Meet The Professor

Optimizing the Management of HER2-Positive Breast Cancer

Tuesday, November 8, 2022
5:00 PM – 6:00 PM ET

Faculty

Lisa A Carey, MD, ScM

Moderator

Neil Love, MD

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Daiichi Sankyo Inc, and Seagen Inc.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc and Zymeworks Inc.

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Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Dr Carey — Disclosures

No relevant conflicts of interest to disclose.

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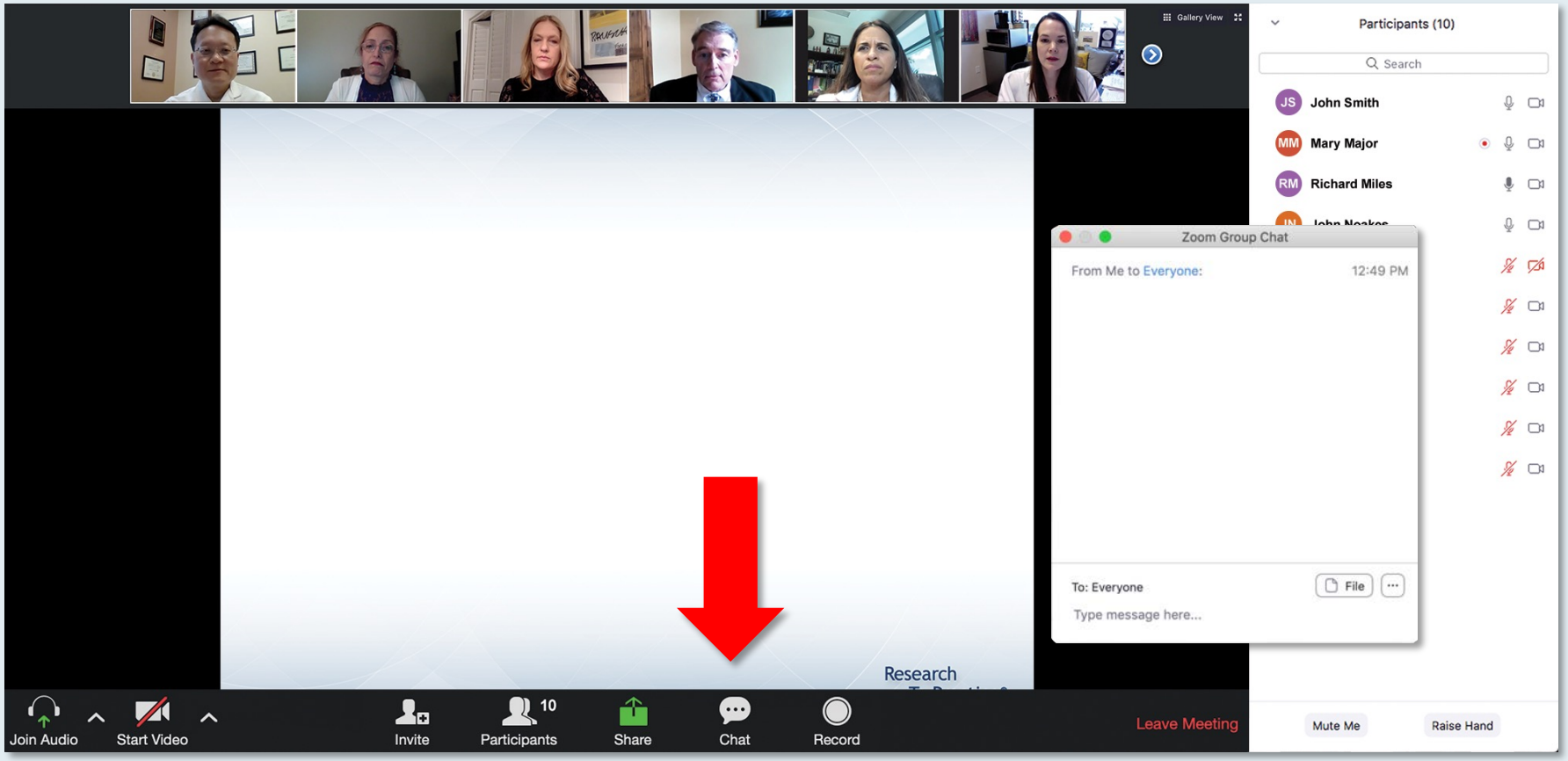
We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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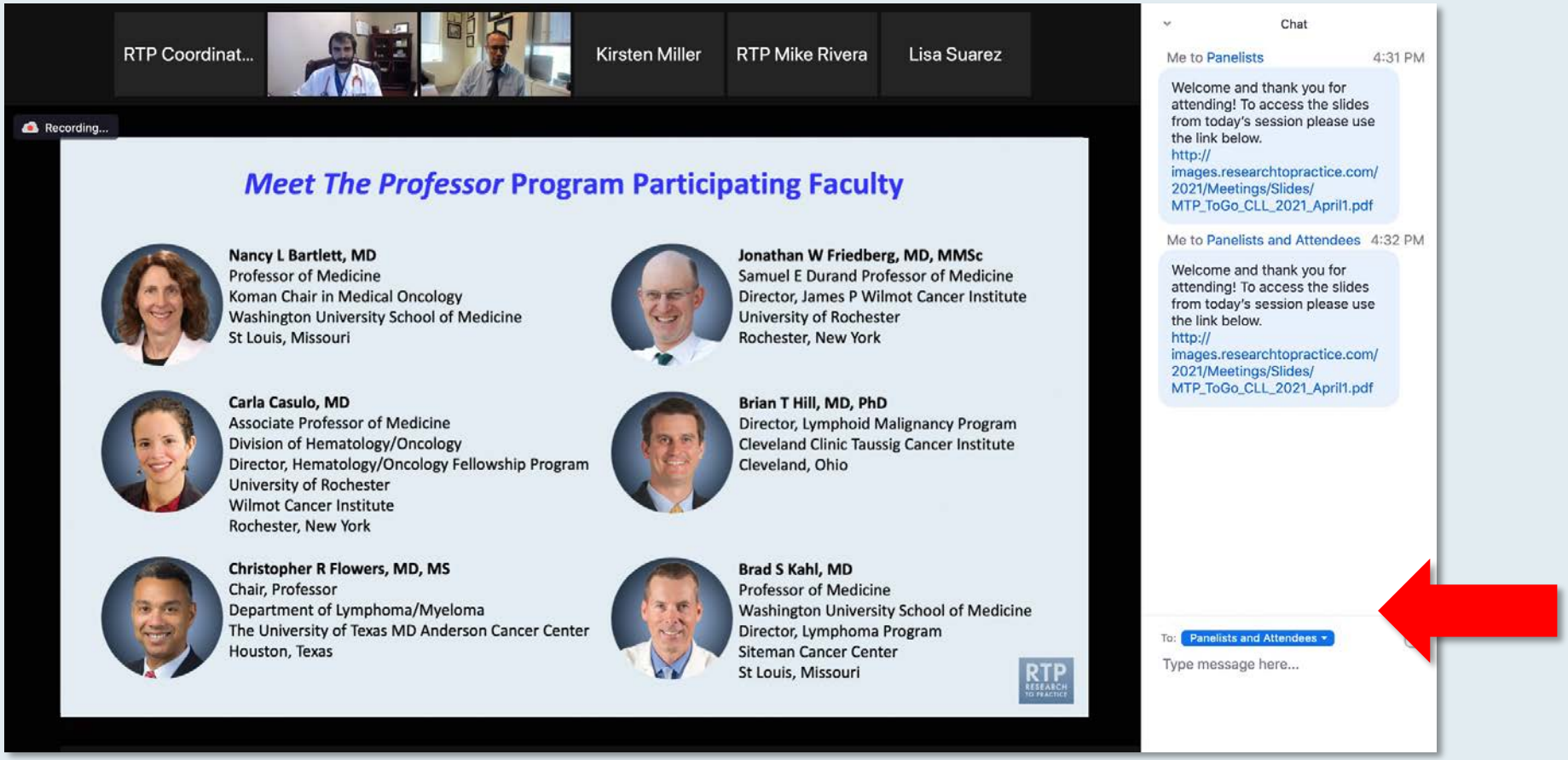
Familiarizing Yourself with the Zoom Interface

Expand chat submission box

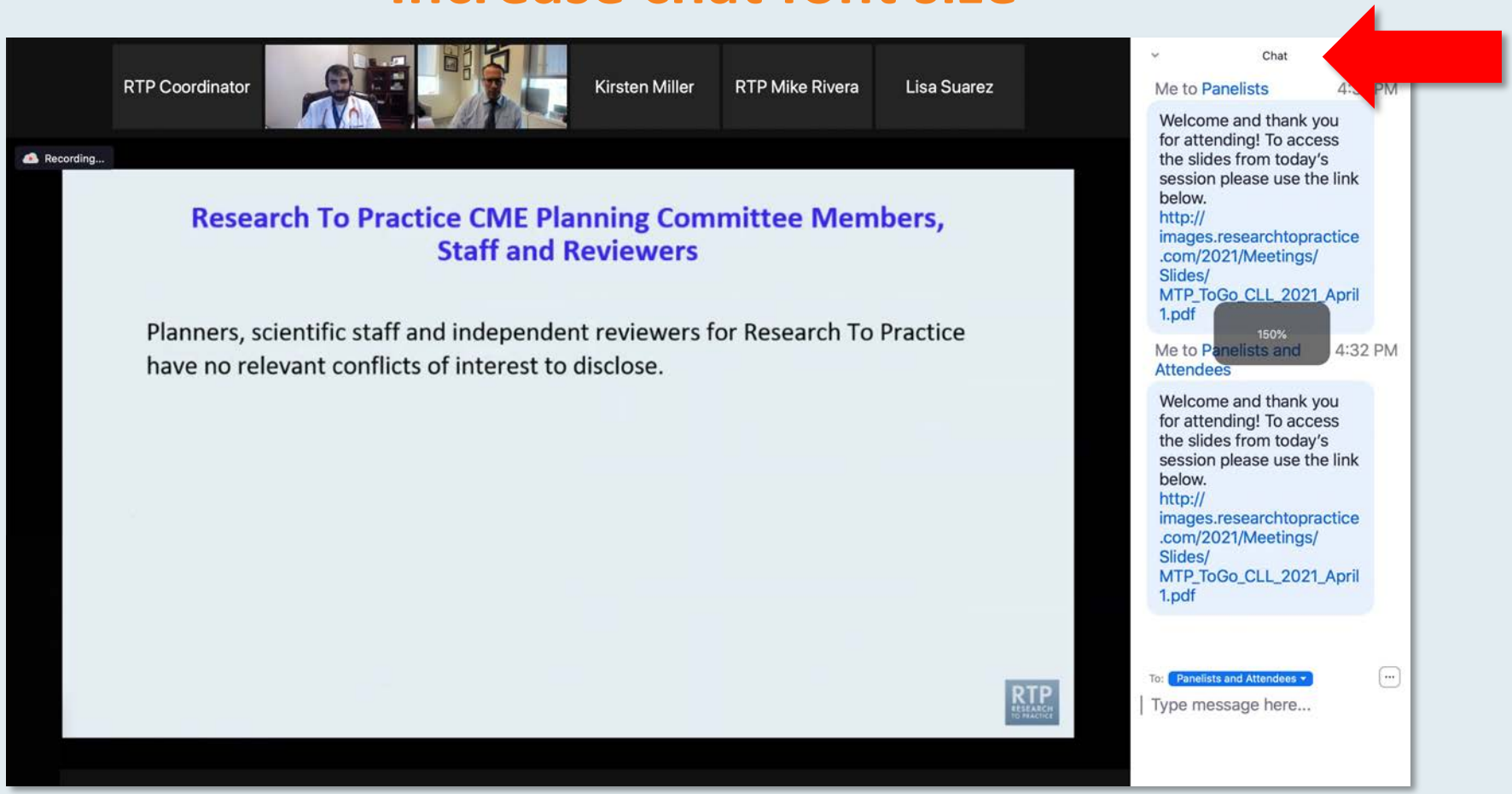


Drag the white line above the submission box up to create more space for your message.

RTP RESEARCH TO PRACTICE

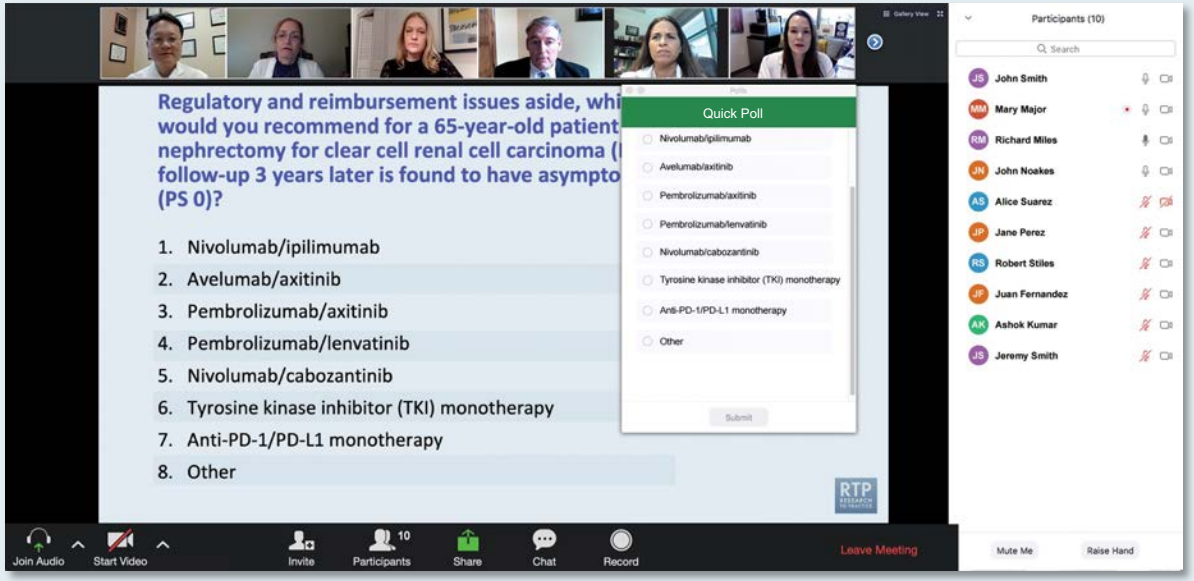
Familiarizing Yourself with the Zoom Interface

Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys



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ONCOLOGY TODAY

WITH DR NEIL LOVE

Management of HER2-Low Breast Cancer

DR SHANU MODI
MEMORIAL SLOAN KETTERING CANCER CENTER

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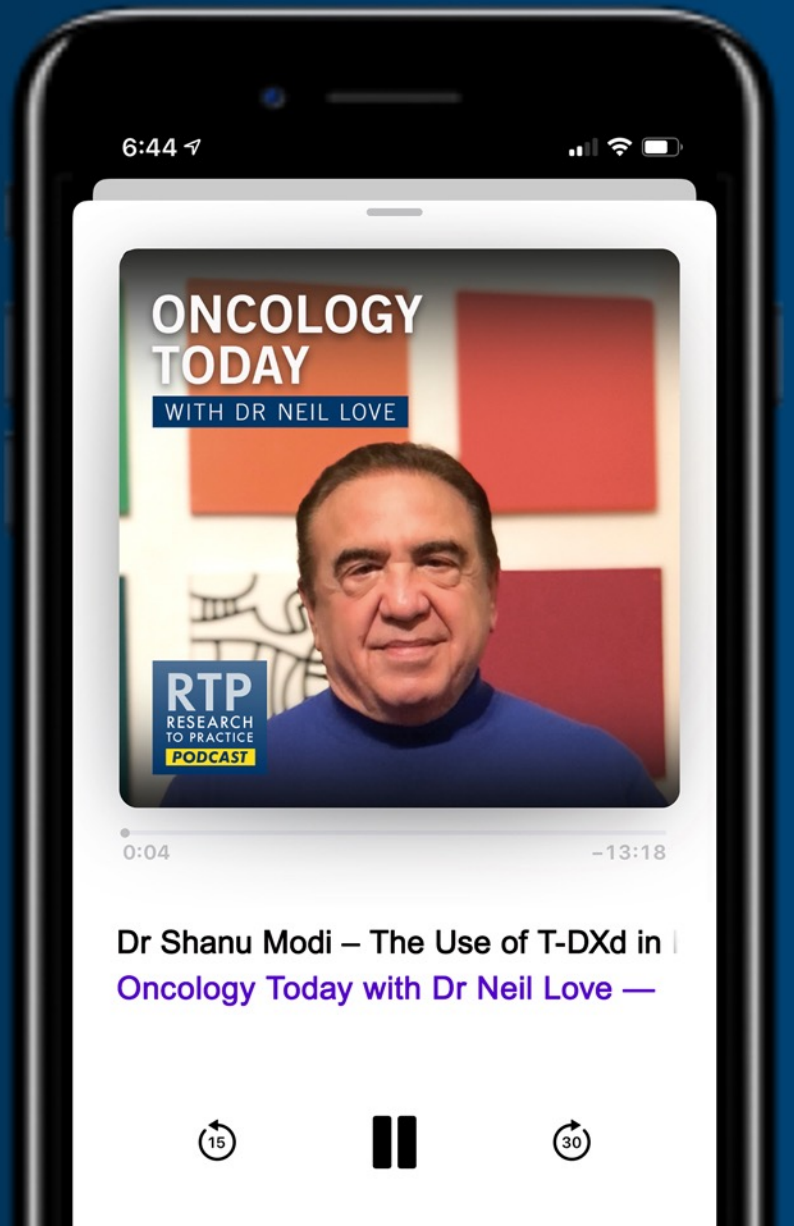
Listen on Google Podcasts



