# *Meet The Professor*

# Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

**Wednesday, April 12, 2023**
**5:00 PM – 6:00 PM ET**

## Faculty

**Sara A Hurvitz, MD**

## Moderator

**Neil Love, MD**

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TO PRACTICE

# Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Exact Sciences Corporation, Sanofi, and TerSera Therapeutics LLC.

# 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 US Inc, Gilead Sciences Inc, Grail Inc, GSK, 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, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, 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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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

# Dr Hurvitz — Disclosures

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| **Contracted Research** | Ambrx, Amgen Inc, Arvinas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Celcuity, CytomX Therapeutics, Daiichi Sankyo Inc, Dantari, Dignitana AB, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Greenwich LifeSciences Inc, GSK, Lilly, MacroGenics Inc, Novartis, OBI Pharma Inc, Orinove Inc, Orum Therapeutics, Pfizer Inc, Phoenix Molecular Designs, Pieris Pharmaceuticals Inc, Puma Biotechnology Inc, Radius Health Inc, Samumed, Sanofi, Seagen Inc, Stemline Therapeutics Inc, Zymeworks Inc |
| **Nonrelevant Financial Relationship** | Ideal Implant (spouse) |

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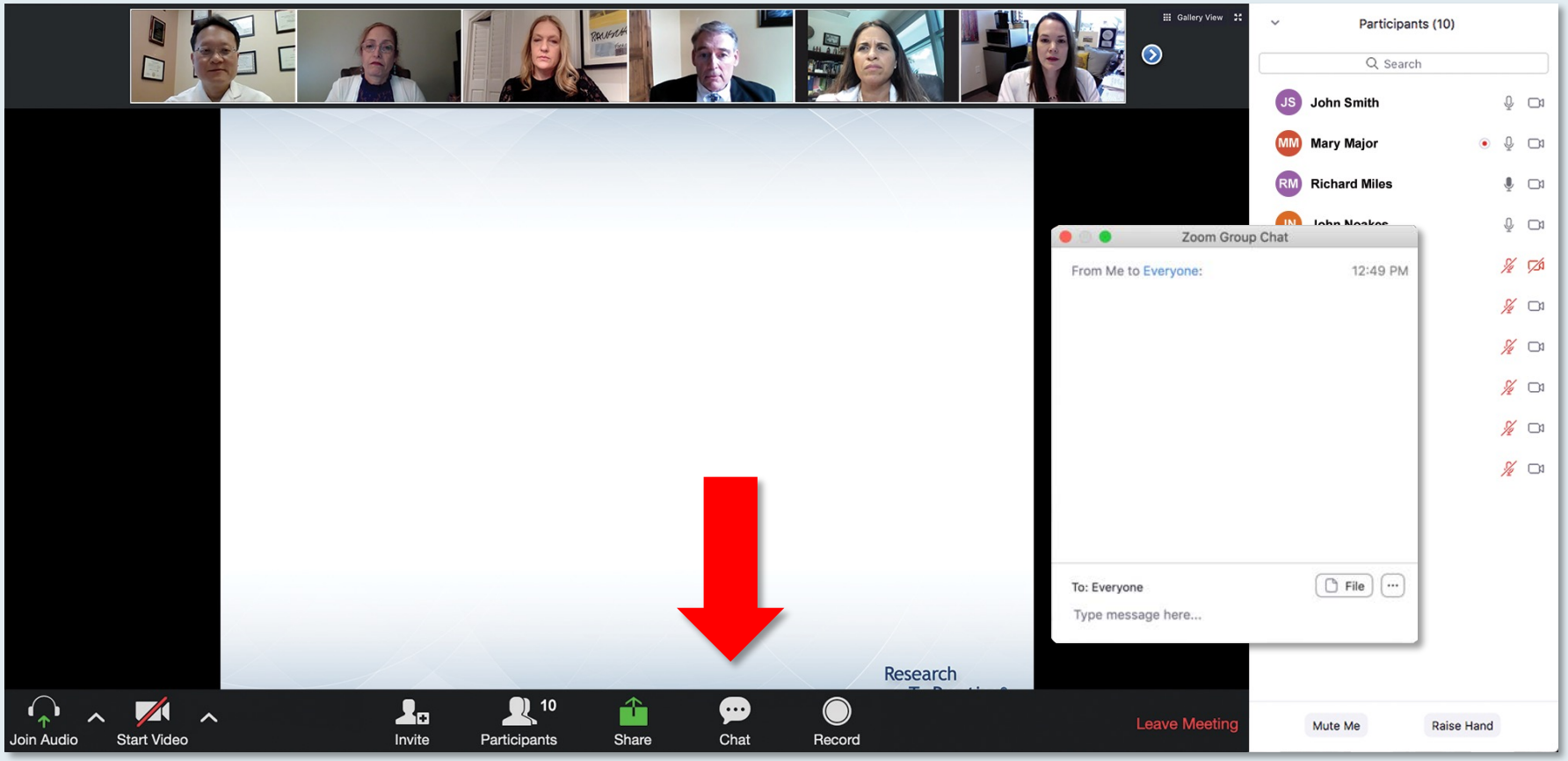
# We Encourage Clinicians in Practice to Submit Questions




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

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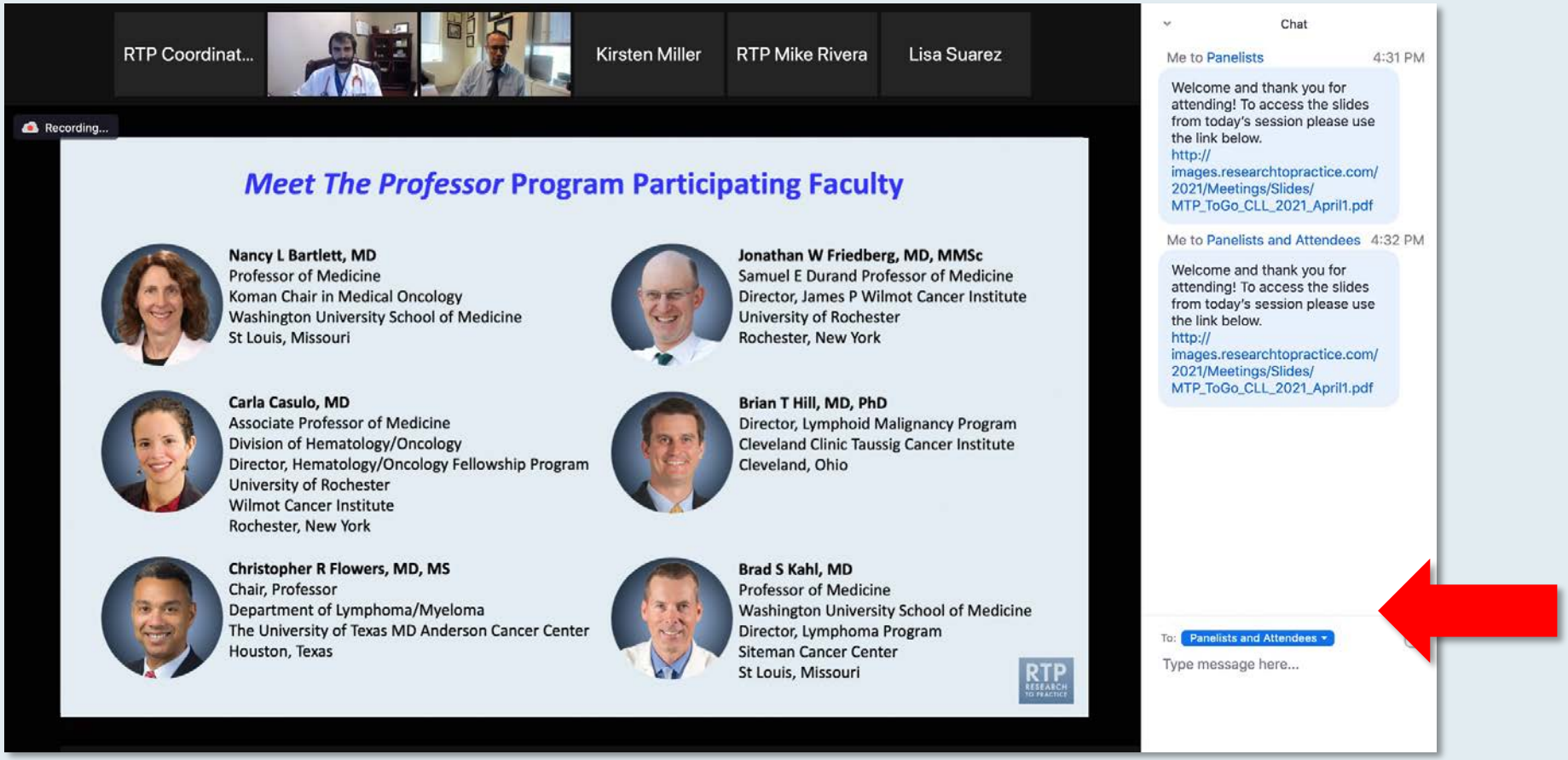
# Familiarizing Yourself with the Zoom Interface

## Expand chat submission box




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

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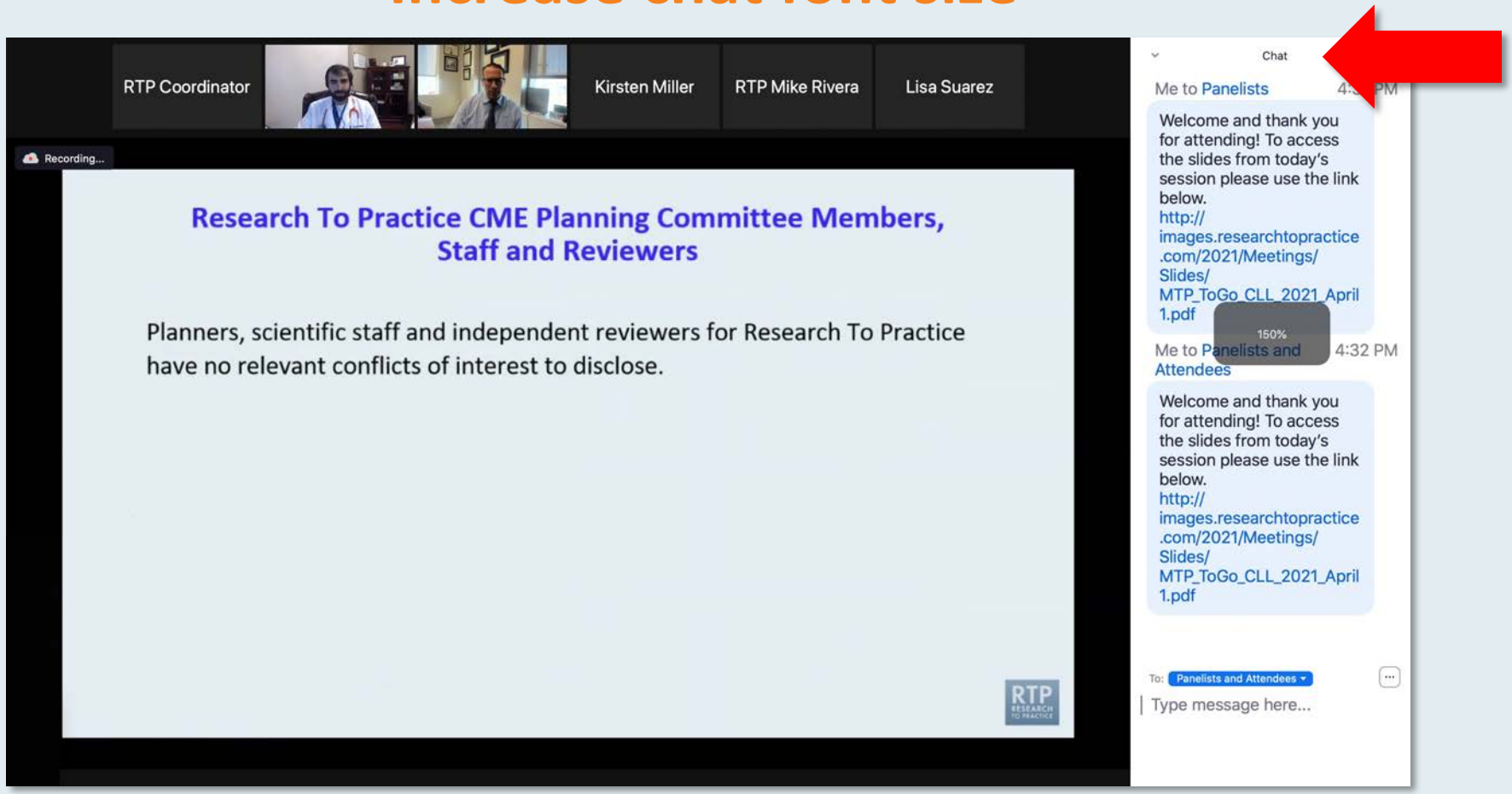
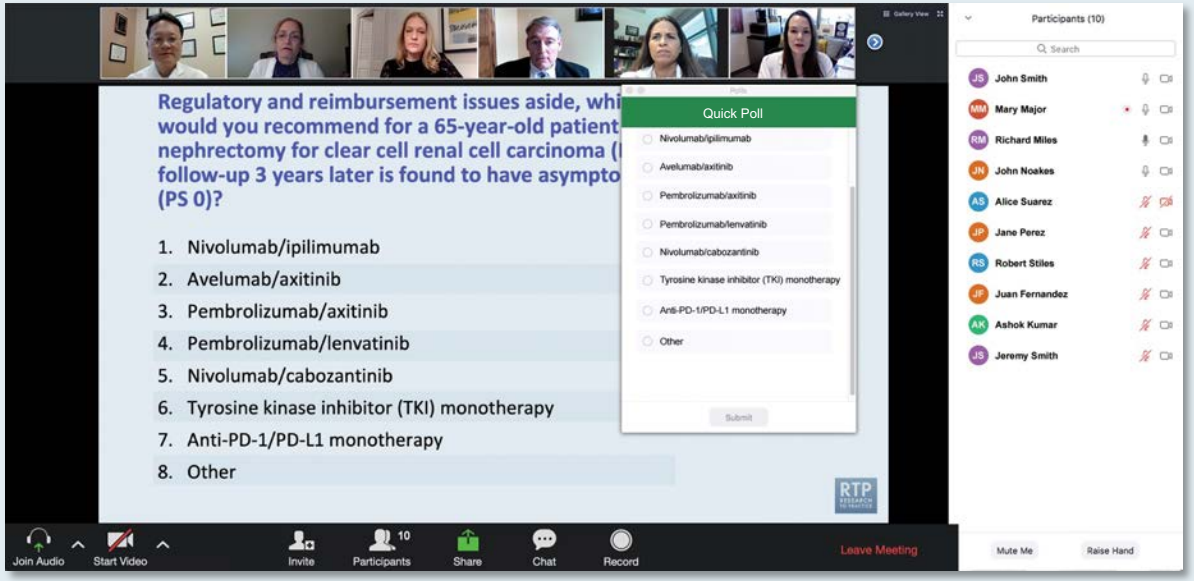
## Increase chat font size




**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

## Special Edition — Management of ER-Positive Breast Cancer

DR ERICA MAYER
DANA-FARBER CANCER INSTITUTE

DR RUTH O'REGAN
UNIVERSITY OF ROCHESTER

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Listen on Google Podcasts

# Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

*A Multitumor CME/MOC-Accredited Live Webinar Series*

# Immunotherapy and Other Nontargeted Approaches for Lung Cancer

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RTP Year in Review 2023

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**Pashtoon M Kasi, MD, MS**

**Wells A Messersmith, MD**

## Moderator

**Neil Love, MD**

RTP Year in Review 2023

# What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

***Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress***

## Cervical and Endometrial Cancer

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Paula J Anastasia, MN, RN, AOCN
Michael J Birrer, MD, PhD
Jennifer Filipi, MSN, NP
Brian M Slomovitz, MD

