Current and Future Integration of Antibody-Drug Conjugates into the Management of Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, September 30, 2025
5:00 PM – 6:00 PM ET

Faculty

Aditya Bardia, MD, MPH
Adam M Brufsky, MD, PhD

Moderator

Neil Love, MD

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Faculty

Aditya Bardia, MD, MPH
Program Director, Breast Medical Oncology
Assistant Chief (Translational Research)
Division of Hematology-Oncology
Director of Translational Research Integration
UCLA Health Jonsson Comprehensive Cancer Center
Professor of Medicine, Geffen School of Medicine
University of California Los Angeles
Los Angeles, California

Adam M Brufsky, MD, PhD
Professor of Medicine
UPMC Hillman Cancer Center
Department of Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Commercial Support

This activity is supported by an educational grant from Gilead Sciences Inc.

Dr Love — Disclosures

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Contracted Research	AstraZeneca Pharmaceuticals LP, Daiichi Sankyo Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Lilly, Menarini Group, Merck, Novartis, OnKure Therapeutics, Pfizer Inc

Dr Brufsky — Disclosures

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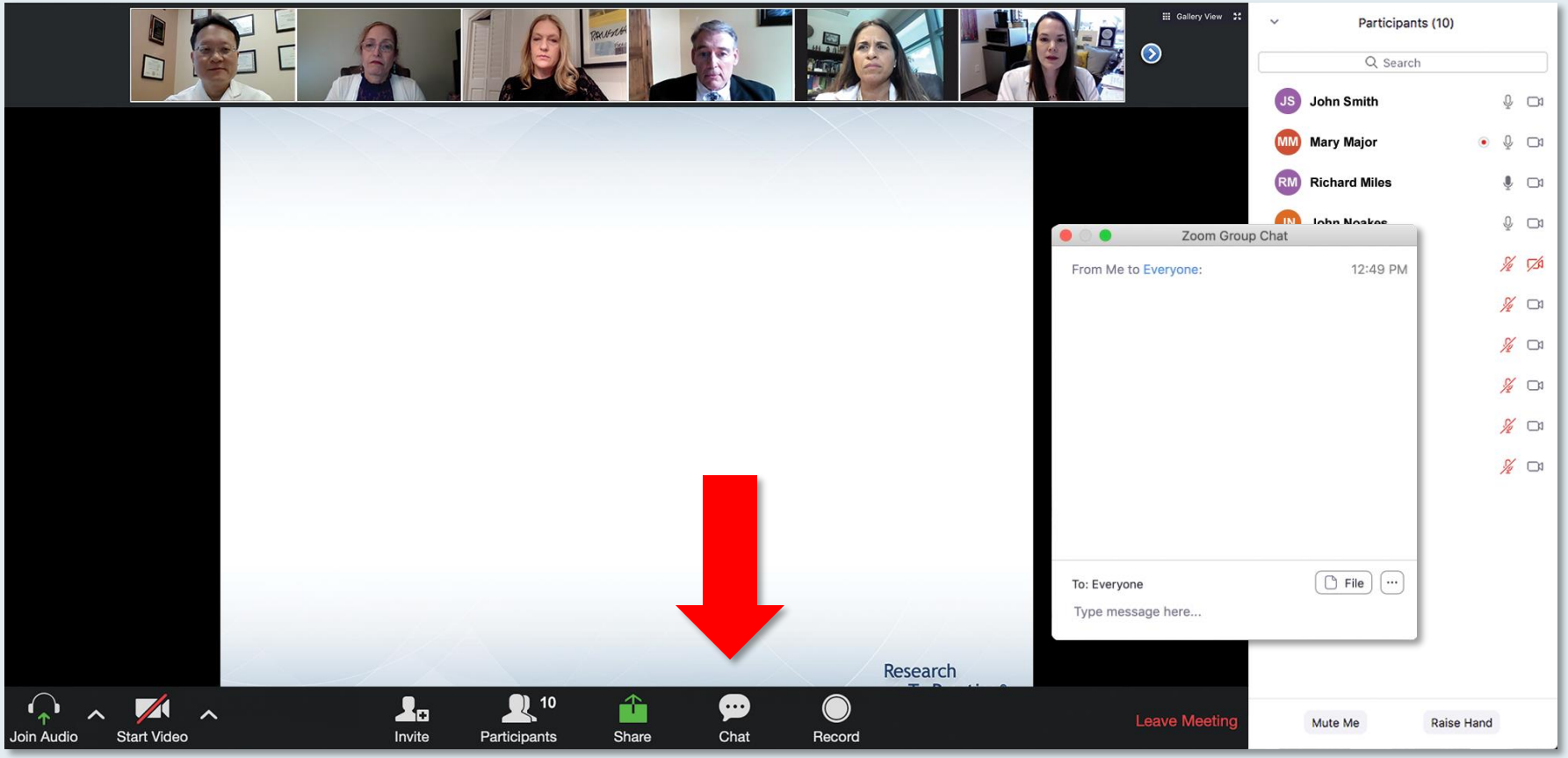

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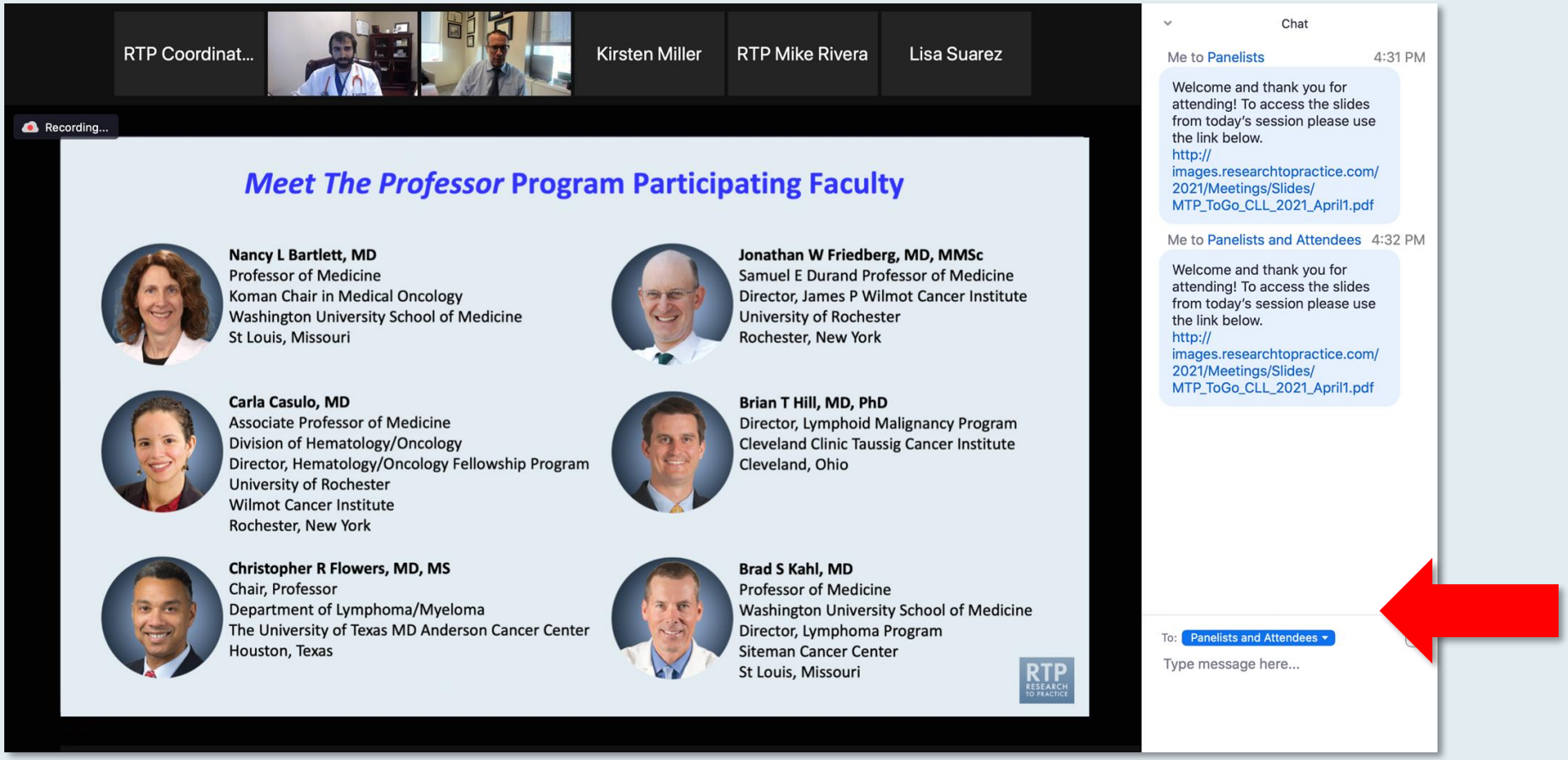

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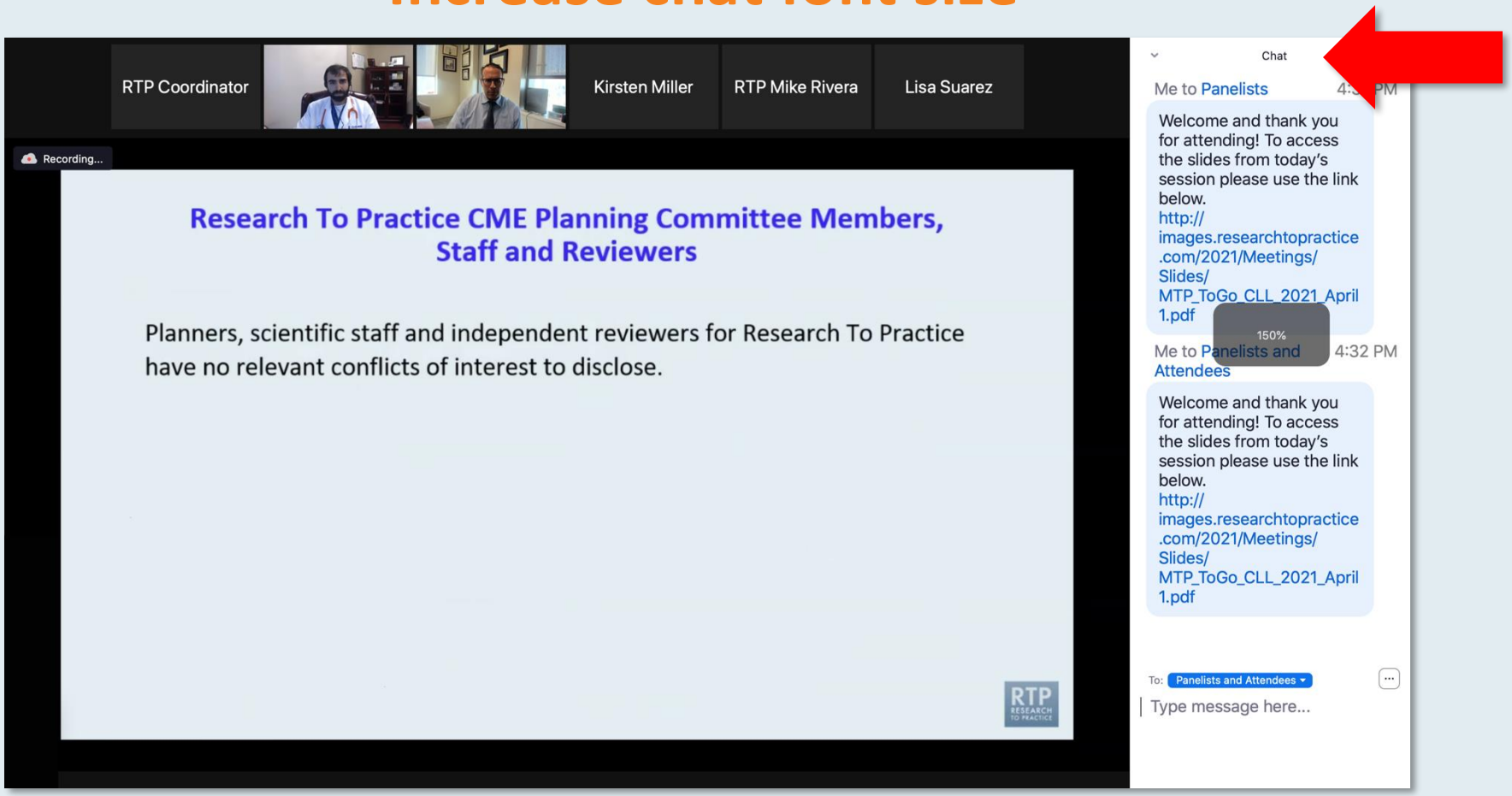

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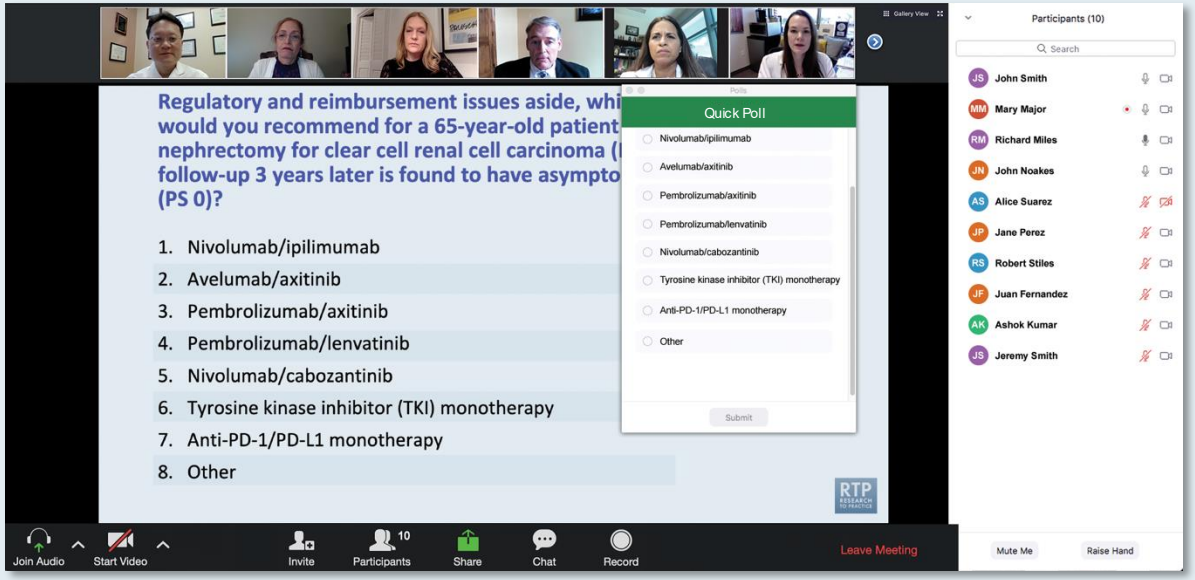

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WITH DR NEIL LOVE

Optimizing the Management of Metastatic BRCA-Negative, Triple-Negative Breast Cancer

PROF PETER SCHMID
BARTS CANCER INSTITUTE

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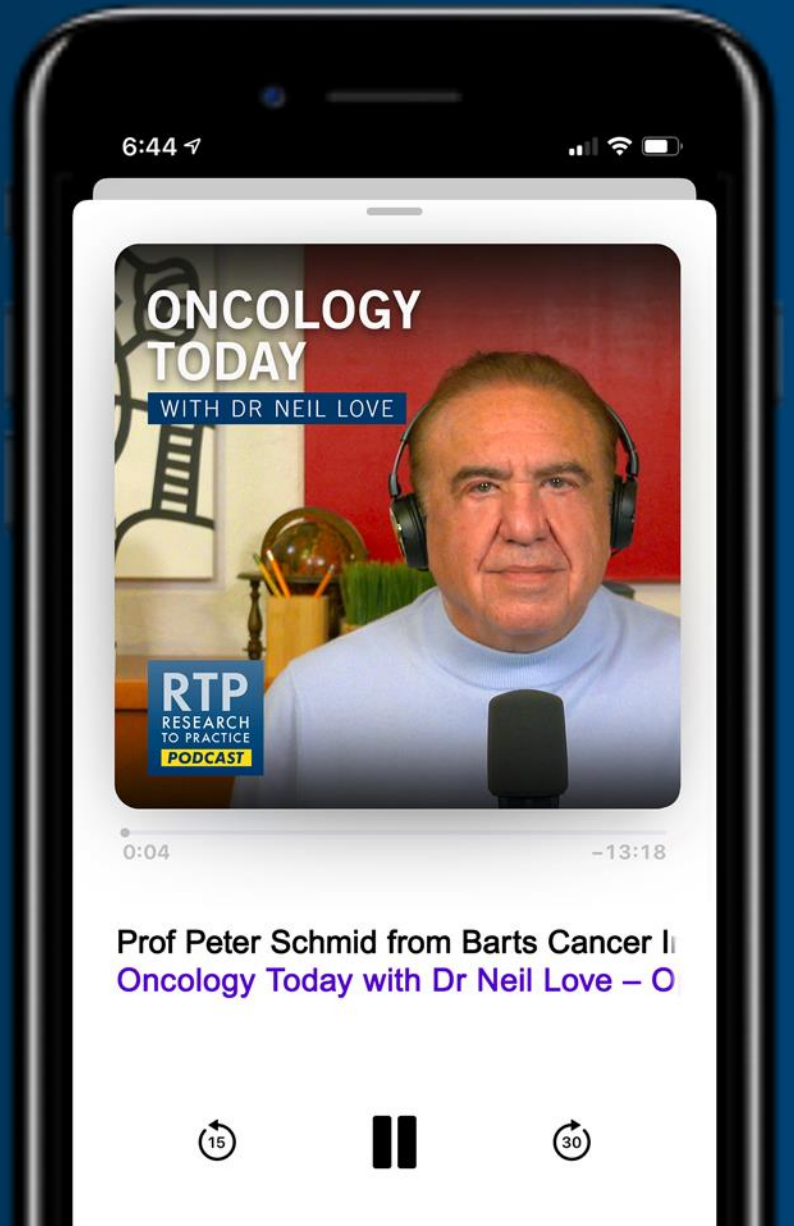

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The Ritz-Carlton Orlando, Grande Lakes | Orlando, Florida

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Harold J Burstein, MD, PhD
Matthew P Goetz, MD
Christopher Lieu, MD
Matthew Lunning, DO
Heather McArthur, MD, MPH, FASCO
Rita Nanda, MD
Matthew R Smith, MD, PhD
Sonali M Smith, MD
John Strickler, MD

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Lung Cancer

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Chronic Lymphocytic Leukemia

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Exciting CME Events You Do Not Want to Miss

A Friday Satellite Symposium Series Preceding the 67th ASH Annual Meeting

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Myelofibrosis
3:15 PM – 5:15 PM ET

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Jeff Sharman, MD
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Department of Medicine
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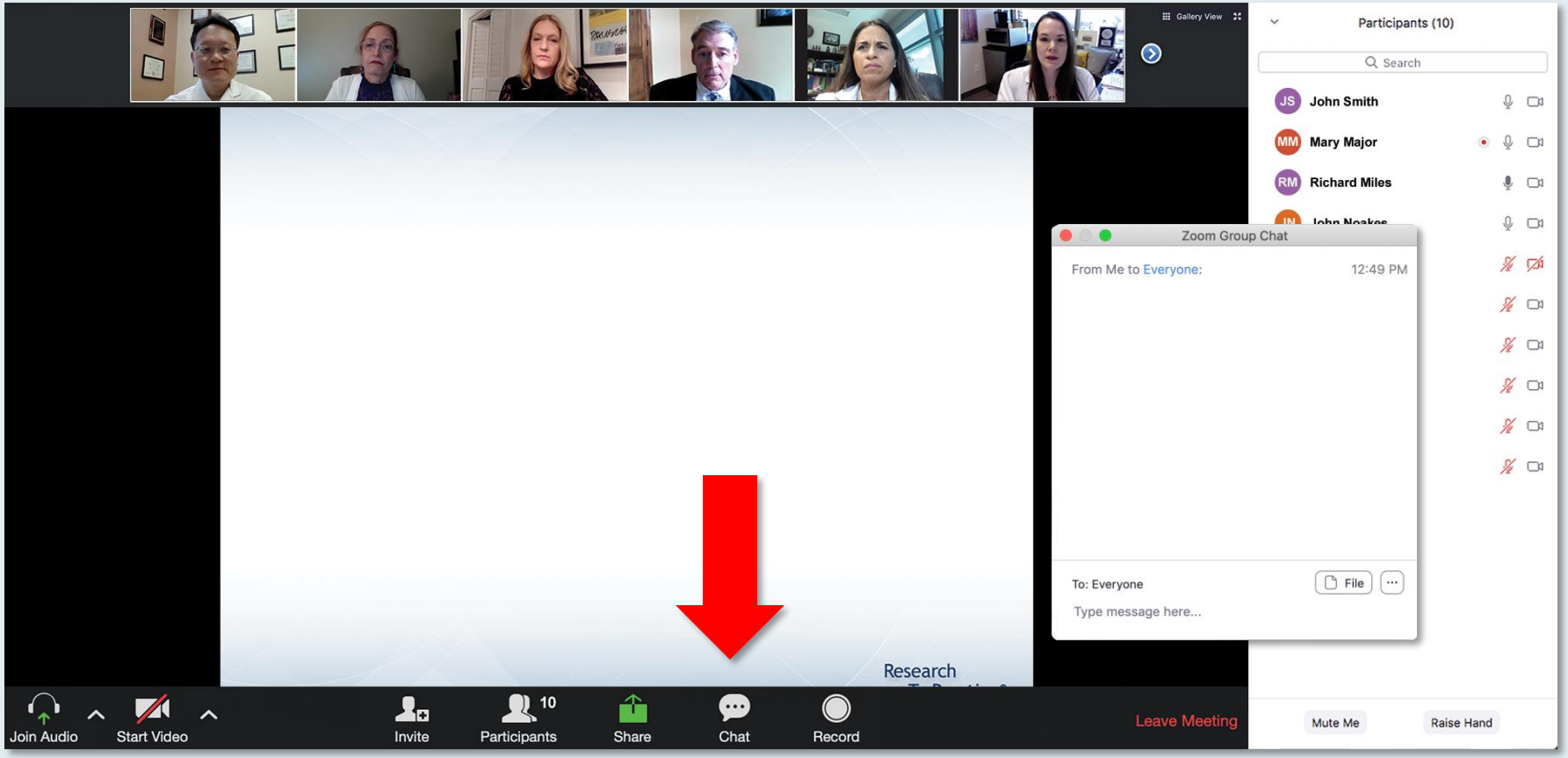