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Wednesday, November 9, 2022
5:00 PM – 6:00 PM ET

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Stéphane Oudard, MD, PhD

Moderator

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Meet The Professor
Optimizing the Management of Multiple Myeloma

Tuesday, November 15, 2022
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Oncology Today with Dr Neil Love — Novel Agents and Strategies in Acute Myeloid Leukemia

A CME/MOC-Accredited Virtual Event

Thursday, November 17, 2022
5:00 PM – 6:00 PM ET

Faculty

Daniel A Pollyea, MD, MS

Moderator

Neil Love, MD

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of HER2-Positive Breast Cancer

Part 1 of a 2-Part CME Satellite Symposium Series Held in Conjunction with the 2022 San Antonio Breast Cancer Symposium®

Wednesday, December 7, 2022

7:15 PM – 9:15 PM CT (8:15 PM – 10:15 PM ET)

Faculty

Erika Hamilton, MD

Sara A Hurvitz, MD

Ian E Krop, MD, PhD

Shanu Modi, MD

Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of ER-Positive Breast Cancer

Part 2 of a 2-Part CME Satellite Symposium Series Held in Conjunction with the 2022 San Antonio Breast Cancer Symposium®

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Faculty

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Matthew P Goetz, MD

Virginia Kaklamani, MD, DSc

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RTP RESEARCH TO PRACTICE

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Rafael Fonseca, MD
Sagar Lonial, MD
Robert Z Orlowski, MD, PhD
Noopur Raje, MD

Moderator

Neil Love, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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Meet The Professor
Optimizing the Management of HER2-Positive Breast Cancer

Lisa A Carey, MD, ScM
L Richardson and Marilyn Jacobs Preyer
Distinguished Professor for Breast Cancer Research
Deputy Director for Clinical Sciences
Lineberger Comprehensive Cancer Center
University of North Carolina
Chapel Hill, North Carolina

Meet The Professor Program Participating Faculty

Adam M Brufsky, MD, PhD
Professor of Medicine
Co-Director, Comprehensive Breast Cancer Center
UPMC Hillman Cancer Center
Department of Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania

Professor Giuseppe Curigliano, MD, PhD
Clinical Director
Division of Early Drug Development for Innovative Therapy
Co-Chair, Cancer Experimental Therapeutics Program
Department of Oncology and Hemato-Oncology
University of Milano
European Institute of Oncology
Milano, Italy

Lisa A Carey, MD, ScM
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Deputy Director for Clinical Sciences
Lineberger Comprehensive Cancer Center
University of North Carolina
Chapel Hill, North Carolina

Nancy U Lin, MD
Associate Chief, Division of Breast Oncology
Dana-Farber Cancer Institute
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

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Meet The Professor Program Participating Faculty

Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast Cancer Research
Baylor University Medical Center
Director, Breast Cancer Research Program
Texas Oncology
US Oncology
Dallas, Texas

MODERATOR
Neil Love, MD
Research To Practice

Mark D Pegram, MD
Susy Yuan-Huey Hung Endowed Professor
of Oncology
Director, Clinical and Translational Research Unit
Associate Dean for Clinical Research Quality
Stanford University School of Medicine
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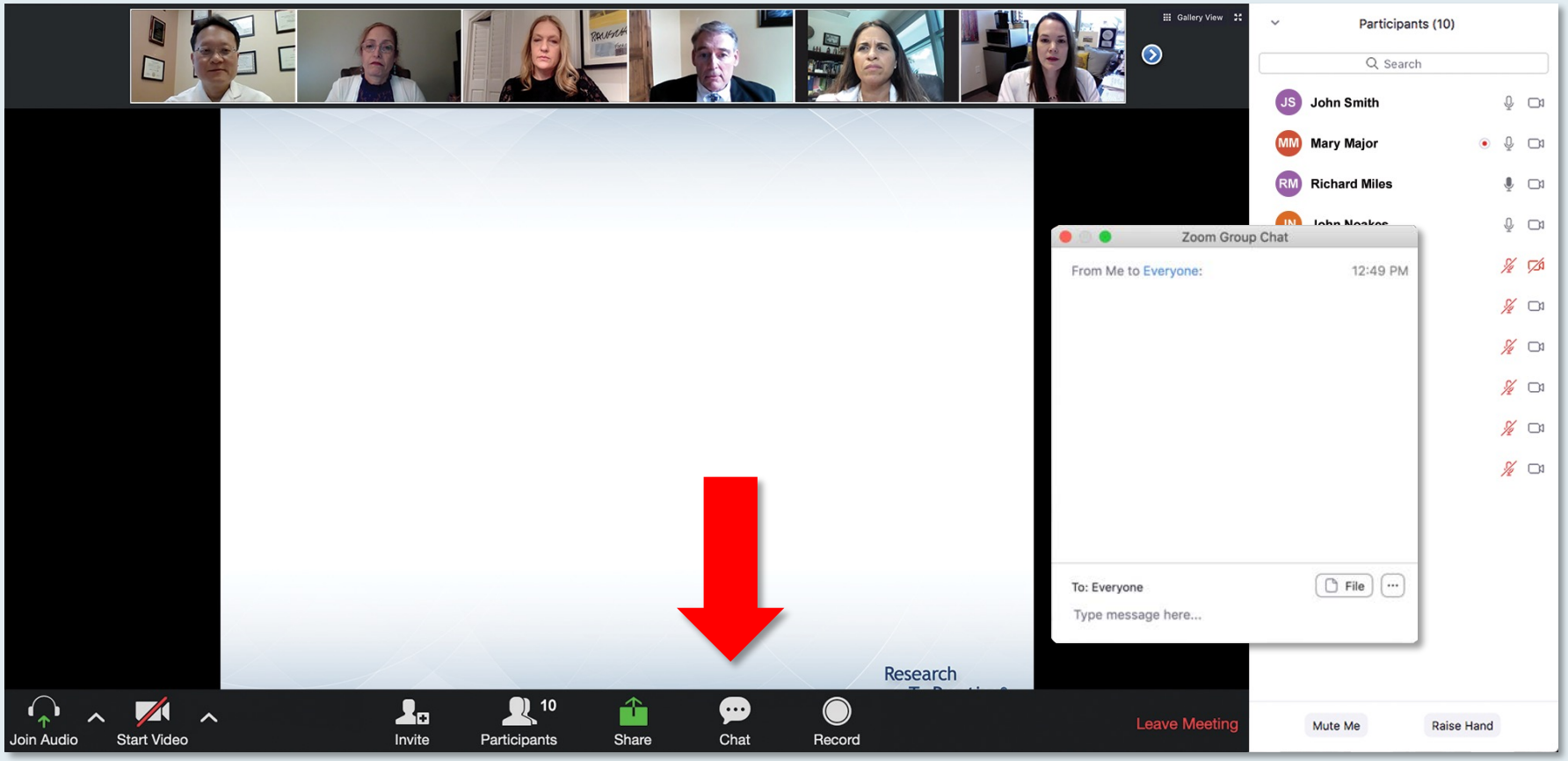

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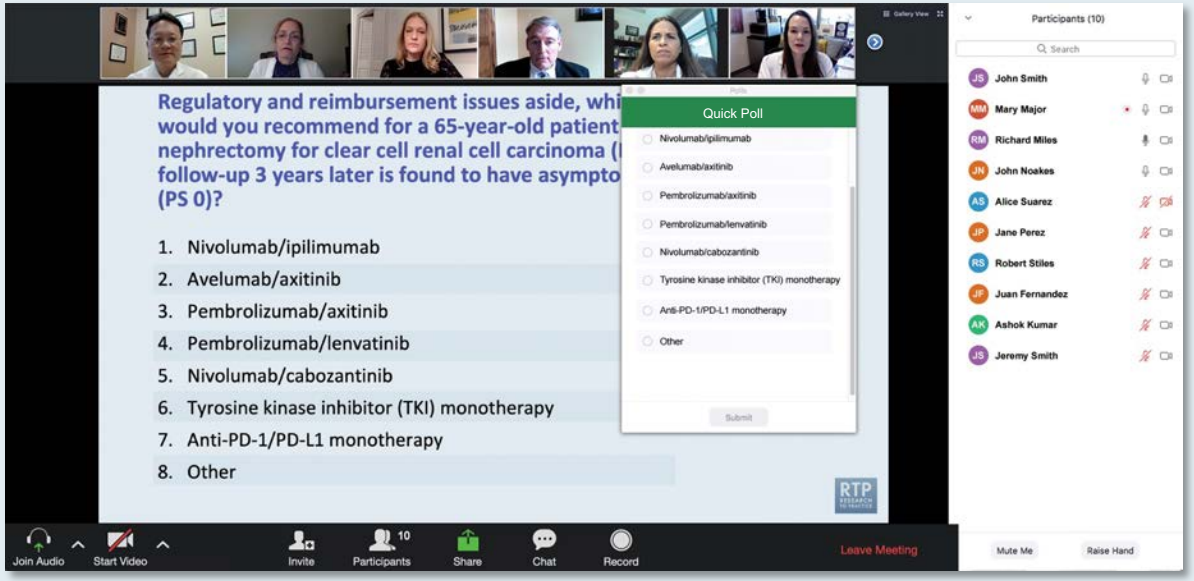

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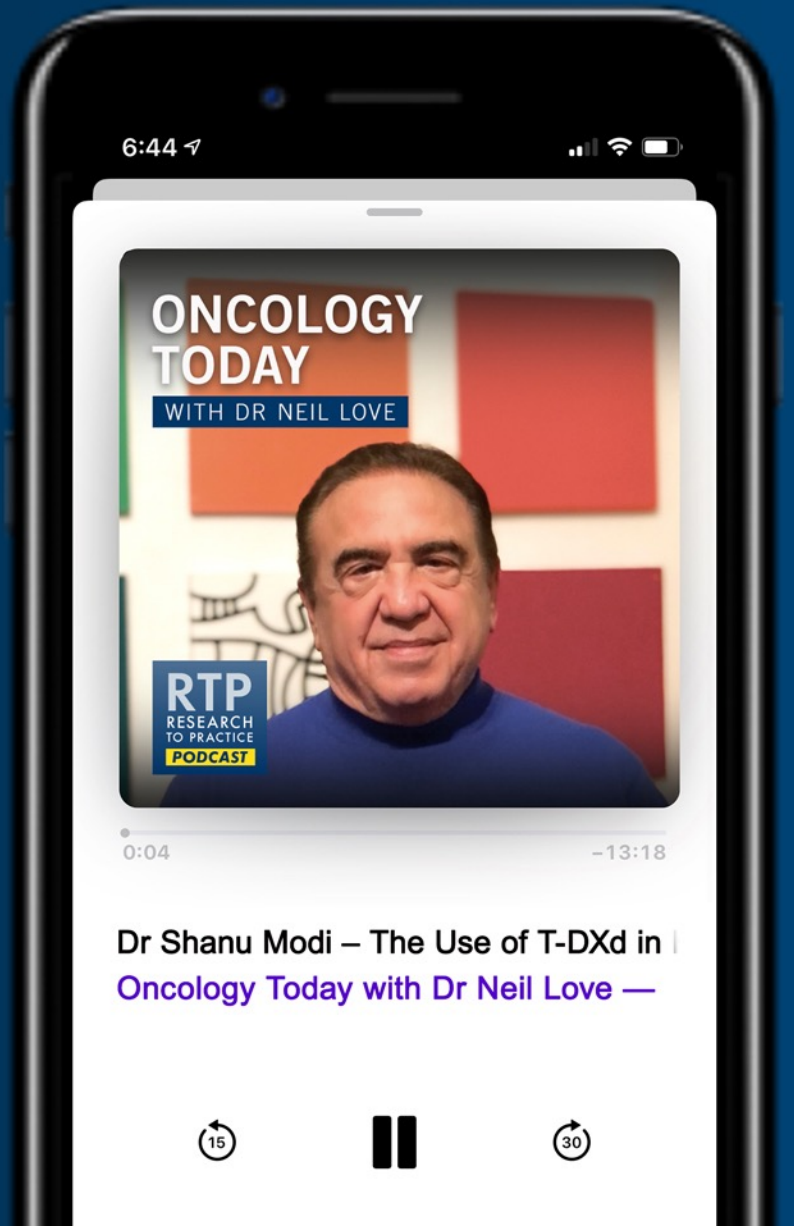

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SABCS SAN ANTONIO BREAST CANCER SYMPOSIUM® MEETING NEWS

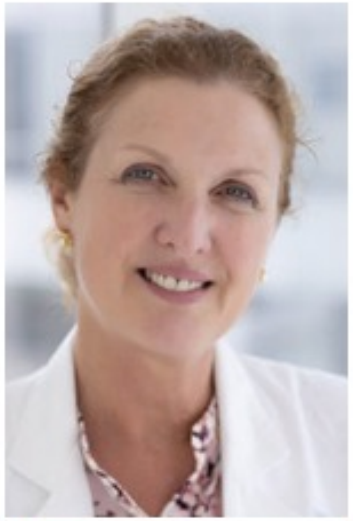
Clinical Controversies: Experts debate topics in breast cancer treatment, research

November 7, 2022

Expert, and sometimes conflicting, opinions in breast cancer treatment are nothing new. But SABCS 2022 features a new way to present those opinions in two special *Controversies* sessions featuring "lightning discussions" between experts in the field on three different topics.

The first of these two special sessions, ***Clinical Controversies***, will be held on Wednesday, December 7 at 2:00 pm CT, in Hall 3 of the convention center. There will be two expert discussants for each of three topics; the moderator is Lisa Carey, MD, ScM, FASCO, Deputy Director of Clinical Sciences, UNC Lineberger Comprehensive Cancer Center.

"These experts are people who are extremely knowledgeable in areas of clinical debate and may have differing perspectives," Dr. Carey said. "They can frame the relevant issues and why there is controversy. They will also give their personal opinions of the strength of the existing data and how they approach these issues in their practices."



Lisa Carey, MD, ScM, FASCO

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Dr Carey — Disclosures

No relevant conflicts of interest to disclose.