## Breast Cancer

**Wednesday, April 26, 2023**
6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)

**Faculty**
Jamie Carroll, APRN, MSN, CNP
Virginia Kaklamani, MD, DSc
Joyce O'Shaughnessy, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

## Diffuse Large B-Cell Lymphoma

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Amy Goodrich, CRNP
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**Faculty**
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Jacqueline Broadway-Duren, PhD, DNP, APRN, FNP-BC
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Adam S Kittai, MD

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Kelly EH Goodwin, MSN, RN, ANP-BC
Caroline Kuhlman, MSN, APRN-BC
Zev Wainberg, MD, MSc
*Additional faculty to be announced*

## Ovarian Cancer

**Friday, April 28, 2023**
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**Faculty**
Courtney Arn, CNP
David M O'Malley, MD
Richard T Penson, MD, MRCP
Jaclyn Shaver, MS, APRN, CNP, WHNP

## Hepatobiliary Cancers

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**Faculty**
Ahmed Omar Kaseb, MD, CMQ
Blanca Ledezma, MSN, NP, AOCNP
Amanda K Wagner, APRN-CNP, AOCNP
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## Lung Cancer

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Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Susan K Roethke, MSN, CRNP, AOCNP, ANP-BC
Sandy Srinivas, MD

# Beyond The Guidelines: Urologic Oncology Investigators Provide Perspectives on the Optimal Management of Urothelial Bladder Cancer

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## Faculty

**Sia Daneshmand, MD**

**Joshua J Meeks, MD, PhD**

**Matthew Milowsky, MD**

**J Alfred Witjes, MD, PhD**

## Moderator

**Arlene Siefker-Radtke, MD**

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## Faculty

**Stephen J Freedland, MD**
**Fred Saad, MD**
**Neal D Shore, MD**
**Matthew R Smith, MD, PhD**

## Moderator

***To be announced***

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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 ER-Positive and Triple-Negative Breast Cancer

**Sara A Hurvitz, MD**
Professor of Medicine
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Division of Hematology-Oncology
David Geffen School of Medicine at UCLA
Los Angeles, California

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David Geffen School of Medicine at UCLA
Los Angeles, California

**Kathy D Miller, MD**
Ballvé-Lantero Professor
Division of Hematology/Oncology
Associate Director for Clinical Research
The Indiana University Melvin and Bren Simon Cancer Center
Indianapolis, Indiana

**Komal Jhaveri, MD**
Associate Attending Physician
Breast Medicine Service and Early Drug Development Service
Section Head, Endocrine Therapy Research Program
Clinical Director, Early Drug Development Service
Department of Medicine
Memorial Sloan Kettering Cancer Center
Assistant Professor of Medicine
Weill Cornell College of Medicine
New York, New York

**Ann Partridge, MD, MPH**
Vice Chair of Medical Oncology
Director, Program for Young Women with Breast Cancer
Director, Adult Survivorship Program
Dana-Farber Cancer Institute
Professor of Medicine
Harvard Medical School
Boston, Massachusetts

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# *Meet The Professor* Program Participating Faculty

**Melinda Telli, MD**
Associate Professor of Medicine
Stanford University School of Medicine
Director, Breast Cancer Program
Stanford Cancer Institute
Stanford, California

**MODERATOR**
**Neil Love, MD**
Research To Practice
Miami, Florida

**Sara M Tolaney, MD, MPH**
Chief, Division of Breast Oncology
Associate Director, Susan F Smith Center for Women's Cancers
Senior Physician
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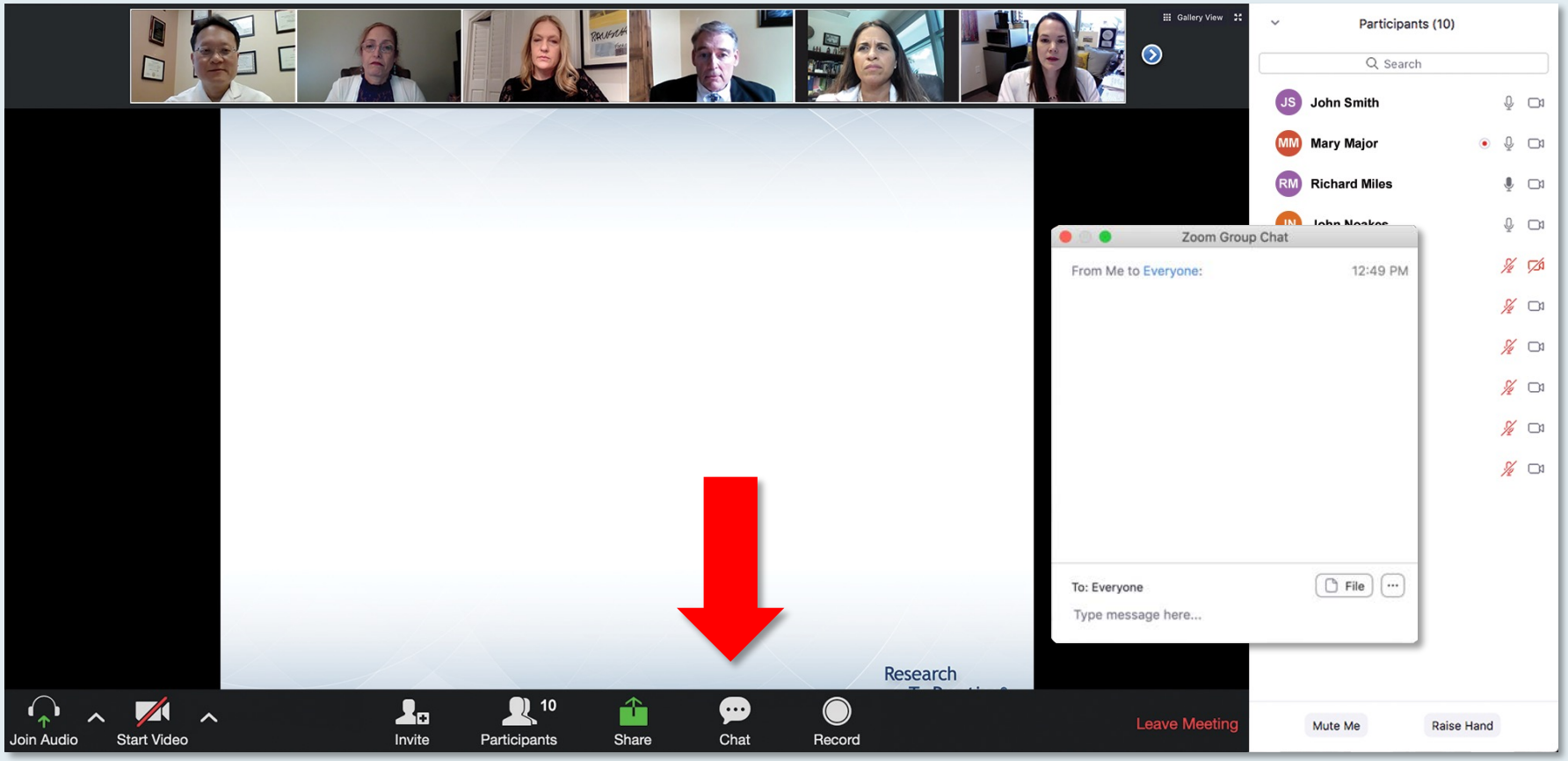


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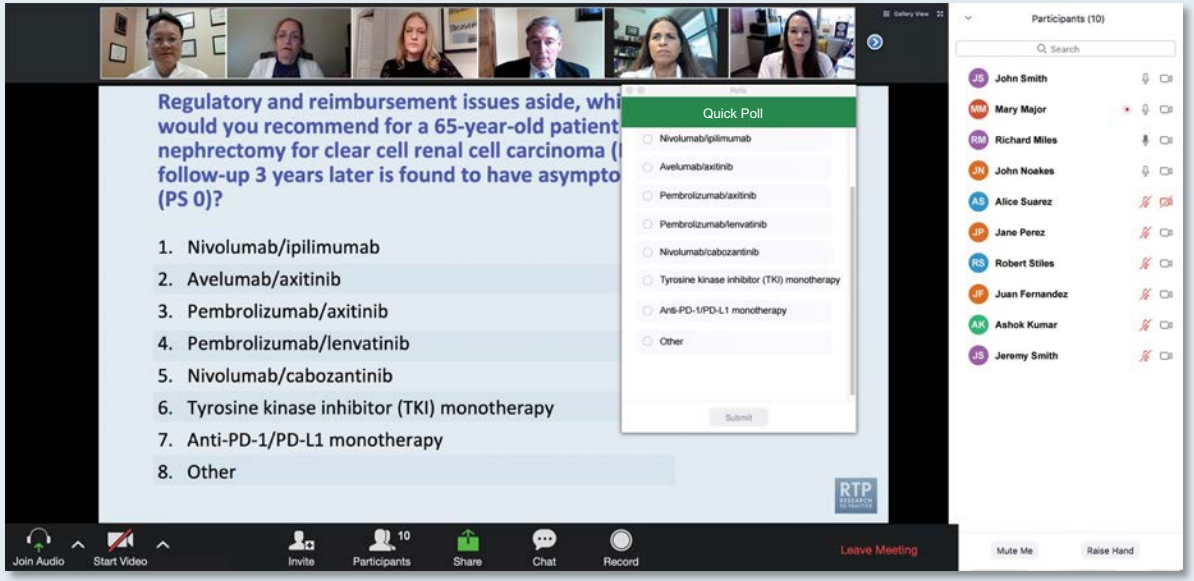


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WITH DR NEIL LOVE

## Special Edition — Management of ER-Positive Breast Cancer

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DANA-FARBER CANCER INSTITUTE

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UNIVERSITY OF ROCHESTER

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# Dr Hurvitz — Disclosures

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| **Nonrelevant Financial Relationship** | Ideal Implant (spouse) |

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**Alan B Astrow, MD**
NewYork-Presbyterian Brooklyn
Methodist Hospital
Brooklyn, New York

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

**Gigi Chen, MD**
John Muir Health
Pleasant Hill, California

**Ranju Gupta, MD**
Cancer Institute
Lehigh Valley Topper Cancer Institute
Bethlehem, Pennsylvania

**Jennifer L Dallas, MD**
Oncology Specialists of Charlotte
Charlotte, North Carolina

**Zanetta S Lamar, MD**
Florida Cancer Specialists
Naples, Florida

**Victoria Giffi, MD**
Meritus Hematology and
Oncology Specialists
Hagerstown, Maryland

**Nick Leasure, MD**
Tower Health Reading
West Reading, Pennsylvania

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**Rajalaxmi McKenna, MD**
Southwest Medical
Consultants SC
Willowbrook, Illinois

**Nasfat Shehadeh, MD**
Oncology Specialists of Charlotte
Charlotte, North Carolina

**William R Mitchell, MD**
Southern Oncology Specialists
Charlotte, North Carolina

# Meet The Professor with Dr Hurvitz

**Introduction: Antibody-Drug Conjugates in Breast Cancer**

**MODULE 1: Case Presentations**

**Appendix**

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TO PRACTICE

- Dr Gupta: 48-year-old premenopausal woman with 0.8-cm ER/PR-positive, HER2-negative IDC with 2 positive nodes and an Onco*type* DX® Recurrence Score® (RS) of 9
- Dr Leasure: 42-year-old premenopausal woman with 5-cm ER/PR-positive, HER2-negative Grade I IDC
- Dr Chen: 70-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic IDC receiving T-DXd with mixed response
- Dr Lamar: 48-year-old woman with multicentric gBRCA1-mutant TNBC who receives treatment per KEYNOTE-522 and achieves a CR to neoadjuvant treatment
- Dr Mitchell: 50-year-old premenopausal woman with bilateral ER/PR-positive, HER2-negative, PALB2-mutant IDC and multiple, bilateral positive nodes
- Dr Shehadeh: 46-year-old woman with ER/PR-positive, HER2-negative, gBRCA1-mutant metastatic breast cancer receiving fulvestrant/Palbociclib
- Dr Astrow: 36-year-old woman who is 18 weeks pregnant with ER/PR-positive, HER2-negative IDC and an Onco*type* DX RS of 17
- Dr Gosain: 49-year-old woman with ER/PR-positive, HER2-negative, NTRK-mutant metastatic breast cancer with CNS involvement who receives entrectinib
- Dr McKenna: 63-year-old woman with ER/PR-positive, HER2-negative metaplastic breast cancer with an Onco*type* DX RS of 51 who has received adjuvant AI x 16 years
- Dr Dallas: 73-year-old woman with ER/PR-positive, HER2-negative, node-negative breast cancer and an Onco*type* DX RS of 29 who receives adjuvant TC and develops taxane-associated pain syndrome
- Dr Giffi: 35-year-old woman with ER/PR-positive, HER2-negative, node-positive IDC and residual disease after neoadjuvant chemotherapy and mastectomy who receives adjuvant RT and abemaciclib with goserelin and letrozole

# Meet The Professor with Dr Hurvitz

## Introduction: Antibody-Drug Conjugates in Breast Cancer

**MODULE 1: Case Presentations**

**Appendix**

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Clinical outlook

https://doi.org/10.1038/s43018-022-00495-7

# Recent progress in antibody–drug conjugate therapy for cancer

Sara A. Hurvitz

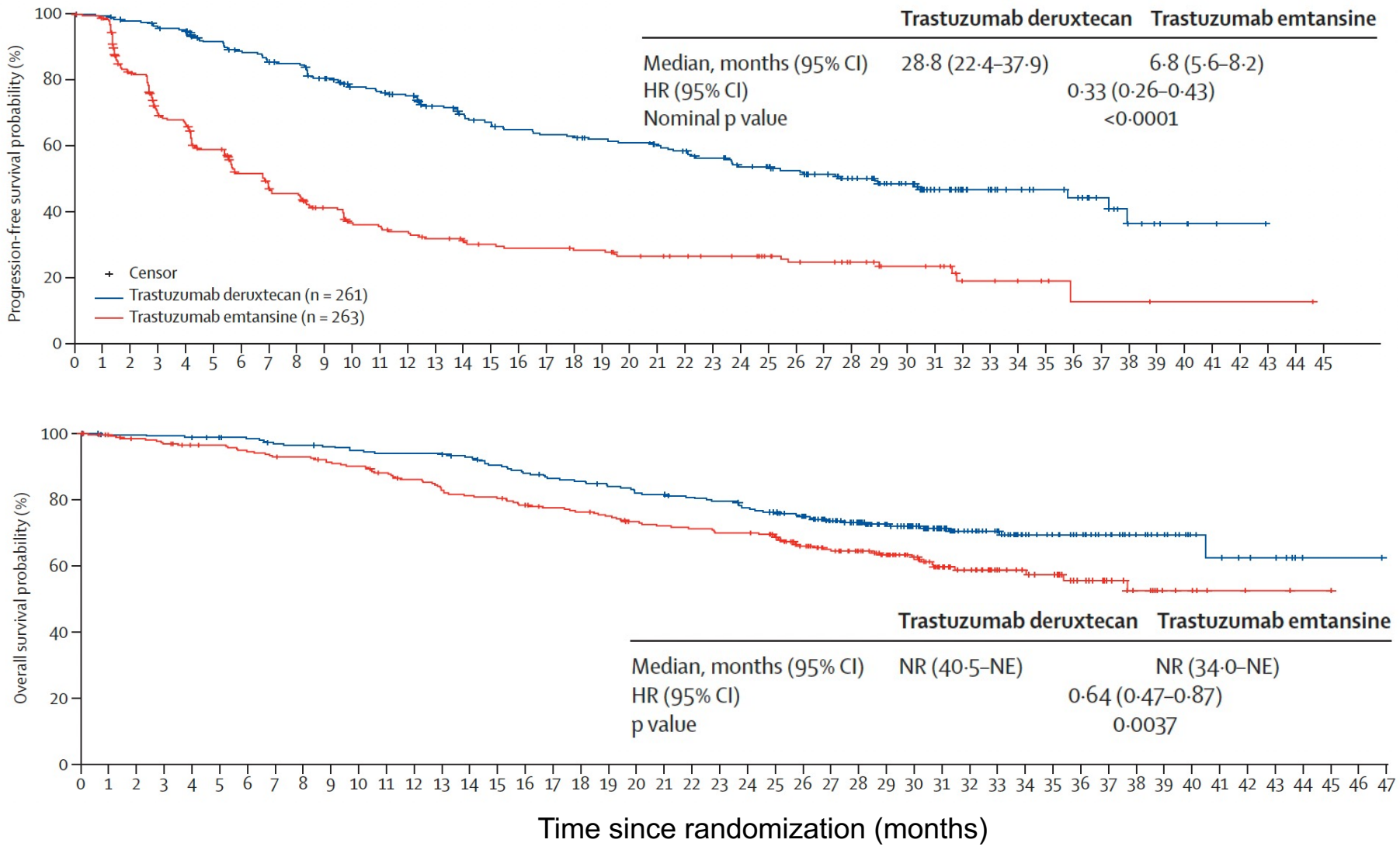
*Nat Cancer* 2022 December;3(12):1412-3.