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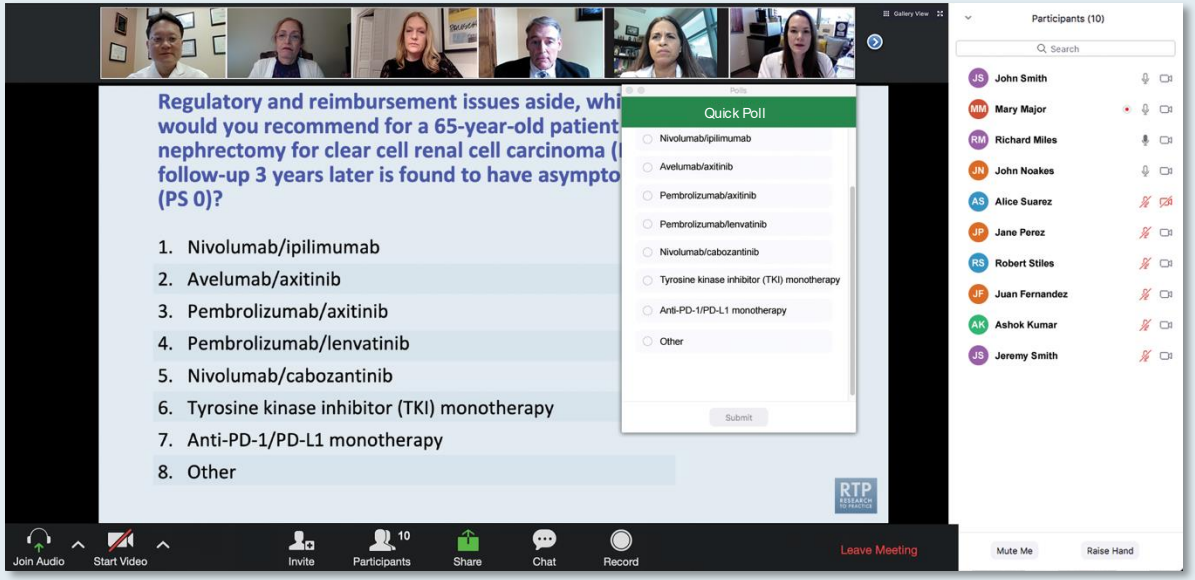

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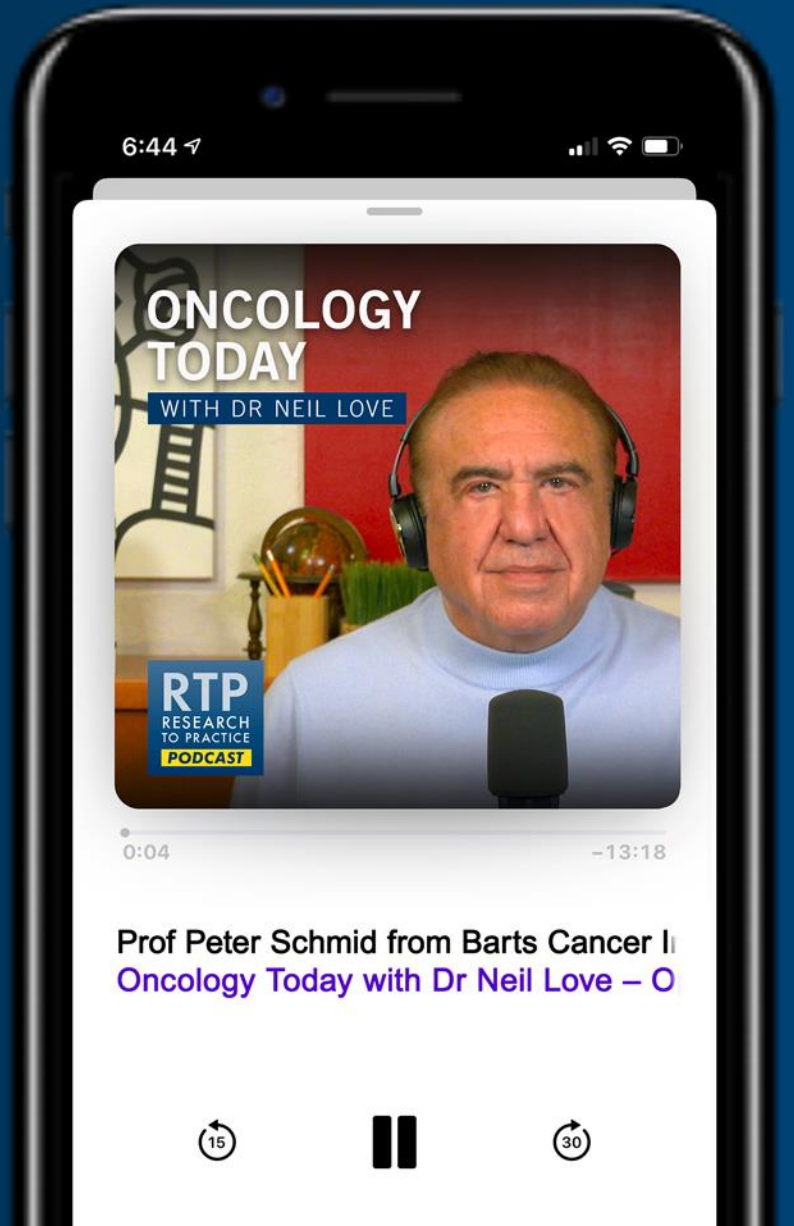

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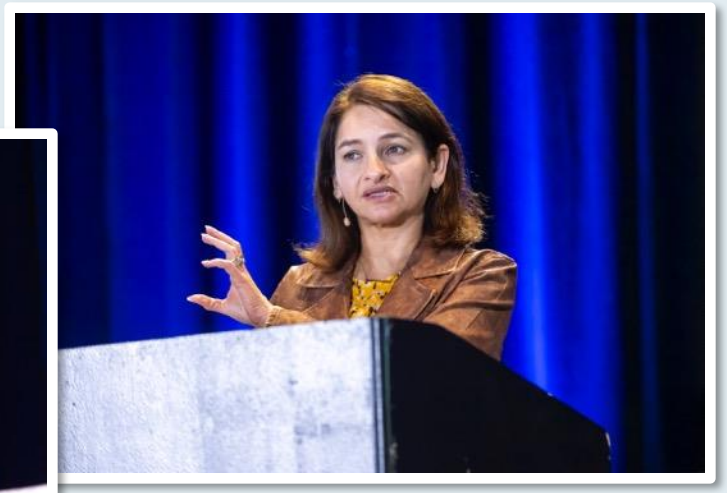
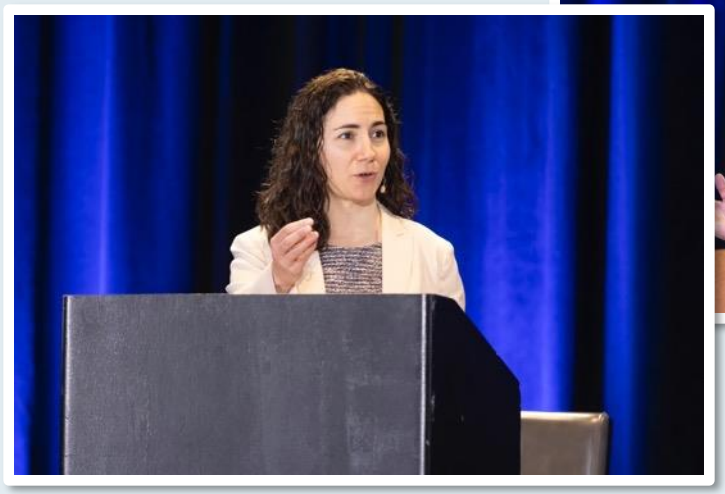
Florida Cancer Specialists/Research To Practice
CME Annual Retreat Program
2005 to 2025





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Data + Perspectives: Clinical Investigators Explore the Application of Recent Datasets in Current Oncology Care

Agenda

7:15 AM – 9:15 AM — Breast Cancer

- Localized Hormone Receptor (HR)-Positive Breast Cancer; Initial Therapy for Metastatic Disease
- Therapeutic Options for Relapsed/Refractory HR-Positive Metastatic Breast Cancer
- Management of HER2-Positive Breast Cancer
- Treatment Approaches for Triple-Negative Breast Cancer

9:15 AM – 9:30 AM — Break

9:30 AM – 10:30 AM — Prostate Cancer

- Optimizing the Role of Hormonal Therapy in the Care of Patients with Prostate Cancer
- Other Available and Emerging Therapeutic Approaches

10:30 AM – 11:30 AM — Colorectal Cancer (CRC)

- Current and Future Role of Immune Checkpoint Inhibitors in the Management of CRC
- Other Biomarker-Based Strategies for Patients with CRC

11:30 AM – 12:30 PM — Diffuse Large B-Cell Lymphoma (DLBCL) and Follicular Lymphoma (FL)

- Available and Emerging Novel Therapies for DLBCL and FL
- Role of Chimeric Antigen Receptor T-Cell Therapy and Bispecific Antibodies in Treatment for DLBCL and FL

12:30 PM — Meeting Adjourns

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RTP RESEARCH TO PRACTICE

Integrating New Advances into the Care of Patients with Cancer

Agenda

10:00 AM – 10:50 AM — Module 1: Targeted Therapy for Non-Small Cell Lung Cancer (NSCLC)

10:50 AM – 11:40 AM — Module 2: Nontargeted Therapy for NSCLC; Small Cell Lung Cancer

11:40 AM – 12:30 PM — Lunch

12:30 PM – 1:20 PM — Module 3: Chronic Lymphocytic Leukemia

1:20 PM – 2:10 PM — Module 4: Ovarian Cancer

2:10 PM – 3:00 PM — Module 5: Gastroesophageal Cancers

3:00 PM — Meeting Adjourns

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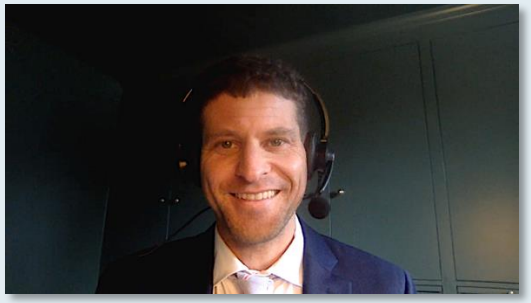
Contributing General Medical Oncologists

Laila Agrawal, MD
Norton Cancer Institute
Louisville, Kentucky

Alan B Astrow, MD
Weill Cornell Medicine
Brooklyn, New York



Eric Fox, DO
Bryn Mawr Medical Specialists Association
Bryn Mawr, Pennsylvania

Kimberly Ku, MD
Illinois Cancer Care
Bloomington, Illinois

Eleonora Teplinsky, MD
Valley-Mount Sinai
Comprehensive Cancer Care
Paramus, New Jersey

Lai (Amber) Xu, MD, PhD
Northwest Oncology
and Hematology
Rolling Meadows, Illinois

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Agenda

Introduction: Antibody-drug conjugates (ADCs) in localized breast cancer

Case 1: Dr Fox – 78-year-old frail woman

- Key Datasets: Targeting TROP2 in recurrent metastatic disease

Case 2: Dr Xu – 61-year-old woman

- Key Datasets: Management of HER2-low and HER2-ultralow breast cancer

Case 3: Dr Astrow – 74-year-old woman

- Key Datasets: TROP2-targeted ADCs as first-line treatment

Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

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Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

RTP RESEARCH TO PRACTICE

2025 ASCO ANNUAL MEETING

DESTINY Breast09

Trastuzumab deruxtecan (T-DXd) + pertuzumab vs taxane + trastuzumab + pertuzumab (THP) for first-line treatment of patients with human epidermal growth factor receptor 2–positive (HER2+) advanced/metastatic breast cancer: interim results from DESTINY-Breast09

Sara M Tolaney, MD, MPH
Dana-Farber Cancer Institute, Boston, MA, US

Monday, June 2, 2025

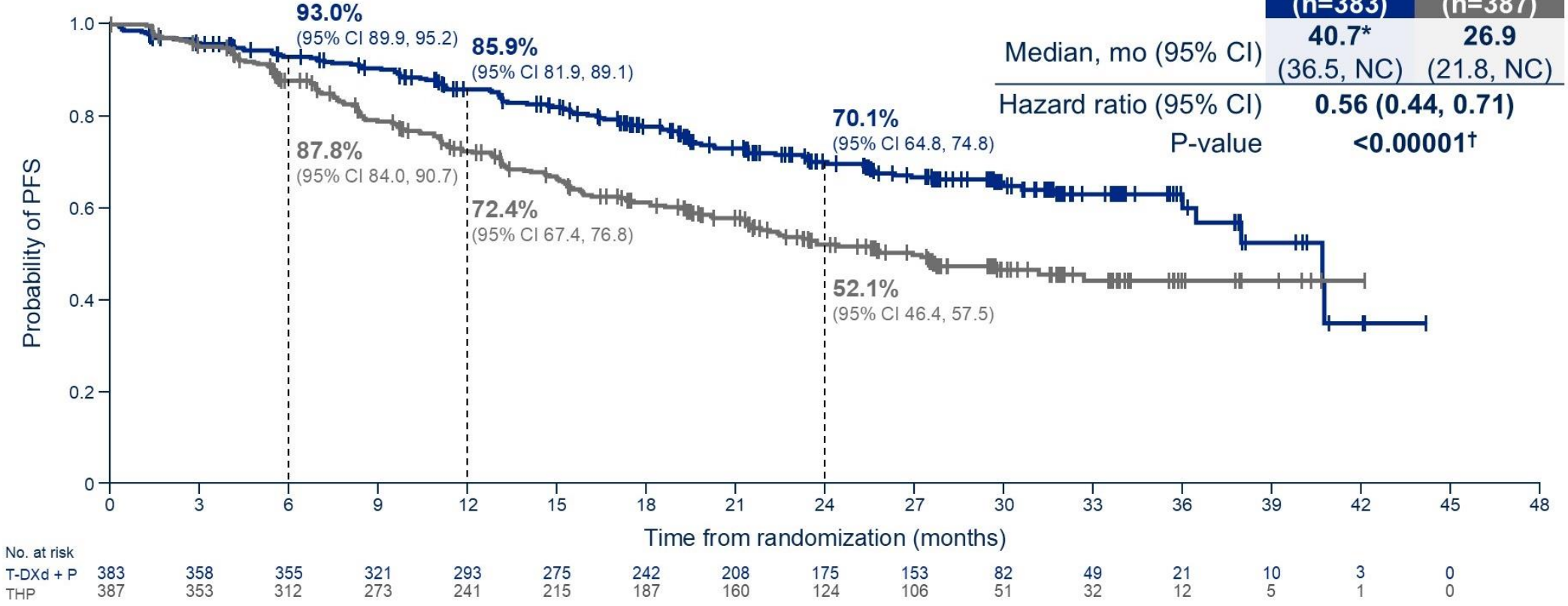
Additional authors: Zefei Jiang, Qingyuan Zhang, Romualdo Barroso-Sousa, Yeon Hee Park, Mothaffar F Rimawi, Cristina Saura, Andreas Schneeweiss, Masakazu Toi, Yee Soo Chae, Yasemin Kemal, Mukesh Chaudhari, Toshinari Yamashita, Monica Casalnuovo, Michael A Danso, Jie Liu, Jagdish Shetty, Pia Herbolsheimer, Sibylle Loibl

On behalf of the DESTINY-Breast09 investigators

Abstract LBA1008

RTP RESEARCH TO PRACTICE

Phase III DESTINY-Breast09 (Interim): PFS (BICR)

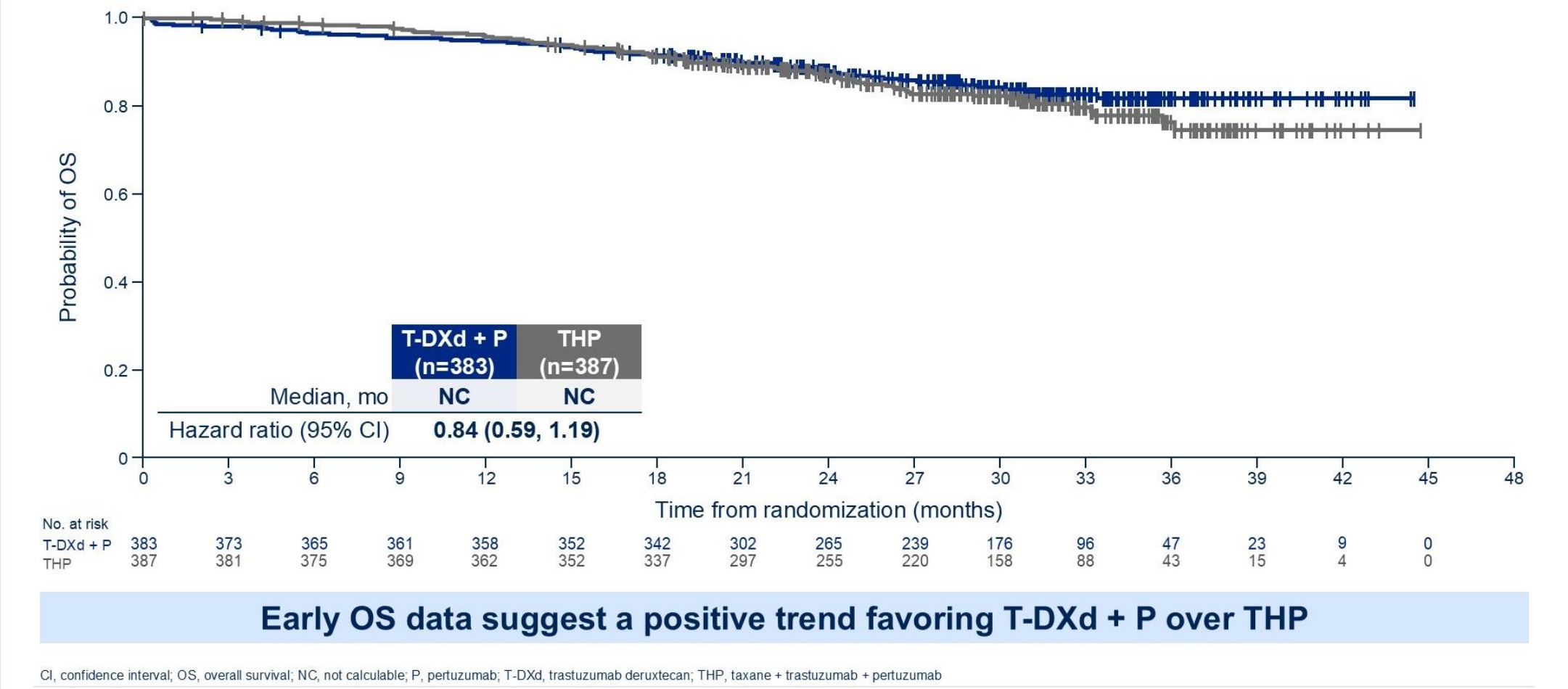


Statistically significant and clinically meaningful PFS benefit with T-DXd + P (median Δ 13.8 mo)

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

Tolaney SM et al. ASCO 2025;Abstract LBA1008.

Phase III DESTINY-Breast09 (Interim): OS (~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

Tolaney SM et al. ASCO 2025;Abstract LBA1008.

Trastuzumab Deruxtecan (T-DXd) Followed by THP Before Surgery Showed Statistically Significant and Clinically Meaningful Improvement in Pathologic Complete Response for Patients with High-Risk HER2-Positive Localized Breast Cancer in the DESTINY-Breast11 Phase III Trial

Press Release: May 7, 2025

"Positive high-level results from the DESTINY-Breast11 Phase III trial showed T-DXd followed by paclitaxel, trastuzumab and pertuzumab (THP) demonstrated a statistically significant and clinically meaningful improvement in pathologic complete response (pCR) rate versus standard of care (dose-dense doxorubicin and cyclophosphamide followed by THP [ddAC-THP]) when used in the neoadjuvant setting (before surgery) in patients with high-risk, locally advanced HER2-positive early-stage breast cancer. Pathologic complete response is defined as no evidence of invasive cancer cells in the removed breast tissue and lymph nodes following treatment.