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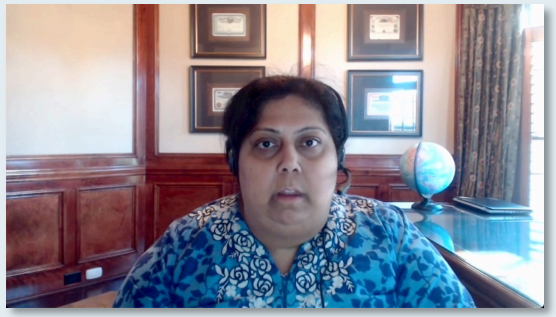
Laila Agrawal, MD
Norton Cancer Institute
Louisville, Kentucky

Zanetta S Lamar, MD
Florida Cancer Specialists
Naples, Florida

Mamta Choksi, MD
Florida Cancer Specialists
New Port Richey, Florida



Niyati A Nathwani, MD
Carolina Blood and Cancer Care Associates
Charlotte, North Carolina

Rahul Gosain, MD
Guthrie Corning Cancer Center
Corning, New York

Namrata I Peswani, MD
UT Southwestern Medical Center
Harold C Simmons Comprehensive Cancer Center
Richardson, Texas

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Meet The Professor with Dr Carey

Introduction: Journal Club with Dr Carey

MODULE 1: Case Presentations

MODULE 2: Faculty Survey

MODULE 3: Ongoing Trials; Reported Data; Review Articles

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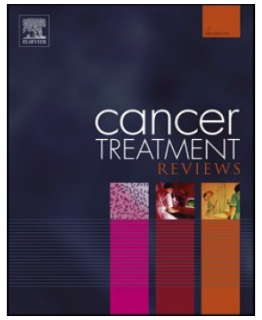
Cancer Treatment Reviews 103 (2022) 102324

Contents lists available at ScienceDirect

Cancer Treatment Reviews

journal homepage: www.elsevier.com/locate/ctrv

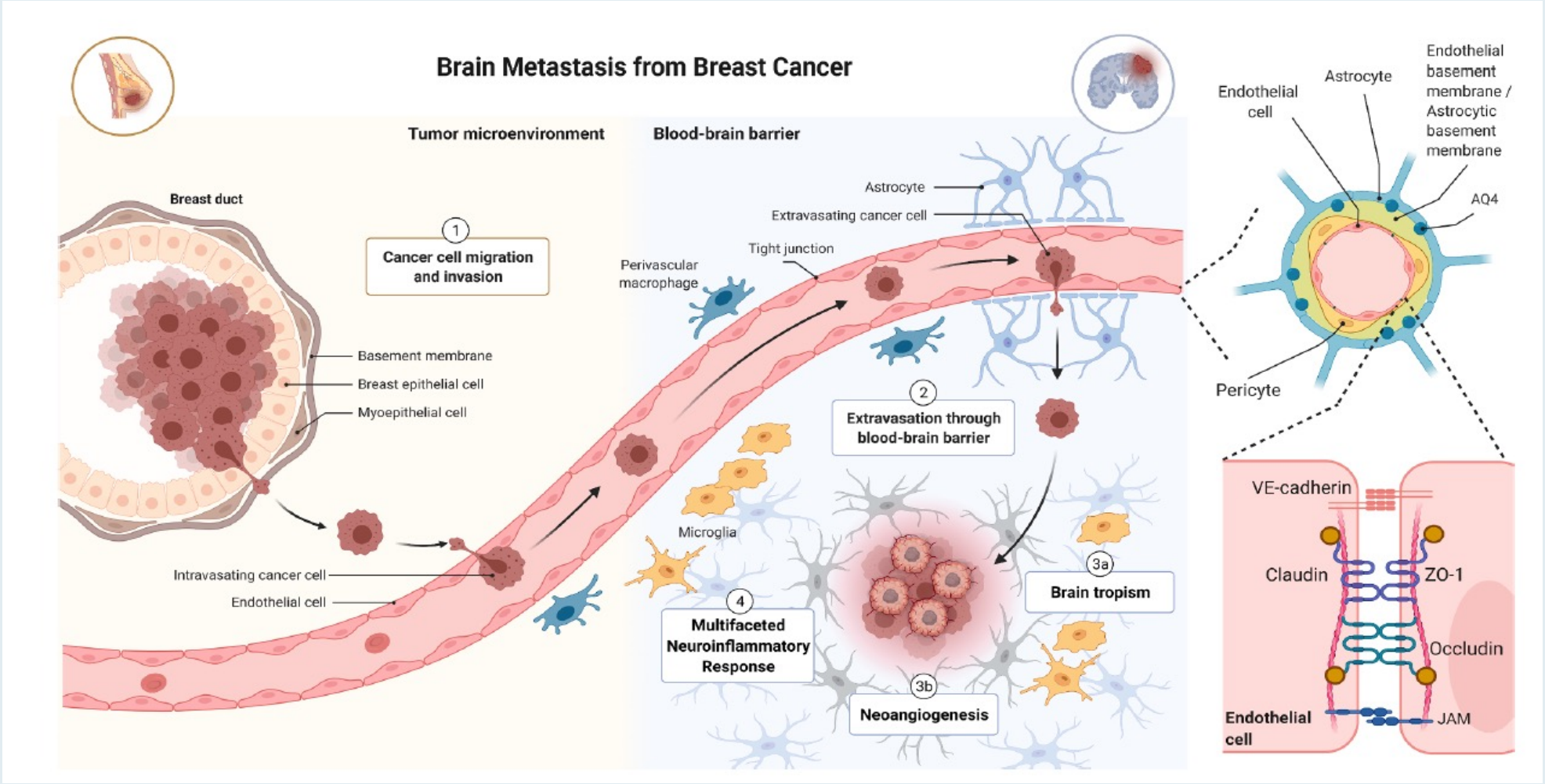


Anti-tumour Treatment

Targeting brain metastases in breast cancer

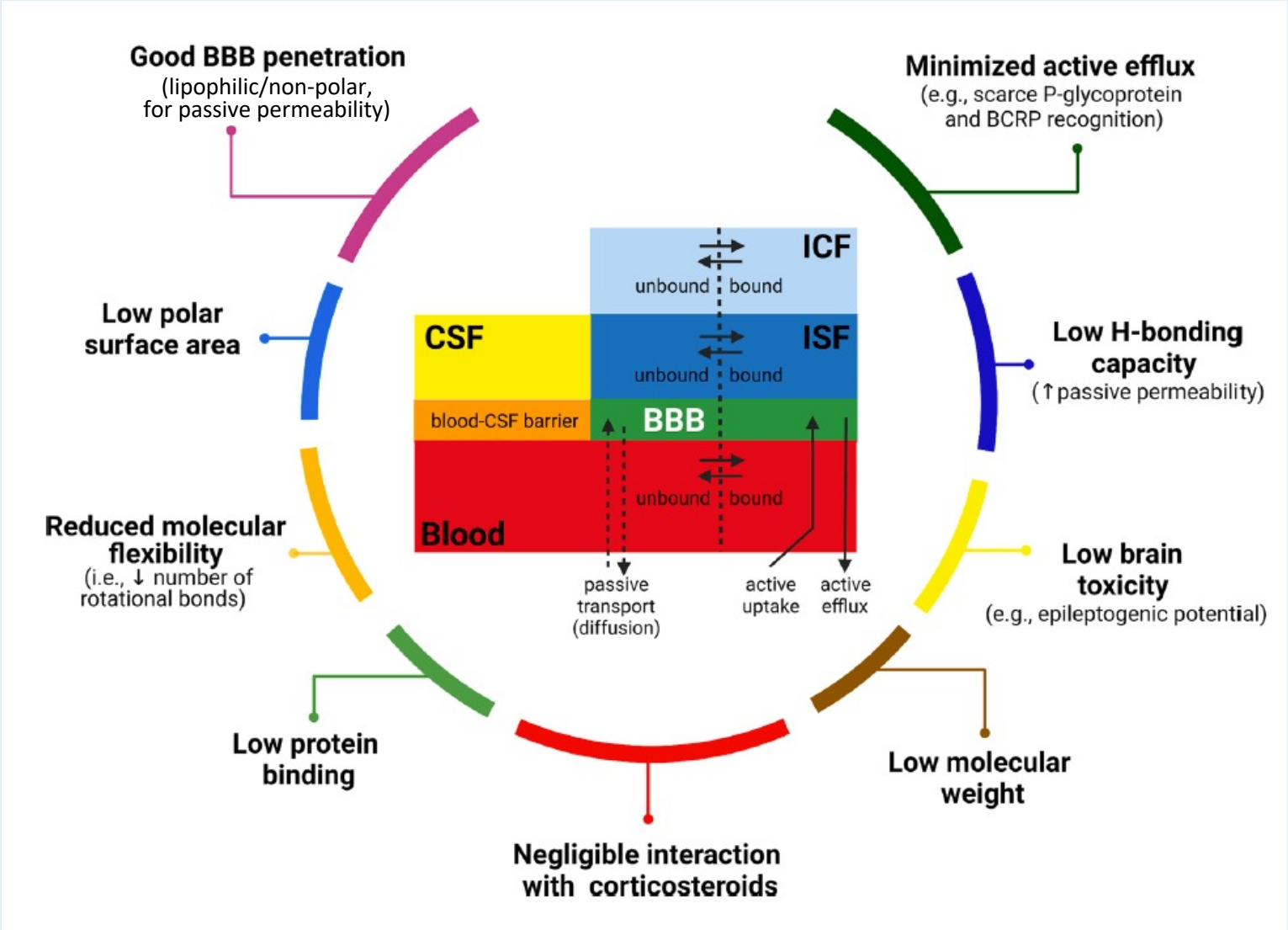
Chiara Corti [a,b,*], Gabriele Antonarelli [a,b], Carmen Criscitiello [a,b], Nancy U. Lin [c], Lisa A. Carey [d], Javier Cortés [e,f,g,h,i], Philip Poortmans [j], Giuseppe Curigliano [a,b]

Hypothesized Mechanism of Spread to the Central Nervous System by Breast Cancer Cells



Corti C et al. *Cancer Treat Rev* 2022;103:102324.

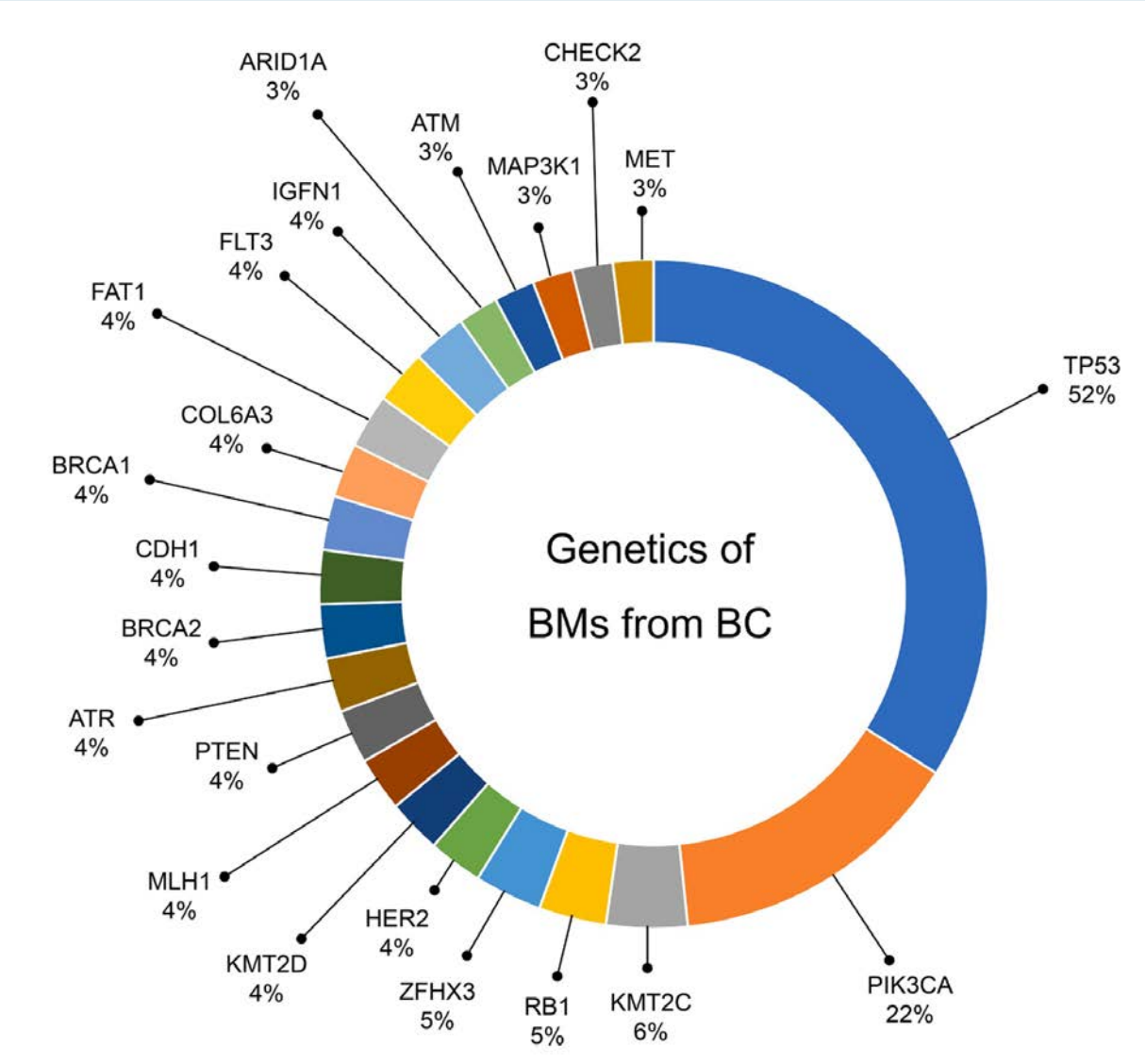
Optimal Drug Design for Targeting Brain Metastases



BBB = blood-brain barrier; ICF = intracellular fluid; CSF = cerebrospinal fluid; ISF = interstitial fluid

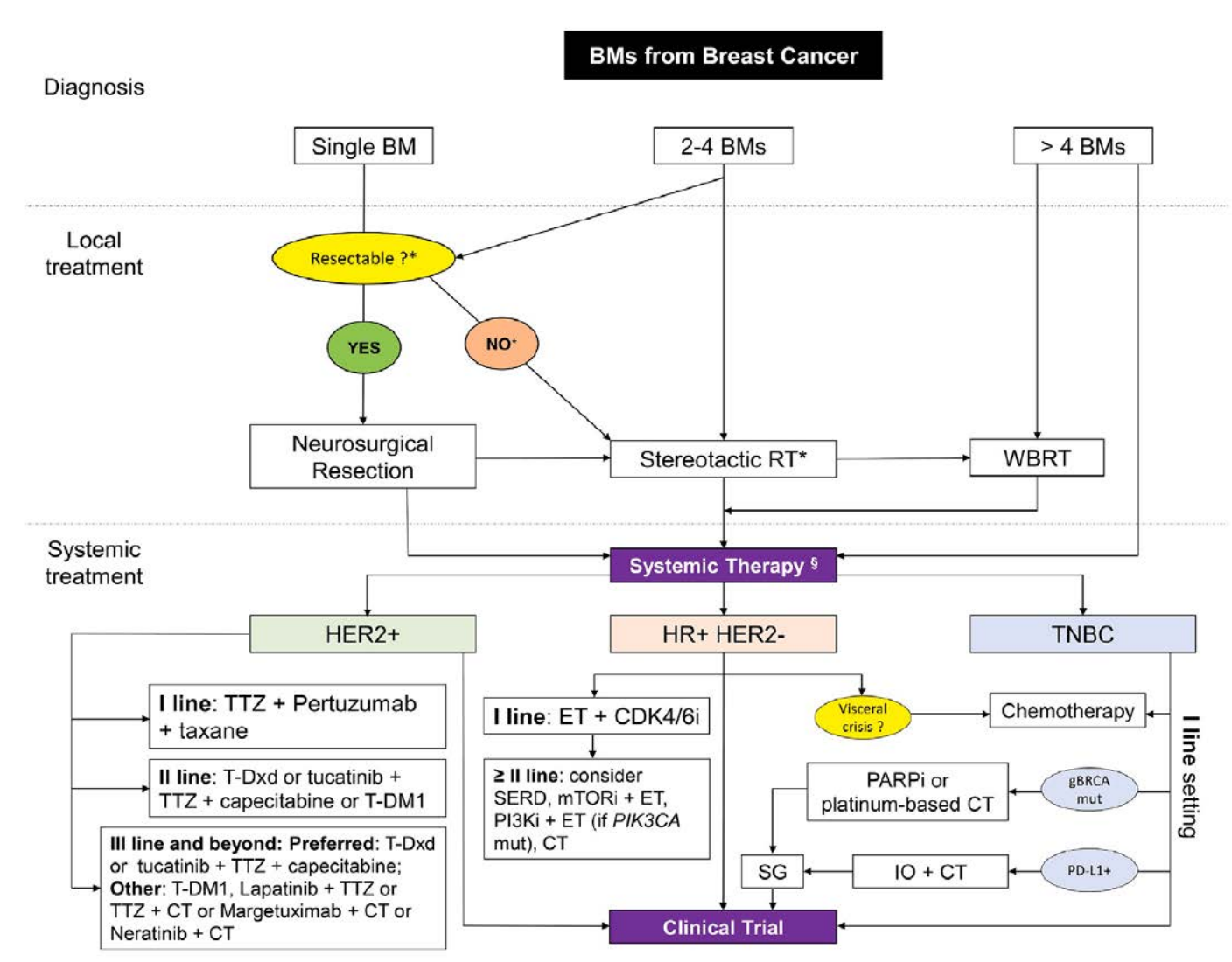
Corti C et al. *Cancer Treat Rev* 2022;103:102324.

Commonly Mutated Genes in Brain Metastases from Breast Cancer



Corti C et al. *Cancer Treat Rev* 2022;103:102324.

