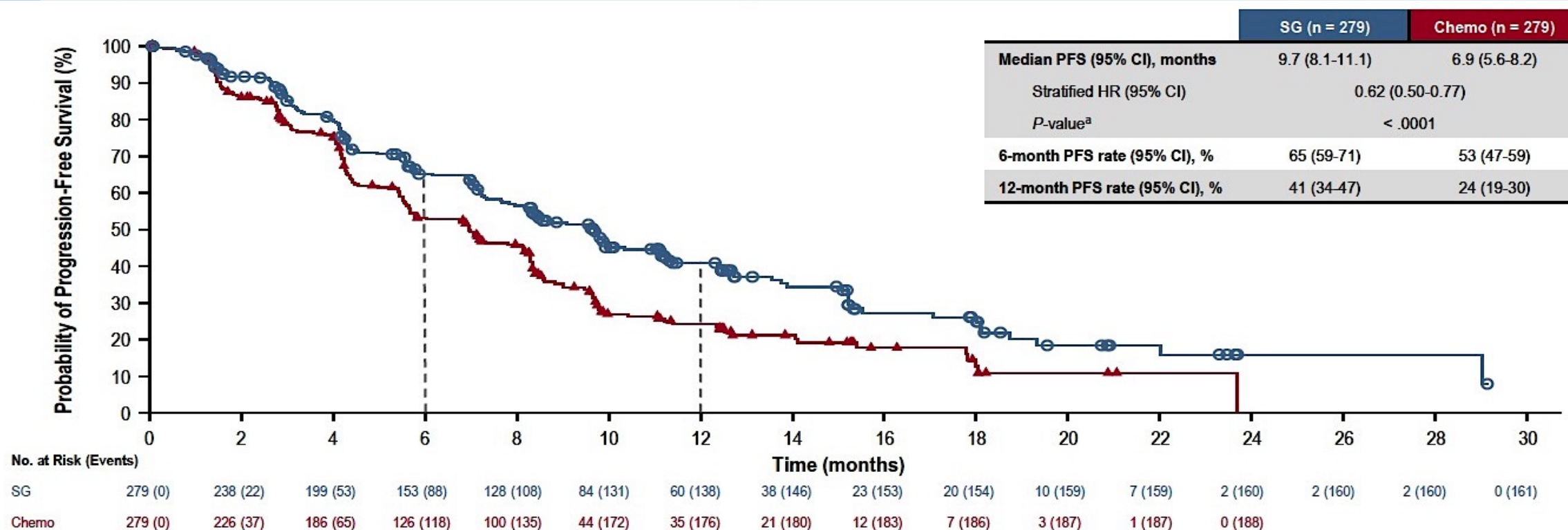
Stratification factors:

- United States/Canada/Western Europe vs rest of the world
- De novo mTNBC^c vs recurrent within 6 to 12 months of treatment vs recurrent after > 12 months from treatment in curative setting

Eligible patients were offered crossover to 2L SG provided through the study following BICR-verified disease progression

ClinicalTrials.gov identifier: NCT05382299. ^aTNBC status was centrally confirmed and determined according to standard American Society of Clinical Oncology-College of American Pathologists criteria. ^bPD-L1 CPS was centrally confirmed and defined using the PD-L1 IHC 22C3 assay. ^cUp to 35% de novo mTNBC. ^dPer Response Evaluation Criteria in Solid Tumors version 1.1. 2L, second line; AUC, area under the curve; BICR, blinded independent central review; CNS, central nervous system; CPS, combined positive score; DOR, duration of response; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein-1; PD-L1, programmed cell death ligand 1; PD-(L)1, PD-1 or PD-L1; PFS, progression-free survival; QOL, quality of life; R, randomization; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; TTR, time to response.

Phase III ASCENT-03: PFS by BICR



SG demonstrated statistically significant and clinically meaningful improvement in PFS vs chemo by BICR analysis, with a 38% reduction in risk of disease progression or death

Data cutoff date: April 2, 2025. ^aTwo-sided P-value from stratified log-rank test.