The secondary endpoint of event-free survival (EFS) was not mature at the time of analysis; however, EFS data showed an early positive trend favouring T-DXd followed by THP compared to standard of care. The trial will continue to follow EFS."

https://www.astrazeneca.com/media-centre/press-releases/2025/enhertu-improved-pcr-in-early-stage-breast-cancer.html

RTP RESEARCH TO PRACTICE

T-DXd Demonstrated Highly Statistically Significant and Clinically Meaningful Improvement in Invasive Disease-Free Survival in Comparison to T-DM1 in the DESTINY-Breast05 Phase III Trial for Patients with High-Risk Localized Breast Cancer After Neoadjuvant Therapy

Press Release: September 29, 2025

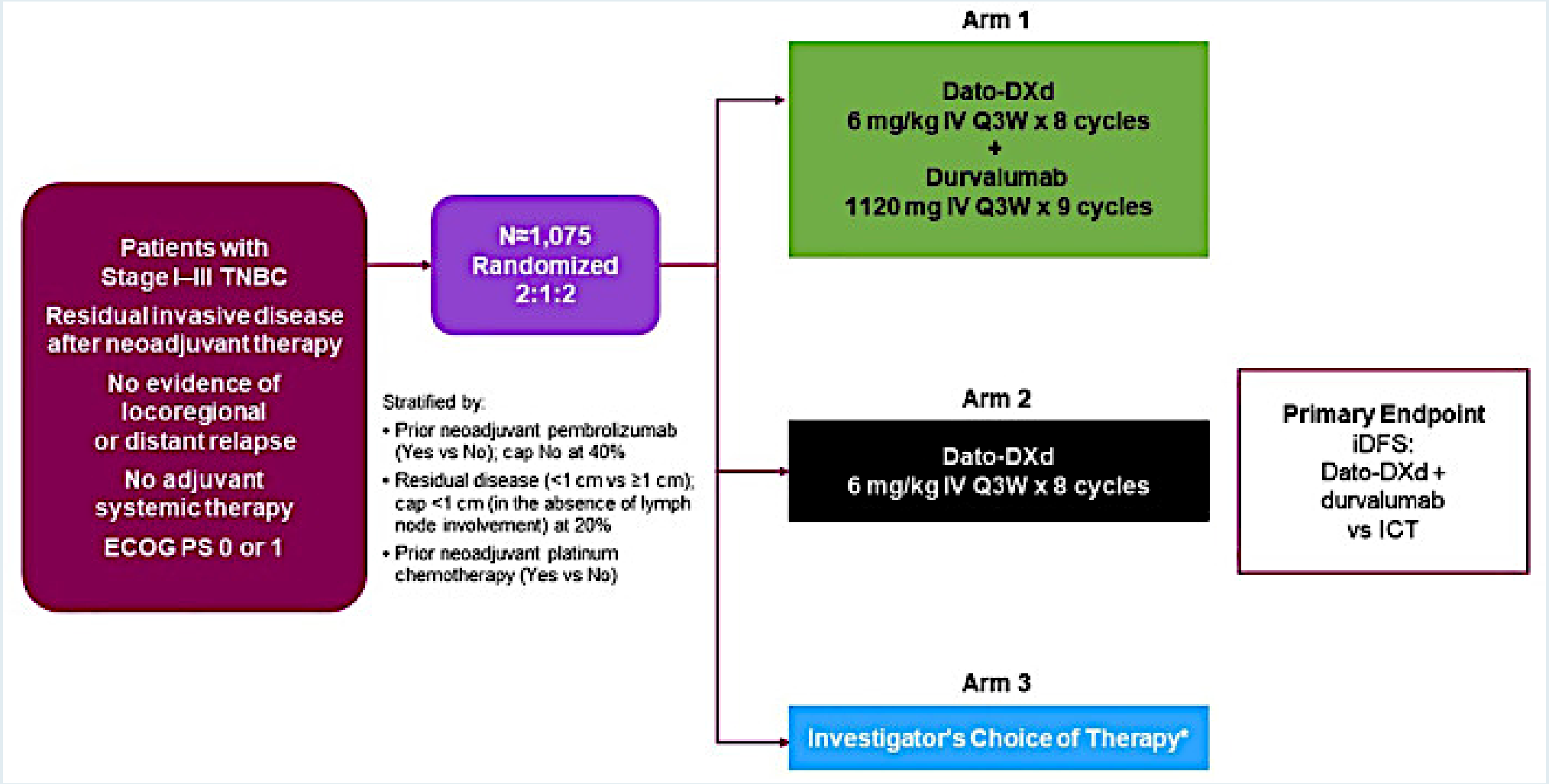
"Positive high-level results from a planned interim analysis of the DESTINY-Breast05 Phase III trial showed trastuzumab deruxtecan demonstrated a highly statistically significant and clinically meaningful improvement in invasive disease-free survival (IDFS) versus trastuzumab emtansine (T-DM1) in patients with HER2-positive early breast cancer with residual invasive disease in the breast or axillary lymph nodes after neoadjuvant treatment and a high risk of disease recurrence. This is the second positive Phase III trial of T-DXd in the HER2-positive early breast cancer setting following positive results from the Destiny-Breast11 Phase III neoadjuvant trial earlier this year.

Overall survival (OS) was not mature at the time of this planned interim analysis and will be assessed at a subsequent analysis.

Data from DESTINY-Breast05 (Abstract #LBA1) and DESTINY-Breast11 (Abstract #291O) will be presented during Presidential Symposium 1 on 18 October at the upcoming European Society for Medical Oncology (ESMO) Congress 2025. The DESTINY-Breast05 data will also be shared with global regulatory authorities."

https://www.astrazeneca.com/media-centre/press-releases/2025/enhertu-improved-idfs-in-early-bc-in-db-05.html

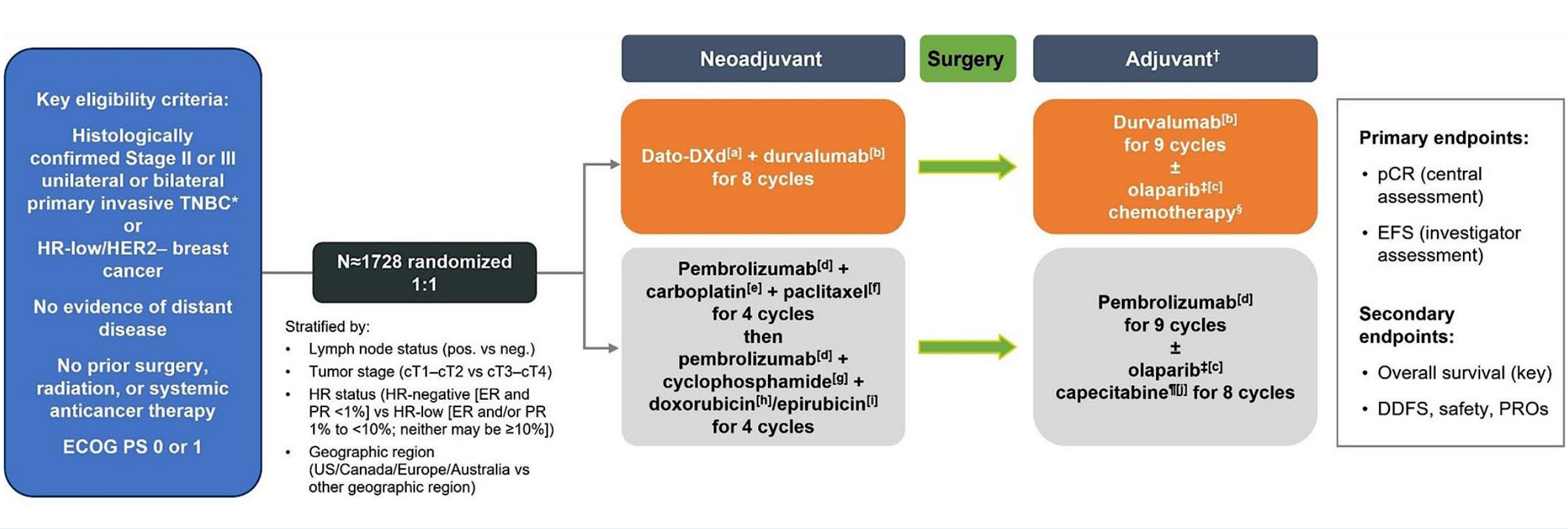
Adjuvant Datopotamab Deruxtecan (Dato-DXd): TROPION-Breast03 Trial



iDFS = invasive disease-free survival; ICT = investigator's choice of therapy

Bardia A et al. *Ther Adv Med Oncol* 2024 April 29:16:17588359241248336.

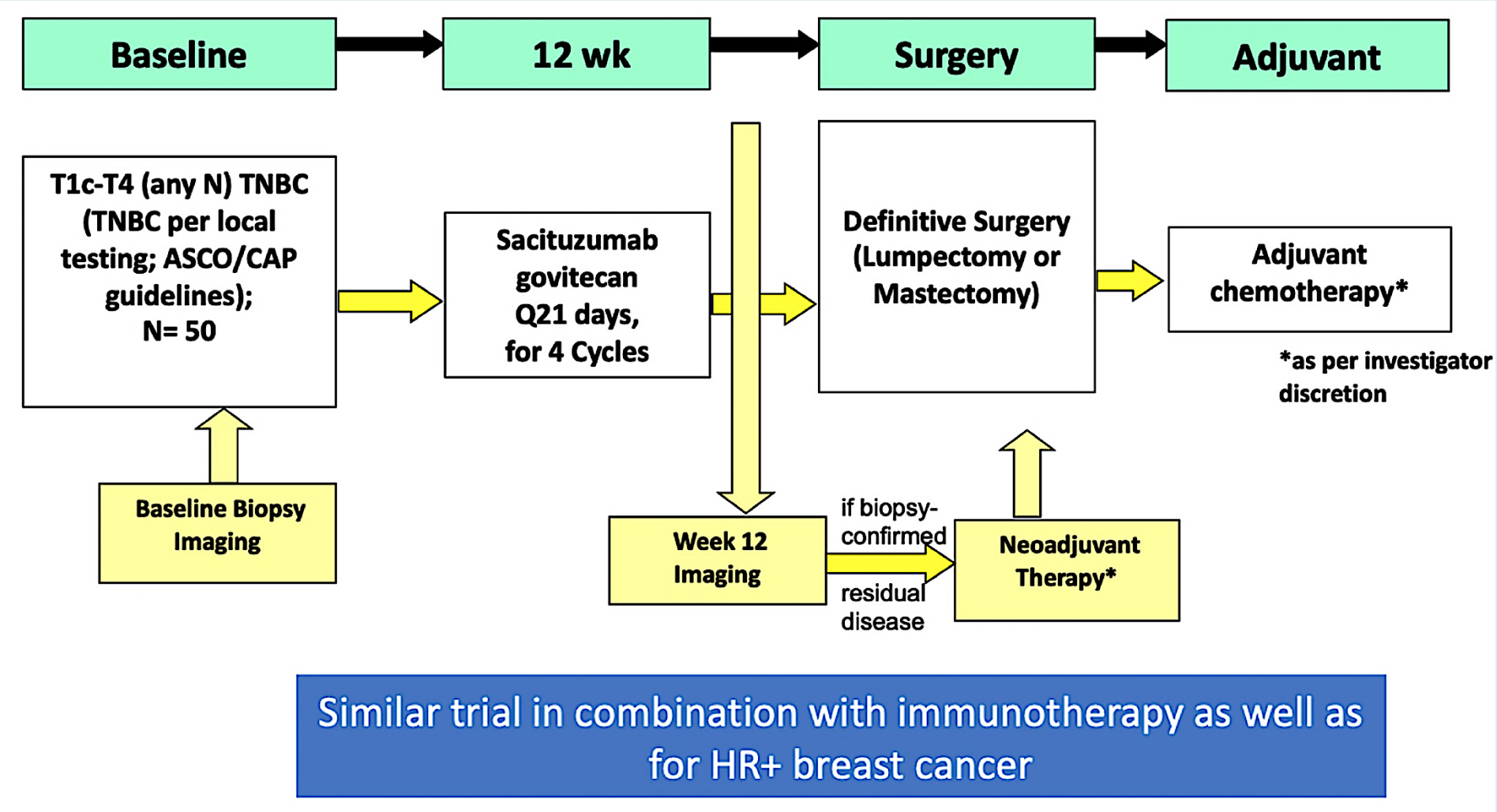
Neodjuvant Dato-DXd: TROPION-Breast04 Trial



pCR = pathological complete response; EFS = event-free survival; DDFS = distant disease-free survival; PROs = patient-reported outcomes

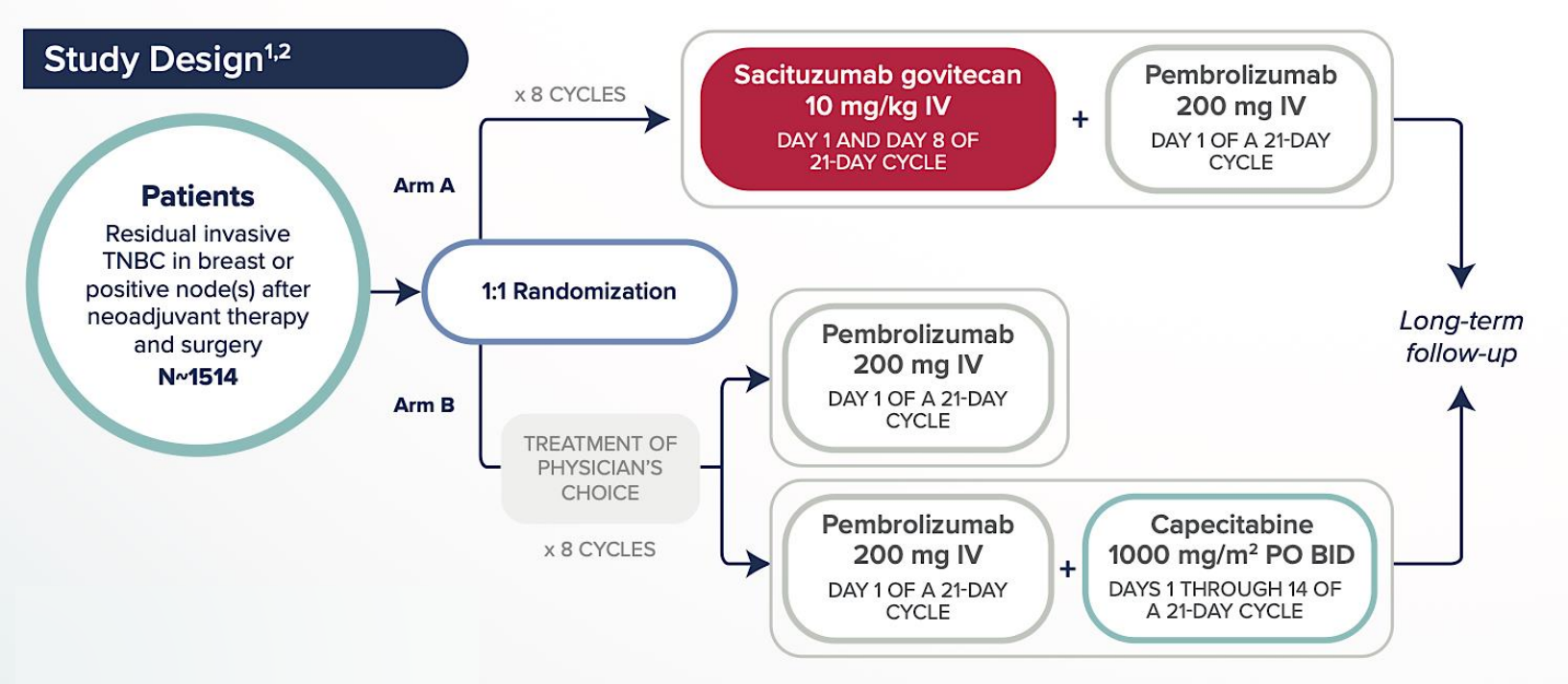
McArthur HL et al. *Ther Adv Med Oncol* 2025 February 5;17:17588359251316176.

Neoadjuvant Sacituzumab Govitecan: NeoSTAR Trial



Abelman RO et al. *Hematol Oncol Clin North Am* 2023 February;37(1):151-67.

Adjuvant Sacituzumab Govitecan: ASCENT-05/OptimICE-RD Trial



ascent-05

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- Age ≥18 years of age
- ECOG performance status of 0 or 1
- Adequate renal and hepatic function
- Adequate excision and surgical removal of all clinically evident disease in the breast and/or lymph nodes
- Submission of both pre-neoadjuvant treatment diagnostic biopsy and resected residual invasive disease tissue
- Patients must have received appropriate radiotherapy and have recovered prior to starting study treatment

Key Exclusion Criteria

- Positive serum pregnancy test or women who are breastfeeding
- Stage IV breast cancer as well as history of any prior ipsilateral or contralateral invasive breast cancer
- Prior treatment with another stimulatory or coinhibitory T-cell receptor agent, prior treatment with any HER2 directed agent
- Evidence of recurrent disease following preoperative therapy and surgery
- Prior treatment with topoisomerase 1 inhibitors or ADCs containing a topoisomerase inhibitor
- Myocardial infarction within 6 months of enrollment or history of serious ventricular arrhythmia or LVEF <50%
- Active serious infection requiring anti-microbial treatment

Endpoints[1,2]

Primary Endpoint

- iDFS

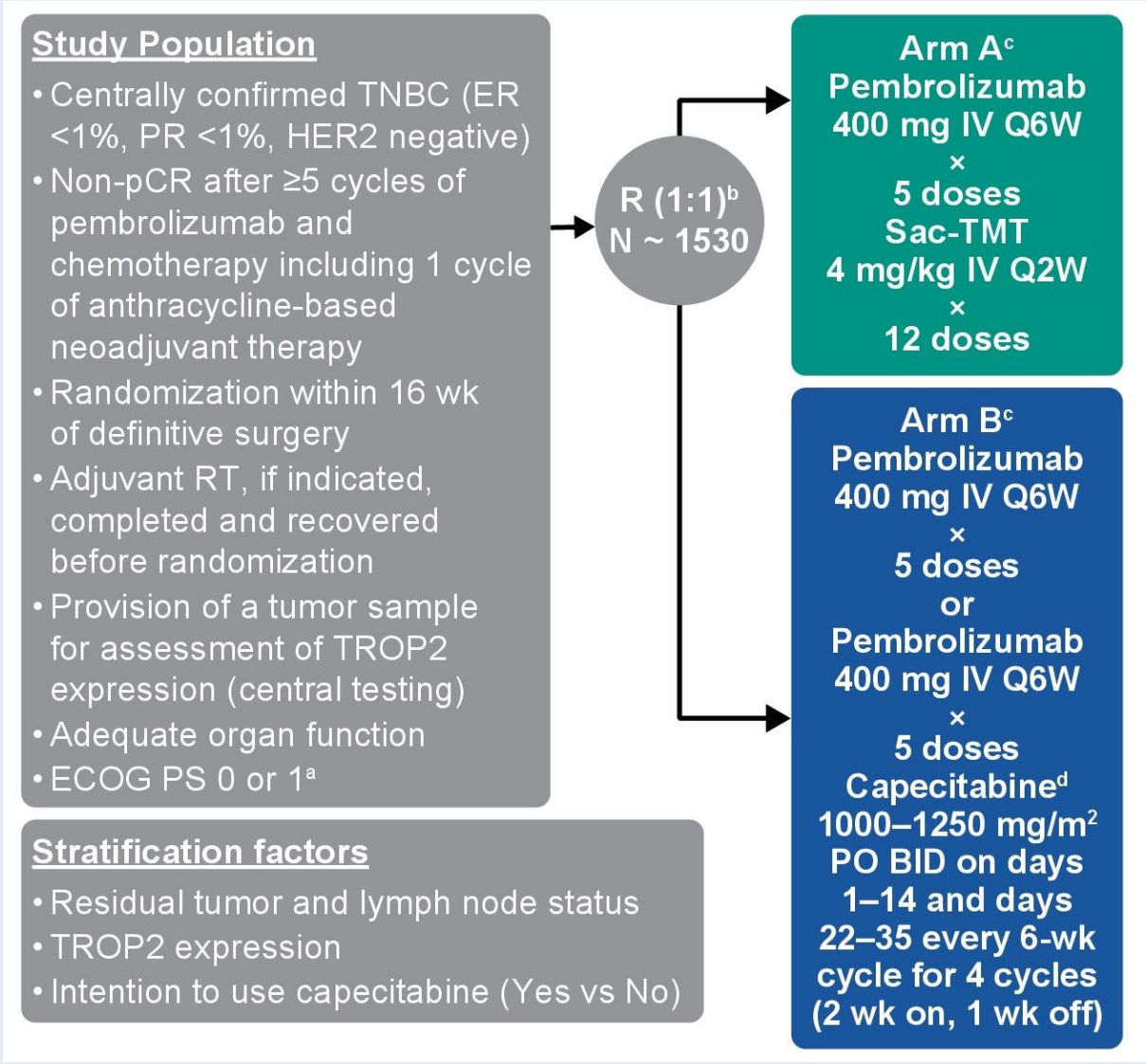
Secondary Endpoints

- OS
- dDFS
- Safety
- QoL
- RFS

iDFS = invasive disease-free survival; OS = overall survival; dDFS = distant disease-free survival; QoL = quality of life; RFS = recurrence-free survival

RTP RESEARCH TO PRACTICE

Adjuvant Sacituzumab Tirumotecan (Sac-TMT) + Pembrolizumab: TroFuse-012 Trial



McArther H et al. ASCO 2025;Abstract TPS616.