*Lancet* 2023;401:105-17.

# Trastuzumab deruxtecan versus trastuzumab emtansine in patients with HER2-positive metastatic breast cancer: updated results from DESTINY-Breast03, a randomised, open-label, phase 3 trial

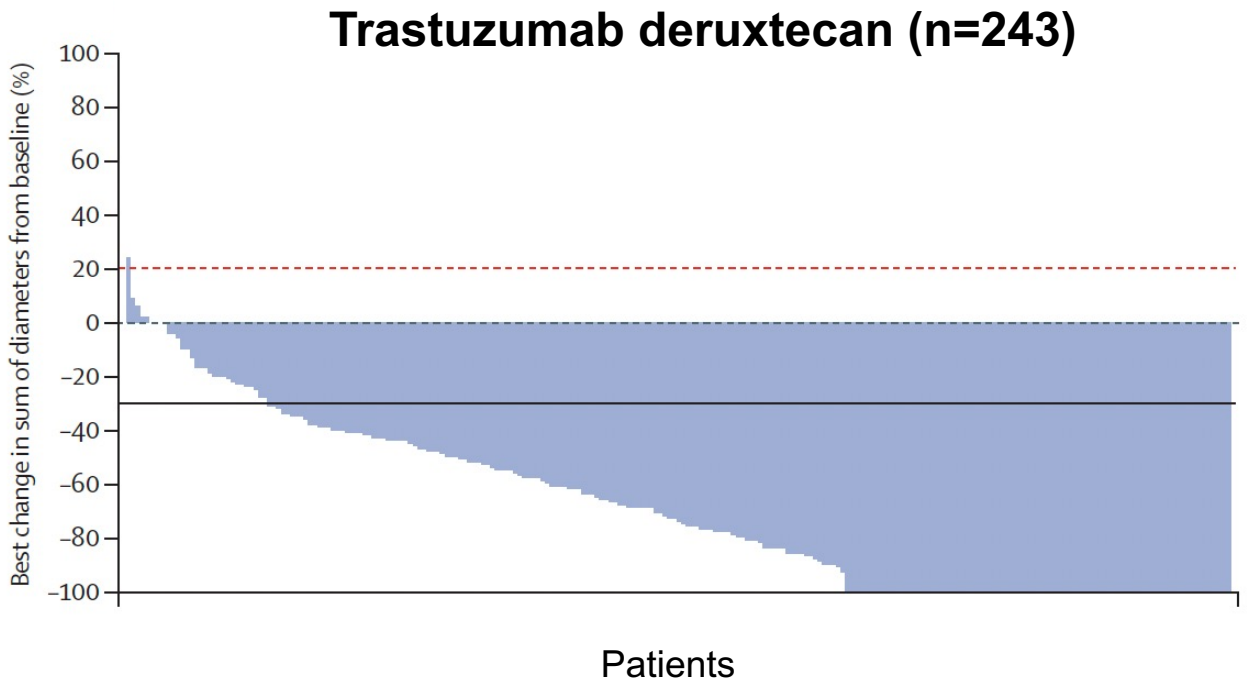
*Sara A Hurvitz, Roberto Hegg, Wei-Pang Chung, Seock-Ah Im, William Jacot, Vinod Ganju, Joanne Wing Yan Chiu, Binghe Xu, Erika Hamilton, Srinivasan Madhusudan, Hiroji Iwata, Sevilay Altintas, Jan-Willem Henning, Giuseppe Curigliano, José Manuel Perez-Garcia, Sung-Bae Kim, Vanessa Petry, Chiun-Sheng Huang, Wei Li, Jean-Sebastien Frenel, Silvia Antolin, Winnie Yeo, Giampaolo Bianchini, Sherene Loi, Junji Tsurutani, Anton Egorov, Yali Liu, Jillian Cathcart, Shahid Ashfaque, Javier Cortés*

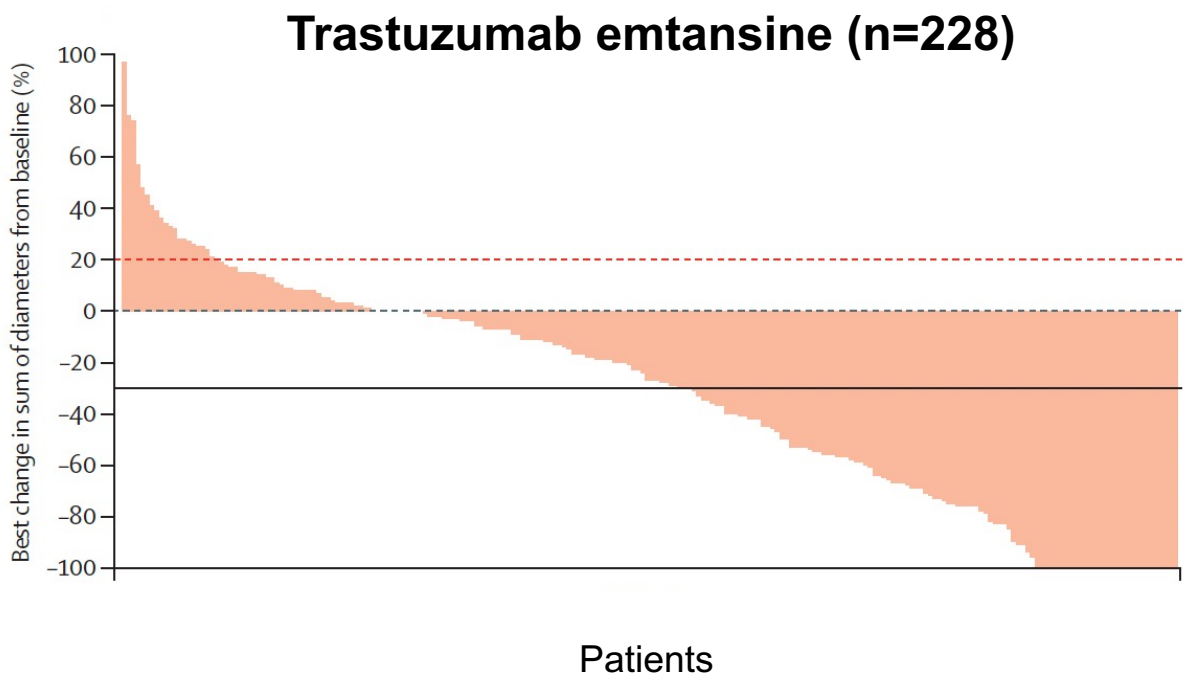
# DESTINY-Breast03: Progression-Free and Overall Survival




Hurvitz SA et al. *Lancet* 2023;401:105-17.

# DESTINY-Breast03: Antitumor Activity of Trastuzumab Deruxtecan and Trastuzumab Emtansine




Hurvitz SA et al. *Lancet* 2023;401:105-17.

The NEW ENGLAND JOURNAL of MEDICINE

2022 July 7;387(1):75-6.

EDITORIALS

# DESTINY-Changing Results for Advanced Breast Cancer

Sara A. Hurvitz, M.D.

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*

*"The implications of the results of the DESTINYBreast04 trial reported by Modi et al in this issue of the Journal are difficult to overstate…"*

Hurvitz SA. *N Engl J Med* 2022 July 7;387(1):75-6.

*"This will undoubtedly translate into a new therapeutic option for nearly half the patients who receive a diagnosis of metastatic breast cancer, an extraordinary finding…"*

Hurvitz SA. *N Engl J Med* 2022 July 7;387(1):75-6.

*"These results should inspire scientists to begin the rigorous yet critically important translational components of this trial, including efforts to accurately identify those patients who are most likely to benefit."*

Hurvitz SA. *N Engl J Med* 2022 July 7;387(1):75-6.

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

*Cancer Discov* 2022 October 18:CD-22-0837.

RESEARCH BRIEF

# Trastuzumab Deruxtecan in HER2-Positive Metastatic Breast Cancer Patients with Brain Metastases: A DESTINY-Breast01 Subgroup Analysis

Guy Jerusalem[1], Yeon Hee Park[2], Toshinari Yamashita[3], Sara A. Hurvitz[4], Shanu Modi[5], Fabrice Andre[6], Ian E. Krop[7], Xavier Gonzàlez Farré[8], Benoit You[9], Cristina Saura[10], Sung-Bae Kim[11], Cynthia R. Osborne[12,13], Rashmi K. Murthy[14], Lorenzo Gianni[15], Toshimi Takano[16], Yali Liu[17], Jillian Cathcart[17], Caleb Lee[17], and Christophe Perrin[18]

JC JOURNAL CLUB

RTP RESEARCH TO PRACTICE

PD13-08

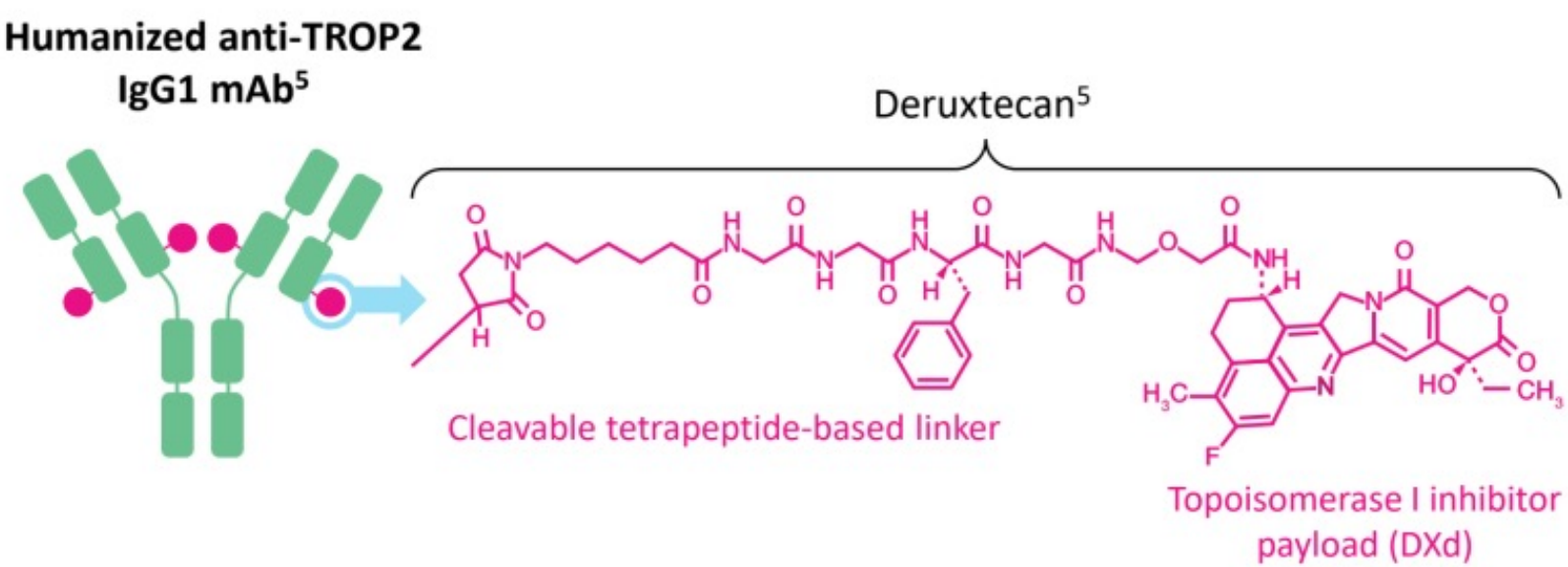
SABCS 2022

# Phase 1 TROPION-PanTumor01 Study Evaluating Datopotamab Deruxtecan (Dato-DXd) in Unresectable or Metastatic Hormone Receptor–Positive/HER2-Negative Breast Cancer

Funda Meric-Bernstam,[1] Ian E. Krop,[2] Dejan Juric,[3] Takahiro Kogawa,[4] Erika P. Hamilton,[5,6] Alexander I. Spira,[7] Toru Mukohara,[8] Takuya Tsunoda,[9] Senthil Damodaran,[1] Jonathan Greenberg,[10,11] Wen Gu,[10] Fumiaki Kobayashi,[12] Hong Zebger-Gong,[10,11] Yui Kawasaki,[11] Rie Wong,[12] Aditya Bardia[3]

[1]The University of Texas MD Anderson Cancer Center, Houston, TX; [2]Yale Cancer Center, New Haven, CT; [3]Massachusetts General Hospital Cancer Center, Department of Medicine, Harvard Medical School, Boston, MA; [4]Department of Advanced Medical Development, Cancer Institute Hospital of JFCR, Tokyo, Japan; [5]Sarah Cannon Research Institute, Nashville, TN; [6]Tennessee Oncology, PLLC, Nashville, TN; [7]Virginia Cancer Specialists (VCS) Research Institute, Fairfax, VA; [8]National Cancer Center Hospital East, Kashiwa, Japan; [9]Division of Medical Oncology, Showa University, School of Medicine, Tokyo, Japan; [10]Daiichi Sankyo, Inc, Basking Ridge, NJ; [11]Daiichi Sankyo Europe GmbH, Munich, Germany; [12]Daiichi Sankyo, Co., Ltd, Tokyo, Japan

# Datopotamab Deruxtecan Mechanism of Action



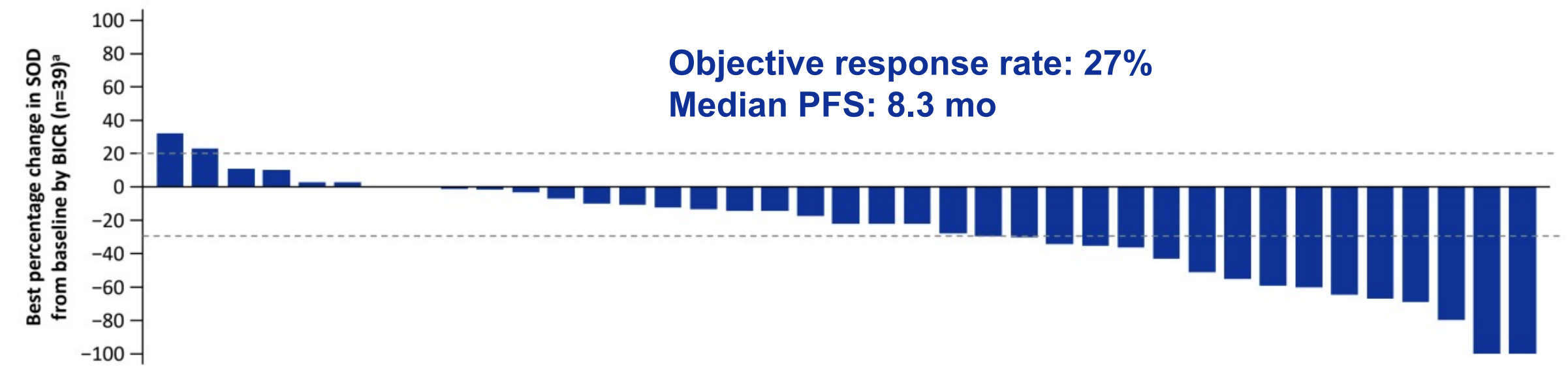

**7 Key Attributes**

- Payload mechanism of action: topoisomerase I inhibitor[5-7,a]
- High potency of payload[5-7,a]
- Optimized drug to antibody ratio ≈4[5,a,b]
- Payload with short systemic half-life[5-7,a,b]
- Stable linker-payload[5-7,a]
- Tumor-selective cleavable linker[5-7,a]
- Bystander antitumor effect[6,8,a]

[a] The clinical relevance of these features is under investigation.
[b] Based on animal data.