Treatment Algorithm for Patients with Brain Metastases (BMs) from Breast Cancer



WBRT = whole-brain radiation therapy; TTZ = trastuzumab

Corti C et al. *Cancer Treat Rev* 2022;103:102324.

NPJ Breast Cancer 2022 September 8;8(1):103.

www.nature.com/npjbcancer

npj | breast cancer

ARTICLE OPEN

A biomarker of aging, p16, predicts peripheral neuropathy in women receiving adjuvant taxanes for breast cancer

Natalia Mitin[1], Kirsten A. Nyrop[2,3], Susan L. Strum[1], Anne Knecht[1], Lisa A. Carey[2,3], Katherine E. Reeder-Hayes[2,3], E. Claire Dees[2,3], Trevor A. Jolly[2,3], Gretchen G. Kimmick[4], Meghan S. Karuturi[5], Raquel E. Reinbolt[6], JoEllen C. Speca[2,3], Erin A. O'Hare[2,3] and Hyman B. Muss[2,3]✉

ORIGINAL ARTICLE

Cancer 2022 October 12;[Online ahead of print].

Burden of lymphedema in long-term breast cancer survivors by race and age

Yumeng Ren ScM[1] | Michael A. Kebede MPH[1] | Adeyemi A. Ogunleye MD[2] | Marc A. Emerson PhD[1] | Kelly R. Evenson PhD[1] | Lisa A. Carey MD[3] | Sandra C. Hayes PhD[4] | Melissa A. Troester PhD[1]

Meet The Professor with Dr Carey

MODULE 1: Case Presentations

- Dr Lamar: 78-year-old woman presents with triple-positive breast cancer and a suspicious mass in the liver
- Dr Nathwani: 44-year-old woman with ER/PR-negative, HER2-positive metastatic breast cancer with CR to THP develops multiple brain metastases 3 months later
- Dr Gosain: 36-year-old woman with triple-positive breast cancer develops brain metastases 5 years after primary neoadjuvant treatment
- Dr Agrawal: 45-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic breast cancer experiences PD after abemaciclib/OFS and an AI
- Dr Choksi: 62-year-old woman with ER/PR-positive, HER2-negative localized breast cancer develops triple-positive metastatic breast cancer
- Dr Peswani: 50-year-old woman with 1.2-cm triple-positive breast cancer underwent mastectomy (surgical specimen HER2-negative) and adjuvant TH. Now presents with HER2-negative localized recurrence

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Case Presentation: 78-year-old woman presents with triple-positive breast cancer and a suspicious mass in the liver

Dr Zanetta Lamar (Naples, Florida)

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Case Presentation: 44-year-old woman with ER/PR-negative, HER2-positive metastatic breast cancer with CR to THP develops multiple brain metastases 3 months later

Dr Niyati Nathwani (Charlotte, North Carolina)

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Case Presentation: 36-year-old woman with triple-positive breast cancer develops brain metastases 5 years after primary neoadjuvant treatment

Dr Rahul Gosain (Corning, New York)

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Case Presentation: 45-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic breast cancer experiences PD after abemaciclib/OFS and an AI

Dr Laila Agrawal (Louisville, Kentucky)

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Case Presentation: 45-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic breast cancer experiences PD after abemaciclib/OFS and an AI (continued)

Dr Laila Agrawal (Louisville, Kentucky)

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Case Presentation: 62-year-old woman with ER/PR-positive, HER2-negative localized breast cancer develops triple-positive metastatic breast cancer

Dr Mamta Choksi (New Port Richey, Florida)

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Case Presentation: 50-year-old woman with 1.2-cm triple-positive breast cancer underwent mastectomy (surgical specimen HER2-negative) and adjuvant TH. Now presents with HER2-negative local recurrence

Dr Namrata Peswani (Richardson, Texas)

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A 65-year-old woman with an ER-negative, HER2-positive IDC experiences asymptomatic recurrence in the liver and multiple brain metastases 12 months after completing neoadjuvant TCHP followed by adjuvant T-DM1. Would you use radiation therapy (RT)? Regulatory and reimbursement issues aside, which systemic treatment would you recommend?

 Dr Brufsky	Yes, RT followed by tucatinib + trastuzumab/ capecitabine	 Dr Lin	Yes, RT followed by paclitaxel/HP
 Dr Carey	No, defer RT and administer tucatinib + trastuzumab/ capecitabine	 Dr O'Shaughnessy	Yes, RT followed by T-DXd
 Prof Curigliano	No, defer RT and administer T-DXd	 Dr Pegram	Yes, RT followed by tucatinib + trastuzumab/ capecitabine

T-DXd = trastuzumab deruxtecan

A 65-year-old woman with an ER-negative, HER2-positive IDC experiences asymptomatic recurrence in the liver and 3 small brain metastases that are amenable to stereotactic radiation therapy 12 months after completing neoadjuvant TCHP followed by adjuvant T-DM1. Would you use SBRT? Regulatory and reimbursement issues aside, which systemic treatment would you recommend?

 Dr Brufsky	Yes, SBRT followed by tucatinib + trastuzumab/ capecitabine	 Dr Lin	No, defer SBRT and administer paclitaxel/HP
 Dr Carey	Yes, SBRT followed by THP	 Dr O'Shaughnessy	Yes, RT followed by T-DXd
 Prof Curigliano	No, defer SBRT and administer T-DXd	 Dr Pegram	Yes, SBRT followed by T-DXd or tucatinib-based tx

SBRT = stereotactic body radiation therapy

RTP RESEARCH TO PRACTICE

A woman who has completed 5 years of an adjuvant aromatase inhibitor for ER-positive, HER2 IHC 2+, FISH-negative breast cancer develops asymptomatic, low-volume, nonvisceral metastases 3 years later. Regulatory and reimbursement issues aside, when would you most likely offer trastuzumab deruxtecan?

RTP RESEARCH TO PRACTICE

A woman undergoes neoadjuvant chemotherapy and surgery for BRCA wild-type, ER-negative, HER2 IHC 2+, FISH-negative breast cancer and develops asymptomatic, low-volume, nonvisceral metastases while receiving adjuvant capecitabine. Regulatory and reimbursement issues aside, when would you most likely offer trastuzumab deruxtecan?

 Dr Brufsky	As third-line therapy	 Dr Lin	As second-line therapy
 Dr Carey	As second-line therapy	 Dr O'Shaughnessy	As third-line therapy
 Prof Curigliano	As second-line therapy	 Dr Pegram	As first-line if PD-L1(-), second-line if PD-L1(+)

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, would you offer trastuzumab deruxtecan to a patient with HER2 IHC 0 metastatic breast cancer (mBC) with a HER2 mutation?

 Dr Brufsky	No	 Dr Lin	Yes
 Dr Carey	Yes	 Dr O'Shaughnessy	Yes
 Prof Curigliano	Yes	 Dr Pegram	No

RTP RESEARCH TO PRACTICE

A 65-year-old woman presents with a 3.4-cm ER-positive, HER2-positive IDC with biopsy-proven positive axillary nodes, receives neoadjuvant TCHP and at surgery is found to have 1.2 cm of residual tumor in the breast and 2 positive nodes. Regulatory and reimbursement issues aside, which adjuvant anti-HER2 therapy would you recommend?

 Dr Brufsky	T-DM1 → neratinib	 Dr Lin	T-DM1
 Dr Carey	T-DM1	 Dr O'Shaughnessy	T-DM1 → neratinib
 Prof Curigliano	T-DM1 alone or followed by neratinib	 Dr Pegram	T-DM1 → neratinib

RTP RESEARCH TO PRACTICE

A patient presenting with localized HER2-positive (IHC 3+) breast cancer presents with metastatic disease after prior neoadjuvant and postoperative adjuvant treatment. Would a liquid biopsy finding of HER2 0 change your approach to treatment?

 Dr Brufsky	No, I would continue to use anti-HER2 therapy as before	 Dr Lin	No, I would continue to use anti-HER2 therapy as before
 Dr Carey	No, I would confirm result with tissue biopsy before changing therapy	 Dr O'Shaughnessy	No, I would confirm result with tissue biopsy before changing therapy
 Prof Curigliano	No, I would continue to use anti-HER2 therapy as before	 Dr Pegram	No, I would continue to use anti-HER2 therapy as before

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Carey

Introduction: Journal Club with Dr Carey

MODULE 1: Case Presentations

MODULE 2: Faculty Survey

MODULE 3: Ongoing Trials; Reported Data; Review Articles

RTP
RESEARCH
TO PRACTICE

ASCO special articles

Systemic Therapy for Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: ASCO Guideline Update

Sharon H. Giordano, MD, MPH[1]; Maria Alice B. Franzoi, MD[2]; Sarah Temin, MSPH[3]; Carey K. Anders, MD[4]; Sarat Chandarlapaty, MD, PhD[5]; Jennie R. Crews, MD[6]; Jeffrey J. Kirshner, MD[7]; Ian E. Krop, MD, PhD[8]; Nancy U. Lin, MD[8]; Aki Morikawa, MD, PhD[9]; Debra A. Patt, MD, MPH, MBA[10]; Jane Perlmutter, PhD[11]; Naren Ramakrishna, MD, PhD[12]; and Nancy E. Davidson, MD[13]

J Clin Oncol 2022 August;40:2612-35.

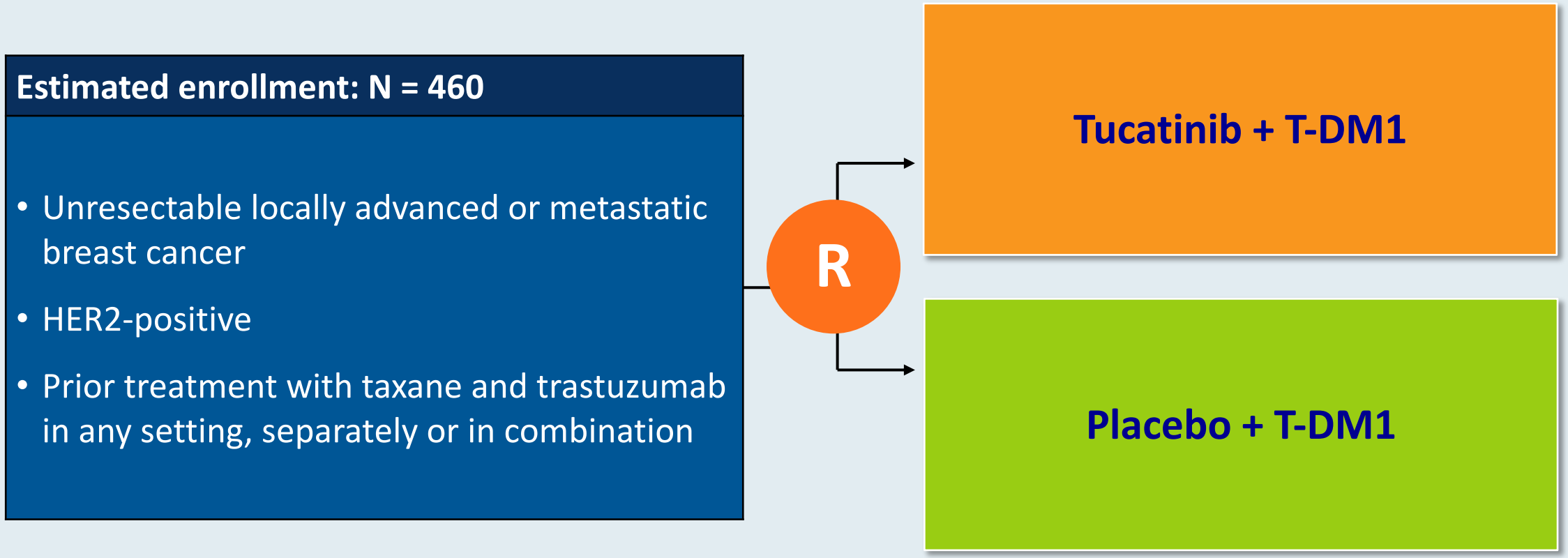
RTP RESEARCH TO PRACTICE

Updated Results of Tucatinib vs Placebo Added to Trastuzumab and Capecitabine for Patients with Pretreated HER2+ Breast Cancer with and without Brain Metastases (HER2CLIMB)

Curigliano G et al.

ASCO 2022;Abstract 1043.

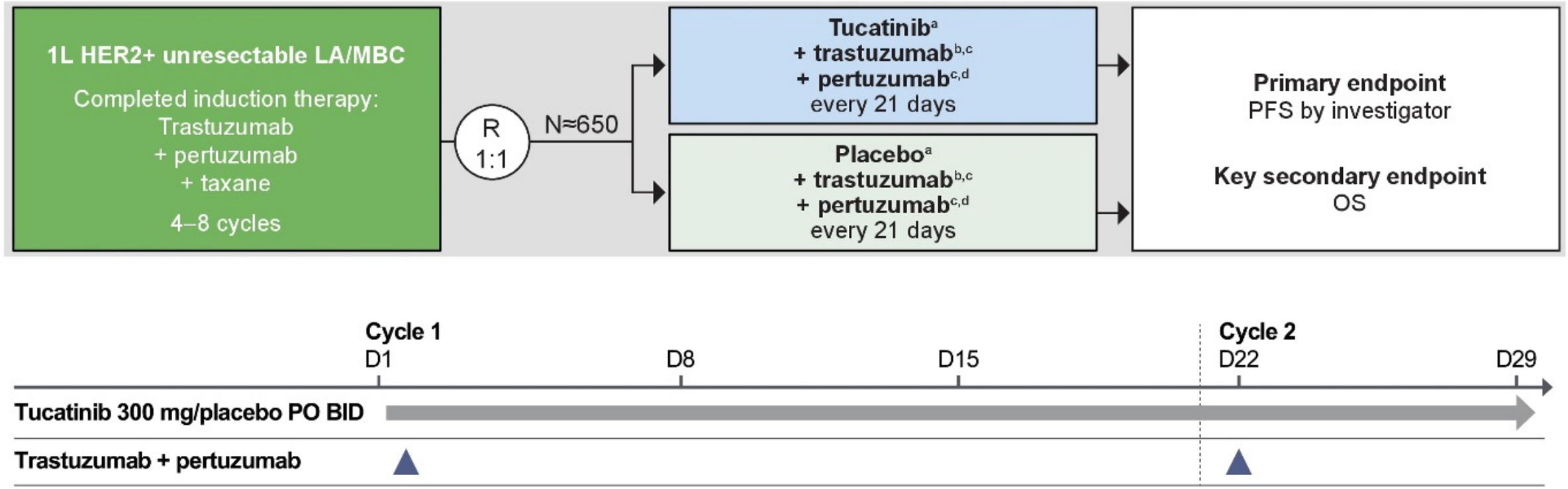
HER2CLIMB-02 Phase III Trial Design



Primary endpoint: PFS by investigator assessment

www.clinicaltrials.gov. NCT03975647. Accessed August 2022.

HER2CLIMB-05 Phase III Study Schema



Hamilton E et al. ASCO 2022;Abstract TPS1108.

ASCO special articles

Management of Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer and Brain Metastases: ASCO Guideline Update

Naren Ramakrishna, MD, PhD[1]; Carey K. Anders, MD[2]; Nancy U. Lin, MD[3]; Aki Morikawa, MD, PhD[4]; Sarah Temin, MSPH[5]; Sarat Chandarlapaty, MD, PhD[6]; Jennie R. Crews, MD[7]; Nancy E. Davidson, MD[8]; Maria Alice B. Franzoi, MD[9]; Jeffrey J. Kirshner, MD[10]; Ian E. Krop, MD, PhD[3]; Debra A. Patt, MD, MPH, MBA[11]; Jane Perlmutter, PhD[12]; and Sharon H. Giordano, MD, MPH[13]

J Clin Oncol 2022 August;40:2636-55.

RTP RESEARCH TO PRACTICE

Phase 2 Trial of Tucatinib plus Trastuzumab Deruxtecan in Patients with HER2+ Locally Advanced or Metastatic Breast Cancer with and without Brain Metastases (HER2CLIMB-04, Trial in Progress)

Krop I et al.