Agenda

Introduction: Antibody-drug conjugates (ADCs) in localized breast cancer

Case 1: Dr Fox – 78-year-old frail woman

- Key Datasets: Targeting TROP2 in recurrent metastatic disease

Case 2: Dr Xu – 61-year-old woman

- Key Datasets: Management of HER2-low and HER2-ultralow breast cancer

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- Key Datasets: TROP2-targeted ADCs as first-line treatment

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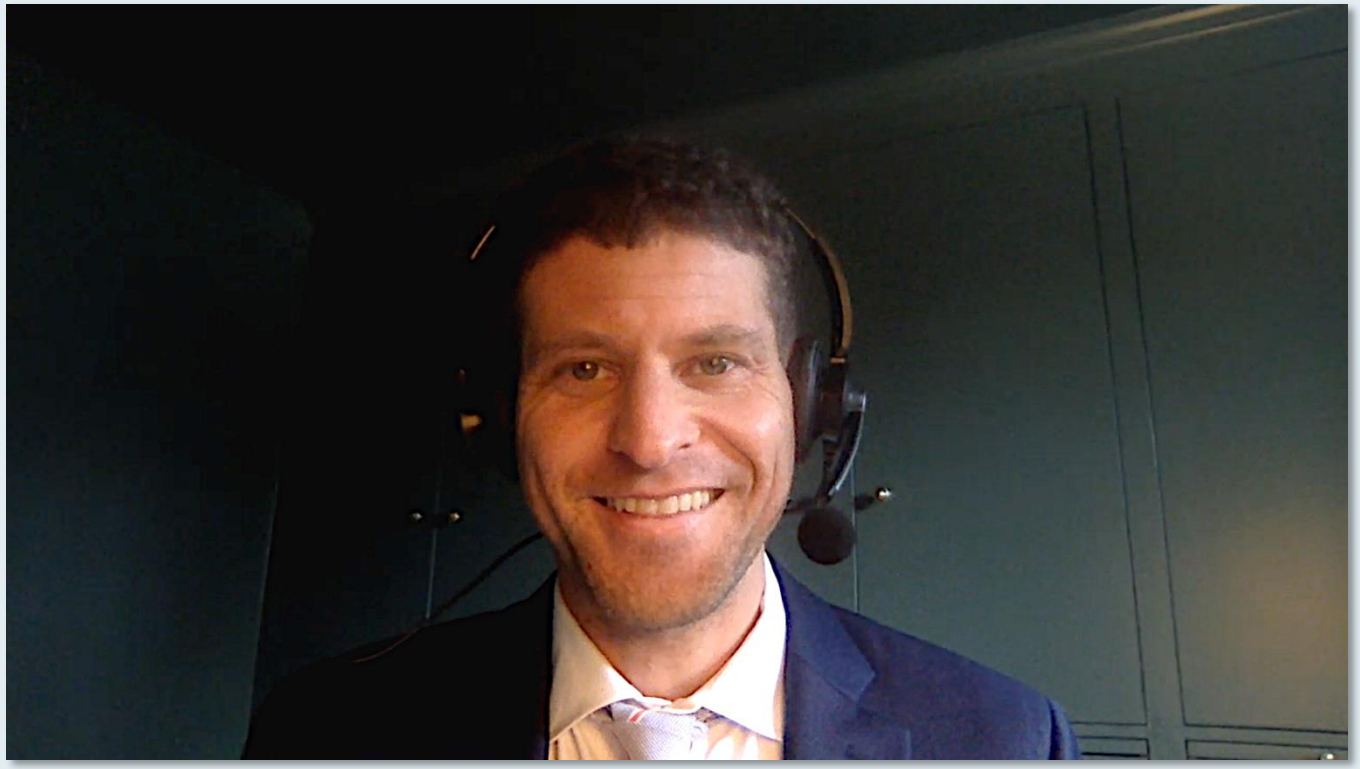
Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

RTP RESEARCH TO PRACTICE

Case Presentation: 78-year-old frail woman with cough and ER-positive, HER2-low (IHC 1+) mBC s/p multiple lines of therapy receives sacituzumab govitecan

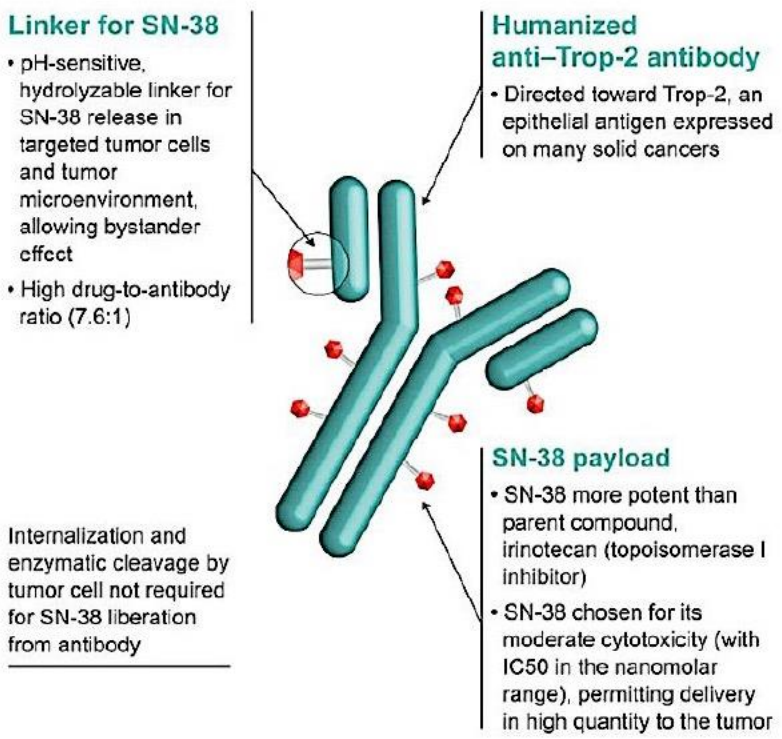


Dr Eric Fox (Bryn Mawr, Pennsylvania)

RTP RESEARCH TO PRACTICE

Targeting TROP2 in Metastatic Breast Cancer

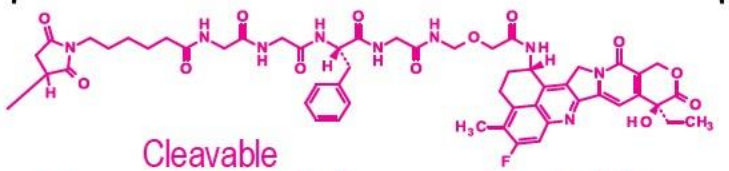
Sacituzumab govitecan



Datopotamab deruxtecan

- Payload mechanism of action: Topo-I inhibitor*
- High potency payload*
- Optimised drug to antibody ratio ≈4*†
- Payload with short systemic half-life*†
- Stable linker-payload*
- Tumour-selective cleavable linker*
- Bystander antitumour effect*

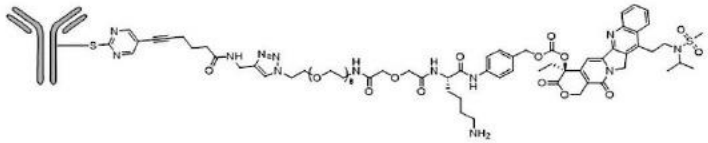
Deruxtecan



Cleavable tetrapeptide-based linker

Topo-I inhibitor payload (DXd)

Sacituzumab tirumotecan (SKB264/MK-2870)



- anti-TROP2 ADC
- Sulfonyl pyrimidine-CL2A-carbonate linker
- **Payload**: belotecan-derivative topoisomerase I inhibitor
- **DAR**: 7.4

Courtesy of Rebecca A Dent, MD, MSc

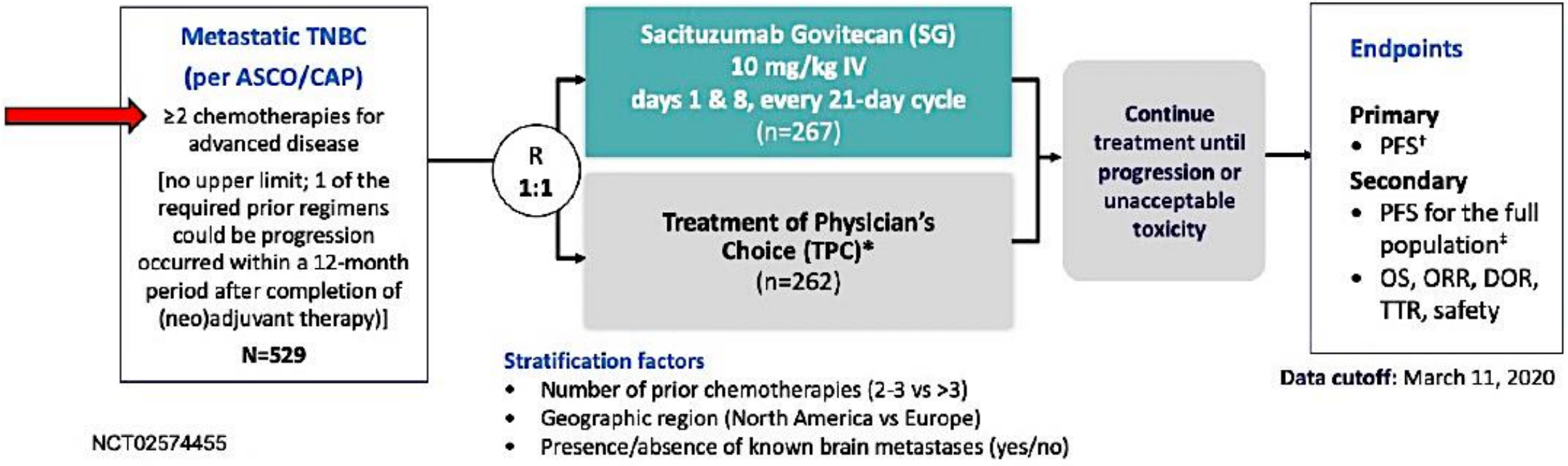
OPEN ACCESS | CLINICAL TRIAL UPDATES | | February 29, 2024

Final Results From the Randomized Phase III ASCENT Clinical Trial in Metastatic Triple-Negative Breast Cancer and Association of Outcomes by Human Epidermal Growth Factor Receptor 2 and Trophoblast Cell Surface Antigen 2 Expression

Authors: Aditya Bardia, MD, MPH, Hope S. Rugo, MD, Sara M. Tolaney, MD, MPH, Delphine Loirat, PhD, MD, Kevin Punie, MD, Mafalda Oliveira, MD, PhD, Adam Brufsky, MD, PhD, ... SHOW ALL ... , and Sara A. Hurvitz, MD, FACP | AUTHORS INFO & AFFILIATIONS

J Clin Oncol;42(15):1738-44.

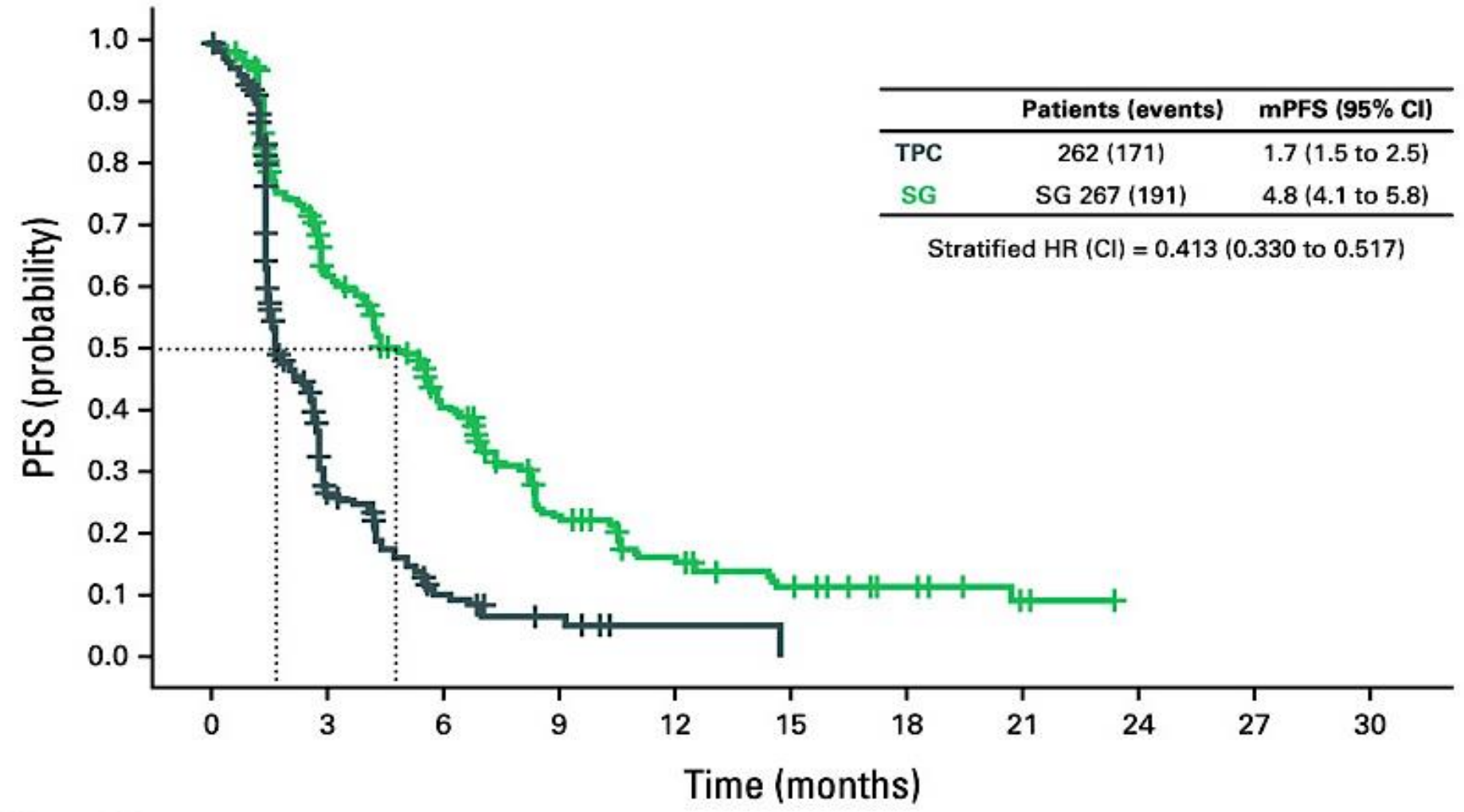
Phase III ASCENT Study Design



TTR = time to response

Bardia A et al. *J Clin Oncol* 2024;42(15):1738-44.

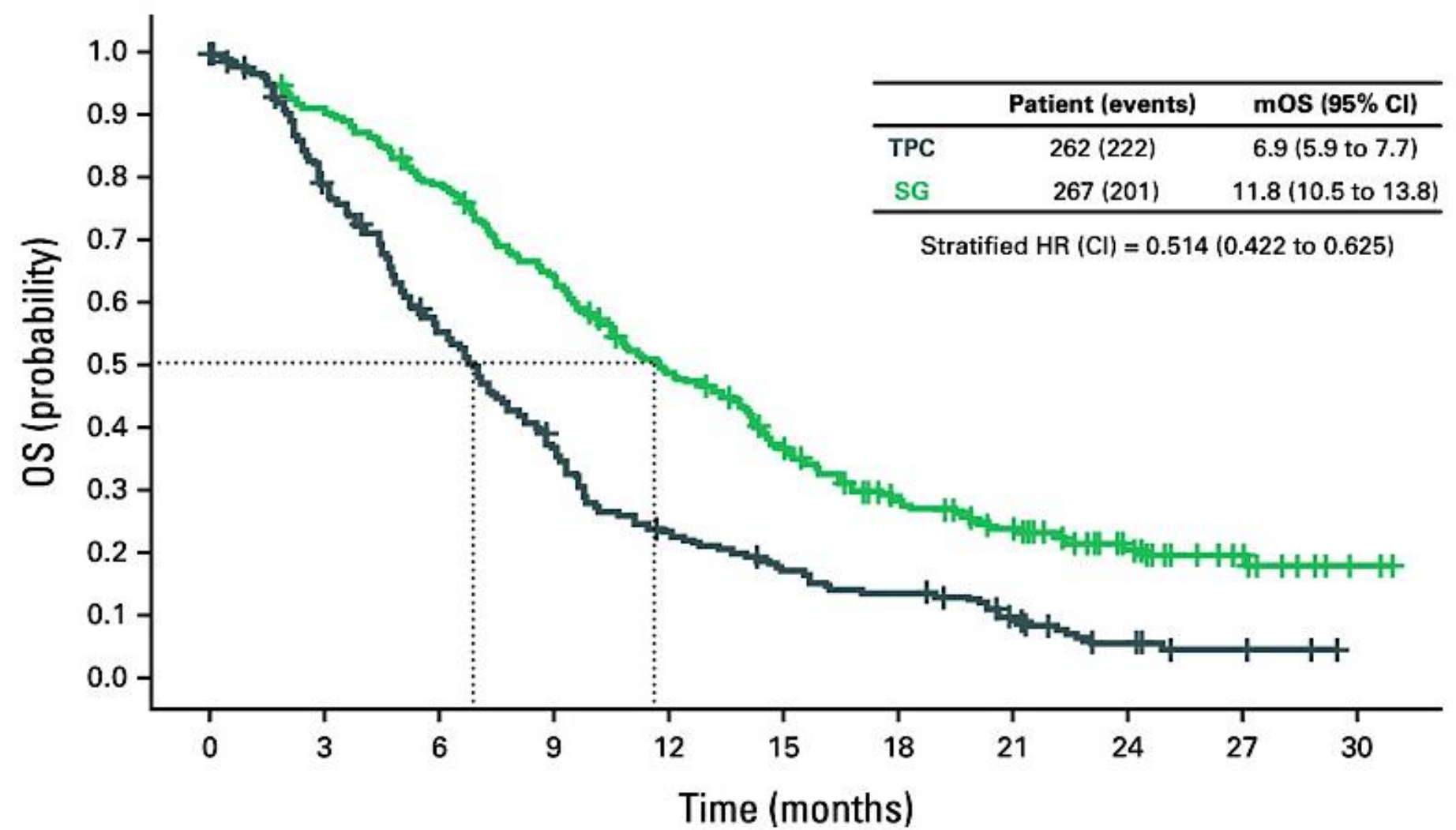
Phase III ASCENT: Progression-Free Survival (PFS)



mPFS = median progression-free survival

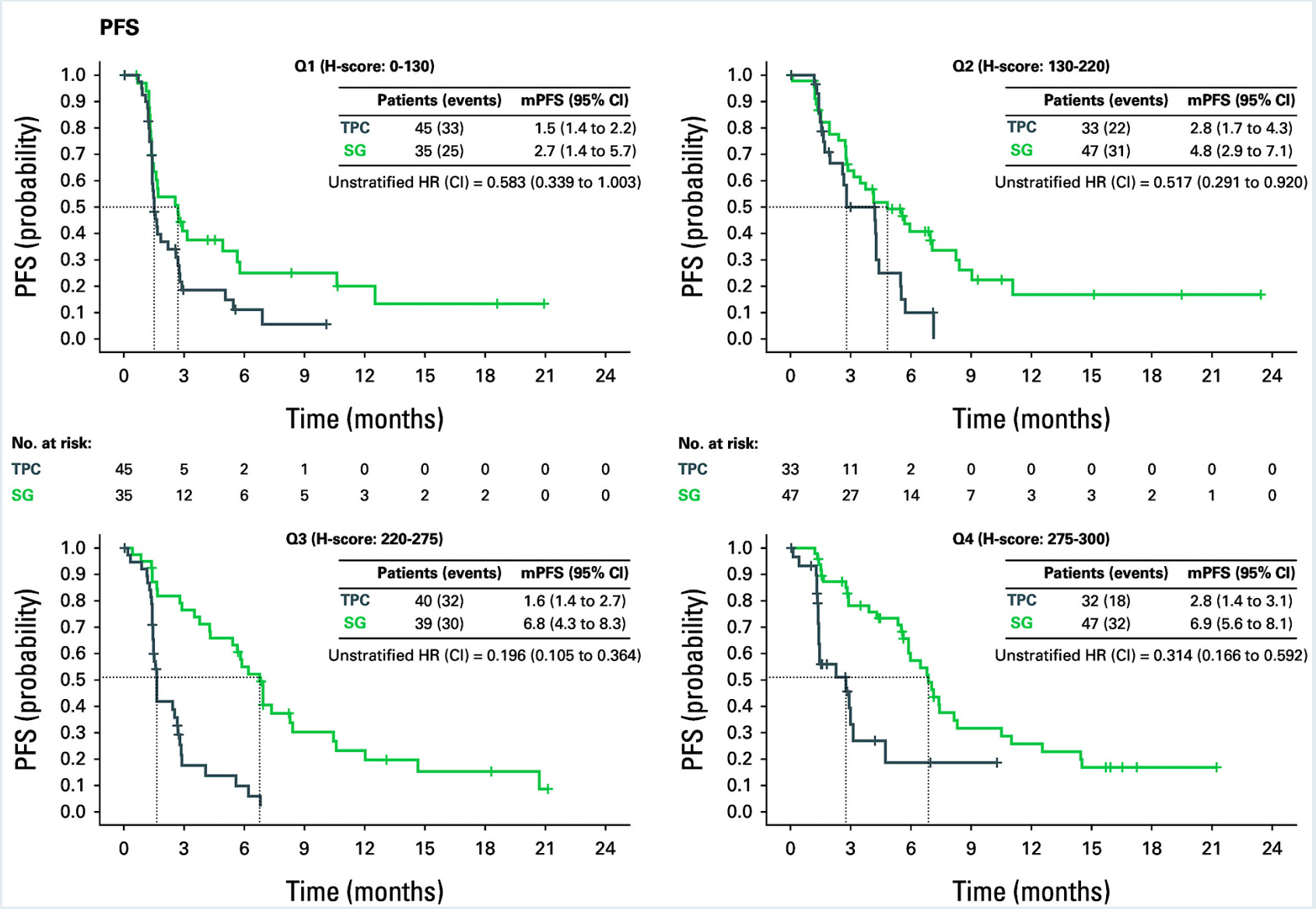
Bardia A et al. *J Clin Oncol* 2024;42(15):1738-44.