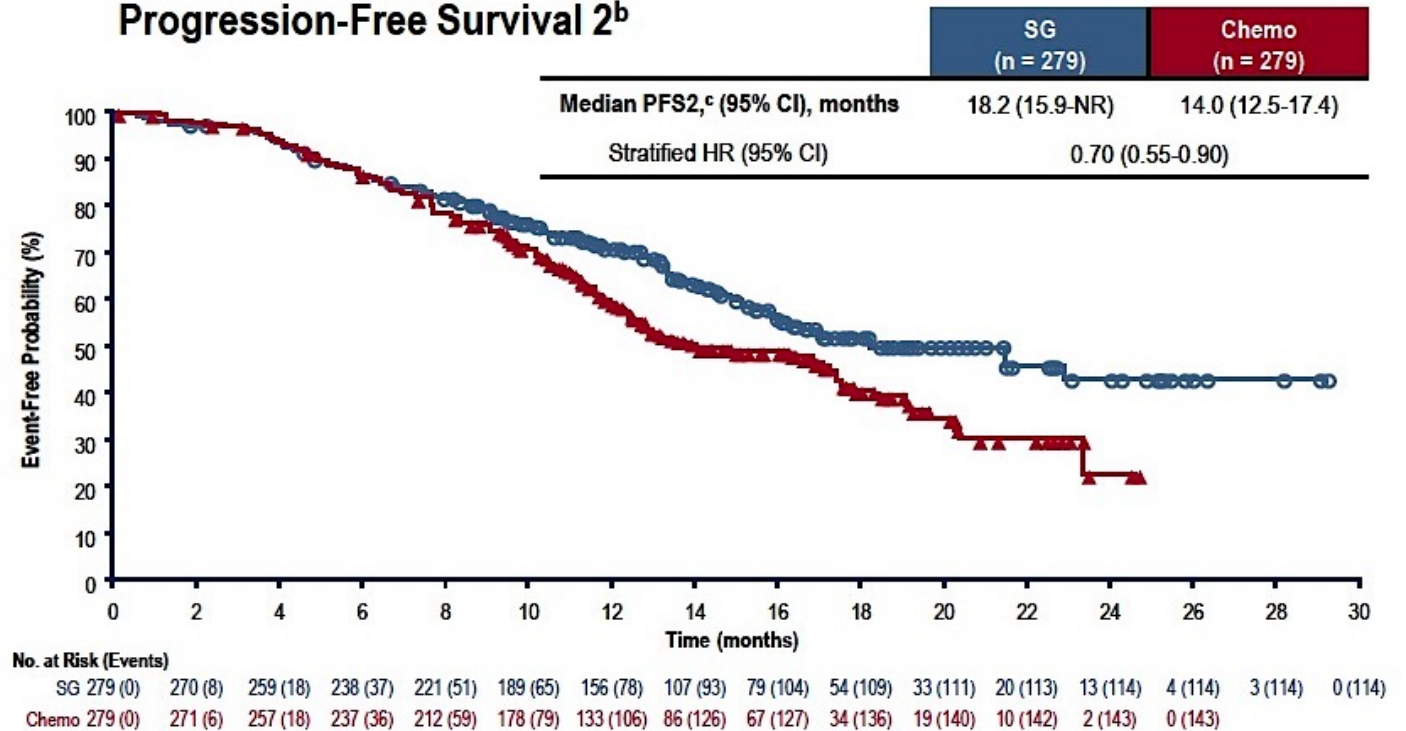
BICR, blinded independent central review; chemo, chemotherapy; HR, hazard ratio; PFS, progression-free survival; SG, sacituzumab govitecan.