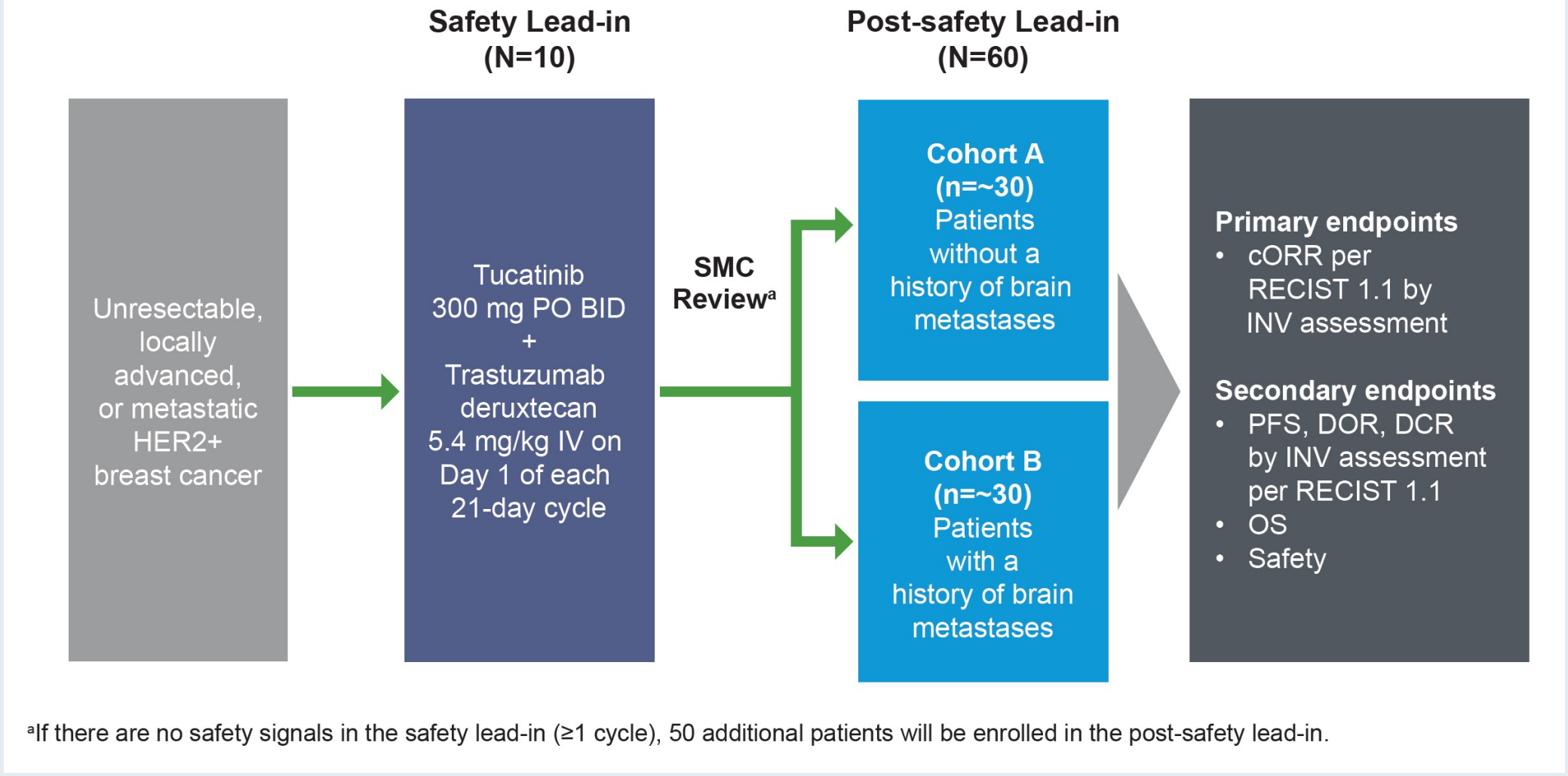
ASCO 2022;Abstract TPS1111.

HER2CLIMB-04: Phase II Trial of Tucatinib + Trastuzumab Deruxtecan in Patients with HER2+ Locally Advanced or Metastatic Breast Cancer with and without Brain Metastases

Carey L et al.

ESMO 2021;Abstract 331TiP.

HER2CLIMB-04 Study Design



[a]If there are no safety signals in the safety lead-in (≥1 cycle), 50 additional patients will be enrolled in the post-safety lead-in.

Carey L et al. ESMO 2021;Abstract 331TiP.

HER2CLIMB-04: CNS Eligibility Criteria

Key CNS Inclusion Criteria	Key CNS Exclusion Criteria
• Patients with a history of brain metastases must have 1 of the following: ◦ Untreated brain metastases not needing immediate local therapy ◦ Previously treated brain metastases • Brain metastases previously treated with local therapy may either be stable or may have progressed since prior local CNS therapy • Patients treated with CNS local therapy for newly identified or previously treated progressing lesions found on contrast brain MRI performed during screening for this study may be eligible to enroll if all the predefined criteria are met	• Based on medical history and screening contrast brain MRI, patients must not have any of the following: ◦ Brain metastases requiring immediate local therapy ◦ Untreated brain lesions >2.0 cm in size[b] ◦ Ongoing treatment with corticosteroids for control of symptoms of brain metastases at a total daily dose of >2 mg dexamethasone or equivalent ◦ Known or suspected leptomeningeal disease ◦ Poorly controlled generalized or complex partial seizures, or manifest neurological progression due to brain metastases

[a]A full list of brain metastases inclusion and exclusion criteria can be found at: https://www.clinicaltrials.gov/ct2/show/NCT04539938.
[b]Unless discussed with medical monitor and approval for enrollment is given.

Carey L et al. ESMO 2021;Abstract 331TiP.

Trastuzumab-Deruxtecan (T-DXd) in HER2-Positive Breast Cancer Patients (Pts) with Active Brain Metastases: Primary Outcome Analysis from the TUXEDO-1 Trial

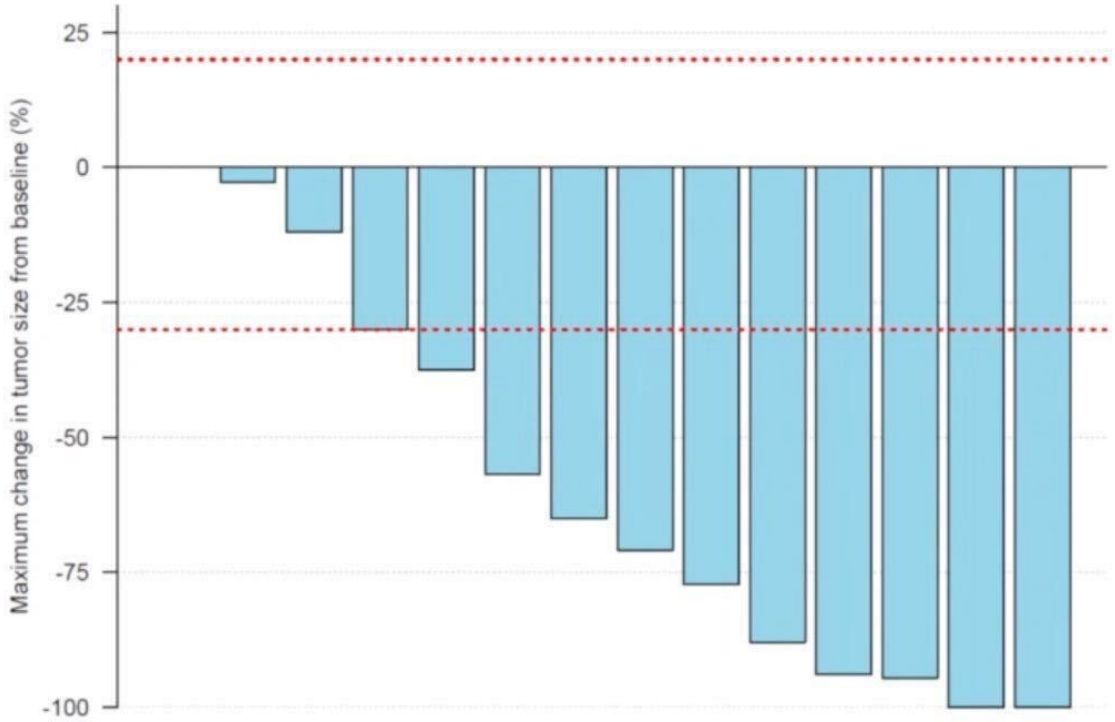
Bartsch R et al.

ESMO Breast 2022;Abstract 165MO.

Primary Endpoint

Objective Response Rate (RANO-BM criteria)

ORR (intention-to-treat population; *n*=15): 73.3% (95% CI 48.1-89.1)



One patient with dural metastases

RR (per-protocol-population; *n*=14): 78.6%

Bartsch R et al. ESMO Breast 2022;Abstract 165MO.

N Engl J Med 2022 March 24;386:1143-54.

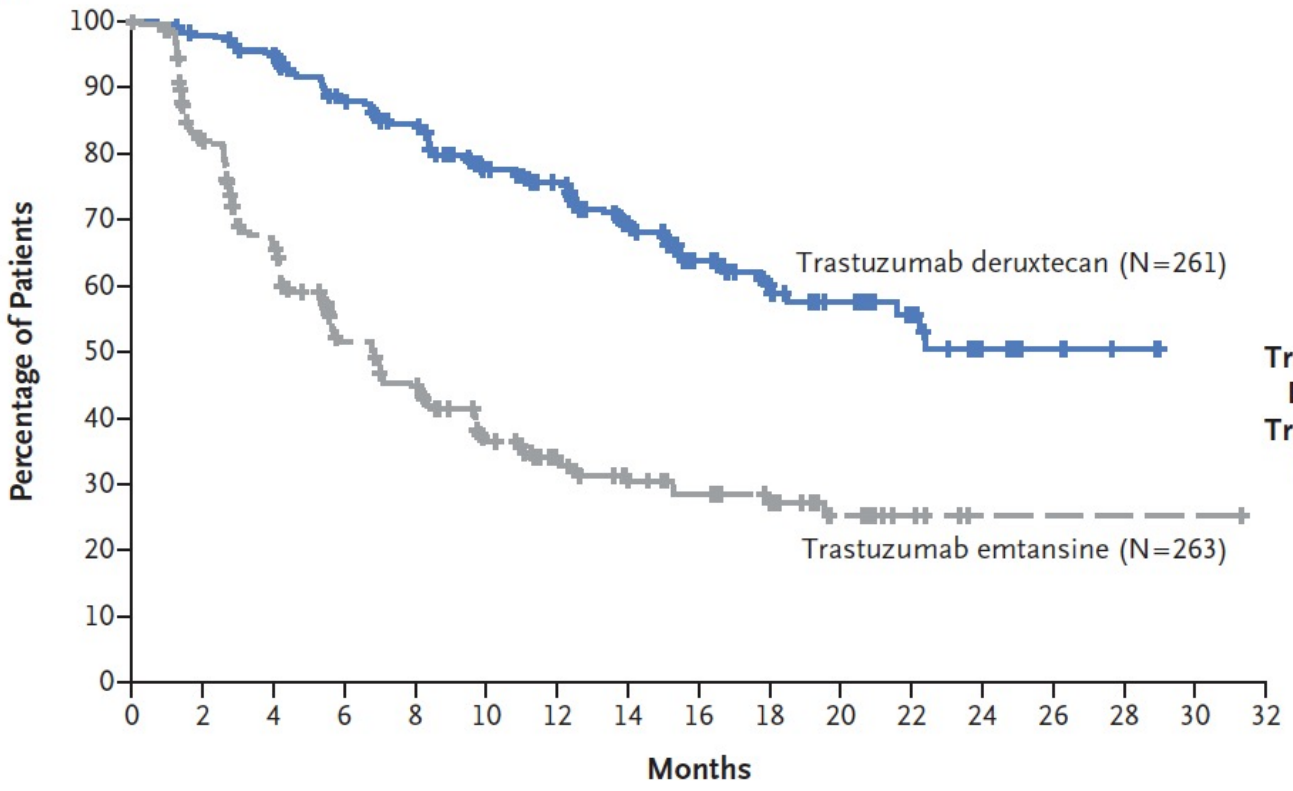
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trastuzumab Deruxtecan versus Trastuzumab Emtansine for Breast Cancer

J. Cortés, S.-B. Kim, W.-P. Chung, S.-A. Im, Y.H. Park, R. Hegg, M.H. Kim, L.-M. Tseng, V. Petry, C.-F. Chung, H. Iwata, E. Hamilton, G. Curigliano, B. Xu, C.-S. Huang, J.H. Kim, J.W.Y. Chiu, J.L. Pedrini, C. Lee, Y. Liu, J. Cathcart, E. Bako, S. Verma, and S.A. Hurvitz, for the DESTINY-Breast03 Trial Investigators*

DESTINY-Breast03: Progression-Free Survival



	Median Progression-free Survival (95% CI)	12-Mo Progression-free Survival (95% CI)
	mo	%
Trastuzumab Deruxtecan	NR (18.5–NE)	75.8 (69.8–80.7)
Trastuzumab Emtansine	6.8 (5.6–8.2)	34.1 (27.7–40.5)

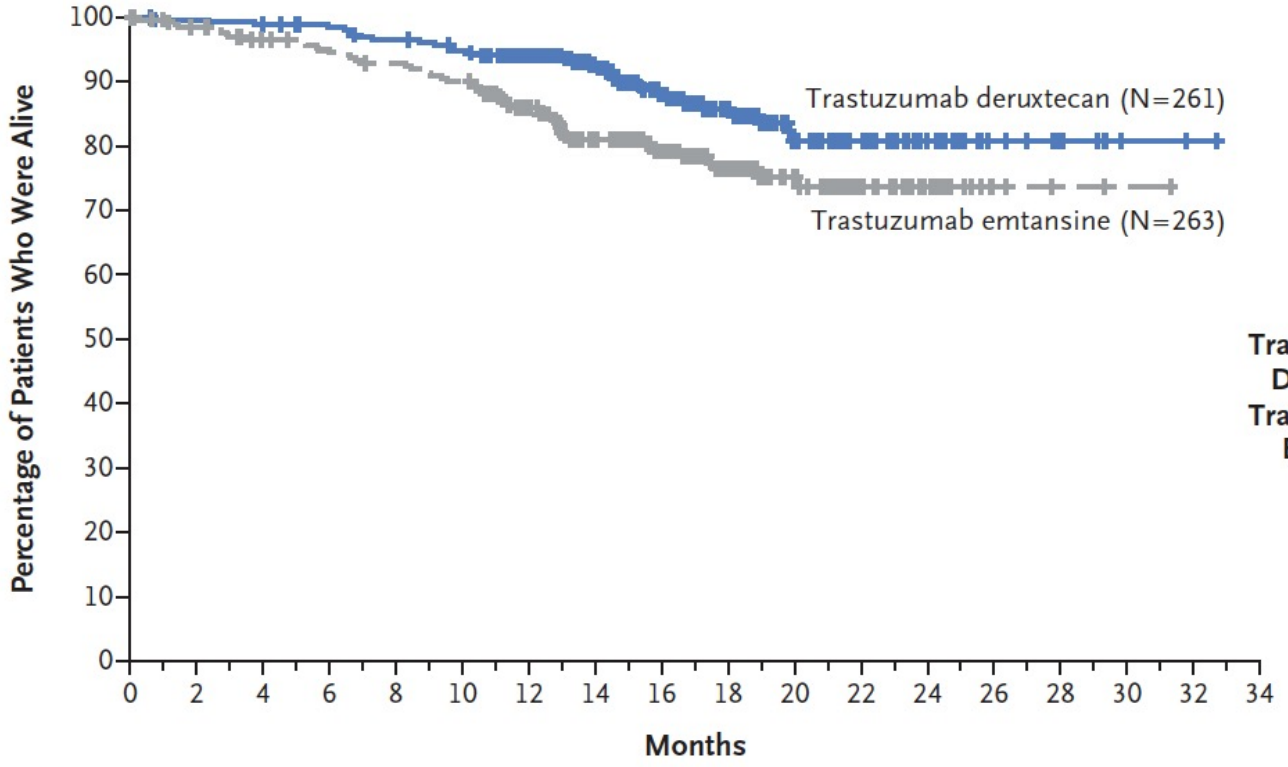
Hazard ratio for disease progression or death, 0.28 (95% CI, 0.22–0.37)
P<0.001

No. at Risk

Trastuzumab deruxtecan	261	250	240	214	200	168	150	112	79	53	36	25	10	5	2	
Trastuzumab emtansine	263	200	155	108	93	65	51	37	29	21	12	6	1	1	1	0

Cortés J et al. *N Engl J Med* 2022;386(12):1143-54.

DESTINY-Breast03: First Interim Analysis of Overall Survival



	Median Overall Survival (95% CI)	12-Mo Overall Survival (95% CI)
	mo	%
Trastuzumab Deruxtecan	NE (NE–NE)	94.1 (90.3–96.4)
Trastuzumab Emtansine	NE (NE–NE)	85.9 (80.9–89.7)

Hazard ratio for death, 0.55
(95% CI, 0.36–0.86)
P=0.007

No. at Risk

Trastuzumab deruxtecan	261	256	254	249	243	237	218	180	133	86	56	42	24	11	7	6	2	2	1	0
Trastuzumab emtansine	263	253	243	236	231	224	188	151	120	75	52	32	18	5	3	3	1	1	0	

Cortés J et al. *N Engl J Med* 2022;386(12):1143-54.