Phase III ASCENT: Overall Survival (OS)



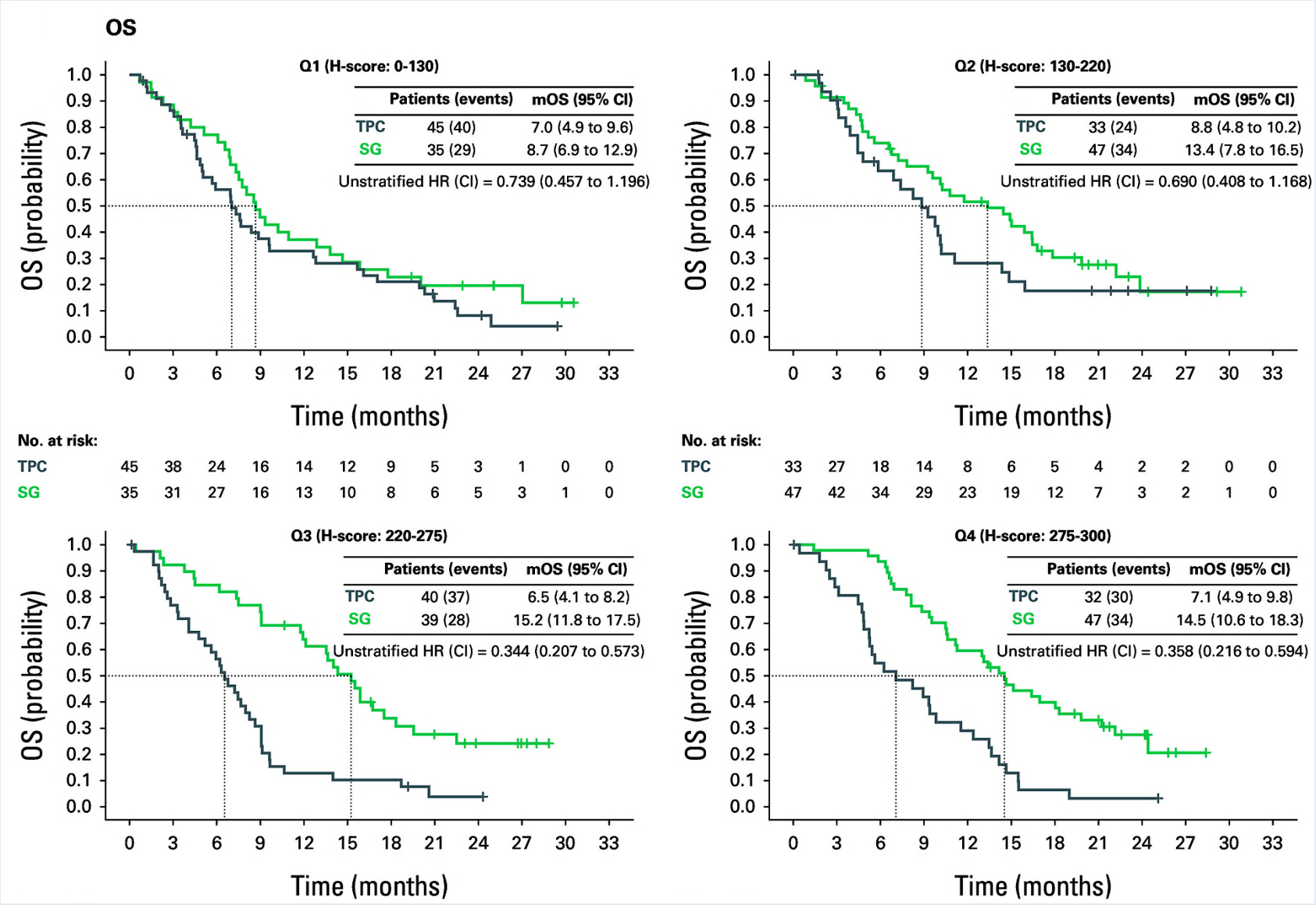
Bardia A et al. *J Clin Oncol* 2024;42(15):1738-44.

Phase III ASCENT: PFS by TROP2 Expression



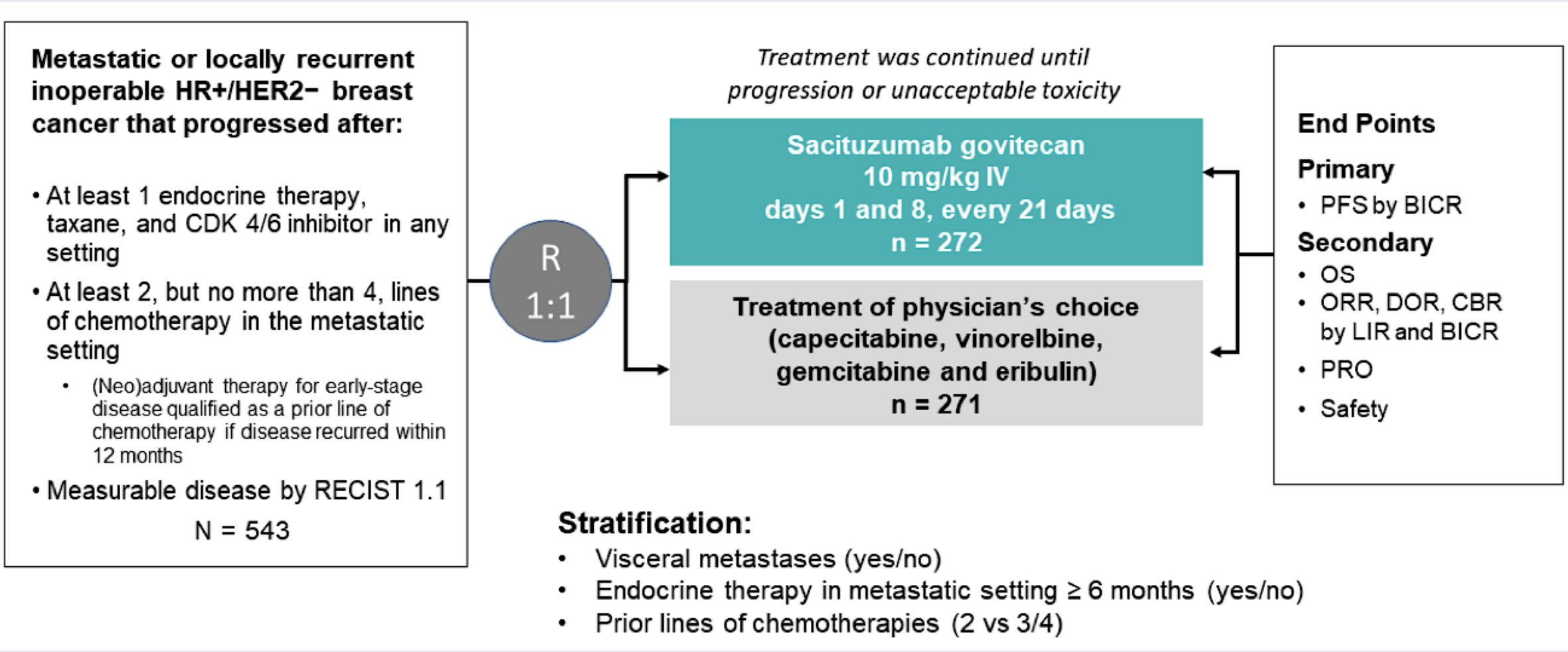
Bardia A et al. *J Clin Oncol* 2024;42(15):1738-44.

Phase III ASCENT: OS by TROP2 Expression



Bardia A et al. *J Clin Oncol* 2024;42(15):1738-44.

Phase III TROPiCS-02 Study Design

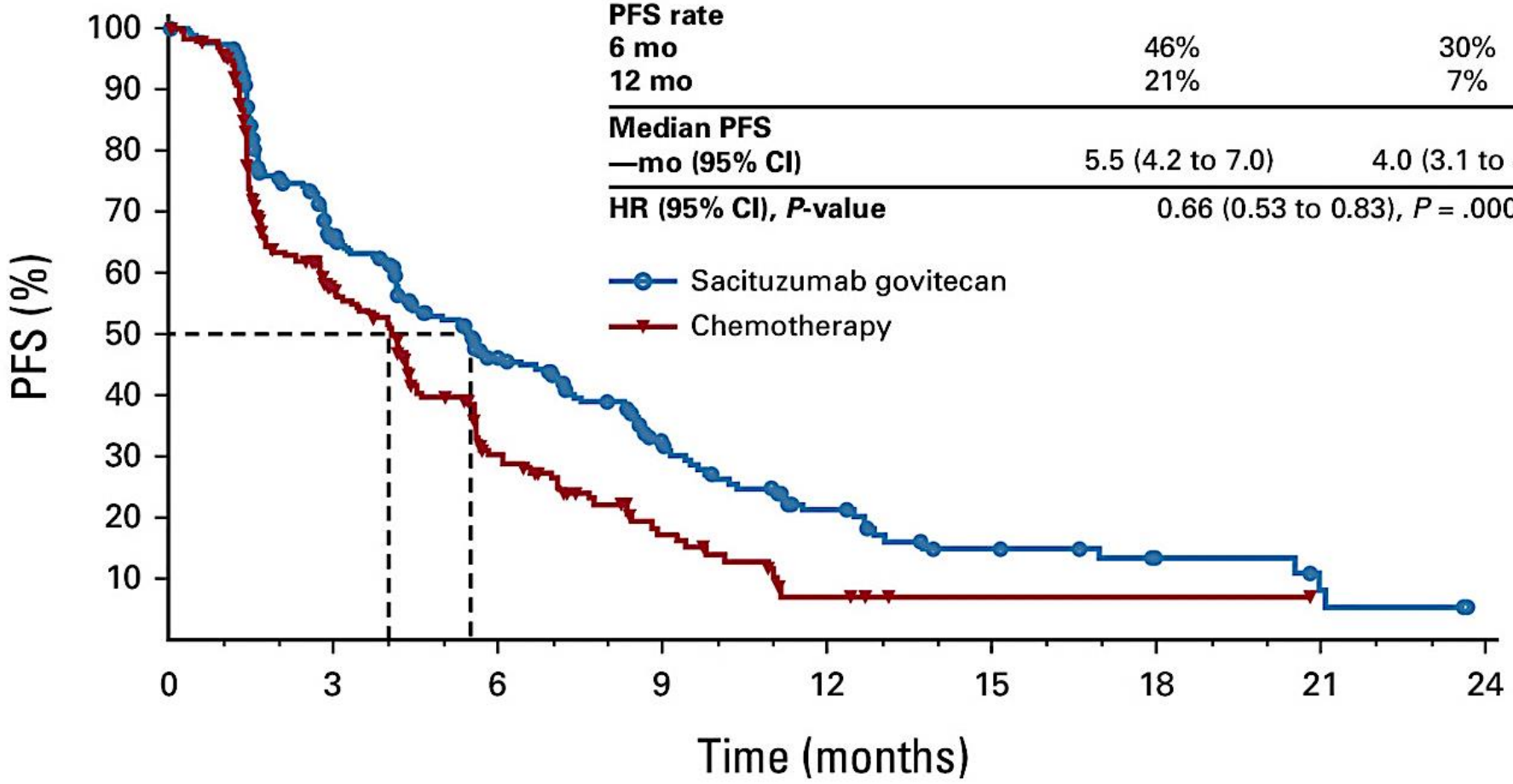


PFS = progression-free survival; BICR = blinded independent central review; OS = overall survival; ORR = objective response rate; DOR = duration of response; CBR = clinical benefit rate; LIR = local investigator review; PRO = patient-reported outcome

Rugo HS et al. *Lancet* 2023 October 21;402(10411):1423-33.

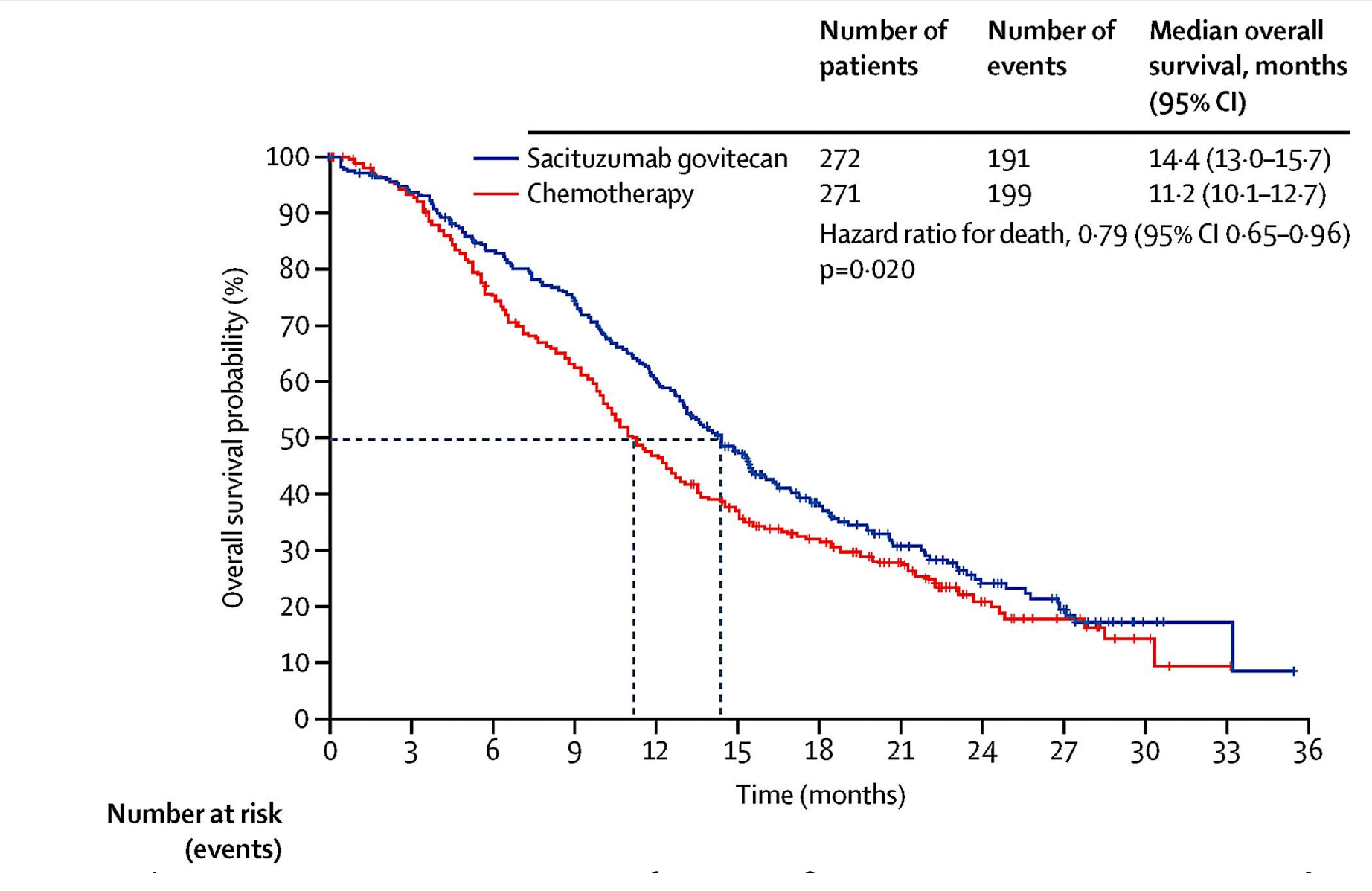
Phase III TROPiCS-02: Final PFS (Intent-to-Treat Population)

	Sacituzumab govitecan (n = 272)	Chemotherapy (n = 271)
No. of events	170	159
PFS rate		
6 mo	46%	30%
12 mo	21%	7%
Median PFS —mo (95% CI)	5.5 (4.2 to 7.0)	4.0 (3.1 to 4.4)
HR (95% CI), *P*-value	0.66 (0.53 to 0.83), *P* = .0003	



Rugo HS et al. *J Clin Oncol* 2022 October 10;40(29):3365-76.

Phase III TROPiCS-02: Final OS (Intent-to-Treat Population)



Rugo HS et al. *Lancet* 2023 October 21;402(10411):1423-33.

FDA Approves Datopotamab Deruxtecan-dlnk for Unresectable or Metastatic HR-Positive, HER2-Negative Breast Cancer

Press Release: January 17, 2025

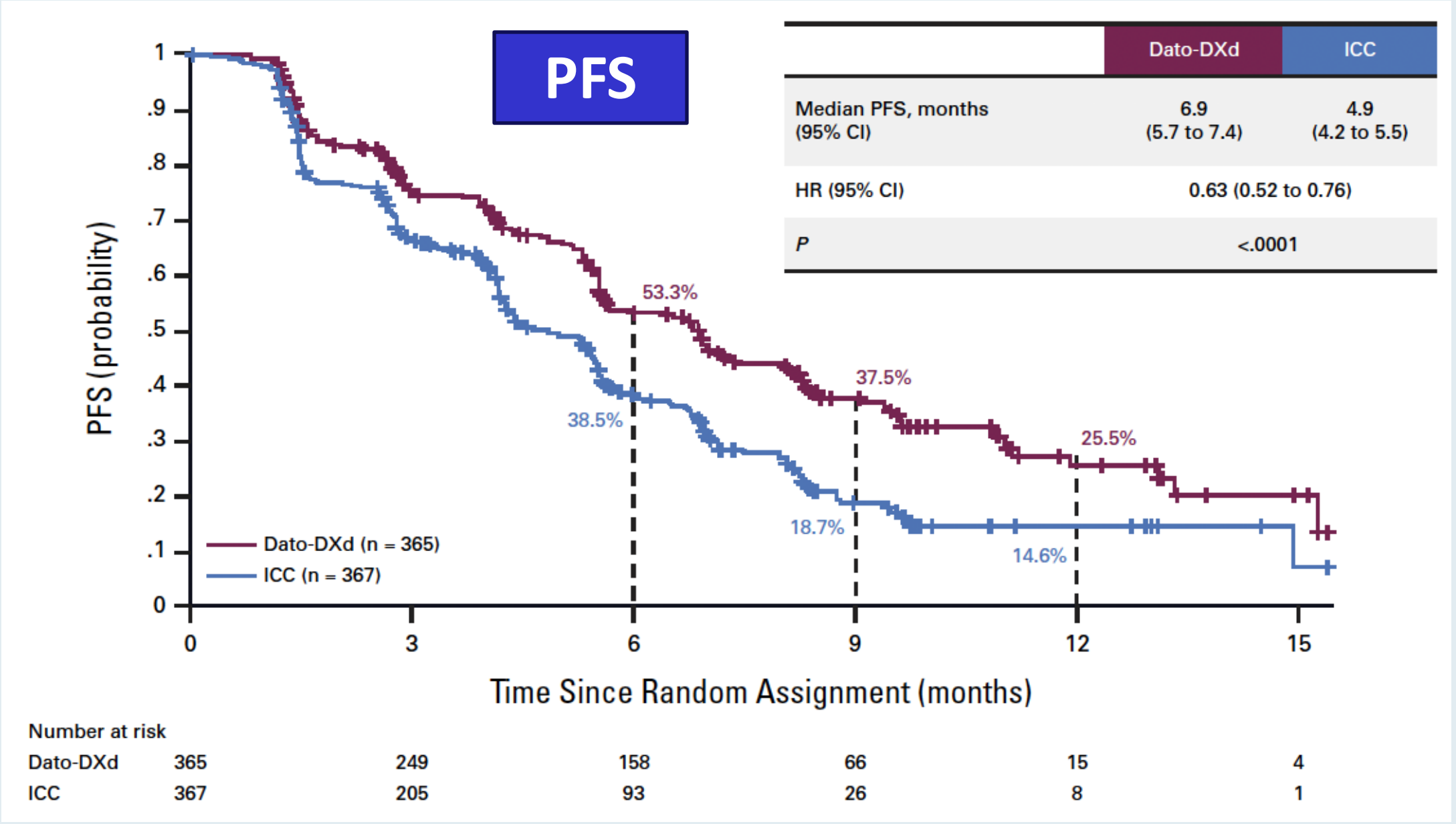
"On January 17, 2025, the Food and Drug Administration approved datopotamab deruxtecan-dlnk, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, for adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC1+ or IHC2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

Efficacy was evaluated in TROPION-Breast01 (NCT05104866), a multicenter, open-label, randomized trial. Patients must have experienced disease progression, been deemed unsuitable for further endocrine therapy, and have received one or two lines of prior chemotherapy for unresectable or metastatic disease. Patients were excluded for a history of ILD/pneumonitis requiring steroids, ongoing ILD/pneumonitis, clinically active brain metastases, or clinically significant corneal disease. Patients also were excluded for ECOG performance status >1."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-datopotamab-deruxtecan-dlnk-unresectable-or-metastatic-hr-positive-her2-negative-breast

RTP RESEARCH TO PRACTICE

Phase III TROPION-Breast01: Progression-Free Survival (PFS)