Phase III ASCENT-03: Descriptive OS and PFS2

- Overall survival not yet mature^a
- Study continues to first formal OS analysis
- Of 179 patients who initiated subsequent treatment after chemo, 147 (82%) received SG

Overall survival	SG (n = 279)	Chemo (n = 279)
Number of events, %	103 (37)	103 (37)
Median (95% CI), months	21.5 (17.7-NR)	20.2 (18.2-NR)
Stratified HR (95% CI)	0.98 (0.75-1.30)	
OS rate (95% CI), %		
12-month	75 (70-80)	73 (67-78)
24-month	46 (36-56)	42 (29-54)

Progression-Free Survival 2^b

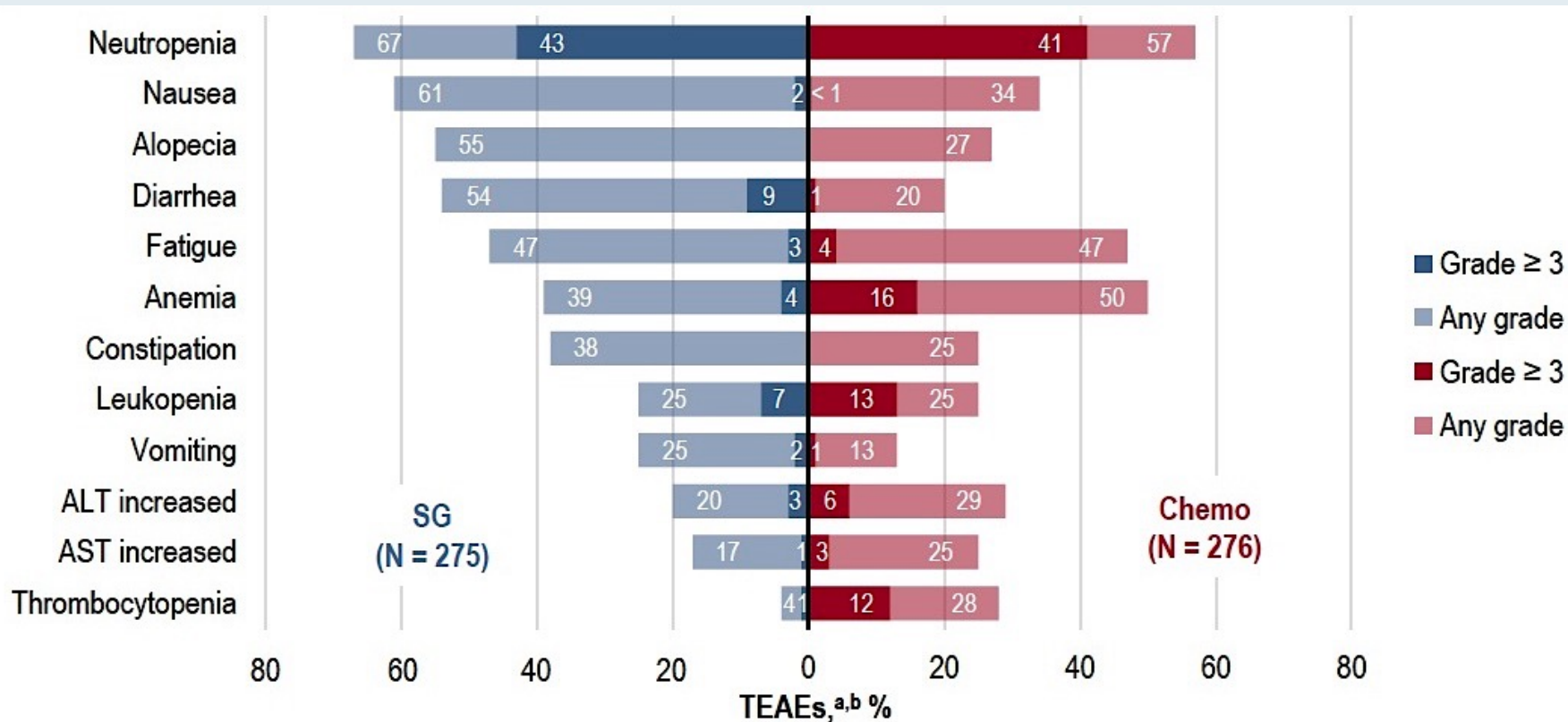


At the time of primary analysis, overall survival was immature and PFS2 was longer with SG vs chemo by investigator assessment

Data cutoff date: April 2, 2025. ^aAt the time of this analysis, OS data maturity was 37%. ^bPFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of progressive disease or death due to any cause, whichever occurs first. ^cBy investigator assessment.