DESTINY-Breast09 Phase III Trial Design

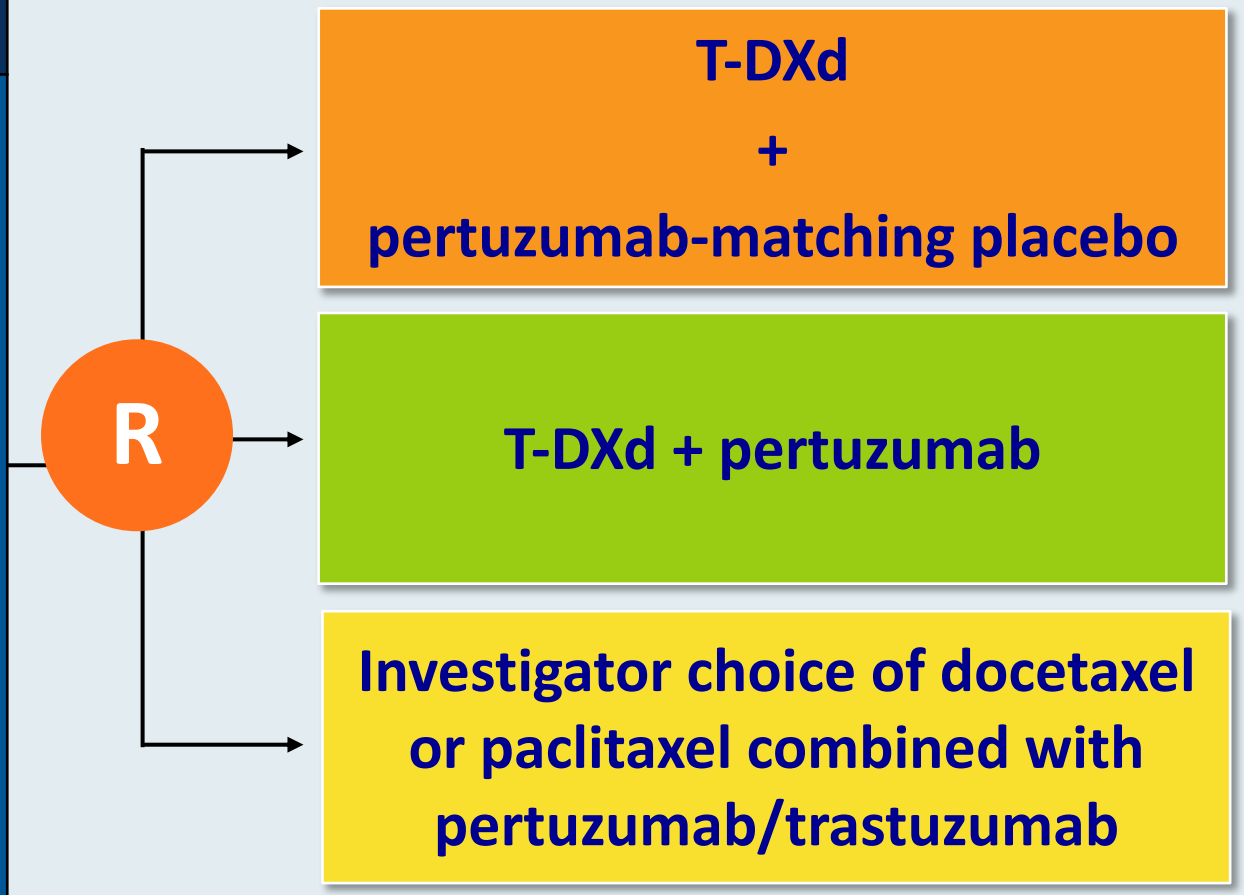
Estimated enrollment: N = 1,134

Pathologically documented breast cancer:

- Advanced or metastatic
- Locally assessed and prospectively centrally confirmed as IHC 3+ or ISH+
- Documented by local testing as HR-positive or negative in the metastatic setting

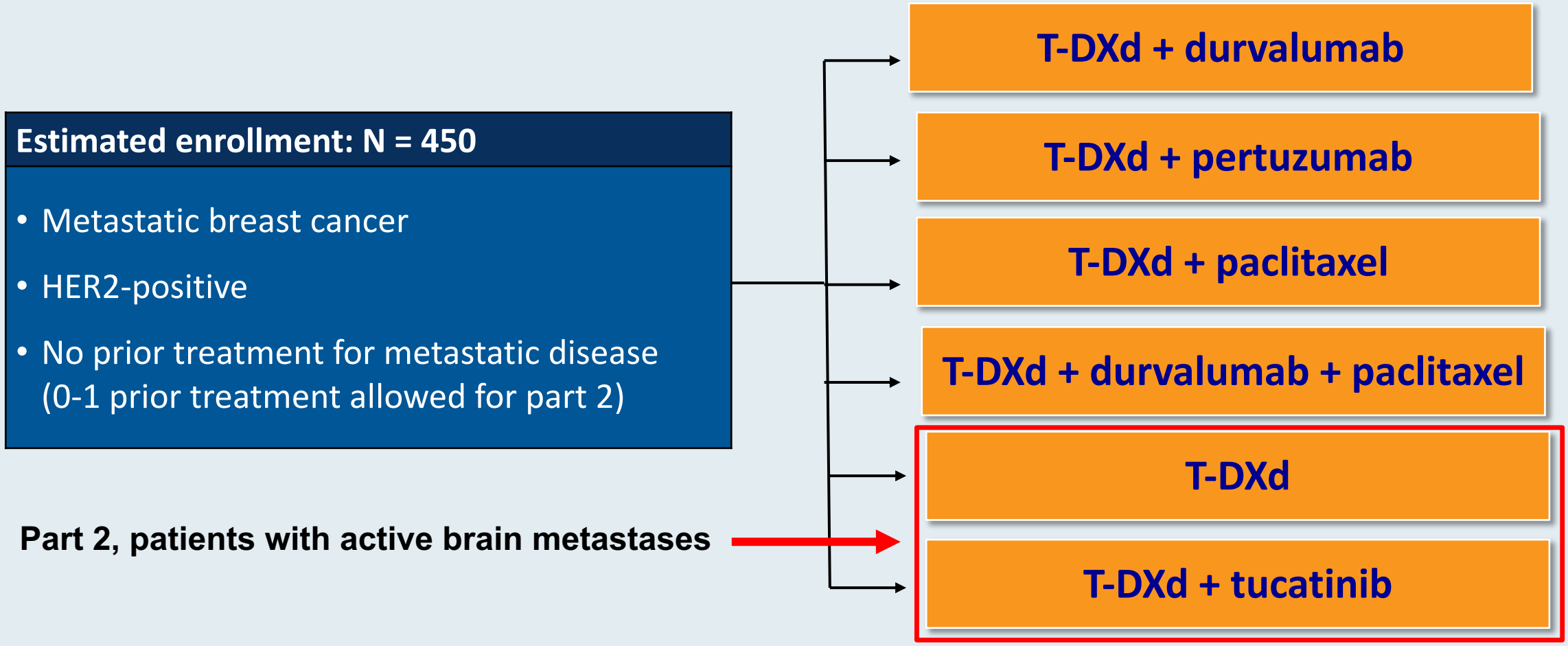
No prior chemotherapy or HER2-targeted therapy for advanced or metastatic disease or only 1 previous line of ET in the metastatic setting

Prior (neo)adjuvant chemotherapy or HER2-targeted therapy allowed if >6 months from treatment to diagnosis of metastasis



www.clinicaltrials.gov. NCT04784715. Accessed August 2022.

DESTINY-Breast07 Phase I/II Trial Design



Primary endpoints: AEs, serious AEs

Secondary endpoints: Objective response rate, PFS, PFS2, DoR, OS

www.clinicaltrials.gov. NCT04538742. Accessed August 2022.

2022 ASCO ANNUAL MEETING **Abstract LBA3** DESTINY-Breast04

Trastuzumab deruxtecan (T-DXd) vs treatment of physician's choice in patients with HER2-low unresectable and/or metastatic breast cancer: Results of DESTINY-Breast04, a randomized, phase 3 study

Shanu Modi Memorial Sloan Kettering Cancer Center, Memorial Hospital, New York, NY, USA

June 5, 2022

Additional authors: William Jacot, Toshinari Yamashita, Joo Hyuk Sohn, Maria Vidal, Eriko Tokunaga, Junji Tsurutani, Naoto Ueno, Yee Soo Chae, Keun Seok Lee, Naoki Niikura, Yeon Hee Park, Xiaojia Wang, Binghe Xu, Dhiraj Gambhire, Lotus Yung, Gerold Meinhardt, Yibin Wang, Nadia Harbeck, David Cameron

On behalf of the DESTINY-Breast04 investigators

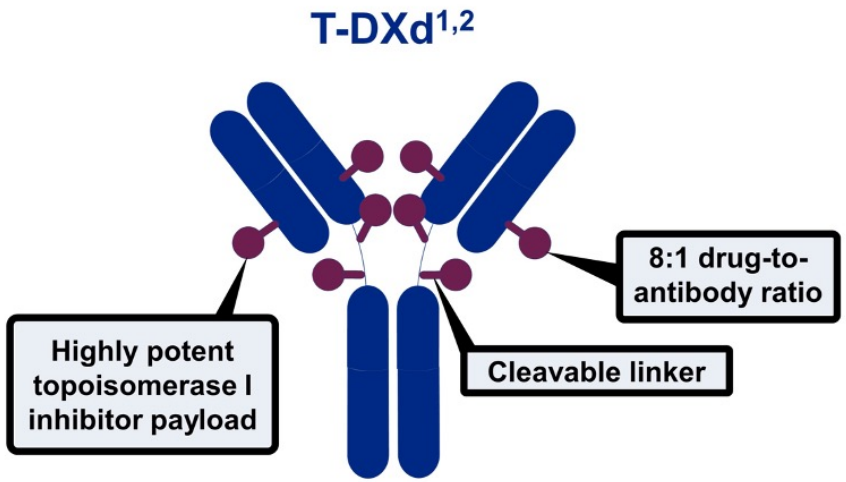
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 7, 2022 VOL. 387 NO. 1

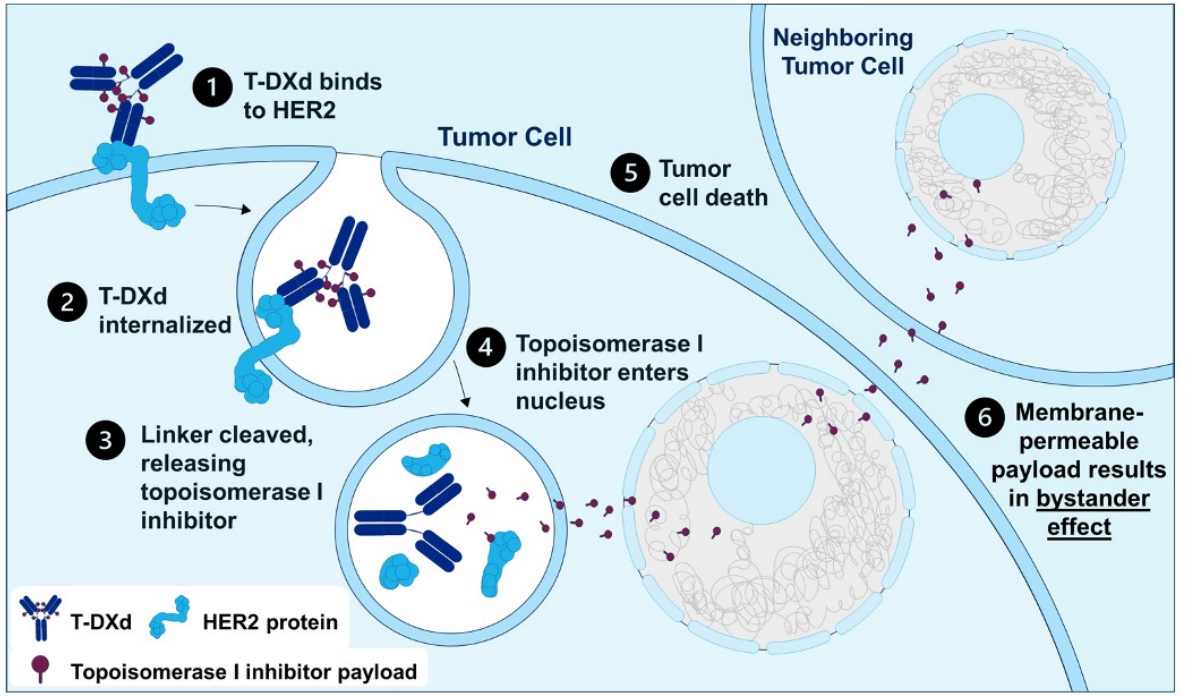
Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer

S. Modi, W. Jacot, T. Yamashita, J. Sohn, M. Vidal, E. Tokunaga, J. Tsurutani, N.T. Ueno, A. Prat, Y.S. Chae, K.S. Lee, N. Niikura, Y.H. Park, B. Xu, X. Wang, M. Gil-Gil, W. Li, J.-Y. Pierga, S.-A. Im, H.C.F. Moore, H.S. Rugo, R. Yerushalmi, F. Zagouri, A. Gombos, S.-B. Kim, Q. Liu, T. Luo, C. Saura, P. Schmid, T. Sun, D. Gambhire, L. Yung, Y. Wang, J. Singh, P. Vitazka, G. Meinhardt, N. Harbeck, and D.A. Cameron, for the DESTINY-Breast04 Trial Investigators*

T-DXd Mechanism of Action, Bystander Effect and Rationale for Targeting HER2-Low Breast Cancer



Internalization of T-DXd leads to release of the DXd payload and subsequent cell death in the target tumor cell and neighboring tumor cells through the bystander effect[1,2]

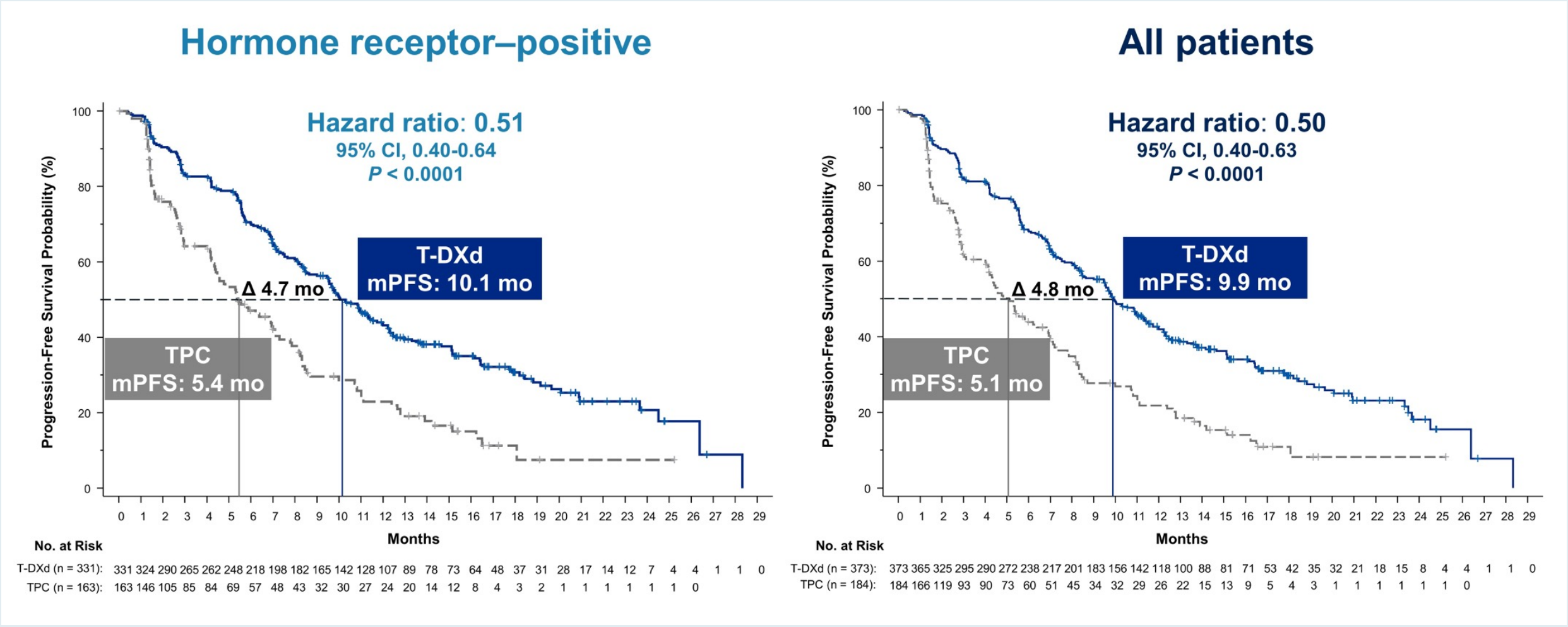


Adapted with permission from Modi S, et al. *J Clin Oncol* 2020;38:1887-96. CC BY ND 4.0.