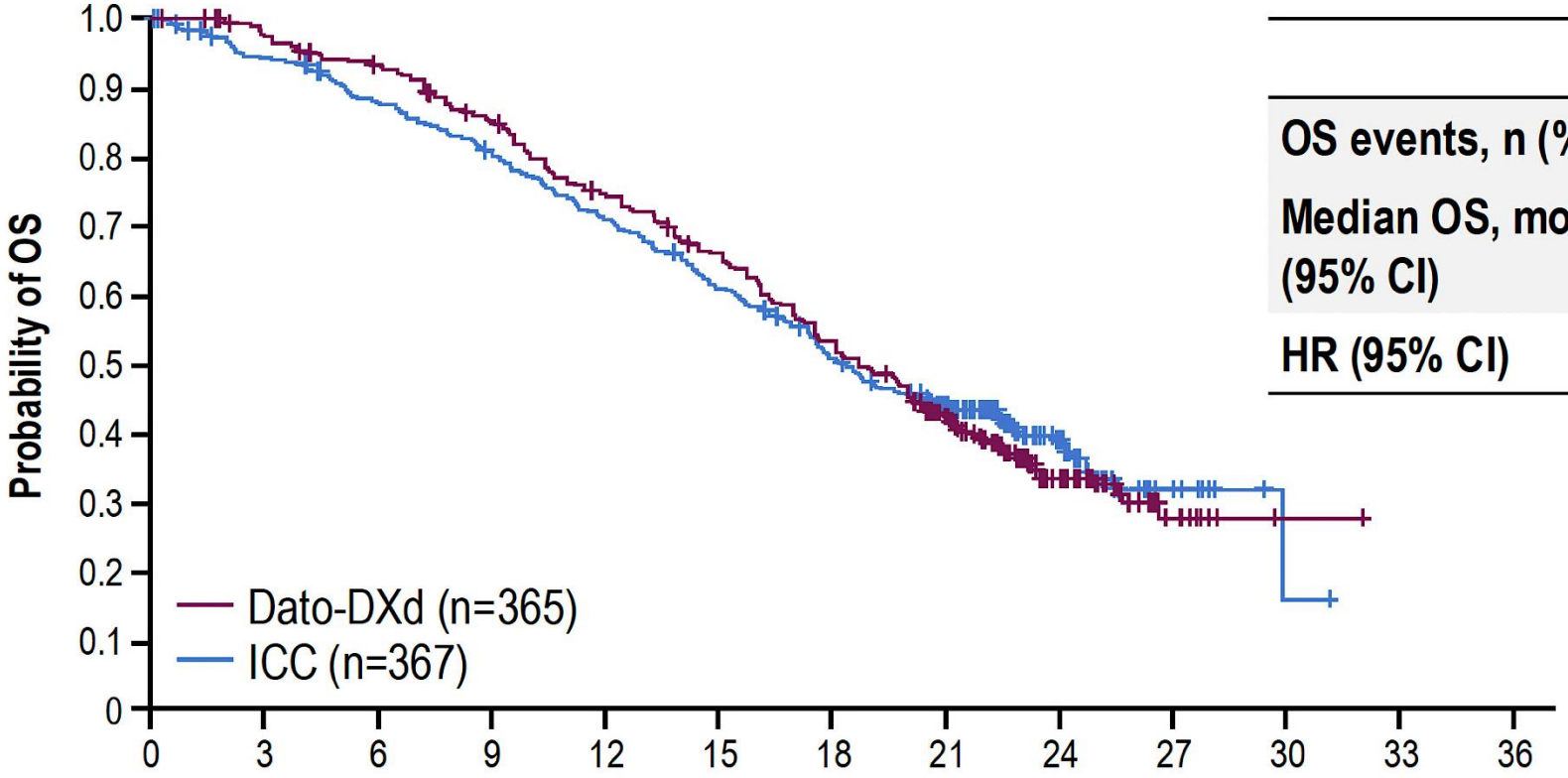
	Dato-DXd	ICC
Median PFS, months (95% CI)	6.9 (5.7 to 7.4)	4.9 (4.2 to 5.5)
HR (95% CI)	0.63 (0.52 to 0.76)	
P	<.0001	

Bardia A et al. *J Clin Oncol* 2025;43(3):285-96.

Dato-DXd = datopotamab deruxtecan; ICC = investigator's choice of chemotherapy

RTP RESEARCH TO PRACTICE

Phase III TROPION-Breast01: Overall Survival



Number at risk

Dato-DXd	365	349	331	299	259	227	180	118	49	12	1
ICC	367	335	309	283	249	213	175	123	51	9	1

	Dato-DXd	ICC
OS events, n (%)	223 (61)	213 (58)
Median OS, months (95% CI)	18.6 (17.3–20.1)	18.3 (17.3–20.5)
HR (95% CI)	**1.01 (0.83–1.22)**	

- Maturity: 59.6%
- Median follow-up: 22.8 months
- Protocol prespecified OS sensitivity analysis based on the stratification factors according to the eCRF*: **HR 0.99 (95% CI: 0.82–1.20)**

Pistilli B et al. ESMO Virtual Plenary 2025;Abstract VP1-2025.

Phase III TROPION-Breast01: Overall Safety Summary

TRAEs, n (%)	Dato-DXd (n=360)	ICC (n=351)
All grades	341 (95)	303 (86)
Grade ≥3	80 (22)	160 (46)
Associated with dose reduction	87 (24)	106 (30)
Associated with dose interruption	57 (16)	85 (24)
Associated with discontinuation	12 (3)	9 (3)
Associated with death	0	1 (0.3)*
Serious TRAEs	22 (6)	32 (9)

- Compared with the primary PFS data cutoff, with an additional ~12 months follow-up:
  - Overall safety profile was consistent
  - No late-onset toxicities were observed
- **Rate of grade ≥3 TRAEs in the Dato-DXd group was less than half that in the ICC group**
- Fewer TRAEs leading to dose reductions or interruptions with Dato-DXd compared with ICC; rates of TRAEs leading to discontinuation were similar between arms

Data cutoff: 24 July 2024. The safety analysis population included all patients who received at least 1 dose of study drug. *Investigator-reported cause of death: febrile neutropenia.
TRAEs, treatment-related adverse events.

ESMO ON AIR

Pistilli B et al. ESMO Virtual Plenary 2025;Abstract VP1-2025.

nature medicine

Article

https://doi.org/10.1038/s41591-025-03630-w

Sacituzumab tirumotecan in previously treated metastatic triple-negative breast cancer: a randomized phase 3 trial

Received: 27 October 2024

Accepted: 4 March 2025

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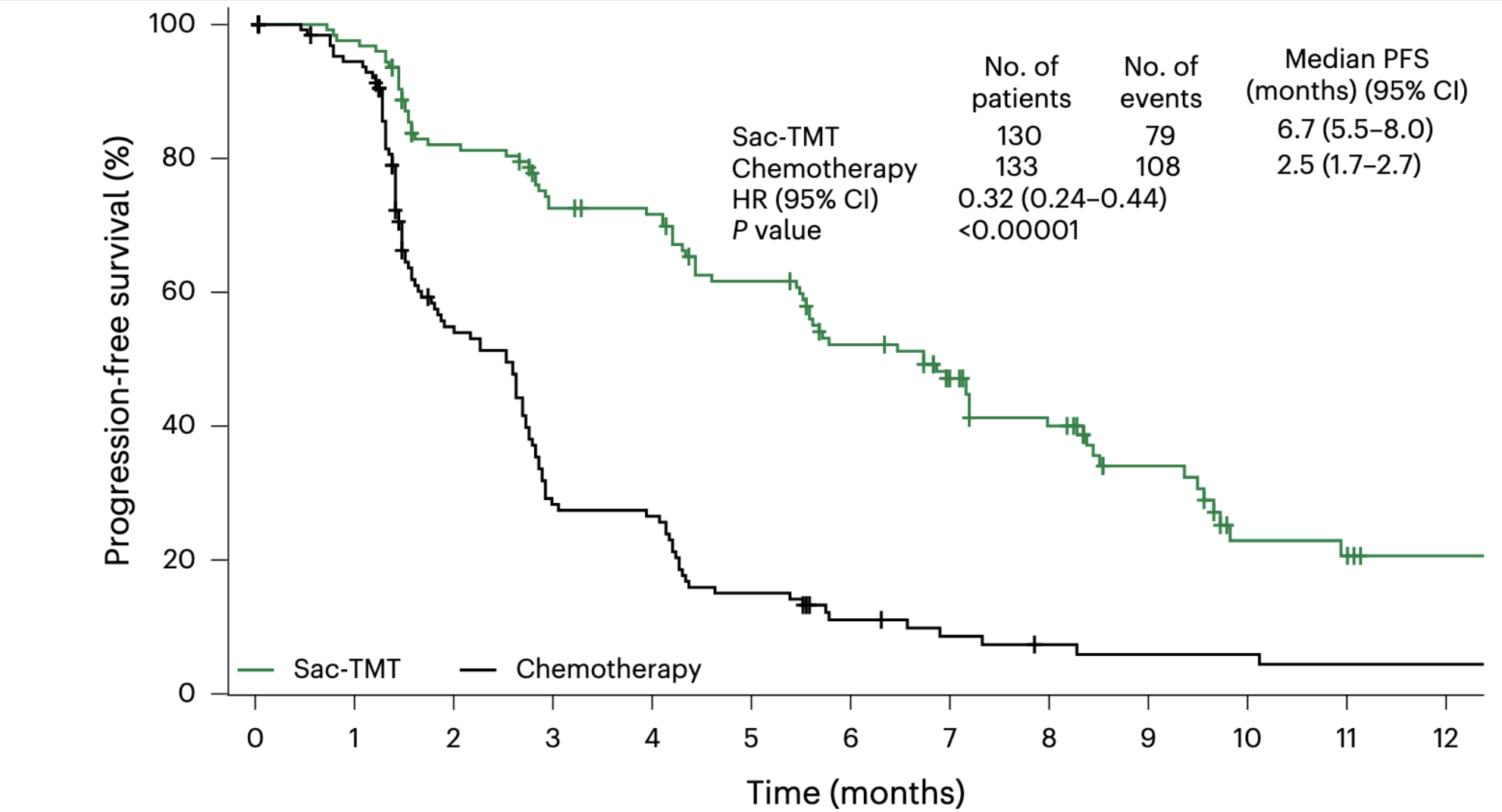
Yongmei Yin[1,17], Ying Fan[2,17], Quchang Ouyang[3,17], Lihua Song[4], Xiaojia Wang[5], Wei Li[6], Man Li[7], Xi Yan[8], Shusen Wang[9], Tao Sun[10], Yuee Teng[11], Xianjun Tang[12], Zhongsheng Tong[13], Zhengkui Sun[14], Junyou Ge[15,16], Xiaoping Jin[15], Yina Diao[15], Gesha Liu[15] & Binghe Xu[2]

Phase III OptiTROP-Breast01 Trial: Final PFS Analysis by BICR



Yin Y et al. *Nat Med* 2025;31(6):1969-75.

ESMO 2025 Abstracts of Interest (HR-Positive, HER2-Negative mBC)

Sacituzumab Tirumotecan
LBA23 — Sacituzumab tirumotecan (sac-TMT) vs investigator's choice of chemotherapy (ICC) in previously treated locally advanced or metastatic hormone receptor-positive, HER2-negative (HR+/HER2-) breast cancer (BC): Results from the randomized, multi-center phase 3 OptiTROP-Breast02 study *Speaker: Ying Fan*

RTP RESEARCH TO PRACTICE

Agenda

Introduction: Antibody-drug conjugates (ADCs) in localized breast cancer

Case 1: Dr Fox – 78-year-old frail woman

- Key Datasets: Targeting TROP2 in recurrent metastatic disease

Case 2: Dr Xu – 61-year-old woman

- Key Datasets: Management of HER2-low and HER2-ultralow breast cancer

Case 3: Dr Astrow – 74-year-old woman

- Key Datasets: TROP2-targeted ADCs as first-line treatment

Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

Case Presentation: 61-year-old woman with NTRK-mutant ER-negative, HER2-low (IHC 2+) recurrent mBC and PD on chemoimmunotherapy and larotrectinib receives trastuzumab deruxtecan

Dr Amber Xu (Rolling Meadows, Illinois)

RTP RESEARCH TO PRACTICE

2024 ASCO ANNUAL MEETING

DESTINY BREAST06

Trastuzumab deruxtecan vs physician's choice of chemotherapy in patients with hormone receptor–positive, human epidermal growth factor receptor 2 (HER2)–low or HER2-ultralow metastatic breast cancer with prior endocrine therapy: primary results from DESTINY-Breast06

Giuseppe Curigliano
European Institute of Oncology, IRCCS, Milan, Italy;
Department of Oncology and Hematology-Oncology, University of Milan, Italy

Sunday, June 2, 2024

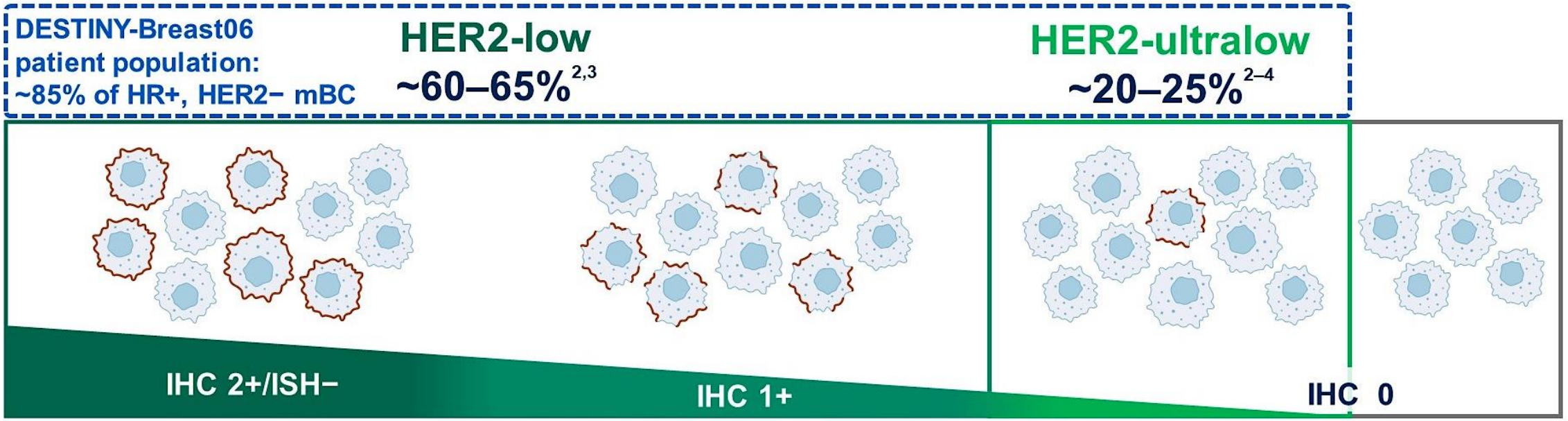
Additional authors: Xichun Hu, Rebecca Dent, Kan Yonemori, Carlos H Barrios, Joyce A O'Shaughnessy, Hans Wildiers, Qingyuan Zhang, Seock-Ah Im, Cristina Saura, Laura Biganzoli, Joohyuk Sohn, Christelle Lévy, William Jacot, Natasha Begbie, Jun Ke, Gargi Patel, Aditya Bardia

On behalf of the DESTINY-Breast06 investigators

Abstract LBA1000

RTP RESEARCH TO PRACTICE

HER2-Low and Ultralow Disease



ASCO/CAP, American Society of Clinical Oncology / College of American Pathologists; HER2, human epidermal growth factor receptor 2; HR+, hormone receptor–positive; IHC, immunohistochemistry; ISH, in situ hybridization; mBC, metastatic breast cancer; T-DXd, trastuzumab deruxtecan

Images adapted from Venetis K, et al. *Front Mol Biosci.* 2022;9:834651. CC BY 4.0 license available from: https://creativecommons.org/licenses/by/4.0/

1. Wolff AC, et al. *J Clin Oncol.* 2023;41:3867–3872; 2. Denkert C, et al. *Lancet Oncol.* 2021;22:1151–1161; 3. Chen Z, et al. *Breast Cancer Res Treat.* 2023;202:313–323; 4. Mehta S, et al. *J Clin Oncol.* 2024;42(Suppl. 16):Abstract e13156

Curigliano G et al. ASCO 2024;Abstract LBA1000.

Phase III DESTINY-Breast06 Study Design

DESTINY-Breast06: a Phase 3, randomized, multicenter, open-label study (NCT04494425)

PATIENT POPULATION

- HR+ mBC
- HER2-low (IHC 1+ or IHC 2+/ISH−) or HER2-ultralow (IHC 0 with membrane staining)*
- **Chemotherapy naïve in the mBC setting**

Prior lines of therapy

- ≥2 lines of ET ± targeted therapy for mBC
  OR
- 1 line for mBC **AND**
  - Progression ≤6 months of starting first-line ET + CDK4/6i
    OR
  - Recurrence ≤24 months of starting adjuvant ET

R 1:1

T-DXd
5.4 mg/kg Q3W
(n=436)

HER2-low = 713
HER2-ultralow = 153†

TPC
(n=430)

Options:
capecitabine,
nab-paclitaxel,
paclitaxel

ENDPOINTS

Primary

- PFS (BICR) in HER2-low

Key secondary

- PFS (BICR) in ITT (HER2-low + ultralow)
- OS in HER2-low
- OS in ITT (HER2-low + ultralow)

Other secondary

- PFS (INV) in HER2-low
- ORR (BICR/INV) and DOR (BICR/INV) in HER2-low and ITT (HER2-low + ultralow)
- Safety and tolerability
- Patient-reported outcomes‡

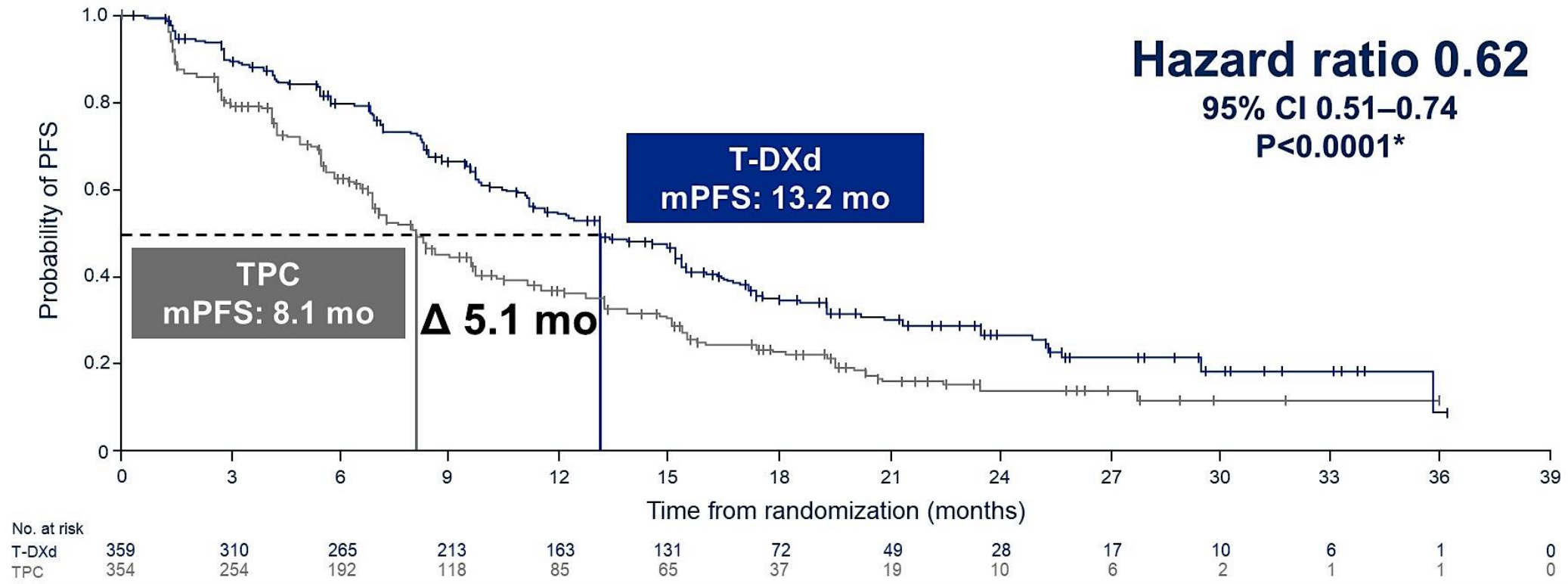
Stratification factors

- Prior CDK4/6i use (yes vs no)
- HER2 expression (IHC 1+ vs IHC 2+/ISH− vs IHC 0 with membrane staining)
- Prior taxane in the non-metastatic setting (yes vs no)

*Study enrollment was based on central HER2 testing. HER2 status was determined based on the most recent evaluable HER2 IHC sample prior to randomization. HER2-ultralow was defined as faint, partial membrane staining in ≤10% of tumor cells (also known as IHC >0<1+); †HER2-ultralow status as determined per IRT data (note: efficacy analyses in the HER2-ultralow subgroup were based on n=152 as determined per central laboratory testing data); ‡to be presented separately
BICR, blinded independent central review; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; DOR, duration of response; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HR+, hormone receptor–positive; IHC, immunohistochemistry; INV, investigator assessed; IRT, interactive response technology; ISH, in situ hybridization; ITT, intent-to-treat; mBC, metastatic breast cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; T-DXd, trastuzumab deruxtecan; TPC, chemotherapy treatment of physician's choice
NCT04494425. Updated. April 12, 2024. Available from: https://clinicaltrials.gov/study/NCT04494425 (Accessed May 13, 2024)

Curigliano G et al. ASCO 2024;Abstract LBA1000.