2L, second line; chemo, chemotherapy; HR, hazard ratio; NR, not reached; OS, overall survival; PFS2, progression-free survival 2; SG, sacituzumab govitecan.

Phase III ASCENT-03: Common Adverse Events



The AEs observed are consistent with the known safety profile of SG

Data cutoff date: April 2, 2025. ^aTEAEs were included if they occurred in ≥ 20% of patients in either group. ^bCombined preferred terms of Neutropenia includes neutrophil count decreased, Fatigue includes asthenia, Anemia includes hemoglobin decreased and red blood cell count decreased, Leukopenia includes white blood cell count decreased, and Thrombocytopenia includes platelet count decreased.

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; chemo, chemotherapy; SG, sacituzumab govitecan; TEAE, treatment-emergent adverse event.

Phase III TROPION-Breast02 Study Design

Randomised, phase 3, open-label, global study (NCT05374512)

Key inclusion criteria:

- Patients with histologically or cytologically documented locally recurrent inoperable or metastatic TNBC*
- No prior chemotherapy or targeted systemic therapy in the locally recurrent inoperable or metastatic setting
- Immunotherapy not an option†
- ECOG PS 0 or 1
- No minimum DFI‡

1:1

Dato-DXd

6 mg/kg IV Day 1 Q3W
(n=323)

Investigator's choice of chemotherapy (ICC)#

Paclitaxel, nab-paclitaxel, capecitabine, eribulin mesylate/eribulin, carboplatin
(n=321)

Endpoints

Dual primary:

- OS
- PFS by BICR per RECIST v1.1

Secondary included:

- PFS (investigator-assessed)
- ORR, DoR
- Safety

Randomisation stratified by:

- Geographic region (US/Canada/Europe vs other geographic regions)
- PD-L1 status (high [CPS ≥10] vs low [CPS <10])§
- DFI history (*de novo* vs prior DFI 0–12 months vs prior DFI >12 months)¶

- Treatment continued until investigator-assessed RECIST v1.1 progressive disease, unacceptable toxicity, or another discontinuation criterion was met
- Following progression or discontinuation of study treatment, patients could receive subsequent therapies, including approved ADCs or chemotherapy, at the investigator's discretion||

*According to ASCO/CAP criteria. †Including patients with PD-L1-low tumours, or patients with PD-L1-high tumours with (a) disease relapse after prior PD-(L)1 inhibitor therapy for early-stage breast cancer, (b) comorbidities precluding PD-(L)1 inhibitor therapy, or (c) no regulatory access to PD-(L)1 inhibitor therapy. ‡DFI defined as time between date of completion of treatment with curative intent and date of first documented local or distant disease recurrence. §Recruitment of patients with PD-L1-high tumours who would otherwise be eligible for pembrolizumab if regulatory access was available was capped at ~10% of randomised patients. ¶Recruitment of patients with DFI 0–12 months was capped at ~20% of randomised patients. ||If no prior taxane, or prior taxane in the (neo)adjuvant setting and DFI >12 months: paclitaxel 80 mg/m² IV, D1, 8, 15, Q3W, or nab-paclitaxel 100 mg/m² IV, D1, 8, 15, Q4W; if prior taxane and DFI 0–12 months: capecitabine 1000 or 1250 mg/m² orally twice daily, D1–14, Q3W (dose determined by standard institutional practice), or eribulin mesylate 1.4 mg/m² / eribulin 1.23 mg/m² IV, Day 1, 8, Q3W, or carboplatin AUC6 IV, D1, Q3W. ||In the Dato-DXd vs ICC arm, 65% vs 72% of patients received any subsequent therapy in any treatment line; 14% vs 30% received a subsequent ADC (sacituzumab govitecan, sacituzumab tirumotecan, trastuzumab deruxtecan).