Meric-Bernstam F et al. San Antonio Breast Cancer Symposium 2022;Abstract PD13-08.

# TROPION-PanTumor01: Datopotamab Deruxtecan for HR-Positive, HER2-Negative Metastatic Breast Cancer




Meric-Bernstam F et al. SABCS 2022;Abstract PD13-08.

RTP RESEARCH TO PRACTICE

# TROPION-PanTumor01: Safety Summary

| Patients, n (%) | N=41 | |
|---|---|---|
| | Any grade | Grade ≥3 |
| **TEAEs** | 41 (100) | 17 (41) |
| **Treatment-related TEAEs** | 41 (100) | 9 (22) |
| **Dose adjustments due to AEs** | | |
| Dose reductions[a] | 5 (12) | |
| Treatment interruptions[b] | 15 (37) | |
| Treatment discontinuations[c] | 5 (12) | |
| **Serious TEAEs** | 6 (15) | |
| Treatment related[d] | 1 (2) | |

Meric-Bernstam F et al. SABCS 2022;Abstract PD13-08.

# Meet The Professor with Dr Hurvitz

## Introduction: Antibody-Drug Conjugates in Breast Cancer

## MODULE 1: Case Presentations

- Dr Gupta: 48-year-old premenopausal woman with 0.8-cm ER/PR-positive, HER2-negative IDC with 2 positive nodes and an Onco*type* DX® Recurrence Score® (RS) of 9
- Dr Leasure: 42-year-old premenopausal woman with 5-cm ER/PR-positive, HER2-negative Grade I IDC
- Dr Chen: 70-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic IDC receiving T-DXd with mixed response
- Dr Lamar: 48-year-old woman with multicentric gBRCA1-mutant TNBC who receives treatment per KEYNOTE-522 and achieves a CR to neoadjuvant treatment
- Dr Mitchell: 50-year-old premenopausal woman with bilateral ER/PR-positive, HER2-negative, PALB2-mutant IDC and multiple, bilateral positive nodes
- Dr Shehadeh: 46-year-old woman with ER/PR-positive, HER2-negative, gBRCA1-mutant metastatic breast cancer receiving fulvestrant/palbociclib

## Appendix

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# Meet The Professor with Dr Hurvitz

## Introduction: Antibody-Drug Conjugates in Breast Cancer

## MODULE 1: Case Presentations (continued)

- Dr Astrow: 36-year-old woman who is 18 weeks pregnant with ER/PR-positive, HER2-negative IDC and an Onco*type* DX RS of 17
- Dr Gosain: 49-year-old woman with ER/PR-positive, HER2-negative, NTRK-mutant metastatic breast cancer with CNS involvement who receives entrectinib
- Dr McKenna: 63-year-old woman with ER/PR-positive, HER2-negative metaplastic breast cancer with an Onco*type* DX RS of 51 who has received adjuvant AI x 16 years
- Dr Dallas: 73-year-old woman with ER/PR-positive, HER2-negative, node-negative breast cancer and an Onco*type* DX RS of 29 who receives adjuvant TC and develops taxane-associated pain syndrome
- Dr Giffi: 35-year-old woman with ER/PR-positive, HER2-negative, node-positive IDC and residual disease after neoadjuvant chemotherapy and mastectomy who receives adjuvant RT and abemaciclib with goserelin and letrozole

## Appendix

# Case Presentation: 48-year-old premenopausal woman with 0.8-cm ER/PR-positive, HER2-negative IDC with 2 positive nodes and an Oncotype DX RS of 9

Dr Ranju Gupta (Bethlehem, Pennsylvania)

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# Case Presentation: 42-year-old premenopausal woman with 5-cm ER/PR-positive, HER2-negative Grade I IDC

Dr Nick Leasure (West Reading, Pennsylvania)

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## Which adjuvant endocrine therapy (ET) would you most likely recommend for a 30-year-old premenopausal woman with node-negative, ER-positive, HER2-negative localized breast cancer and the Recurrence Score® (RS) below? Would you recommend adjuvant chemotherapy?

| | RS = 8 | | RS = 20 | |
|---|---|---|---|---|
| | ET | Chemotherapy? | ET | Chemotherapy? |
|  Dr Hurvitz | OFS/ablation + tamoxifen, or Tam alone if small tumor | No | OFS/ablation + tamoxifen | Yes, but OFS/ablation as alternative |
|  Dr Jhaveri | Tamoxifen | No | OFS/ablation + tamoxifen or letrozole | Yes, but OFS/ablation as alternative |
|  Dr Miller | OFS/ablation + anastrozole | No | OFS/ablation + anastrozole | Yes, but OFS/ablation as alternative |
|  Dr Partridge | Tamoxifen +/- OFS/ablation | No | OFS/ablation + letrozole | Yes, but OFS/ablation as alternative |
|  Dr Telli | Tamoxifen | No | OFS/ablation + exemestane | No |
|  Dr Tolaney | Tamoxifen | No | OFS/ablation + letrozole | Yes, but OFS/ablation as alternative |

OFS = ovarian function suppression

# Which adjuvant ET would you most likely recommend for a 30-year-old premenopausal woman with ER-positive, HER2-negative localized breast cancer with 1 positive node and the RS below? Would you recommend adjuvant chemotherapy?

| | RS = 8 | | RS = 20 | |
|---|---|---|---|---|
| | ET | Chemotherapy? | ET | Chemotherapy? |
|  Dr Hurvitz | OFS/ablation + tamoxifen | Yes, but OFS/ablation as alternative | OFS/ablation + anastrozole | Yes |
|  Dr Jhaveri | OFS/ablation + tamoxifen or letrozole | Yes, but OFS/ablation as alternative | OFS/ablation + tamoxifen or letrozole | Yes |
|  Dr Miller | OFS/ablation + anastrozole | No | OFS/ablation + anastrozole | Yes, but OFS/ablation as alternative |
|  Dr Partridge | OFS/ablation + tamoxifen or + letrozole | Yes, but OFS/ablation as alternative | OFS/ablation + letrozole | Yes, but OFS/ablation as alternative |
|  Dr Telli | OFS/ablation + exemestane | Yes, but OFS/ablation as alternative | OFS/ablation + exemestane | Yes |
|  Dr Tolaney | OFS/ablation + letrozole | No | OFS/ablation + letrozole | Yes |

OFS = ovarian function suppression

## Which adjuvant ET would you most likely recommend for a 65-year-old postmenopausal woman with ER-positive, HER2-negative localized breast cancer with 1 positive node and the RS below? Would you recommend adjuvant chemotherapy?

| | RS = 8 | | RS = 20 | |
|---|---|---|---|---|
| | ET | Chemotherapy? | ET | Chemotherapy? |
|  Dr Hurvitz | Anastrozole | No | Anastrozole | No |
|  Dr Jhaveri | Letrozole | No | Letrozole | No |
|  Dr Miller | Anastrozole | No | Anastrozole | No |
|  Dr Partridge | Letrozole | No | Letrozole | No |
|  Dr Telli | Anastrozole | No | Anastrozole | No |
|  Dr Tolaney | Letrozole | No | Letrozole | No |

## Which adjuvant ET would you most likely recommend for a 65-year-old postmenopausal woman with ER-positive, HER2-negative localized breast cancer with 3 positive nodes and the RS below? Would you recommend adjuvant chemotherapy?

| | RS = 8 | | RS = 20 | |
|---|---|---|---|---|
| | ET | Chemotherapy? | ET | Chemotherapy? |
|  Dr Hurvitz | Anastrozole | No | Anastrozole | No |
|  Dr Jhaveri | Letrozole | No | Letrozole | No |
|  Dr Miller | Anastrozole | No | Anastrozole | No |
|  Dr Partridge | Letrozole | No | Letrozole | No |
|  Dr Telli | Anastrozole | No | Anastrozole | No |
|  Dr Tolaney | Letrozole | No | Letrozole | No |

## For premenopausal patients (age 20-40 years) with ER-positive, HER2-negative localized breast cancer who are about to receive adjuvant chemotherapy, do you generally offer the option of using OFS during chemotherapy in the following clinical scenarios?

| | For fertility preservation | For ovarian function preservation |
|---|---|---|
|  Dr Hurvitz | Yes | Yes |
|  Dr Jhaveri | No* | Yes |
|  Dr Miller | Yes | No |
|  Dr Partridge | Yes | Yes |
|  Dr Telli | Yes | Yes |
|  Dr Tolaney | Yes | Yes |

OFS = ovarian function suppression; *Fertility specialist discusses with patient

## For premenopausal patients (age 20-40 years) with ER-positive, HER2-positive localized breast cancer who are about to receive adjuvant chemotherapy, do you generally offer the option of using OFS during chemotherapy in the following clinical scenarios?

| | For fertility preservation | For ovarian function preservation |
|---|---|---|
|  Dr Hurvitz | Yes | Yes |
|  Dr Jhaveri | No* | Yes |
|  Dr Miller | No | No |
|  Dr Partridge | Yes | Yes |
|  Dr Telli | Yes | Yes |
|  Dr Tolaney | Yes | Yes |

OFS = ovarian function suppression; *Fertility specialist discusses with patient

# In general, which CDK4/6 inhibitor do you recommend in combination with endocrine therapy as first-line treatment for women with ER-positive, HER2-negative metastatic breast cancer if they are…?

| | Postmenopausal | Premenopausal |
|---|---|---|
|  Dr Hurvitz | Ribociclib | Ribociclib |
|  Dr Jhaveri | Ribociclib | Ribociclib |
|  Dr Miller | Palbociclib | Palbociclib |
|  Dr Partridge | No preference | Ribociclib |
|  Dr Telli | No preference – decision based on patient characteristics, side-effect profile | Ribociclib |
|  Dr Tolaney | Ribociclib | Ribociclib |

**A patient who is receiving palbociclib/letrozole for ER-positive, HER2 IHC 1+ metastatic breast cancer experiences disease progression. Regulatory and reimbursement issues aside, which systemic treatment would you most likely recommend if genomic testing revealed the following results?**

| | PIK3CA mutation | PIK3CA wild type |
|---|---|---|
|  Dr Hurvitz | Alpelisib/fulvestrant | Everolimus/fulvestrant |
|  Dr Jhaveri | Alpelisib/fulvestrant | Everolimus/fulvestrant |
|  Dr Miller | Alpelisib/fulvestrant | Everolimus/fulvestrant |
|  Dr Partridge | Alpelisib/fulvestrant, or possibly T-DXd | Everolimus/exemestane, or possibly T-DXd |
|  Dr Telli | Alpelisib/fulvestrant | Fulvestrant +/- exemestane |
|  Dr Tolaney | Alpelisib/fulvestrant | Everolimus/fulvestrant |

T-DXd = trastuzumab deruxtecan

# Following the recent FDA approval of the oral SERD elacestrant for postmenopausal women or men with ER-positive, HER2-negative, ESR1-mutated advanced breast cancer with disease progression after at least 1 line of endocrine therapy, in what situations, if any, do you plan to use this agent?

| | | | |
|---|---|---|---|
|  Dr Hurvitz | ESR1 mutation, after CDK4/6i and probably after a line of everolimus or alpelisib + fulvestrant, prolonged benefit from CDK4/6i |  Dr Partridge | Second line |
|  Dr Jhaveri | ESR1 mutation, duration of response to CDK4/6i >12 months* |  Dr Telli | Most likely third-line |
|  Dr Miller | As oral therapy rather than fulvestrant |  Dr Tolaney | ESR1 mutation, after progression on CDK4/6i + AI with prolonged benefit* |

*Also PIK3CA wild type

RTP RESEARCH TO PRACTICE

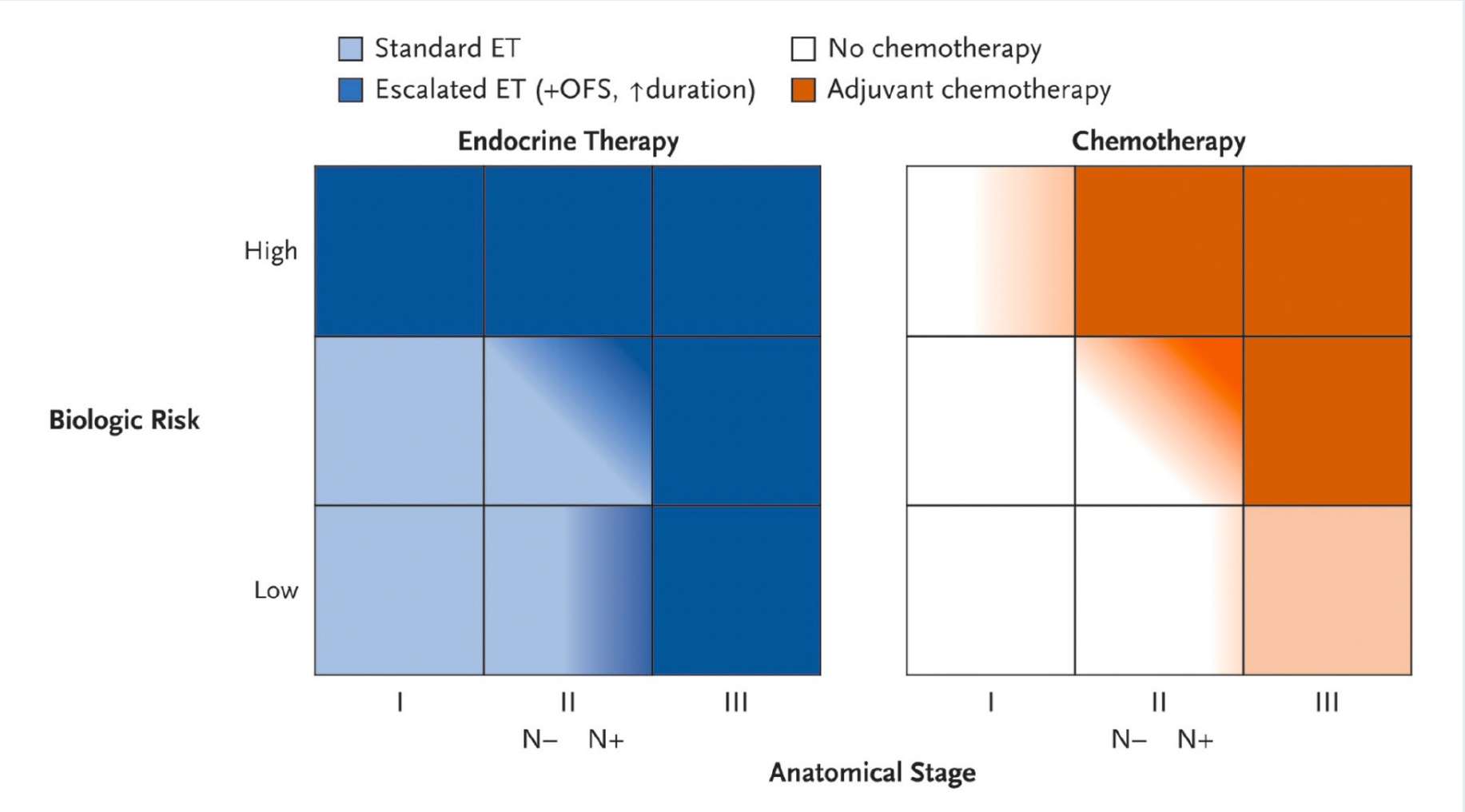
***Cancer* 2022 June 1;128 Suppl 11:2209-23.**

Original Article

# A look at current and potential treatment approaches for hormone receptor-positive, HER2-negative early breast cancer

Nadia Harbeck, MD, PhD[1]; Harold J. Burstein, MD, PhD[2]; Sara A. Hurvitz, MD[3,4]; Stephen Johnston, MA, PhD, FRCP[5]; and Gregory A. Vidal, MD, PhD[6,7]

# Model of Treatment Decision-Making for Patients with HR-Positive Localized Breast Cancer




Harbeck N et al. *Cancer* 2022 June 1;128 Suppl 11:2209-23.