Phase III DESTINY-Breast06: PFS in HER2-Low Disease (Primary Endpoint)

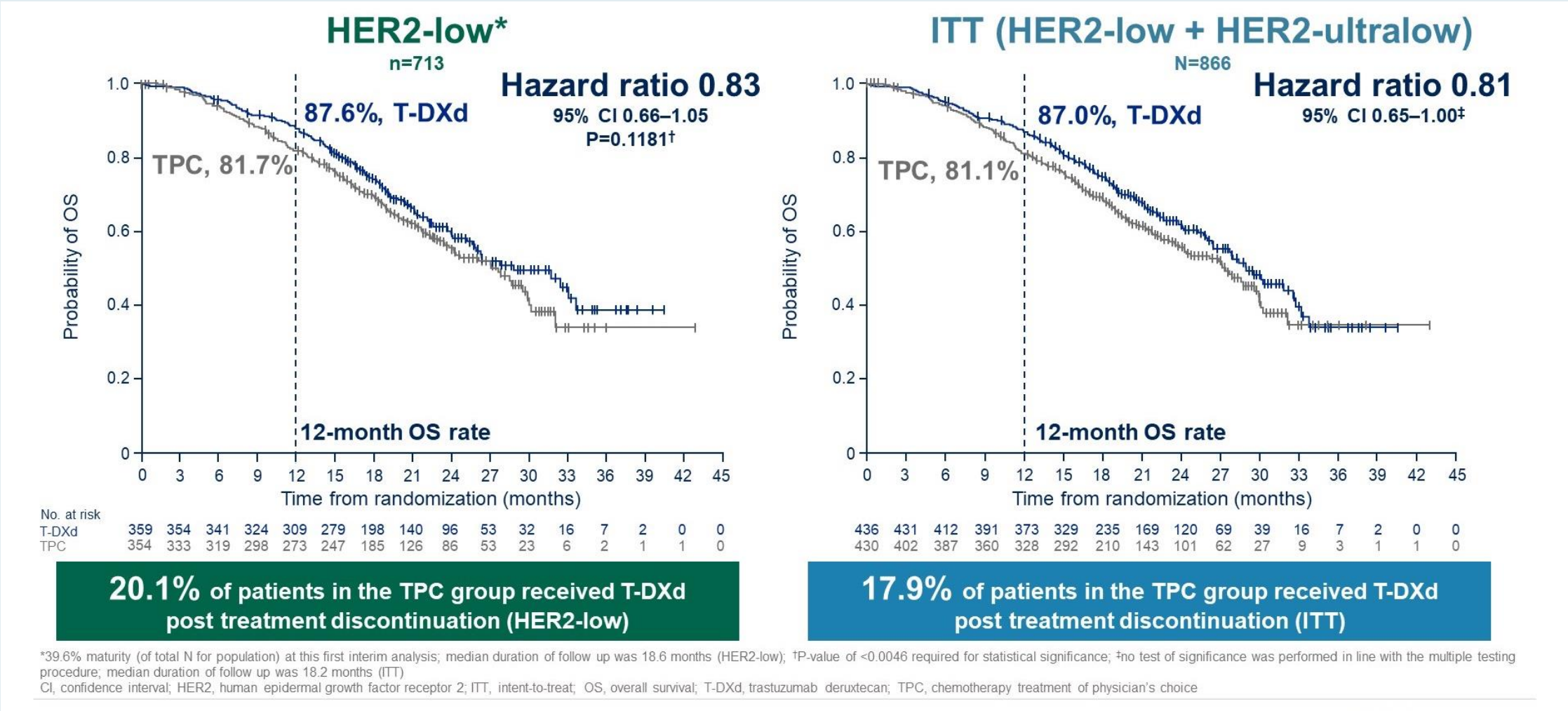


T-DXd demonstrated a statistically significant and clinically meaningful improvement in PFS compared with standard-of-care chemotherapy in HER2-low

*P-value of <0.05 required for statistical significance
BICR, blinded independent central review; CI, confidence interval; HER2, human epidermal growth factor receptor 2; mo, months; (m)PFS, (median) progression-free survival; T-DXd, trastuzumab deruxtecan; TPC, chemotherapy treatment of physician's choice

Curigliano G et al. ASCO 2024;Abstract LBA1000.

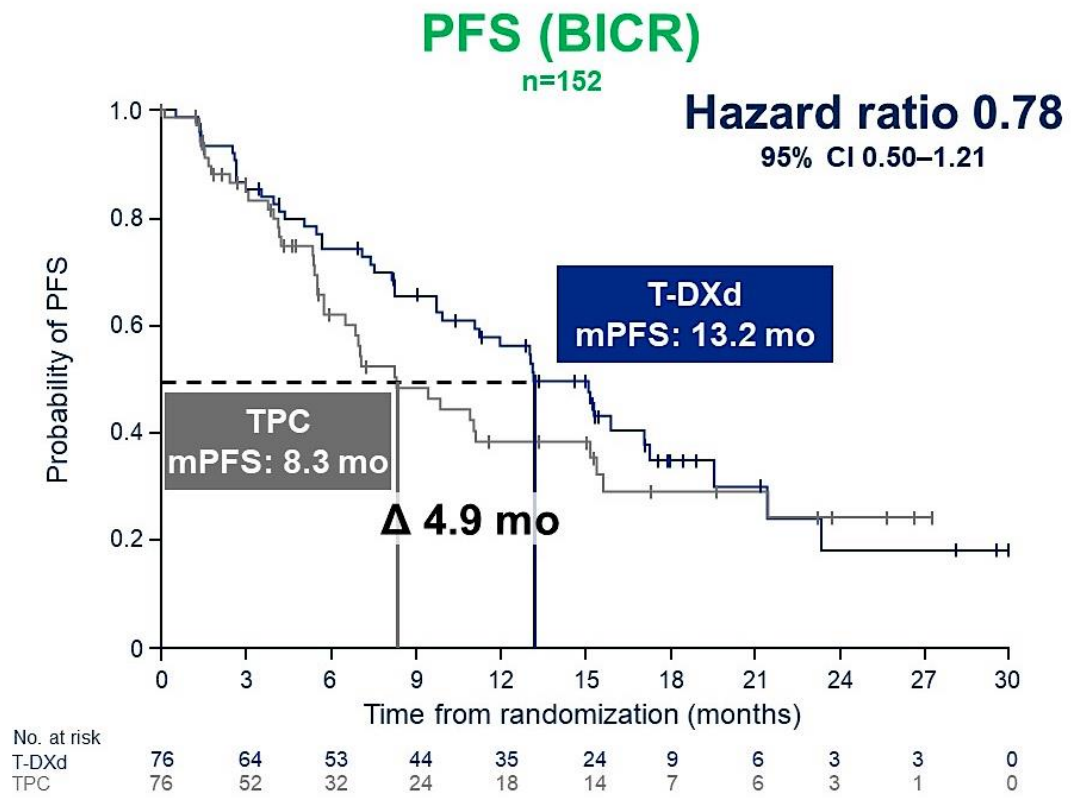
Phase III DESTINY-Breast06: Overall Survival (~40% Maturity)

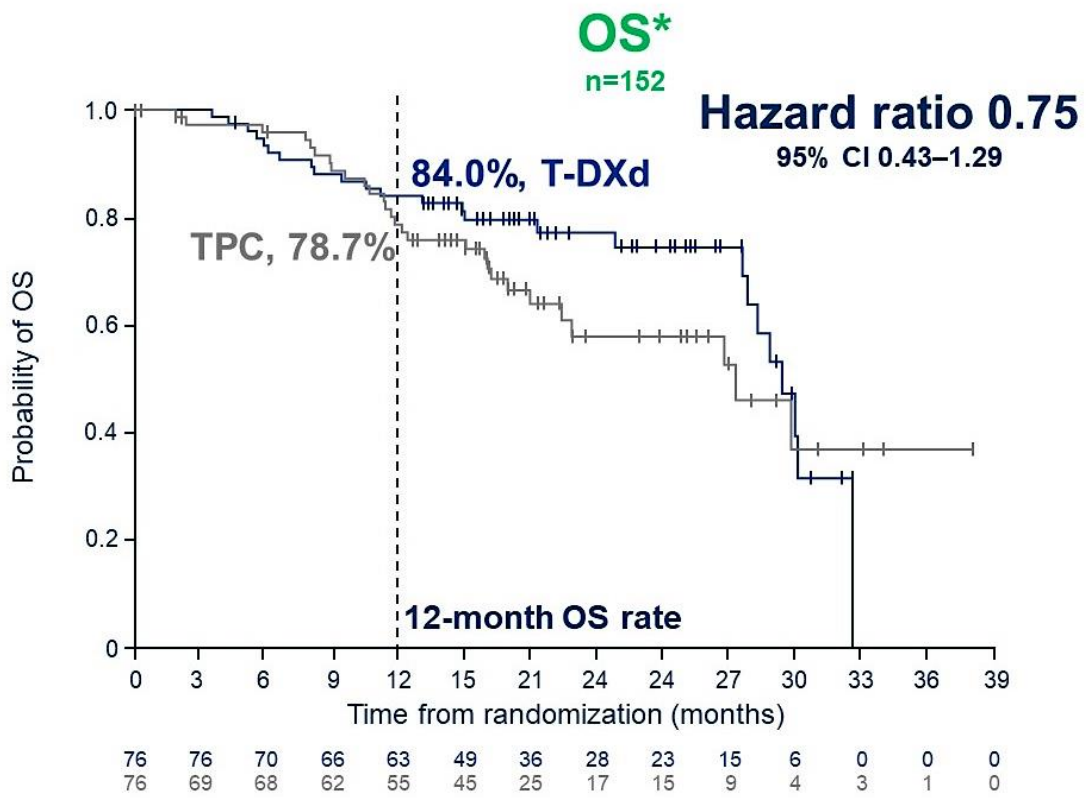


*39.6% maturity (of total N for population) at this first interim analysis; median duration of follow up was 18.6 months (HER2-low); †P-value of <0.0046 required for statistical significance; ‡no test of significance was performed in line with the multiple testing procedure; median duration of follow up was 18.2 months (ITT)
CI, confidence interval; HER2, human epidermal growth factor receptor 2; ITT, intent-to-treat; OS, overall survival; T-DXd, trastuzumab deruxtecan; TPC, chemotherapy treatment of physician's choice

Curigliano G et al. ASCO 2024;Abstract LBA1000.

Phase III DESTINY-Breast06: Survival in HER2-Ultralow Disease



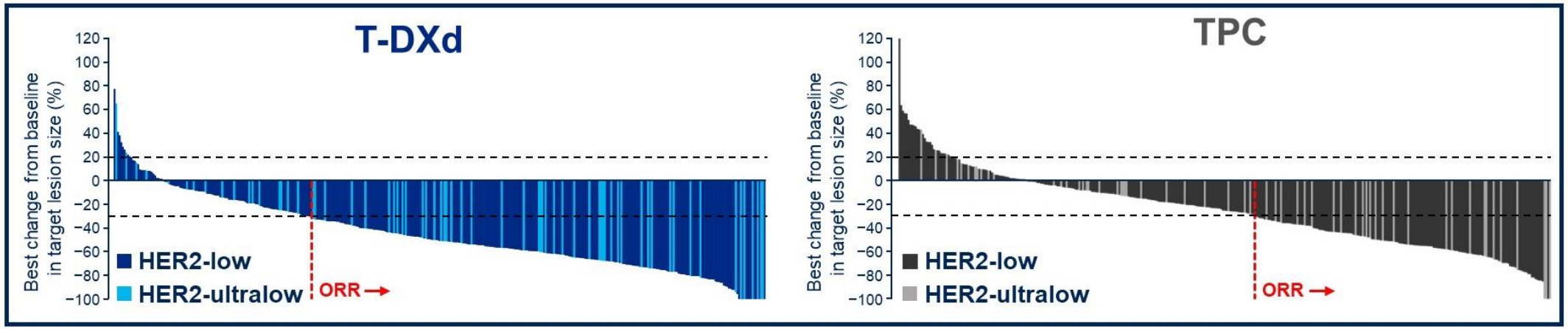


PFS improvement with T-DXd vs TPC in HER2-ultralow was consistent with results in HER2-low

*34.9% maturity (of total N for population) at this first interim analysis; median duration of follow up was 16.8 months
BICR, blinded independent central review; CI, confidence interval; HER2, human epidermal growth factor receptor 2; OS, overall survival; mo, months; (m)PFS, (median) progression-free survival; T-DXd, trastuzumab deruxtecan; TPC, chemotherapy treatment of physician's choice

Curigliano G et al. ASCO 2024;Abstract LBA1000.

Phase III DESTINY-Breast06: Activity by HER2 Expression



	HER2-low*		ITT		HER2-ultralow*	
	T-DXd (n=359)	TPC (n=354)	T-DXd (n=436)	TPC (n=430)	T-DXd (n=76)	TPC (n=76)
Confirmed ORR, n (%)	**203 (56.5)**	**114 (32.2)**	**250 (57.3)**	**134 (31.2)**	**47 (61.8)**	**20 (26.3)**
Best overall response, n (%)						
Complete response	9 (2.5)	0	13 (3.0)	0	4 (5.3)	0
Partial response	194 (54.0)	114 (32.2)	237 (54.4)	134 (31.2)	43 (56.6)	20 (26.3)
Stable disease	125 (34.8)	170 (48.0)	148 (33.9)	212 (49.3)	22 (28.9)	42 (55.3)
Clinical benefit rate, n (%)†	275 (76.6)	190 (53.7)	334 (76.6)	223 (51.9)	58 (76.3)	33 (43.4)
Median duration of response, mo	14.1	8.6	14.3	8.6	14.3	14.1

ORR based on RECIST v1.1; response required confirmation after 4 weeks
*HER2-low status defined at randomization per IRT data, and HER2-ultralow status defined by central laboratory testing data; †defined as complete response + partial response + stable disease at Week 24, by blinded independent central review
HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IRT, interactive response technology; ITT, intent-to-treat; mo, months; ORR, objective response rate; RECIST, Response Evaluation Criteria in Solid Tumors; T-DXd, trastuzumab deruxtecan; TPC, chemotherapy treatment of physician's choice

Curigliano G et al. ASCO 2024;Abstract LBA1000.

Agenda

Introduction: Antibody-drug conjugates (ADCs) in localized breast cancer

Case 1: Dr Fox – 78-year-old frail woman

- Key Datasets: Targeting TROP2 in recurrent metastatic disease

Case 2: Dr Xu – 61-year-old woman

- Key Datasets: Management of HER2-low and HER2-ultralow breast cancer

Case 3: Dr Astrow – 74-year-old woman

- Key Datasets: TROP2-targeted ADCs as first-line treatment

Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

Case Presentation: 74-year-old woman with PIK3CA-mutant recurrent mTNBC and PMH of diverticular abscess on prior neoadjuvant chemoimmunotherapy (KN-522) receives sacituzumab govitecan and pembrolizumab

Dr Alan Astrow (Brooklyn, New York)

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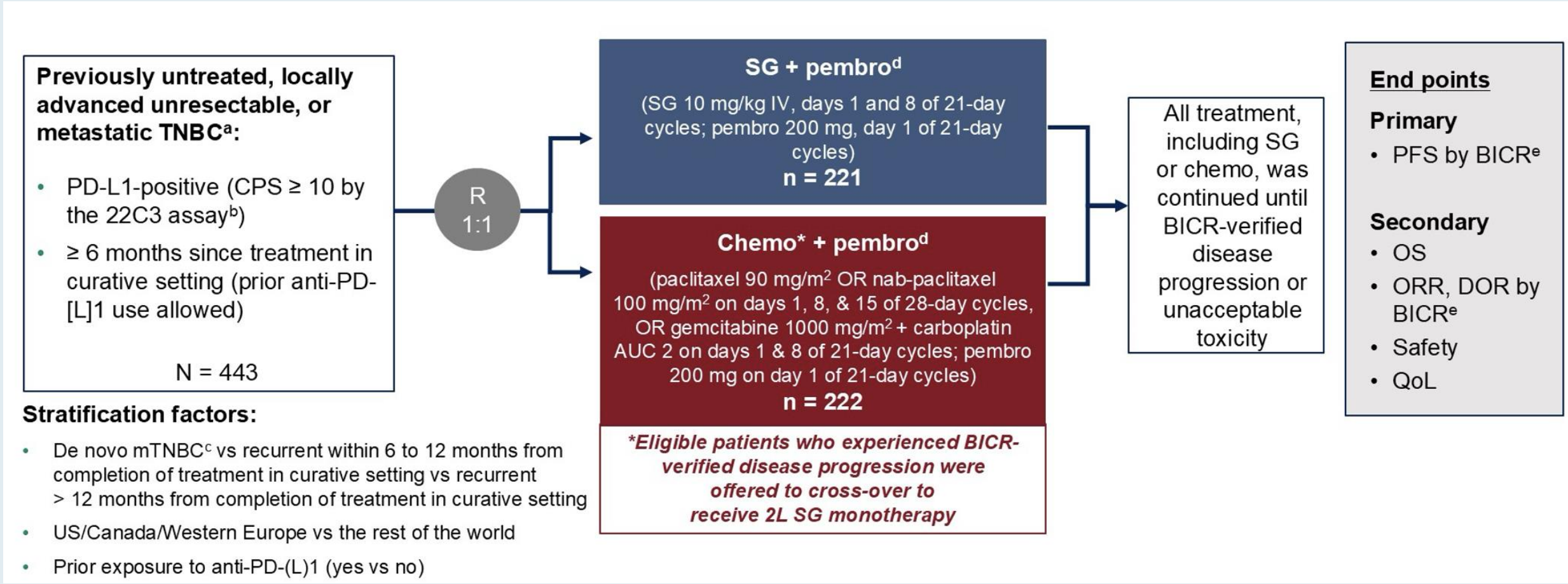
Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study

Sara M Tolaney[1], Evandro de Azambuja[2], Kevin Kalinsky[3], Sherene Loi[4], Sung-Bae Kim[5], Clinton Yam[6], Bernardo Rapoport[7,8], Seock-Ah Im[9], Barbara Pistilli[10], Wassim McHayleh[11], David W Cescon[12], Junichiro Watanabe[13], Manuel Alejandro Lara Banuelas[14], Ruffo Freitas-Junior[15], Javier Salvador Bofill[16], Maryam Afshari[17], Dianna Gary[17], Lu Wang[17], Catherine Lai[17], Peter Schmid[18]

ASCO 2025;Abstract LBA109.

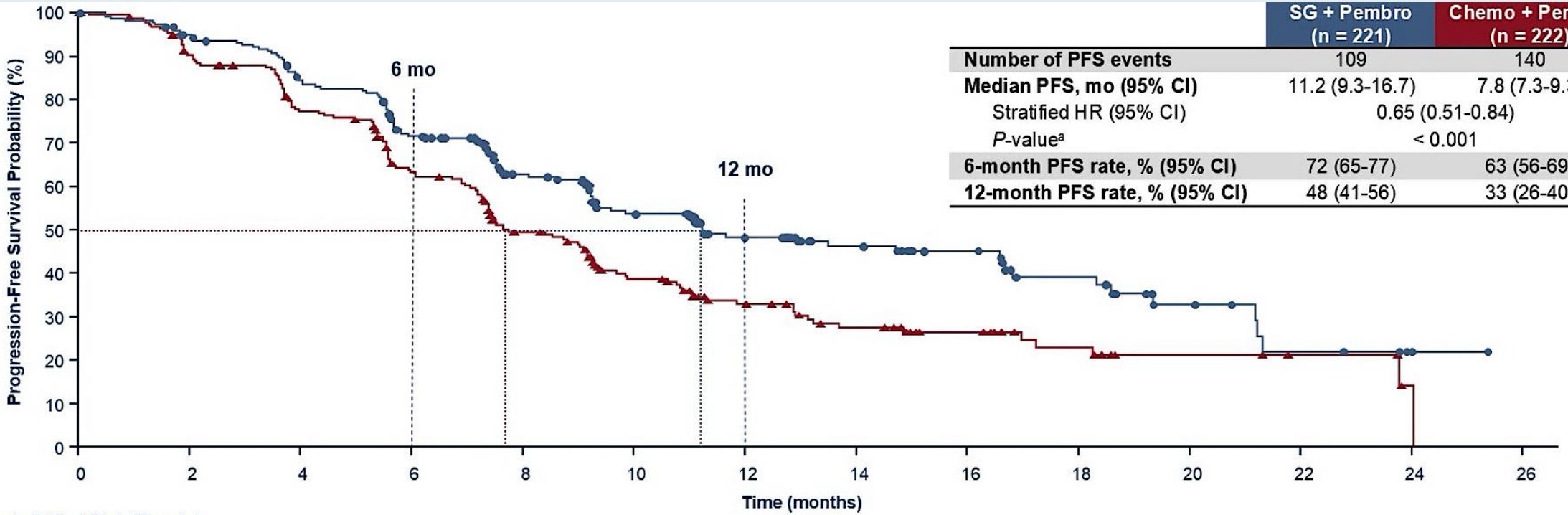
Phase III ASCENT-04/KEYNOTE-D19 Study Design



SG = sacituzumb govitecan; pembro = pembrolizumab; ORR = objective response rate; QoL = quality of life

Tolaney SM et al. ASCO 2025;Abstract LBA109.