- **Results from a phase 1b study have reported efficacy of T-DXd in heavily pretreated patients (N = 54) with HER2-low mBC, with a mPFS of 11.1 months and an ORR of 37.0%[3]**

Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022 July 7;387(1):9-20.

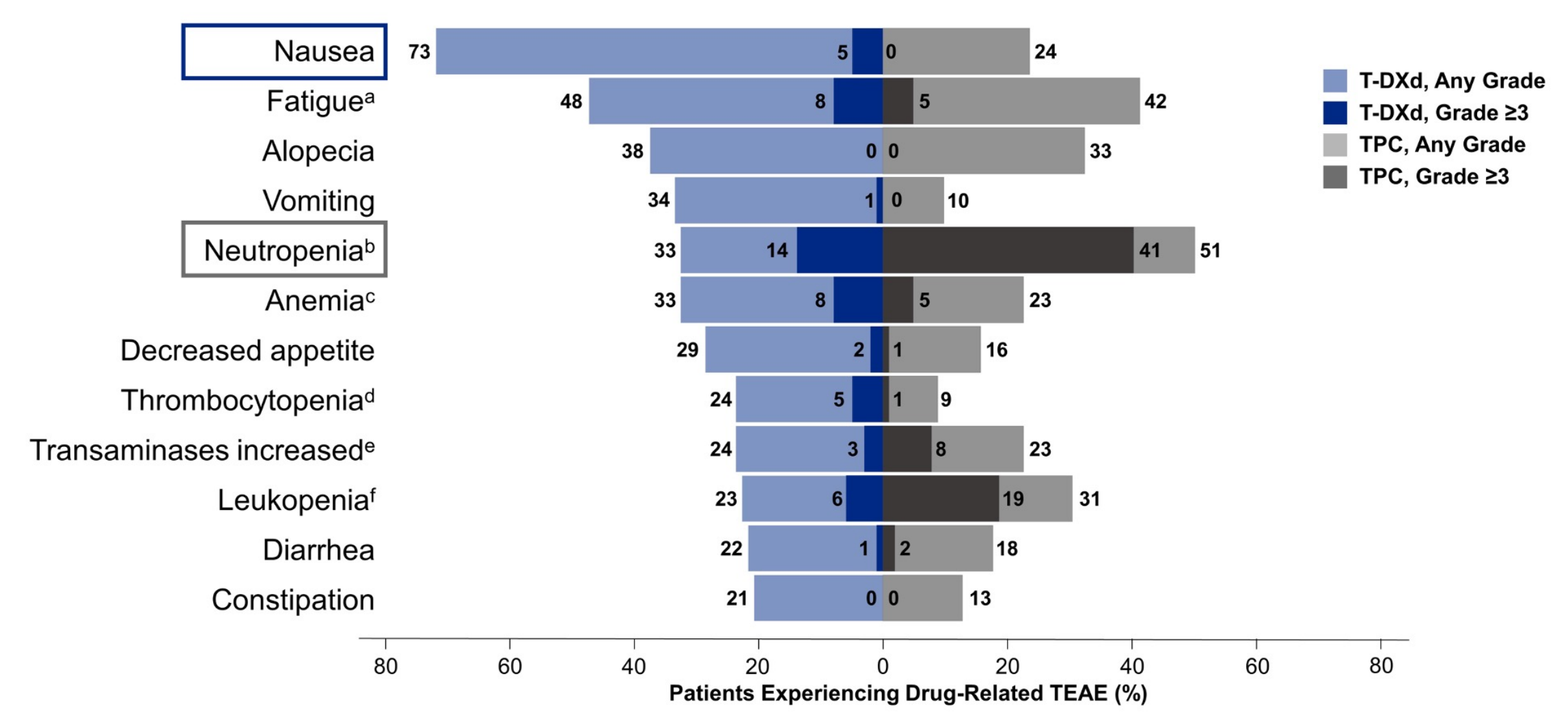
DESTINY-Breast04: PFS for HR-Positive (Primary Endpoint) and All Patients



mPFS = median progression-free survival

Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022 July 7;387(1):9-20.

DESTINY-Breast04: Common Drug-Related TEAEs



Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022 July 7;387(1):9-20.

DESTINY-Breast04: Adverse Events of Special Interest

Adjudicated as drug-related ILD/pneumonitis[a]

n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade
T-DXd (n = 371)	13 (3.5)	24 (6.5)	5 (1.3)	0	3 (0.8)	45 (12.1)
TPC (n = 172)	1 (0.6)	0	0	0	0	1 (0.6)

Left ventricular dysfunction[b]

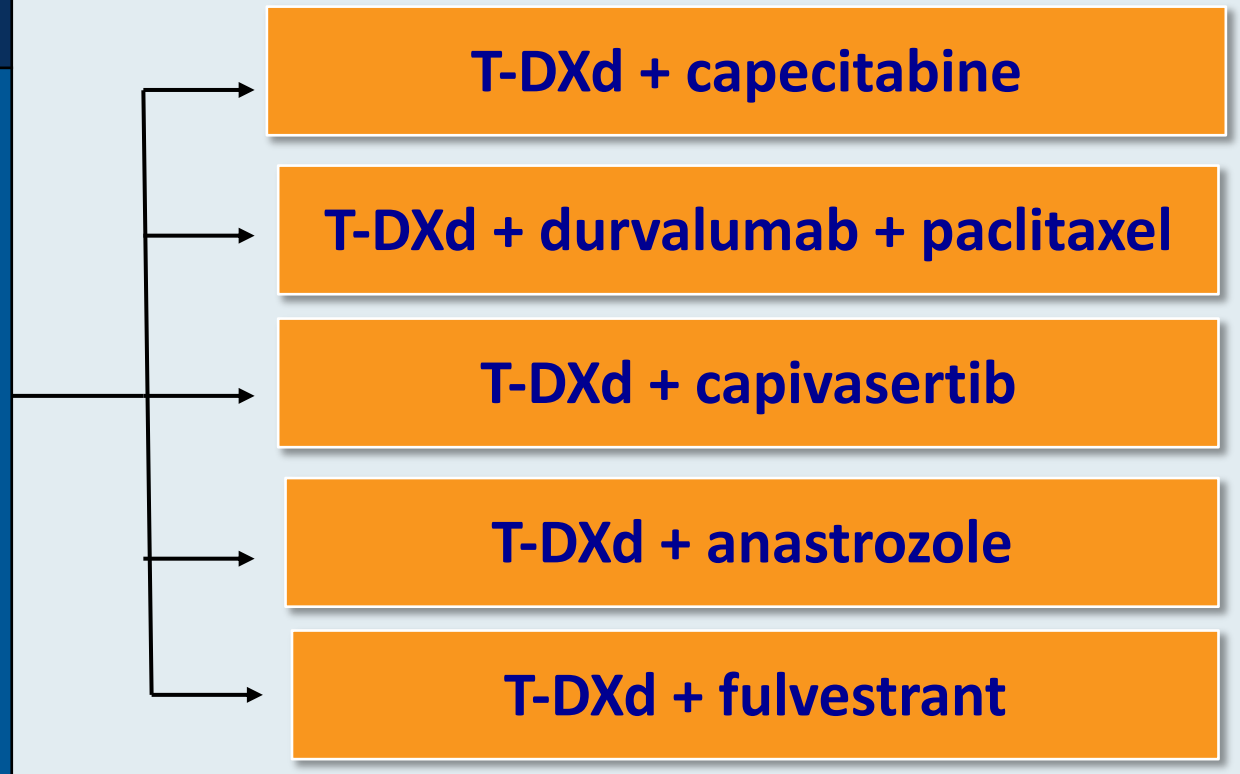
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade
Ejection fraction decreased						
T-DXd (n = 371)	1 (0.3)	14 (3.8)	1 (0.3)	0	0	16 (4.3)
TPC (n = 172)	0	0	0	0	0	0
Cardiac failure[c]						
T-DXd (n = 371)	0	1 (0.3)	1 (0.3)	0	0	2 (0.5)
TPC (n = 172)	0	0	0	0	0	0

Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022 July 7;387(1):9-20.

DESTINY-Breast08 Phase I Trial Design

Estimated enrollment: N = 182

- Metastatic breast cancer (mBC)
- HER2-low (IHC 2+/ISH- or IHC 1+/ISH- or untested)
- HR-positive
- At least 1 prior line of ET +/- targeted therapy and 1 prior line of chemotherapy for mBC (Part 1)
- Only 1 prior line of ET +/- targeted therapy and no prior chemotherapy for mBC (Part 2)



Primary endpoints: Adverse events, serious adverse events

Secondary endpoints: Objective response rate, progression-free survival, duration of response, overall response

www.clinicaltrials.gov. NCT04538742. Accessed August 2022.

PARIS 2022 ESMO congress

Sacituzumab govitecan efficacy in HR+/HER2– metastatic breast cancer by HER2 immunohistochemistry status in the phase 3 TROPiCS-02 study

Peter Schmid,[1] Javier Cortes,[2] Frederik Marmé,[3] Hope S. Rugo,[4] Sara M. Tolaney,[5] Mafalda Oliveira,[6] Delphine Loirat,[7] Komal Jhaveri,[8] Oh Kyu Yoon,[9] Monica Motwani,[9] Hao Wang,[9] Rosemary Delaney,[10] Aditya Bardia[11]

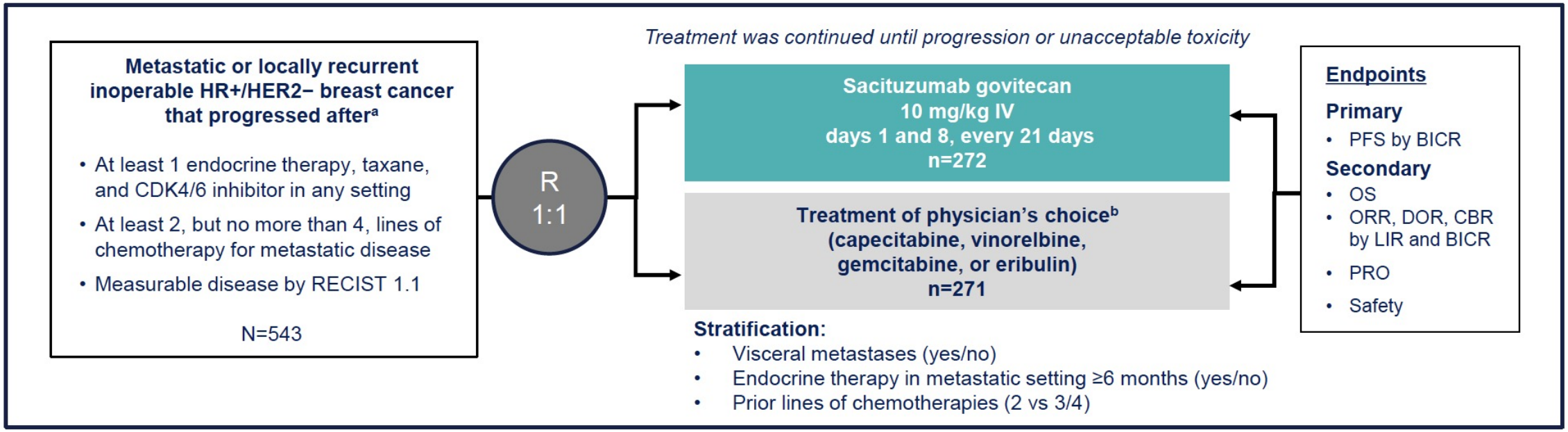
[1]Barts Cancer Institute, Queen Mary University of London, London, United Kingdom; [2]International Breast Cancer Center (IBCC), Quiron Group, Madrid & Barcelona, Spain; [3]Heidelberg University, University Hospital Mannheim, Heidelberg, Germany; [4]University of California San Francisco Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA; [5]Dana-Farber Cancer Institute, Boston, MA, USA; [6]Vall d'Hebron University Hospital and Vall d'Hebron Institute of Oncology, Barcelona, Spain; [7]Institut Curie, Paris, France; [8]Memorial Sloan-Kettering Cancer Center, New York, NY, USA; [9]Gilead Sciences, Inc, Foster City, CA, USA; [10]Gilead Sciences, Inc, Morris Plains, NJ, USA; [11]Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA, USA

Presenter: Dr. Frederik Marmé

Saturday, September 10, 15:40 - 15:45
FPN 214MO

RTP RESEARCH TO PRACTICE

Phase III TROPiCS-02 Trial Schema and Post Hoc Analysis



- For this post hoc subgroup analysis, local IHC and ISH results for the ITT population of TROPiCS-02 were analyzed retrospectively to determine SG efficacy by HER2 IHC status:
  - 52% were HER2-Low (IHC1+, IHC2+ [ISH-negative/unverified[c]]): N=283 (SG, n=149; TPC, n=134)
  - 40% were HER2 IHC0: N=217 (SG, n=101; TPC, n=116)
  - 8% were excluded from the analysis due to missing HER2 IHC status: N=43 (SG, n=22; TPC, n=21)

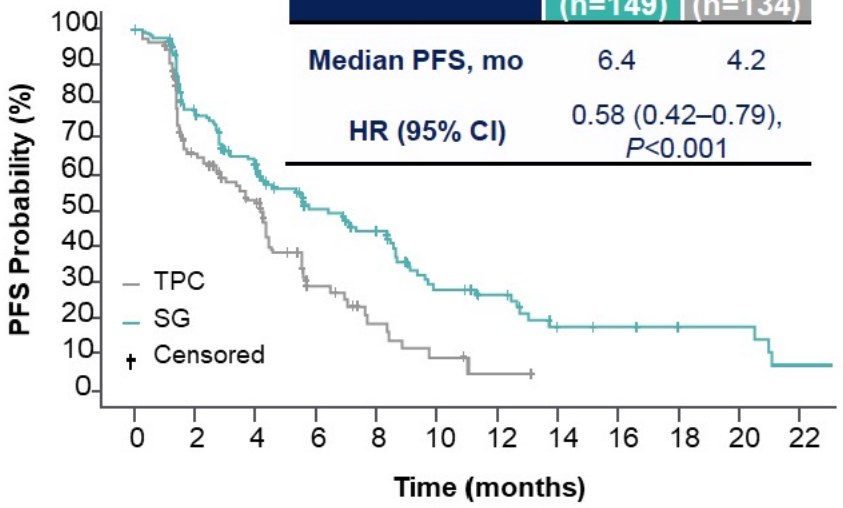
[a]Disease histology based on the ASCO/CAP criteria. [b]Single-agent standard-of-care treatment of physician's choice was specified prior to randomization by the investigator. [c]39 patients with HER2 IHC2+ did not have ISH data documentation available for verification and were presumed to be HER2-Low, consistent with the trial eligibility criteria to enroll HER2-negative patients. A separate sensitivity analysis excluding the 39 ISH-unverified patients was also performed, with consistent results.
HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IHC, immunohistochemistry; ISH, in situ hybridization; ITT, intention-to-treat; SG, sacituzumab govitecan; Trop-2, trophoblast cell surface antigen 2.
1. Rugo HS,et al. *J Clin Oncol*. 2022. doi: 10.1200/JCO.22.01002. (epub ahead of print).

Marmé F et al. ESMO 2022;Abstract 214MO.