# Phase III NATALEE Trial of Ribociclib Meets Its Primary Endpoint at Interim Analysis Demonstrating a Clinically Meaningful Benefit in a Broad Population of Patients with Localized Breast Cancer

## Press Release: March 27, 2023

"• *NATALEE is the first and only positive Phase III study of a CDK4/6 inhibitor demonstrating consistent benefit in a broad population of patients with Stage II and III HR+/HER2- early breast cancer (EBC) at risk of recurrence, including those with no nodal involvement*

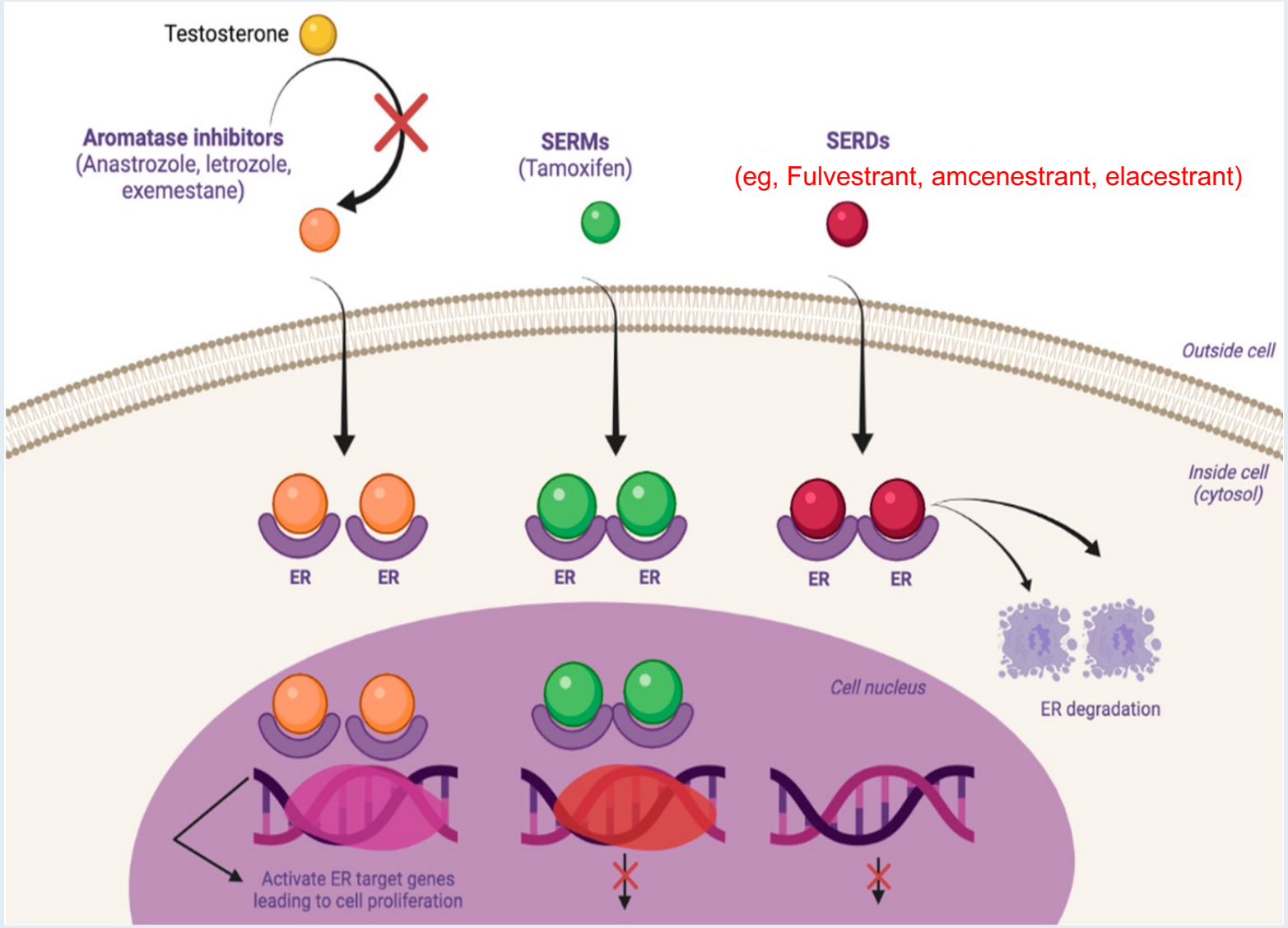
• *Approximately 30% to 60% of people with HR+/HER2- Stage II and III EBC treated with ET only remain at risk of breast cancer recurrence*

Positive topline results [were announced] from an interim analysis of NATALEE, a Phase III trial evaluating ribociclib plus endocrine therapy (ET) in a broad population of patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) early breast cancer (EBC) at risk of recurrence. The Independent Data Monitoring Committee recommended stopping the trial early as the primary endpoint of invasive disease-free survival (iDFS) has been met. Ribociclib plus ET significantly reduced the risk of disease recurrence, compared to standard adjuvant ET alone, with consistent benefit in patients with stage II and stage III EBC regardless of nodal involvement."

https://www.novartis.com/news/media-releases/novartis-kisqali-phase-iii-natalee-trial-meets-primary-endpoint-interim-analysis-demonstrating-clinically-meaningful-benefit-broad-population-patients-early-breast-cancer

RTP RESEARCH TO PRACTICE

# Mechanism of Action of Different Endocrine Therapies




Hernando C et al. *Int J Mol Sci* 2021;22:7812.

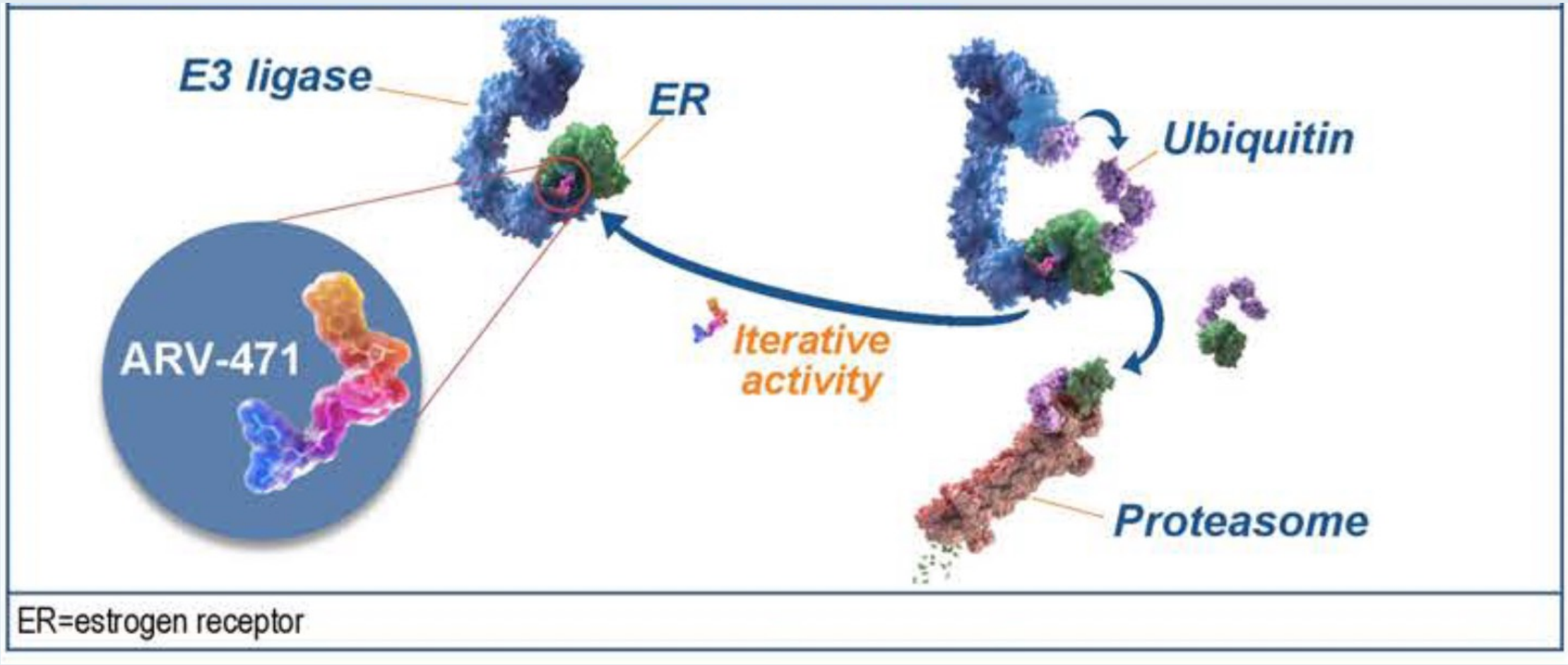
RTP RESEARCH TO PRACTICE

# ARV-471, an Estrogen Receptor (ER) PROTAC Degrader, Combined with Palbociclib in Advanced ER+/Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Breast Cancer: Phase 1b Cohort (Part C) of a Phase 1/2 Study

Hamilton EP et al.

ASCO 2022;Abstract TPS1120.

# ARV-471 Mechanism of Action




Hamilton EP et al. ASCO 2022;Abstract TPS1120.

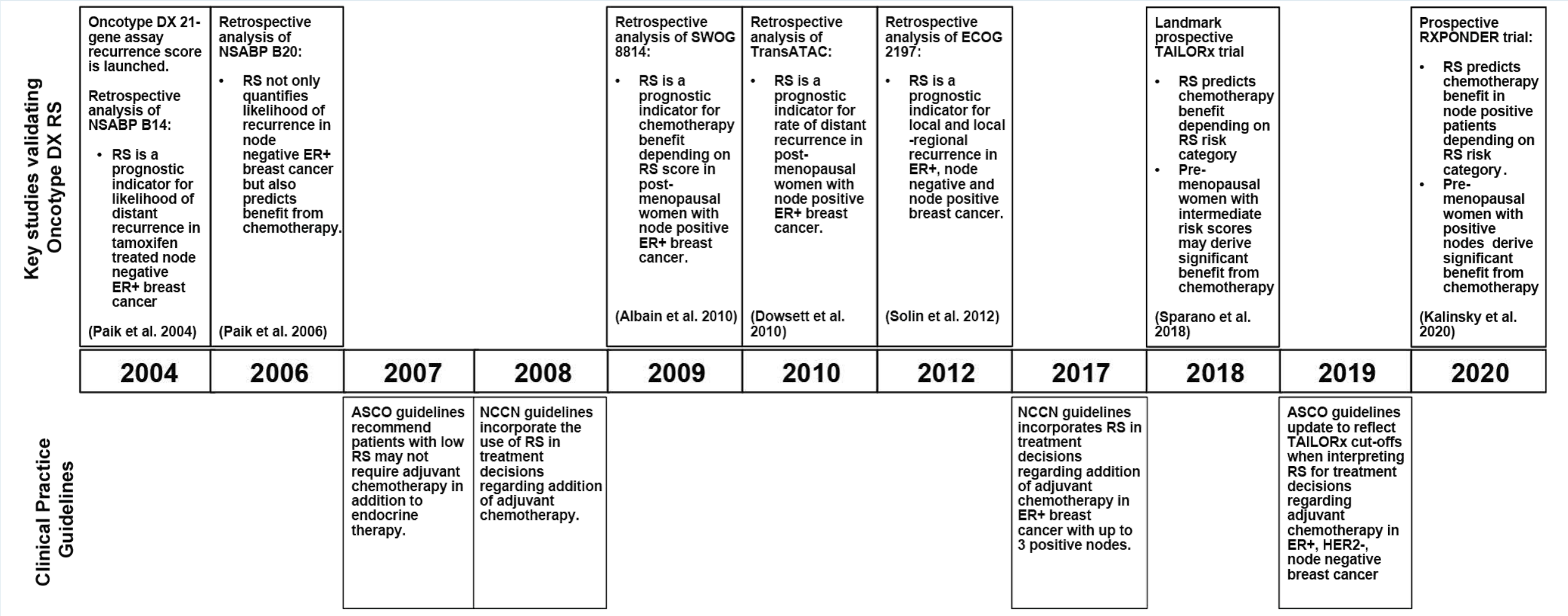
2022 March 10;14:17588359221081077

*Therapeutic Advances in Medical Oncology*

# Oncotype DX Recurrence Score in premenopausal women

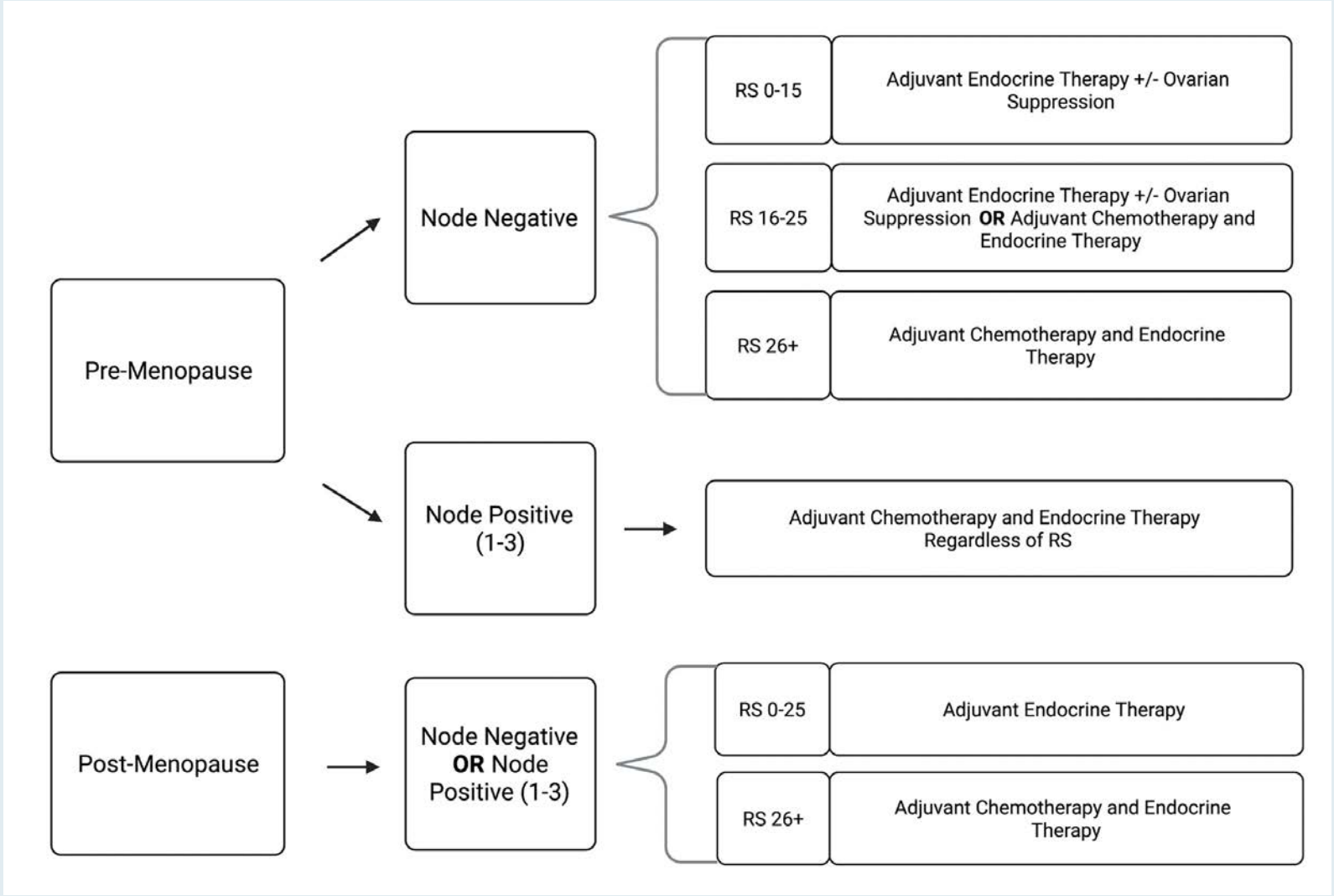
**Shiliang Zhang, Kasey C. Fitzsimmons and Sara A. Hurvitz**