Phase III ASCENT-04/KEYNOTE-D19: Progression-Free Survival by BICR



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

No. of Patients Still at Risk (Events)

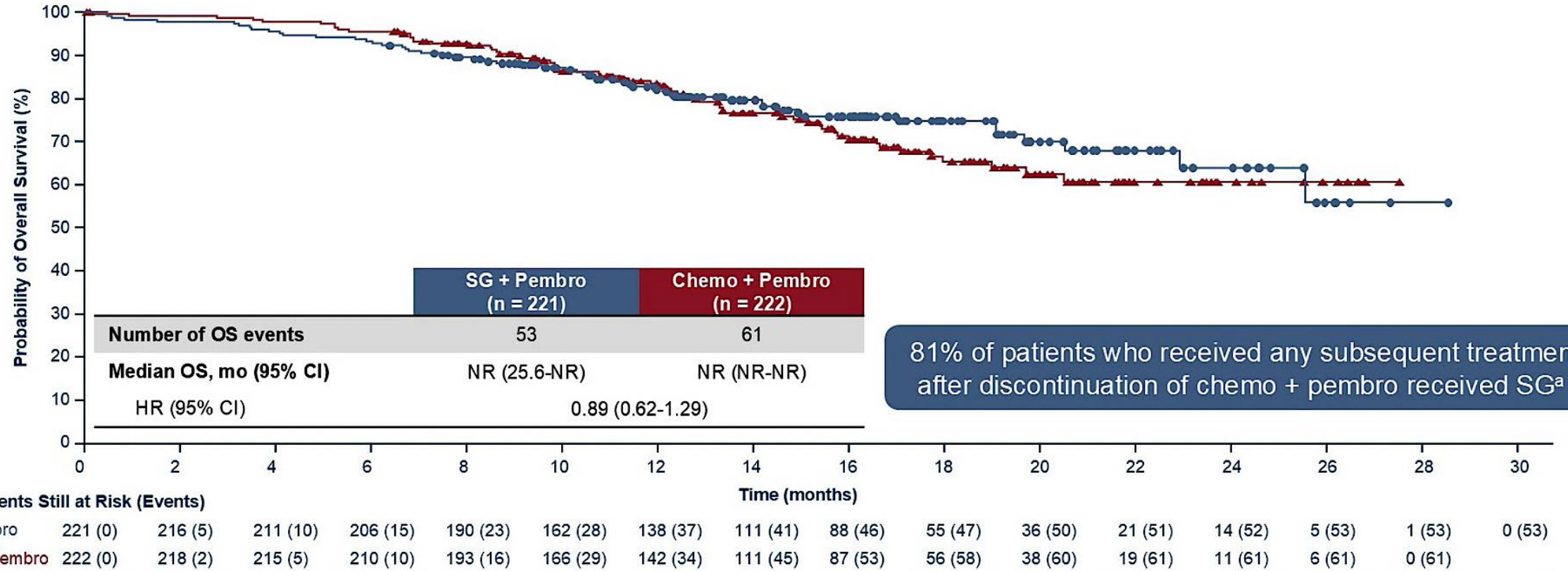
SG + Pembro	221 (0)	202 (11)	174 (33)	142 (59)	105 (75)	78 (89)	58 (96)	42 (98)	34 (99)	22 (103)	11 (106)	6 (109)	2 (109)	0 (109)
Chemo + Pembro	222 (0)	191 (21)	159 (48)	123 (76)	88 (102)	59 (120)	40 (128)	29 (134)	21 (135)	13 (137)	7 (138)	4 (138)	1 (139)	0 (140)

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

BICR = blinded independent central review

Tolaney SM et al. ASCO 2025;Abstract LBA109.

Phase III ASCENT-04/KEYNOTE-D19: Descriptive Overall Survival at Primary Analysis



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

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

Tolaney SM et al. ASCO 2025;Abstract LBA109.

Several Phase 3 clinical trials are evaluating the use of ADCs ± immunotherapy in 1L mTNBC

Target	Trial	Intervention	Control arm
TROP2	**PD-L1–negative or PD-L1/PD-1 inhibitor-ineligible population**		
	ASCENT-03[3]	Sacituzumab govitecan	**TPC** (gemcitabine/carboplatin, paclitaxel, or nab-paclitaxel)
	TROPION Breast-02[4]	Datopotamab deruxtecan	**ICC** (paclitaxel, nab-paclitaxel, carboplatin, capecitabine or eribulin mesylate)
	TroFuse-011[5]	Sacituzumab tirumotecan† ± pembrolizumab	**TPC** (gemcitabine and carboplatin, paclitaxel, or nab-paclitaxel)
	SKB264-III-11[6]	Sacituzumab tirumotecan†	**ICC** (paclitaxel, nab-paclitaxel, capecitabine, eribulin, or carboplatin)
	PD-L1+ population		
	ASCENT-04[7]	Sacituzumab govitecan + pembrolizumab	**TPC** (gemcitabine and carboplatin, paclitaxel, or nab-paclitaxel) + pembrolizumab
	TROPION Breast-05[8]	Datopotamab deruxtecan ± durvalumab	**ICC** (paclitaxel, nab-paclitaxel or gemcitabine + carboplatin) + pembrolizumab

ADCs (T-DXd and SG) are approved globally as monotherapy in previously treated mTNBC; SG, Dato-DXd and Sac-TMT are being evaluated in 1L mTNBC[2,5–9]

Courtesy of Rebecca A Dent, MD, MSc

ASCENT-03: First-Line Sacituzumab Govitecan Demonstrates Highly Statistically Significant and Clinically Meaningful Improvement in PFS for Patients with mTNBC Who Are Not Candidates for Checkpoint Inhibitors

Press Release: May 23, 2025

"[The manufacturer] announced positive topline results from the Phase 3 ASCENT-03 study of sacituzumab govitecan-hziy. The study met its primary endpoint, demonstrating a highly statistically significant and clinically meaningful improvement in progression-free survival (PFS) compared to chemotherapy in patients with first-line metastatic triple-negative breast cancer (mTNBC) who are not candidates for PD-1/PD-L1 inhibitors, meaning they are PD-L1 negative or are ineligible to receive immunotherapy.

The safety profile of sacituzumab govitecan-hziy in the ASCENT-03 study was consistent with prior studies, and no new safety signals were identified in this patient population. Overall survival (OS) is a key secondary endpoint and was not mature at the time of PFS primary analysis. No OS detriment was observed."

ESMO 2025 (LBA20) — Primary results from ASCENT-03: A randomized phase 3 study of sacituzumab govitecan (SG) vs chemotherapy (chemo) in patients (pts) with previously untreated advanced triple-negative breast cancer (TNBC) who are unable to receive PD-(L)1 inhibitors (PD-[L]1i)
Speaker: *Javier C Cortés*

https://www.gilead.com/news/news-details/2025/ascent-03-trodelvy-demonstrates-highly-statistically-significant--clinically-meaningful-improvement-in-progression-free-survival-in-patients-with-first-line-metastatic-triple-negative-breast

RTP RESEARCH TO PRACTICE

TROPION-Breast02 + TROPION-Breast05 Study Design

TROPION-Breast02[1,2]

Patient Population

- Untreated, inoperable/locally advanced or metastatic TNBC
- **PD-L1− (CPS <10) OR PD-L1+ (CPS ≥10)** if treated with an anti-PD-(L)1 agent for eBC or if they cannot be treated with an anti-PD-(L)1 agent due to a comorbidity, or if no regulatory access to an anti-PD-(L)1 agent
- **No minimum DFI since completion of Tx in curative setting** (DFI ≤12 months capped at 20%)
- History of ILD/pneumonitis and clinically significant corneal disease excluded

Study Design

R 1:1 N=644

- Dato-DXd monotherapy
- TPC chemo *(pac, nab-pac, capecitabine, carboplatin, eribulin)*

Stratification Factors

- Geographic region
- PD-L1 status
- De novo vs prior DFI ≤12 months vs prior DFI >12 months

Key Endpoints[a]

- Primary: PFS by BICR, OS
- Secondary: ORR, DOR, PFS (investigator), safety, PROs

TROPION-Breast05[3]

Patient Population

- **PD-L1+ (CPS ≥10)** untreated, inoperable/locally advanced or metastatic TNBC
- **DFI ≥6 months since Tx in curative setting** (DFI 6–12 months capped at 20%)
- Prior PD-(L)1 use allowed in this setting
- History of ILD/pneumonitis and clinically significant corneal disease excluded

Study Design

R 1:1 N~625

- Dato-DXd + durvalumab
- Dato-DXd monotherapy
- TPC chemo + pembrolizumab *(gem + carbo; pac; nab-pac)*

Stratification Factors

- Geographic region
- Prior PD-(L)1
- De novo vs prior DFI 6–12 months vs prior DFI >12 months

Key Endpoints[a]

- Primary: PFS by BICR
- Secondary: OS, PFS (investigator), ORR, safety, PROs

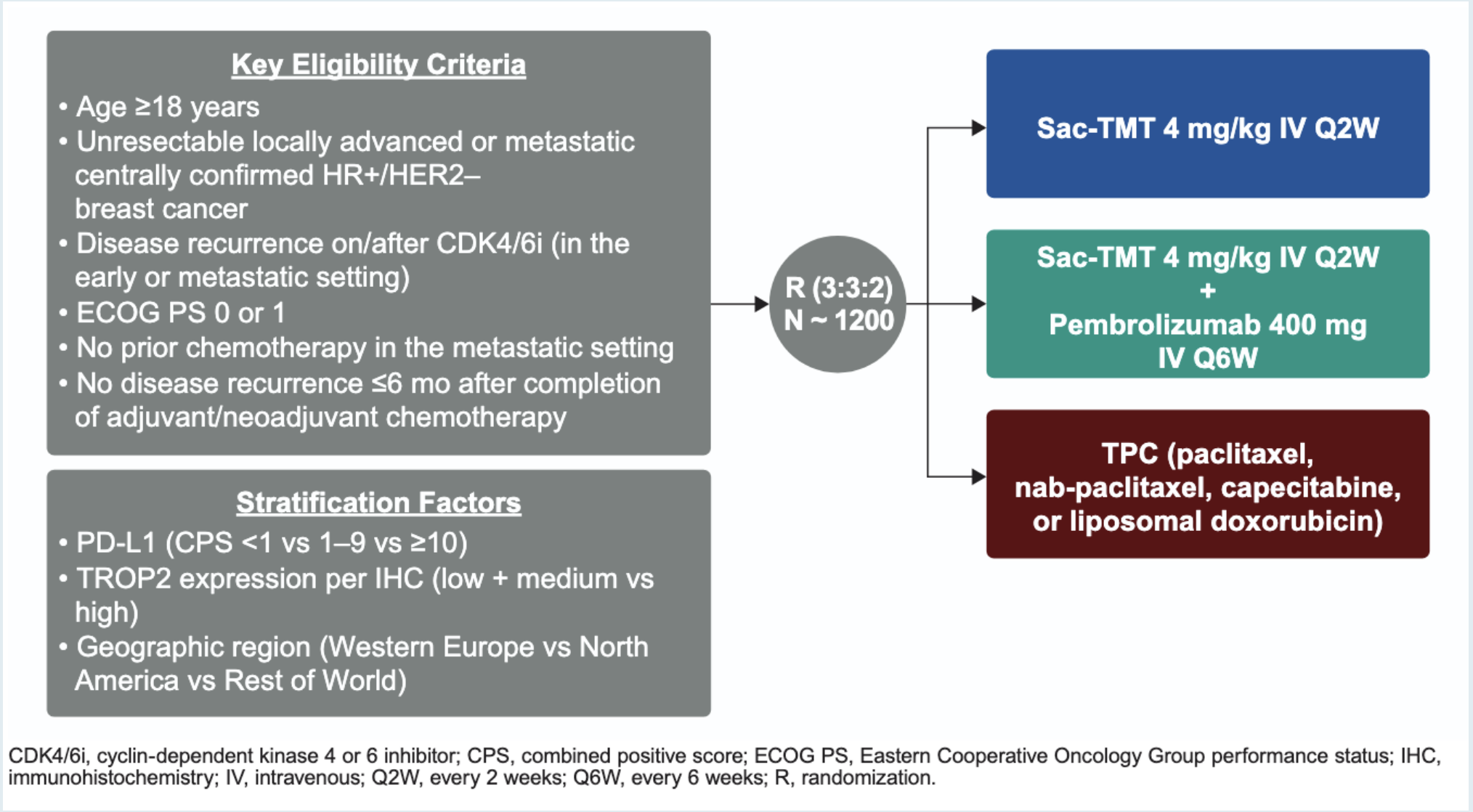
[a]Secondary endpoints not exhaustive.

1L, first line; BICR, blinded independent central review; carbo, carboplatin; chemo, chemotherapy; CPS, combined positive score; Dato-DXd, datopotamab deruxtecan; DFI, disease-free interval; eBC, early-stage breast cancer; gem, gemcitabine; nab-pac, nab-paclitaxel; ORR, objective response rate; OS, overall survival; pac, paclitaxel; PD-1, programmed death protein 1; PD-L1, programmed death ligand 1; PD-L1−, programmed death ligand 1-negative; PD-L1+, programmed death ligand 1-positive; PFS, progression-free survival; PROs, patient-reported outcomes; R, randomization; TNBC, metastatic triple-negative breast cancer; TPC, treatment of physician's choice; Tx, therapy.

1. Dent RA, et al. *Future Oncol*. 2023;19(35):2349–2359; 2. https://clinicaltrials.gov/study/NCT05374512; 3. Schmid P, et al. *Ther Adv Med Oncol*. 2025;17:17588359251327992.

Courtesy of Sara M Tolaney, MD, MPH

TroFuse-010 Study Design



CDK4/6i, cyclin-dependent kinase 4 or 6 inhibitor; CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; IV, intravenous; Q2W, every 2 weeks; Q6W, every 6 weeks; R, randomization.

Tolaney et al. SABCS 2024;Abstract P4-08-09.

ESMO 2025 Abstracts of Interest (TNBC)

Sacituzumab govitecan

LBA20 — Primary results from ASCENT-03: A randomized phase 3 study of sacituzumab govitecan (SG) vs chemotherapy (chemo) in patients (pts) with previously untreated advanced triple-negative breast cancer (TNBC) who are unable to receive PD-(L)1 inhibitors (PD-[L]1i)

Speaker: Javier C Cortés

LBA22 — Patient-reported outcomes (PROs) with sacituzumab govitecan (SG) + pembrolizumab (pembro) vs chemotherapy (chemo) + pembro in patients (pts) with previously untreated PD-L1+ metastatic triple-negative breast cancer (mTNBC) in the phase 3 ASCENT-04/KEYNOTE-D19 study

Speaker: Evandro De Azambuja

Datopotamab deruxtecan

555MO — Datopotamab deruxtecan (Dato-DXd) + durvalumab (D) as first-line (1L) treatment (tx) for unresectable locally advanced/metastatic triple-negative breast cancer (a/mTNBC): Final results from the phase 1b/2 BEGONIA study

Speaker: Peter Schmid

RTP RESEARCH TO PRACTICE

Agenda

Introduction: Antibody-drug conjugates (ADCs) in localized breast cancer

Case 1: Dr Fox – 78-year-old frail woman

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- Key Datasets: Management of HER2-low and HER2-ultralow breast cancer

Case 3: Dr Astrow – 74-year-old woman

- Key Datasets: TROP2-targeted ADCs as first-line treatment

Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

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Case Presentation: 66-year-old woman with ER-negative, HER2-low (IHC 1+) mBC receives sacituzumab govitecan after PD on capecitabine

Dr Laila Agrawal (Louisville, Kentucky)

RTP RESEARCH TO PRACTICE

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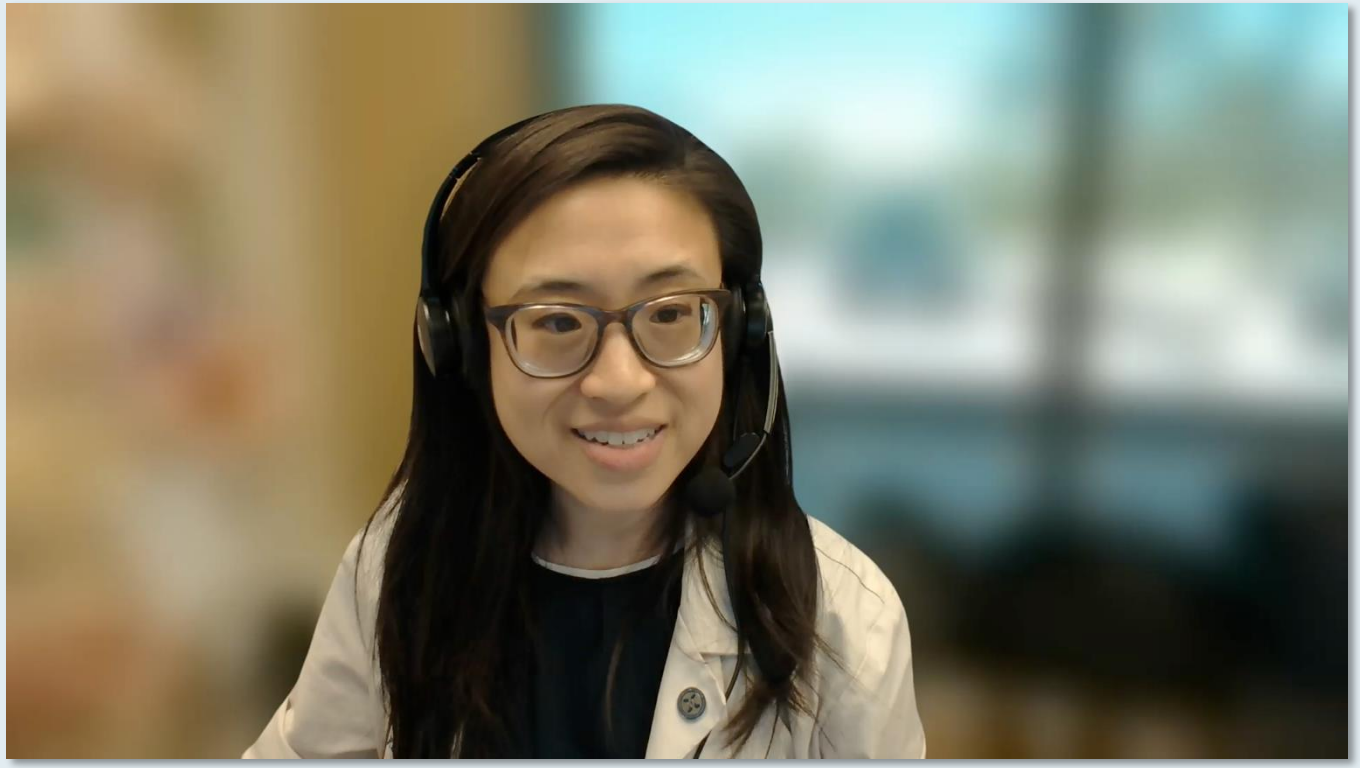
Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

RTP RESEARCH TO PRACTICE

Case Presentation: 59-year-old woman with recurrent ER-negative, HER2-low mBC and PD on sacituzumab govitecan receives trastuzumab deruxtecan



Dr Kimberly Ku (Bloomington, Illinois)

RTP RESEARCH TO PRACTICE

Agenda

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Case 4: Dr Agrawal – 66-year-old woman

Case 5: Dr Ku – 59-year-old woman

Case 6: Dr Teplinsky – 63-year-old woman

Case Presentation: 63-year-old woman with ER-positive, HER2-low mBC with hyperglycemia and disease progression on capivasertib/fulvestrant receives trastuzumab deruxtecan

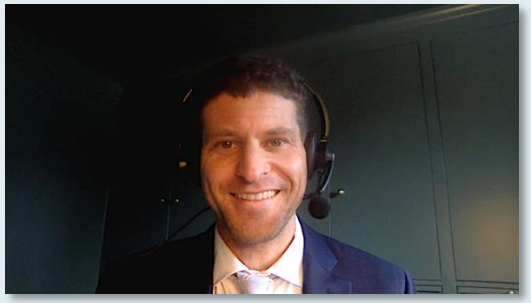
Dr Eleonora Teplinsky (Paramus, New Jersey)

RTP
RESEARCH
TO PRACTICE

Contributing General Medical Oncologists

Laila Agrawal, MD
Norton Cancer Institute
Louisville, Kentucky

Alan B Astrow, MD
Weill Cornell Medicine
Brooklyn, New York



Eric Fox, DO
Bryn Mawr Medical Specialists Association
Bryn Mawr, Pennsylvania

Kimberly Ku, MD
Illinois Cancer Care
Bloomington, Illinois

Eleonora Teplinsky, MD
Valley-Mount Sinai
Comprehensive Cancer Care
Paramus, New Jersey

Lai (Amber) Xu, MD, PhD
Northwest Oncology
and Hematology
Rolling Meadows, Illinois

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TO PRACTICE

Data + Perspectives: Clinical Investigators Explore the Application of Recent Datasets in Current Oncology Care

A Multitumor Symposium in Partnership with Florida Cancer Specialists & Research Institute

Saturday, October 11, 2025
7:15 AM – 12:30 PM ET

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

Faculty

Emmanuel S Antonarakis, MD
Harold J Burstein, MD, PhD
Matthew P Goetz, MD
Christopher Lieu, MD
Matthew Lunning, DO
Heather McArthur, MD, MPH, FASCO
Rita Nanda, MD
Matthew R Smith, MD, PhD
Sonali M Smith, MD
John Strickler, MD

Moderator

Neil Love, MD

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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