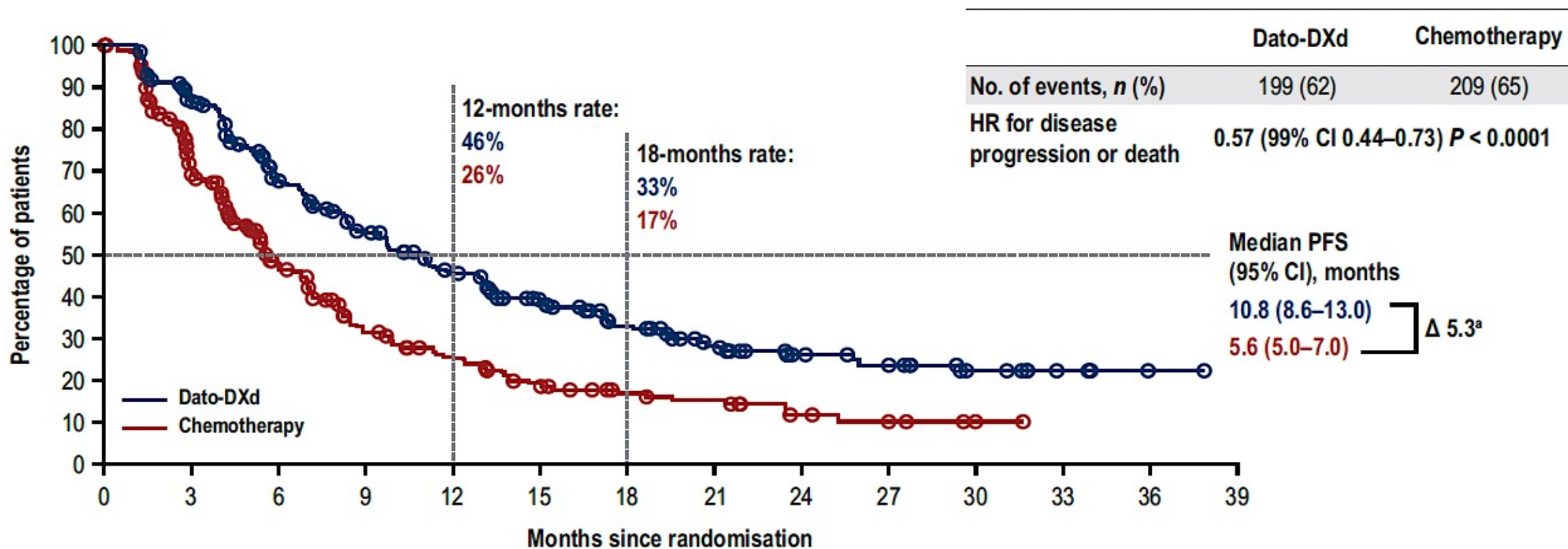
Rebecca A. Dent

ADC, antibody-drug conjugate; BICR, blinded independent central review; CPS, combined positive score; D, day; DFI, disease-free interval; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenously; ORR, objective response rate; PD-(L)1, programmed cell death (ligand) 1; PFS, progression-free survival; Q3W, every 3 weeks.