# Timeline of Key Studies Validating Oncotype DX 21-Gene Assay Recurrence Score and its Incorporation into Breast Cancer Treatment Guidelines




Zhang S et al. *Ther Adv Med Oncol* 2022 March 10;14:17588359221081077.

# Oncotype DX 21-Gene Assay Recurrence Score Interpretation for Premenopausal and Postmenopausal Women with Localized ER-Positive, HER2-Negative Breast Cancer




Zhang S et al. *Ther Adv Med Oncol* 2022 March 10;14:17588359221081077.

# (OT2-03-02) lidERA Breast Cancer: A phase III adjuvant study of giredestrant (GDC-9545) vs physician's choice of endocrine therapy in patients with estrogen receptor+, HER2– early breast cancer

Schmid P et al.
SABCS 2022;Abstract OT-03-02.

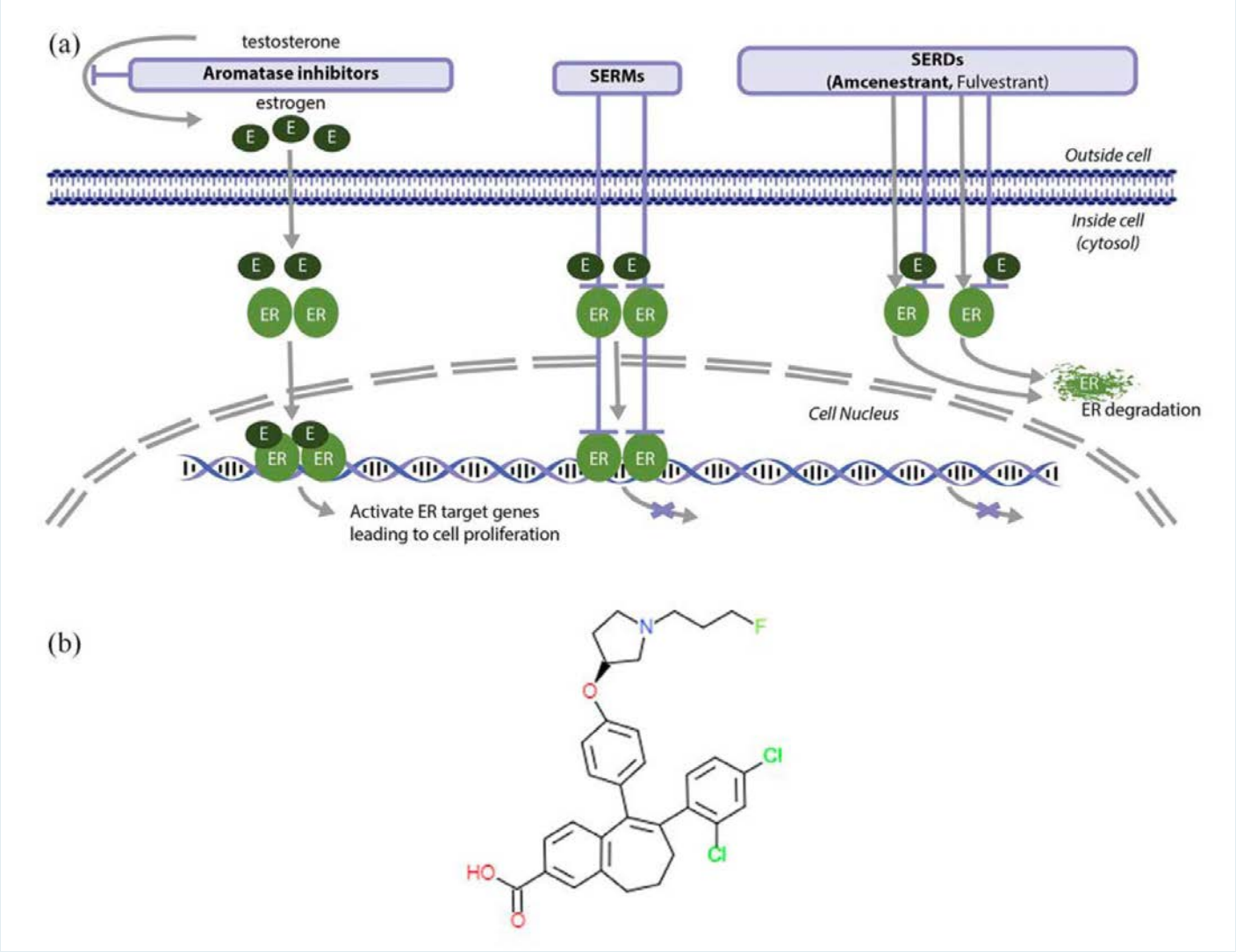
2022 March 15;14:17588359221083956

*Therapeutic Advances in Medical Oncology*

# AMEERA-5: a randomized, double-blind phase 3 study of amcenestrant plus palbociclib *versus* letrozole plus palbociclib for previously untreated ER+/HER2– advanced breast cancer

**Aditya Bardia, Javier Cortes, Sara A. Hurvitz, Suzette Delaloge, Hiroji Iwata, Zhi-Ming Shao, Dheepak Kanagavel, Patrick Cohen, Qianying Liu, Sylvaine Cartot-Cotton, Vasiliki Pelekanou* and Joyce O'Shaughnessy**

# Amcenestrant, an Oral SERD, Antagonizes and Degrades the Estrogen Receptor, Resulting in Inhibition of the ER Signaling Pathway




Bardia A et al. *Ther Adv Med Oncol* 2022 March 15;14:17588359221083956.

# Neoadjuvant Giredestrant (GDC-9545) plus Palbociclib (P) versus Anastrozole (A) plus P in Postmenopausal Women with Estrogen Receptor-Positive, HER2-Negative, Untreated Early Breast Cancer (ER+/HER2- eBC): Final Analysis of the Randomized, Open-Label, International Phase 2 coopERA BC Study

Fasching PA et al.

ASCO 2022;Abstract 589.

*JCO Precis Oncol* 2021 September 1;5:PO.20.00445

BIOMARKERS

original reports

# Genomic Profiling of Premenopausal HR+ and HER2– Metastatic Breast Cancer by Circulating Tumor DNA and Association of Genetic Alterations With Therapeutic Response to Endocrine Therapy and Ribociclib

Aditya Bardia, MD[1]; Fei Su, PhD[2]; Nadia Solovieff, PhD[3]; Seock-Ah Im, MD[4]; Joohyuk Sohn, MD[5]; Keun Seok Lee, MD[6]; Saul Campos-Gomez, MD[7]; Kyung Hae Jung, MD[8]; Marco Colleoni, MD[9]; Rafael Villanueva Vázquez, MD[10]; Fabio Franke, MD[11]; Sara Hurvitz, MD[12]; Nadia Harbeck, MD[13]; Louis Chow, MD[14]; Tetiana Taran, MD[2]; Karen Rodriguez Lorenc, MD[2]; Naveen Babbar, PhD[3]; Debu Tripathy, MD[15]; and Yen-Shen Lu, MD[16]

San Antonio Breast Cancer Symposium®, December 6-10, 2022

## Abstract GS3-02

# Camizestrant, a next-generation oral SERD *vs* fulvestrant in post-menopausal women with advanced ER-positive HER2-negative breast cancer: Results of the randomized, multi-dose Phase 2 SERENA-2 trial

*Mafalda Oliveira, MD, PhD[1], Denys Pominchuk, PhD[2], Zbigniew Nowecki MD[3], Erika Hamilton, MD[4], Yaroslav Kulyaba, MD[5], Timur Andabekov, PhD[6], Yevhen Hotko, MD[7], Tamar Melkadze, MD[8], Gia Nemsadze, MD, PhD[9], Patrick Neven, MD[10], Yuriy Semegen, MD[11], Vladimir Vladimirov, MD[12], Claudio Zamagni, MD[13], Hannelore Denys, MD, PhD[14], Frédéric Forget, MD[15], Zsolt Horvath, MD, PhD[16], Alfiya Nesterova, MD, PhD[17], Maxine Bennett, PhD[18], Bistra Kirova, MBChB, MSc[19], Teresa Klinowska, PhD[20], Justin P O Lindemann, MBChB, MB[18], Delphine Lissa, PharmD, PhD[18], Alastair Mathewson, PhD[18], Christopher J Morrow, PhD[18], Zuzana Traugottova, MD[21], Ruaan van Zyl, PhD[22], Ekaterine Arkania, MD[23]*

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# Select Ongoing Phase III Trials of Oral SERDs in Development for HR-Positive Advanced Breast Cancer (ABC)

| Trial | N | Randomization | Setting | Est primary completion |
|---|---|---|---|---|
| SERENA-4 | 1,342 | • Camizestrant + palbociclib<br>• Anastrozole + palbociclib | Untreated ABC | August 2026 |
| persevERA | 978 | • Giredestrant + palbociclib<br>• Letrozole + palbociclib | Untreated ABC | April 2024 |
| SERENA-6 | 302 | • Camizestrant + (palbociclib or abemaciclib)<br>• (Anastrozole or letrozole) + (palbociclib or abemaciclib) | Detectable ESR1 mutation w/o PD during 1st-line AI + CDK4/6i | Sept 2023 |
| EMBER-3 | 860 | • Imlunestrant<br>• Imlunestrant + abemaciclib<br>• Investigator's choice of ET | ABC previously treated with ET + CDK4/6i | April 2024 |
| evERA | 320 | • Giredestrant + everolimus<br>• Exemestane + everolimus | ABC previously treated with ET + CDK4/6i | July 2024 |
| heredERA | 812 | • Giredestrant + pertuzumab/trastuzumab/hyaluronidase-zzxf<br>• Pertuzumab/trastuzumab/hyaluronidase-zzxf | Untreated ER+, HER2+ ABC after first-line pertuzumab/trastuzumab/ hyaluronidase-zzxf + taxane | August 2026 |

SERD = selective ER degrader

www.clinicaltrials.gov. Accessed November 2022.

RTP RESEARCH TO PRACTICE

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

| Study | N | Setting | Randomization |
|---|---|---|---|
| lidERA | 4,100 | • Node-negative or node-positive | • Giredestrant +/- LHRH agonist<br>• ET of physician's choice +/- LHRH agonist |
| EMBER-4 | 6,000 | • Elevated risk of recurrence after definitive treatment<br>• Completion of at least 2 years and up to 5 years of ET<br>• Previous adjuvant CDK4/6i or PARPi allowed | • Imlunestrant<br>• ET of physician's choice |
| EORTC-2129-BCG | 220 | • Elevated risk of recurrence after definitive treatment<br>• Completion of at least 2 years and up to 7 years of ET<br>• ctDNA-positive<br>• Previous adjuvant CDK4/6i or PARPi allowed | • Elacestrant<br>• Tamoxifen or aromatase inhibitor at time of ctDNA detection |

ctDNA = circulating tumor DNA

www.clinicaltrials.gov. Accessed January 2023.

*Lancet Oncol* 2022 July;23(7):851-64.

# Fulvestrant plus capivasertib versus placebo after relapse or progression on an aromatase inhibitor in metastatic, oestrogen receptor-positive, HER2-negative breast cancer (FAKTION): overall survival, updated progression-free survival, and expanded biomarker analysis from a randomised, phase 2 trial

Sacha J Howell*, Angela Casbard*, Margherita Carucci, Kate Ingarfield, Rachel Butler, Sian Morgan, Magdalena Meissner, Catherine Bale, Pavel Bezecny, Sarah Moon, Chris Twelves, Ramachandran Venkitaraman, Simon Waters, Elza C de Bruin, Gaia Schiavon, Andrew Foxley, Robert H Jones

# Capivasertib and Fulvestrant for Patients with Aromatase Inhibitor-Resistant Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: Results from the Phase III CAPItello-291 Trial

Turner NC et al.

SABCS 2022;Abstract GS3-04.

# CAPItello-291 Phase III Study Design

**Patients with HR+/HER2– ABC**

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

**R1:1 (N=708)**

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

| | | |
|---|---|---|
| Capivasertib | 400 mg twice daily, 4 days on, 3 days off | 43.7% altered |
| Fulvestrant | 500 mg: cycle 1, days 1 & 15; then every 4 weeks | |
| Placebo | Twice daily, 4 days on, 3 days off | 37% altered |
| Fulvestrant | 500 mg: cycle 1, days 1 & 15; then every 4 weeks | |

**Dual primary endpoints**

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

**Secondary endpoints**

**Overall survival**
- Overall
- AKT pathway-altered tumors

**Objective response rate**
- Overall
- AKT pathway-altered tumors

## *Summary of Demographics*

- Median age ~59
- Asian 26%, Black 1%
- Primary ET resistance ~38%
- Visceral metastases ~68%
- One line of prior ET for mBC ~75%
- Prior CDK4/6i for mBC ~70%
- Chemotherapy for ABC ~18%

Turner NC et al. SABCS 2022;Abstract GS3-04.