TROPiCS-02: Post Hoc Analysis of PFS with Sacituzumab Govitecan in the HER2-Low Subgroup

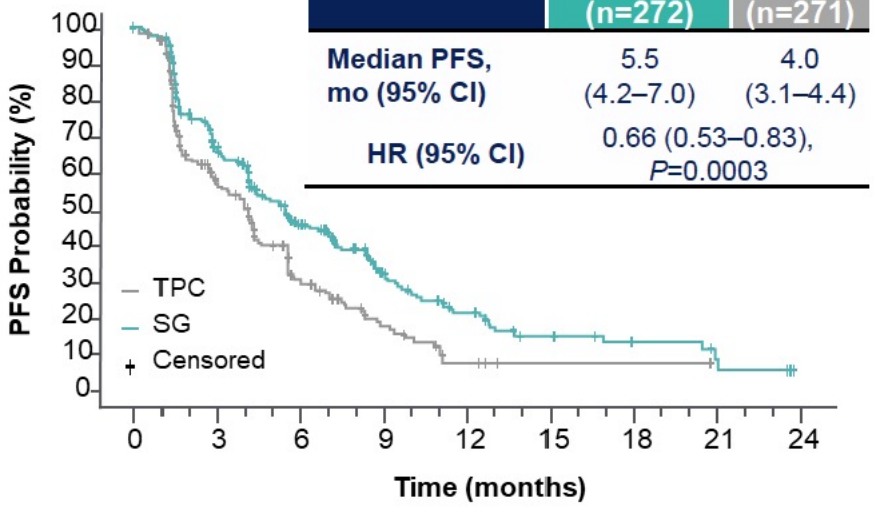
HER2-Low[a]

	SG (n=149)	TPC (n=134)
Median PFS, mo	6.4	4.2
HR (95% CI)	0.58 (0.42–0.79), *P*<0.001	



ITT[1]

	SG (n=272)	TPC (n=271)
Median PFS, mo (95% CI)	5.5 (4.2–7.0)	4.0 (3.1–4.4)
HR (95% CI)	0.66 (0.53–0.83), *P*=0.0003	



- Within the HER2-Low population, median PFS with SG vs TPC for the IHC1+ and IHC2+ subgroups was 7.0 vs 4.3 (HR, 0.57) and 5.6 vs 4.0 (HR, 0.58) months, respectively
- The hazard ratio for median PFS in a sensitivity analysis of the HER2-Low subgroup (excluding ISH-unverified[b]) was similar (HR, 0.53)

[a]HER2-Low defined as IHC1+, or IHC2+ and ISH-negative/unverified.
[b]39 patients with HER2 IHC2+ did not have ISH data documentation available for verification and were presumed to be HER2-low, consistent with the trial eligibility criteria to enroll HER2-negative patients.
HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; PFS, progression-free survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice.
1. Rugo HS, et al. *J Clin Oncol*. 2022. doi: 10.1200/JCO.22.01002. (epub ahead of print). Adapted from Rugo HS, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol*. 2022. doi: 10.1200/JCO.22.01002. Reprinted with permission from American Society of Clinical Oncology.

Marmé F et al. ESMO 2022;Abstract 214MO.

TROPiCS-02: Post Hoc Analysis of Overall Response with Sacituzumab Govitecan by HER2 Status

	HER2-Low[a]		HER2 IHC0		ITT[1]	
	SG (n=149)	TPC (n=134)	SG (n=101)	TPC (n=116)	SG (n=272)	TPC (n=271)
ORR, n (%)	38 (26)	16 (12)	16 (16)	17 (15)	57 (21)	38 (14)
Odds ratio (95% CI)	2.52 (1.33-4.78)		1.10 (0.52-2.30)		1.63 (1.04-2.55)	
Best overall response, n (%)						
CR	2 (1)	0	0	0	2 (1)	0
PR	36 (24)	16 (12)	16 (16)	17 (15)	55 (20)	38 (14)
SD	73 (49)	61 (46)	56 (55)	39 (34)	142 (52)	106 (39)
SD ≥6 mo	18 (12)	10 (7)	15 (15)	8 (7)	35 (13)	21 (8)
PD	29 (19)	36 (27)	23 (23)	38 (33)	58 (21)	76 (28)
NE	9 (6)	21 (16)	6 (6)	22 (19)	15 (6)	51 (19)
CBR, n (%)	56 (38)	26 (19)	31 (31)	25 (22)	92 (34)	59 (22)
Odds ratio (95% CI)	2.50 (1.46-4.30)		1.61 (0.87-2.97)		1.84 (1.25-2.69)	
Median DOR, mo (95% CI)	7.4 (5.8-8.9)	4.1 (2.8-6.1)	8.1 (4.1-NE)	6.1 (2.8-8.3)	7.4 (6.5-8.6)	5.6 (3.8-7.9)

[a]HER2-Low defined as IHC1+, or IHC2+ and ISH-negative/unverified.
CBR, clinical benefit rate; CR, complete response; DOR, duration of response; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; ITT, intention-to-treat; NE, not evaluable; ORR, objective response rate; PR, partial response; SD, stable disease; SG, sacituzumab govitecan; TPC, treatment of physician's choice.
1. Rugo HS, et al. *J Clin Oncol*. 2022. doi: 10.1200/JCO.22.01002. (epub ahead of print).

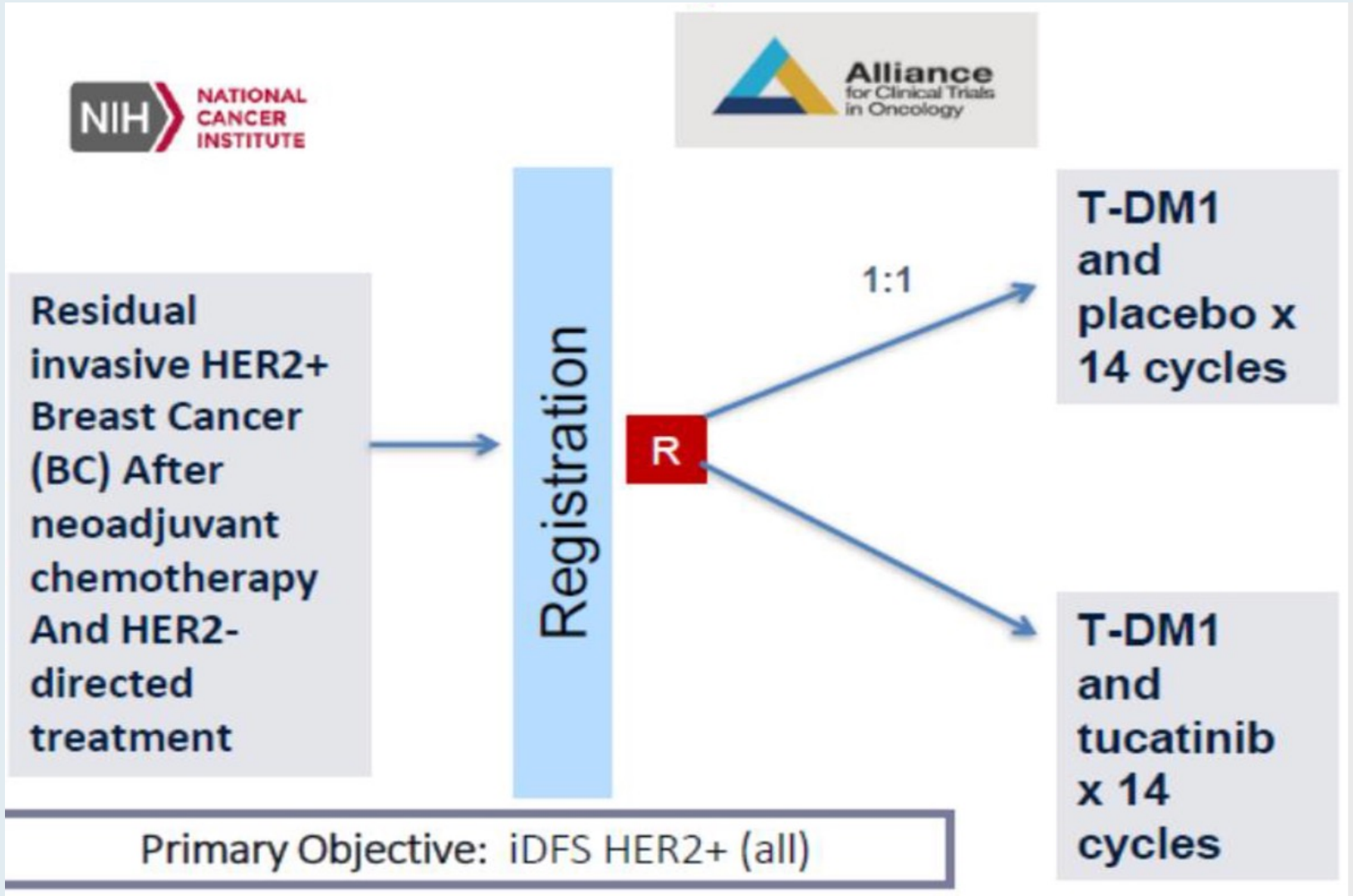
Marmé F et al. ESMO 2022;Abstract 214MO.

A011801 (CompassHER2 RD): Postneoadjuvant T-DM1 + Tucatinib/Placebo in Patients with Residual HER2-Positive Invasive Breast Cancer

O'Sullivan CCM et al.

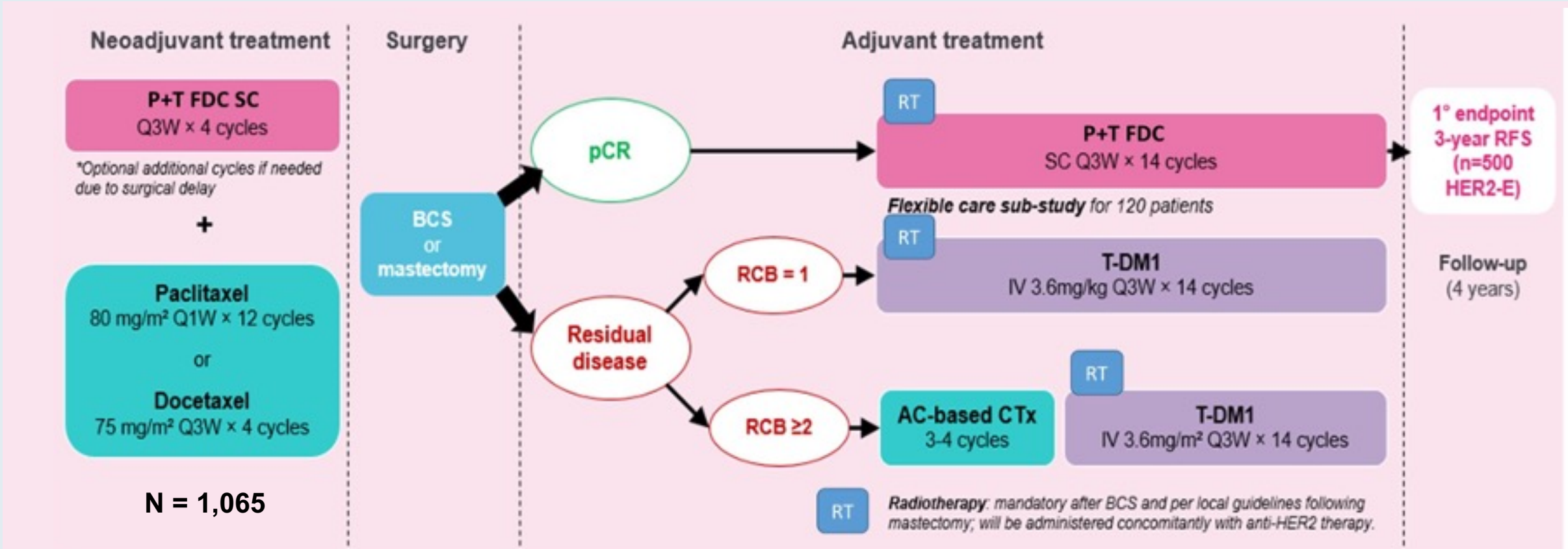
ASCO 2021;Abstract TPS595.

A011801 Schema



O'Sullivan CCM et al. ASCO 2021;Abstract TPS595.

DECRESCENDO Phase II De-escalation Study Design



Inclusion criteria
• Candidates for neoadjuvant treatment • Early HER2+ (IHC 3+ or FISH), HR- (ER<1% and PR<1%) per local assessment • Tumor size between 15 and 50mm • Node 0 (micro metastasis not accepted)

Primary endpoint	**3-year recurrence-free survival (RFS) in patients with HER2-E tumors who achieve pCR (RCB=0) after neoadjuvant treatment**
Key secondary endpoint	• 3-year RFS in all patients with pCR (RCB=0).
Secondary endpoints	• pCR rates in the overall population and by primary tumor dimension. • Short-and long-term safety of paclitaxel, docetaxel, P+T FDC SC, T-DM1.

Debien V et al. ASCO 2022;Abstract TPS621.

Clin Cancer Res 2022 April 1;28(7):1258-67.

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: TARGETED THERAPY

The Phase II MutHER Study of Neratinib Alone and in Combination with Fulvestrant in HER2-Mutated, Non-amplified Metastatic Breast Cancer

Cynthia X. Ma[1,2], Jingqin Luo[2,3], Rachel A. Freedman[4], Timothy J. Pluard[5], Julie R. Nangia[6], Janice Lu[7], Frances Valdez-Albini[8], Melody Cobleigh[9], Jason M. Jones[10], Nancy U. Lin[4], Eric P. Winer[4], P. Kelly Marcom[11], Shana Thomas[1], Jill Anderson[1], Brittney Haas[1], Leslie Bucheit[12], Richard Bryce[13], Alshad S. Lalani[13], Lisa A. Carey[14], Matthew P. Goetz[15], Feng Gao[2,3], Gretchen Kimmick[11], Mark D. Pegram[16], Matthew J. Ellis[17], and Ron Bose[1,2]

Effects of Diarrheal Prophylaxis or Dose Escalation on Neratinib-Associated Diarrhea and Tolerability in Patients with HER2+ Early-Stage Breast Cancer: Final Findings from the CONTROL Trial

Chan A et al.

ESMO Breast 2022;Abstract P73.

npj | breast cancer

NPJ Breast Cancer 2022 May 24;8(1):68.

www.nature.com/npjbcancer

ARTICLE OPEN

Adaptive immune signature in HER2-positive breast cancer in NCCTG (Alliance) N9831 and NeoALTTO trials

Saranya Chumsri[1]✉, Zhuo Li[2], Daniel J. Serie[2], Nadine Norton[3], Afshin Mashadi-Hossein[4], Kathleen Tenner[5], Heather Ann Brauer[4], Sarah Warren[4], Patrick Danaher[4], Gerardo Colon-Otero[1], Ann H. Partridge[6], Lisa A. Carey[7], Florentine Hilbers[8], Veerle Van Dooren[9], Eileen Holmes[10,11], Serena Di Cosimo[11], Olena Werner[12], Jens Bodo Huober[13], Amylou C. Dueck[14], Christos Sotiriou[15], Cristina Saura[16], Alvaro Moreno-Aspitia[1], Keith L. Knutson[17], Edith A. Perez[1] and E. Aubrey Thompson[3]

Lancet 2022 March 19;399(10330):1101-3.

The *Lancet* Breast Cancer Commission: tackling a global health, gender, and equity challenge

Coles CE, Anderson BO, Cameron D, Cardoso F, Horton R, Knaul FM, Mutebi M,

Lee N; Lancet Breast Cancer Commission

Panel: Key Questions to Guide the Work of the Lancet Breast Cancer Commission

1. How do we change the mindset that it is inevitable and therefore acceptable for one in eight women to develop breast cancer during their lifetime and how do we reverse this increasing trend?
2. What lessons can we learn from the COVID-19 global response and how can we apply these lessons to tackling breast cancer worldwide to move forward together in solidarity?
3. What can we learn from patient and public advocacy movements as a powerful and effective mechanism in other disease and health issues to close the global breast cancer gap?
4. What is the impact of stage shift to earlier breast cancer presentation on global survival rates?
5. Financial effects and health-related suffering: what are the wider consequences of inaction beyond immediate health-care costs and how can we quantify the value to patients and society of reducing the avoidable pain and suffering of breast cancer?
6. How can we introduce an aspirational goal of systematic risk assessment and precision breast screening and prevention for young women as part of routine broader health care?
7. How can we enable personalised breast cancer management to become universally applicable?
8. How can we transition from traditional siloed care to integrated patient-centred management, ensuring that all patients with breast cancer (early and metastatic) have access to multidisciplinary specialised care?
9. How can patients' choice in their breast cancer management be empowered through a holistic benefit–risk approach and shared decision making?
10. How do we design innovative clinical trials to test safe reduction in overall patient burden of treatment and management?
11. How can we quantify the overlooked global population with metastatic breast cancer?
12. How can we change the mindset around metastatic breast cancer from a rapidly fatal disease to potentially curable?

Coles CE et al. *Lancet* 2022 March 19;399(10330):1101-3.

Meet The Professor

Optimizing the Use of Hormonal Therapy in the Management of Prostate Cancer

Wednesday, November 9, 2022
5:00 PM – 6:00 PM ET

Faculty

Prof Karim Fizazi, MD, PhD

Stéphane Oudard, MD, PhD

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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