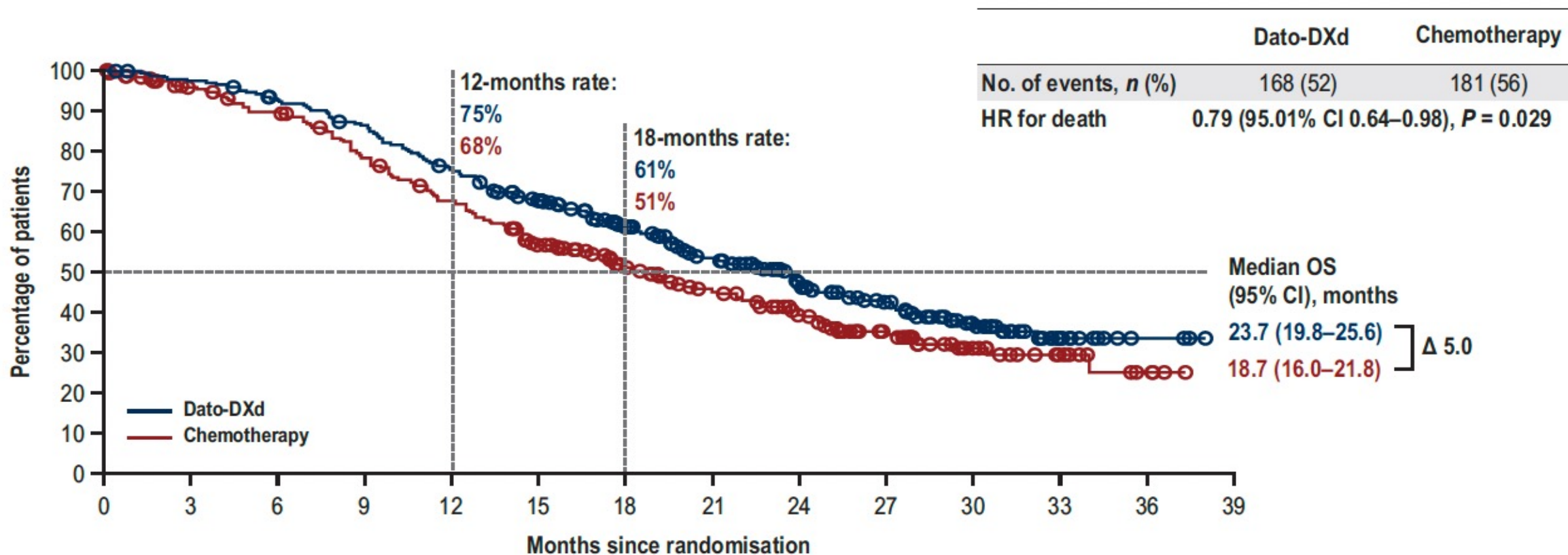


Dato-DXd = datopotamab deruxtecan

Phase III TROPION-Breast02: PFS by BICR



Phase III TROPION-Breast02: OS in the ITT Population



Phase III TROPION-Breast02: Common TRAEs

Treatment-related AEs, n (%)	Dato-DXd (n=319)		ICC (n=309)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Dry eye*	76 (24)	4 (1)	9 (3)	0
Stomatitis	182 (57)	27 (8)	27 (9)	0
Nausea	142 (45)	2 (<1)	53 (17)	2 (<1)
Constipation	72 (23)	1 (<1)	31 (10)	0
Vomiting	65 (20)	4 (1)	23 (7)	1 (<1)
Decreased appetite	49 (15)	1 (<1)	20 (6)	1 (<1)
Neutropenia†	39 (12)	10 (3)	90 (29)	40 (13)
Anaemia‡	48 (15)	6 (2)	64 (21)	10 (3)
Leukopenia§	27 (8)	3 (<1)	55 (18)	13 (4)
Peripheral neuropathy¶	14 (4)	0	75 (24)	5 (2)
Alopecia	130 (41)	0	96 (31)	1 (<1)¶
Fatigue#	101 (32)	8 (3)	86 (28)	9 (3)

Faculty Discussion



Dr Apuri

Questions for the Faculty

A woman in her late 60s with localized TNBC treated initially with surgery, adjuvant chemotherapy and radiation therapy 4 years ago and during surveillance developed upper respiratory symptoms related to lymphadenopathy in the neck. She also had positive intramammary lymph nodes, and biopsies of both demonstrated recurrence. PD-L1 is 0.

Started on sacituzumab govitecan, which resulted in rapid symptom relief and eventually a CR on imaging. She tolerated this well but had neutropenia, which concerned me because she is a school nurse and exposed to multiple young kids on a day-to-day basis, despite the fact that she wears a mask.

Unfortunately, her insurance would not cover long-acting growth factors initially, so I had to write a letter of appeal, and they did agree to it finally, but she was getting short-acting initially.



Dr Apuri

Questions for the Faculty (Continued)

Questions

- Are there any predictors of benefit for TROP2 ADCs? (TROP2 levels?)
- Would a ctDNA test help in deciding when I can hold the treatment?
- Do you use preemptive growth factors for all or select patients receiving sacituzumab? Which preparation and exactly how?
- Do you use preemptive antidiarrheal medication for patients on sacituzumab?

We are taking a short break!

The program will resume at 10:00 AM ET

Up Next ...

**Drs Neeraj Agarwal and Emmanuel S Antonarakis
discuss the management of prostate cancer**