RTP RESEARCH TO PRACTICE

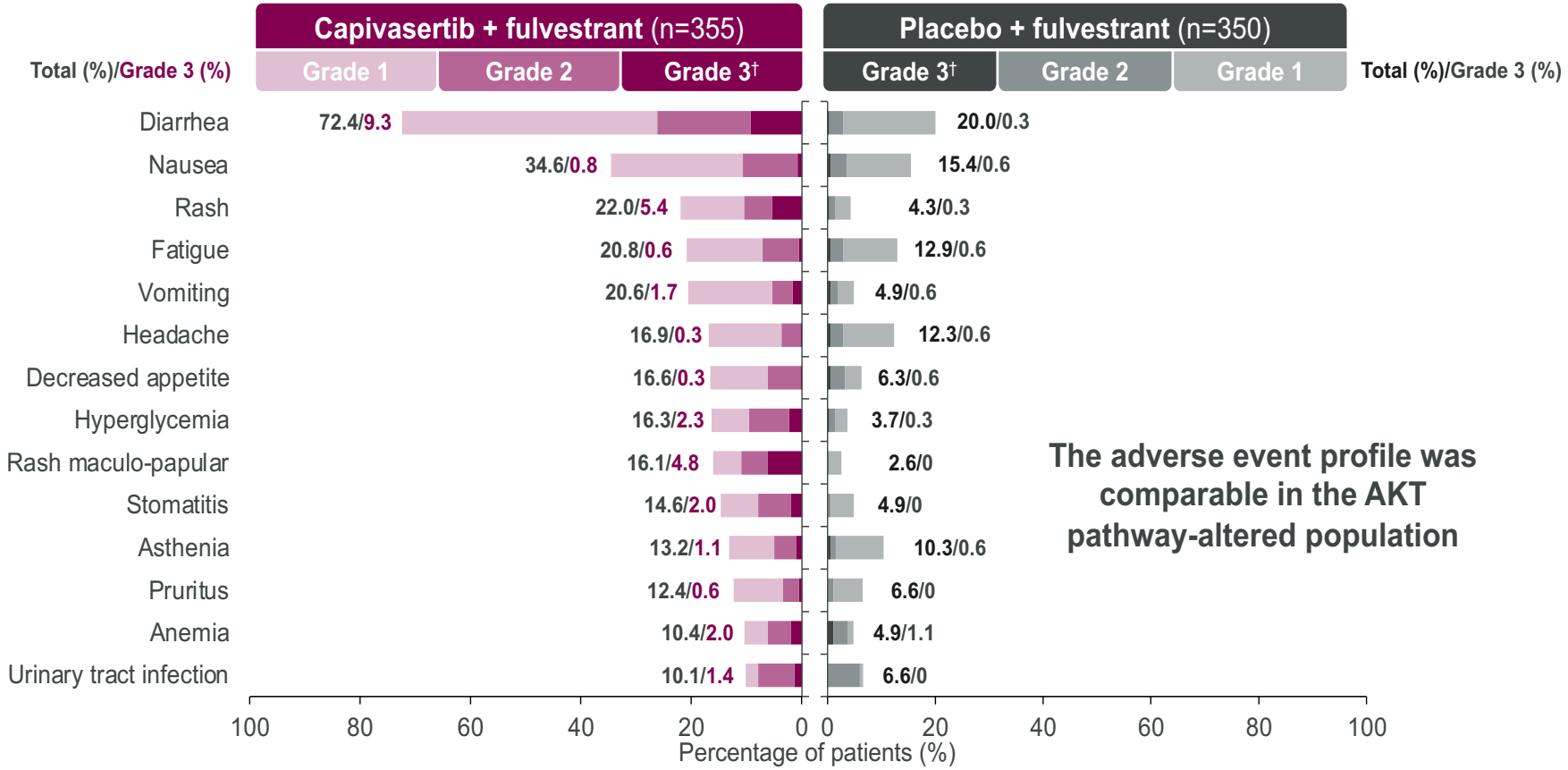
# CAPItello-291: Overall Response per Investigator Assessment

| | Overall population | | AKT pathway-altered population | |
|---|---|---|---|---|
| | Capivasertib + fulvestrant | Placebo + fulvestrant | Capivasertib + fulvestrant | Placebo + fulvestrant |
| Patients with measurable disease at baseline | 310 | 320 | 132 | 124 |
| Objective response rate; n (%) | 71 (22.9) | 39 (12.2) | 38 (28.8) | 12 (9.7) |
| Odds ratio (95% CI) | 2.19 (1.42, 3.36) | | 3.93 (1.93, 8.04) | |

Turner NC et al. SABCS 2022;Abstract GS3-04.

# CAPItello-291: Safety

## Adverse events (>10% of patients) – overall population




**The adverse event profile was comparable in the AKT pathway-altered population**

Adverse events of any grade related to rash (group term including rash, rash macular, maculo-papular rash, rash papular and rash pruritic) were reported in 38.0% of the patients in the capivasertib + fulvestrant arm (grade ≥3 in 12.1%) and in 7.1% of those in the placebo + fulvestrant group (grade ≥3 in 0.3%). †All events shown were Grade 3 except one case of Grade 4 hyperglycemia in the capivasertib + fulvestrant arm.

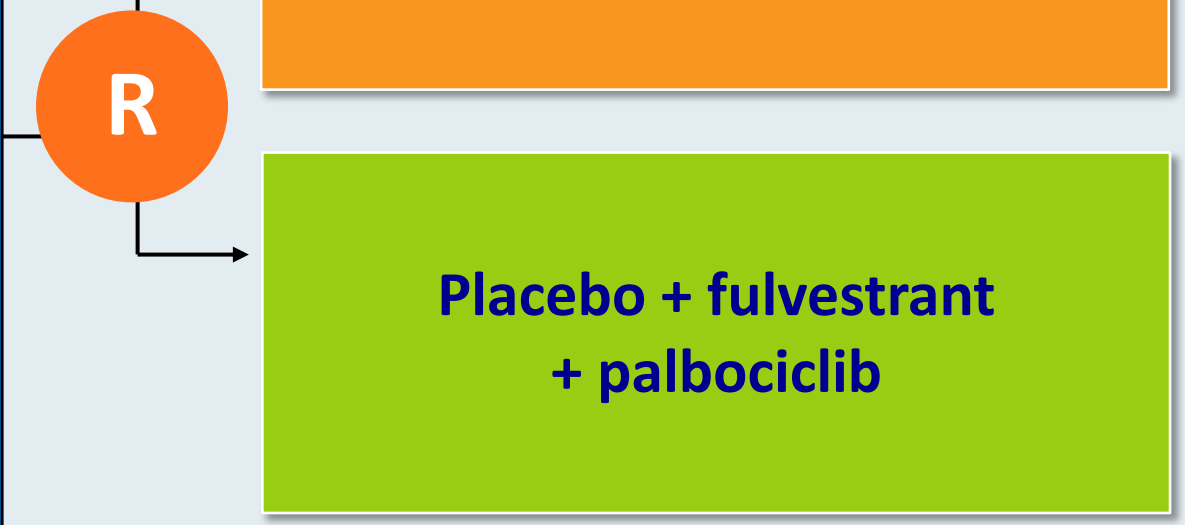


Turner NC et al. SABCS 2022;Abstract GS3-04.

# CAPItello-292 Phase III Study Design

**Estimated enrollment (N = 700)**

- ER-positive, HER2-negative locally advanced unresectable or metastatic breast cancer
- Previous treatment with ET (tamoxifen or AI) as a single agent or in combination with
  - Radiological evidence of breast cancer recurrence or PD while on or within 12 months of completing a neoadjuvant ET regimen OR
  - Radiological evidence of PD while receiving the ET for locally advanced or metastatic breast cancer




**Primary endpoint:** Investigator-assessed PFS

**Secondary endpoints:** OS, PFS by subgroups, PFS2, objective response rate, duration of response, clinical benefit rate, quality of life, safety

www.clinicaltrials.gov. NCT04862663. Accessed November 2022.

# Case Presentation: 70-year-old woman with ER/PR-positive, HER2-low (IHC 1+) metastatic IDC receiving T-DXd with mixed response

Dr Gigi Chen (Pleasant Hill, California)

## Regulatory and reimbursement issues aside, what would be your most likely next therapy for a symptomatic patient with ER-positive, HER2-low breast cancer and diffuse bone pain who has experienced disease progression on adjuvant AC → T followed by an AI, then a CDK4/6 inhibitor and fulvestrant for metastatic disease?

| | | | |
|---|---|---|---|
|  Dr Hurvitz | Depends on duration of response to CDK4/6 inhibitor* |  Dr Partridge | T-DXd |
|  Dr Jhaveri | Chemotherapy |  Dr Telli | Capecitabine |
|  Dr Miller | Capecitabine |  Dr Tolaney | Capecitabine |

*If disease controlled ≥12 mo, would try another line of hormone therapy with everolimus or alpelisib; if disease controlled <12 mo, would use capecitabine

RTP RESEARCH TO PRACTICE

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**





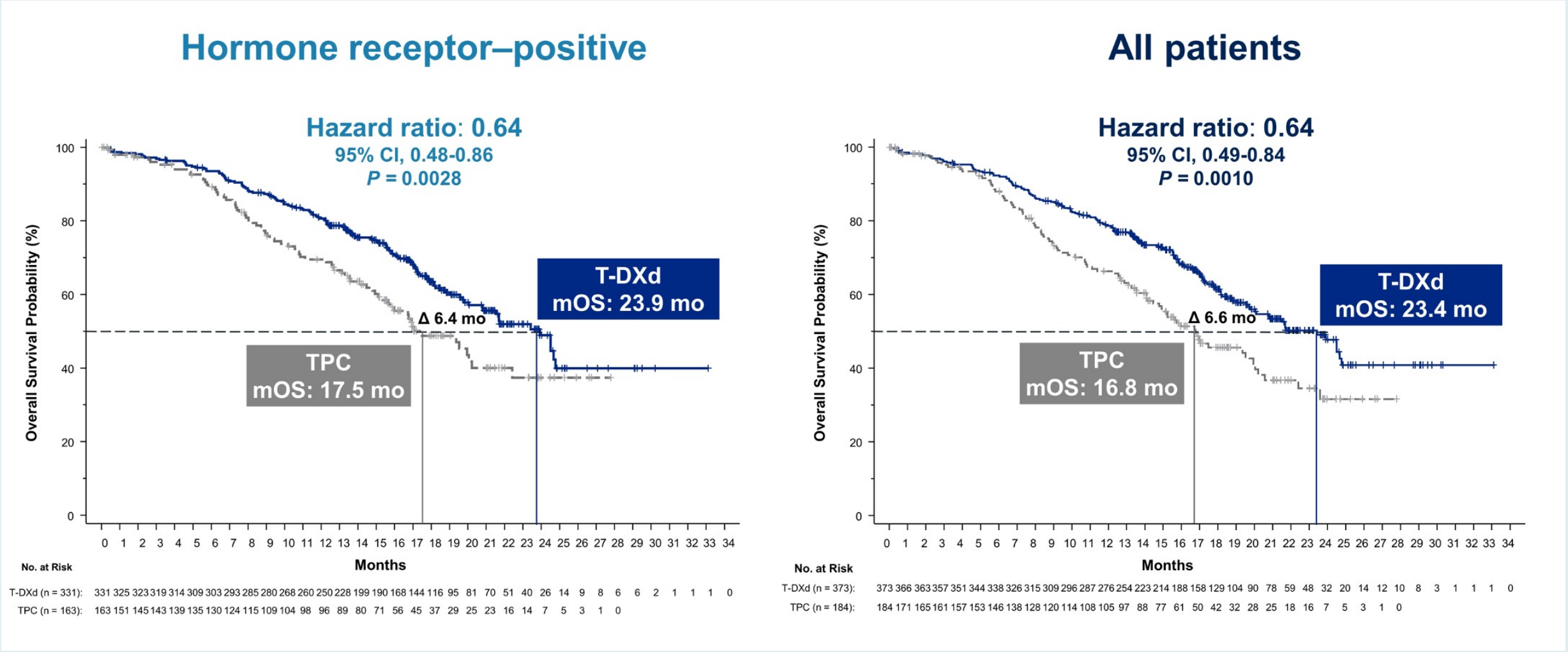
The NEW ENGLAND JOURNAL of MEDICINE

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*

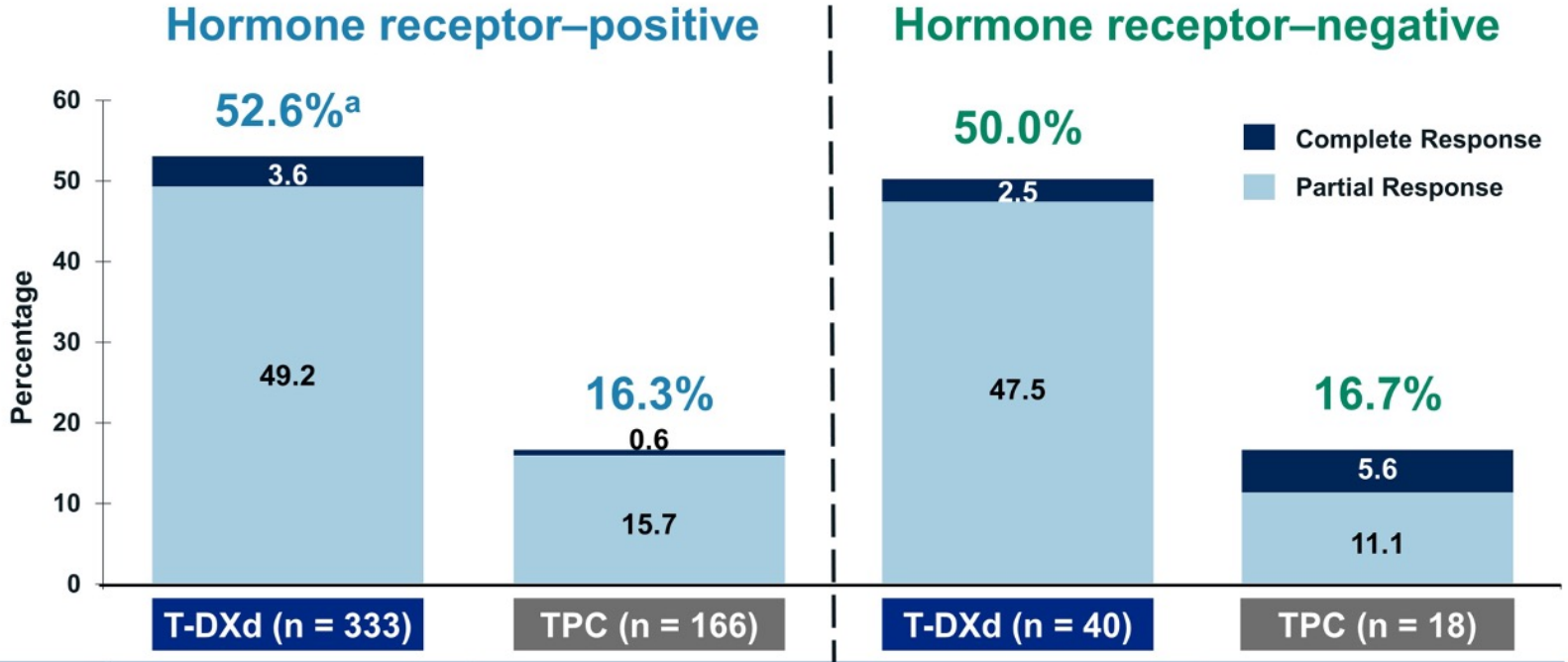
# DESTINY-Breast04: Overall Survival (OS) for HR-Positive and All Patients




mOS = median overall 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: Confirmed Objective Response Rate




| | T-DXd (n = 333) | TPC (n = 166) | T-DXd (n = 40) | TPC (n = 18) |
|---|---|---|---|---|
| Progressive disease, % | 7.8 | 21.1 | 12.5 | 33.3 |
| Not evaluable, % | 4.2 | 12.7 | 7.5 | 5.6 |
| **Clinical benefit rate,[b] %** | 71.2 | 34.3 | 62.5 | 27.8 |
| **Duration of response, months** | 10.7 | 6.8 | 8.6 | 4.9 |

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: Response and Survival with T-DXd in the HR-Negative Population

| | All patients | | | Hormone receptor-negative | | |
|---|---|---|---|---|---|---|
| | T-DXd (N = 373) | TPC (N = 184) | HR (*p*-value) | T-DXd (N = 40) | TPC (N = 18) | Hazard ratio |
| Median PFS | 9.9 mo | 5.1 mo | 0.5 (<0.001) | 8.5 mo | 2.9 mo | 0.46 |
| Median OS | 23.4 mo | 16.8 mo | 0.64 (0.001) | 18.2 mo | 8.3 mo | 0.48 |
| Objective response rate | 52.3% | 16.3% | — | 50.0% | 16.7% | — |

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

# Case Presentation: 48-year-old woman with multicentric gBRCA1-mutant TNBC who receives treatment per KEYNOTE-522 and achieves a CR to neoadjuvant treatment

**Dr Zanetta Lamar (Naples, Florida)**

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# Case Presentation: 50-year-old premenopausal woman with bilateral ER/PR-positive, HER2-negative, PALB2-mutant IDC and multiple, bilateral positive nodes

Dr William Mitchell (Charlotte, North Carolina)

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# Case Presentation: 46-year-old woman with ER/PR-positive, HER2-negative, gBRCA1-mutant metastatic breast cancer receiving fulvestrant/palbociclib

Dr Nasfat Shehadeh (Charlotte, North Carolina)

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## Regulatory and reimbursement issues aside, in general, what would you recommend as adjuvant therapy for a patient with TNBC, a germline BRCA mutation and a PD-L1 combined positive score (CPS) of 1 who has residual disease after neoadjuvant chemotherapy? Does level of PD-L1 expression have any bearing on your response?

| | Adjuvant therapy | PD-L1 expression a factor? |
|---|---|---|
|  Dr Hurvitz | Olaparib for 1 year* | No |
|  Dr Jhaveri | Olaparib + pembrolizumab | No |
|  Dr Miller | Capecitabine + olaparib for 1 year* | No |
|  Dr Partridge | Olaparib for 1 year + or followed by pembrolizumab | No |
|  Dr Telli | Olaparib for 1 year* | No |
|  Dr Tolaney | Olaparib for 1 year* | No |

*If patient received neoadjuvant pembrolizumab, I would complete pembrolizumab in combination with olaparib

# Regulatory and reimbursement issues aside, have you attempted or would you attempt to access olaparib as part of adjuvant therapy for a patient with a somatic BRCA mutation and TNBC who has residual disease after neoadjuvant chemotherapy?

| | | | |
|---|---|---|---|
|  Dr Hurvitz | I haven't but would for the right patient |  Dr Partridge | I haven't and would not |
|  Dr Jhaveri | I have |  Dr Telli | I haven't* |
|  Dr Miller | I have |  Dr Tolaney | I haven't but would for the right patient |

*I do not order tumor NGS in the curative setting

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# Regulatory and reimbursement issues aside, have you attempted or would you attempt to access olaparib as part of adjuvant therapy for a patient with a germline PALB2 mutation and TNBC who has residual disease after neoadjuvant chemotherapy?

# Regulatory and reimbursement issues aside, have you combined or would you combine olaparib with adjuvant pembrolizumab for a patient with a germline BRCA mutation and PD-L1-positive TNBC who has residual disease after neoadjuvant chemotherapy/pembrolizumab?

| | | | |
|---|---|---|---|
|  Dr Hurvitz | I have |  Dr Partridge | I haven't but would for the right patient |
|  Dr Jhaveri | I have |  Dr Telli | I have |
|  Dr Miller | I have |  Dr Tolaney | I have |

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**A 45-year-old woman with an ER-negative, HER2-low (IHC 2+) IDC and a germline BRCA mutation receives neoadjuvant AC-T and adjuvant capecitabine for residual disease and now presents with low-volume metastases to the lung and bones (PD-L1 CPS = 0). Regulatory and reimbursement issues aside, what would likely be your next systemic therapy?**

| | | | |
|---|---|---|---|
|  Dr Hurvitz | Olaparib or talazoparib — coin flip |  Dr Partridge | Olaparib |
|  Dr Jhaveri | Olaparib |  Dr Telli | Olaparib or talazoparib — coin flip |
|  Dr Miller | Olaparib or talazoparib — coin flip |  Dr Tolaney | Olaparib |

IDC = infiltrating ductal carcinoma; CPS = combined positive score

2022 April 1;28(7):1383-90.

CLINICAL CANCER RESEARCH | PRECISION MEDICINE AND IMAGING

# Determinants of Response to Talazoparib in Patients with HER2-Negative, Germline *BRCA1/2*-Mutated Breast Cancer

Joanne L. Blum[1], A. Douglas Laird[2], Jennifer K. Litton[3], Hope S. Rugo[4], Johannes Ettl[5], Sara A. Hurvitz[6], Miguel Martin[7], Henri H. Roché[8], Kyung-Hun Lee[9], Annabel Goodwin[10], Ying Chen[2], Silvana Lanzalone[11], Jijumon Chelliserry[2], Akos Czibere[12], Julia F. Hopkins[13], Lee A. Albacker[13], and Lida A. Mina[14]

# Case Presentation: 36-year-old woman who is 18 weeks pregnant with ER/PR-positive, HER2-negative IDC and an Onco*type* DX RS of 17

Dr Alan Astrow (Brooklyn, New York)

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TO PRACTICE

# Case Presentation: 49-year-old woman with ER/PR-positive, HER2-negative, NTRK-mutant metastatic breast cancer with CNS involvement who receives entrectinib

Dr Rahul Gosain (Corning, New York)

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# Case Presentation: 63-year-old woman with ER/PR-positive, HER2-negative metaplastic breast cancer with an Oncotype DX RS of 51 who has received adjuvant AI x 16 years

Dr Rajalaxmi McKenna (Willowbrook, Illinois)

RTP RESEARCH TO PRACTICE

# Case Presentation: 73-year-old woman with ER/PR-positive, HER2-negative, node-negative breast cancer and an Onco*type* DX RS of 29 who receives adjuvant TC and develops taxane-associated pain syndrome


**Dr Jennifer Dallas (Charlotte, North Carolina)**

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# Case Presentation: 35-year-old woman with ER/PR-positive, HER2-negative, node-positive IDC and residual disease after neoadjuvant chemotherapy and mastectomy who receives adjuvant RT and abemaciclib with goserelin and letrozole

Dr Victoria Giffi (Hagerstown, Maryland)

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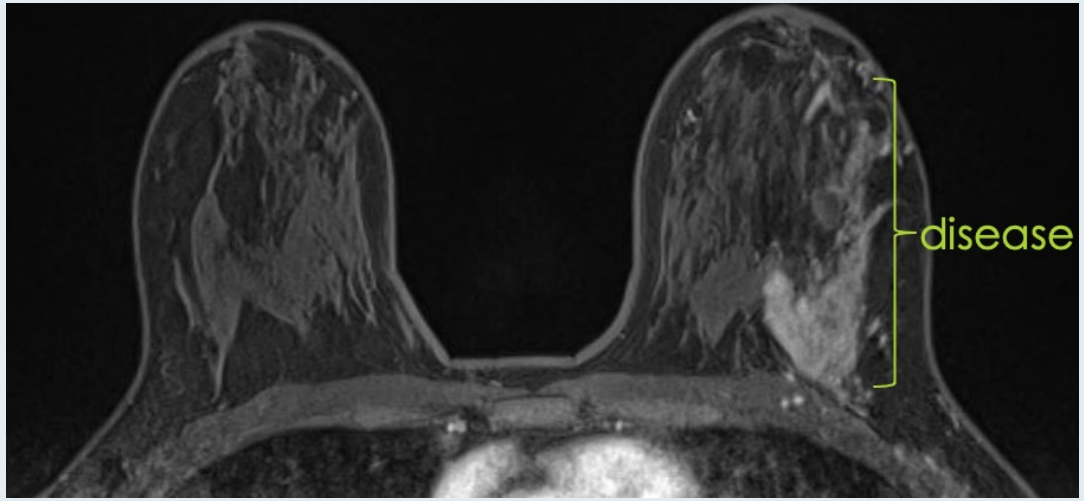
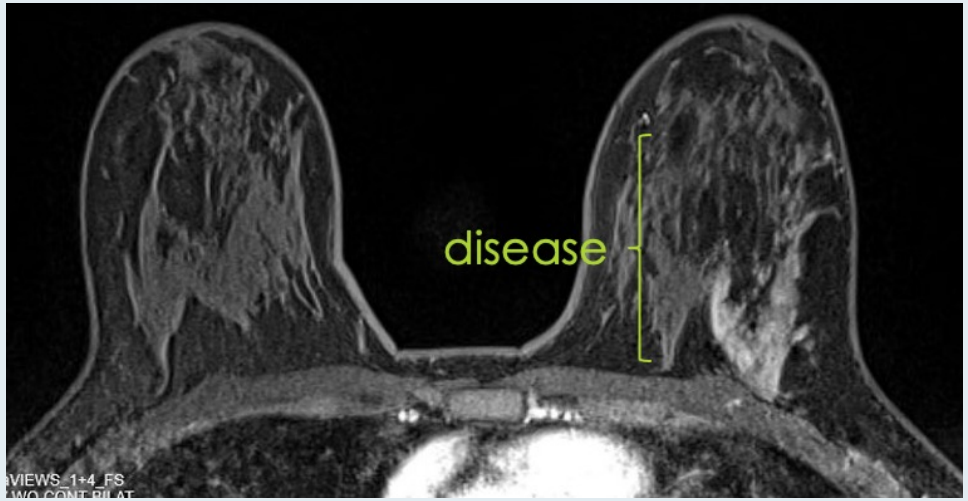
# MRI: Breast Disease

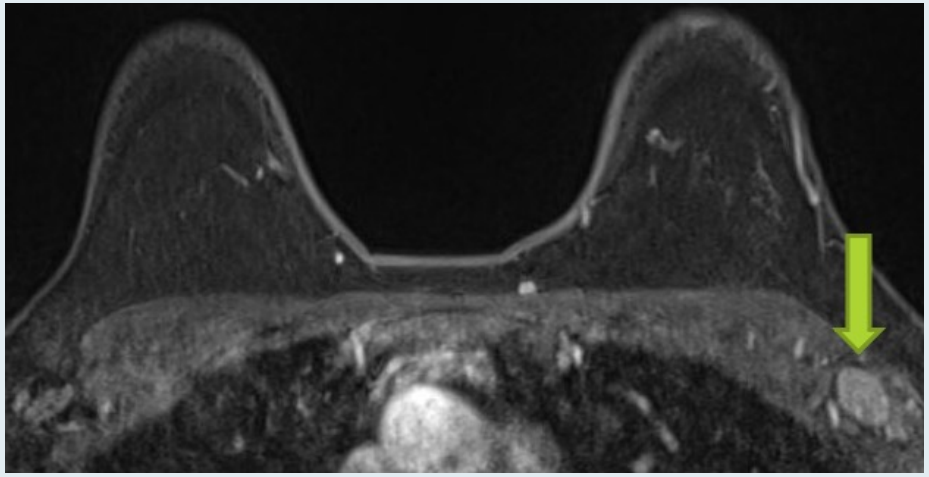
## Before Treatment

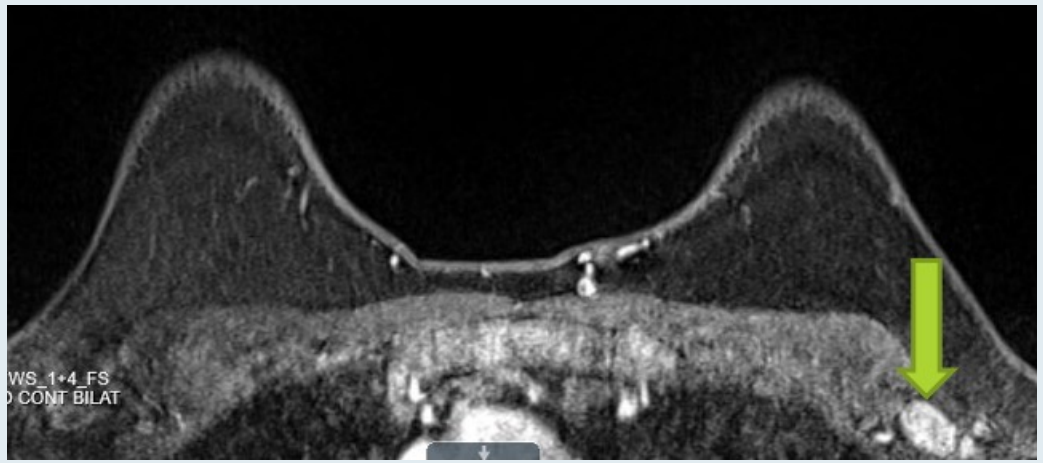



## After ddAC




# MRI: Nodal Disease





# Case Presentation: 35-year-old woman with ER/PR-positive, HER2-negative, node-positive IDC and residual disease after neoadjuvant chemotherapy and mastectomy who receives adjuvant RT and abemaciclib with goserelin and letrozole (continued)

Dr Victoria Giffi (Hagerstown, Maryland)

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TO PRACTICE

# Meet The Professor with Dr Hurvitz

**Introduction: Antibody-Drug Conjugates in Breast Cancer**

**MODULE 1: Case Presentations**

**Appendix**

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# Indication Broadened for Abemaciclib in HR-Positive, HER2-Negative, High-Risk Localized Breast Cancer

## Press Release: March 3, 2023

"The US Food and Drug Administration (FDA) approved an expanded indication for abemaciclib, in combination with endocrine therapy (ET), for the adjuvant treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, early breast cancer (EBC) at a high risk of recurrence. High risk patients eligible for abemaciclib can now be identified solely based on nodal status, tumor size, and tumor grade (4+ positive nodes, or 1-3 positive nodes and at least one of the following: tumors that are ≥5 cm or Grade 3). This expanded adjuvant indication removes the Ki-67 score requirement for patient selection.

This label expansion is supported by four-year data from the Phase 3 monarchE trial of adjuvant abemaciclib in combination with ET, which showed a deepened benefit in invasive disease-free survival (IDFS) beyond the two-year treatment course with adjuvant abemaciclib. The absolute difference in IDFS between treatment groups increased over time."

https://finance.yahoo.com/news/u-fda-broadens-indication-verzenio-195800378.html?guccounter=1

RTP RESEARCH TO PRACTICE

San Antonio Breast Cancer Symposium – December 6-10, 2022

# Trial Assigning IndividuaLized Options for TReatment (TAILORx): An Update Including 12-Year Event Rates

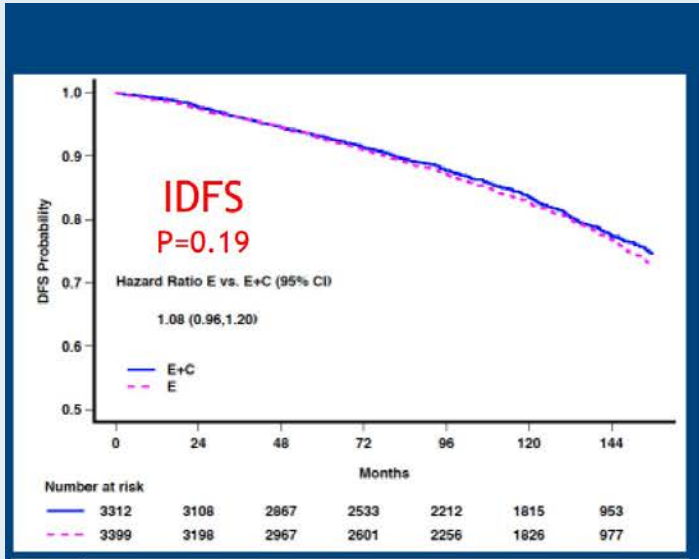
## Abstract GS1-05

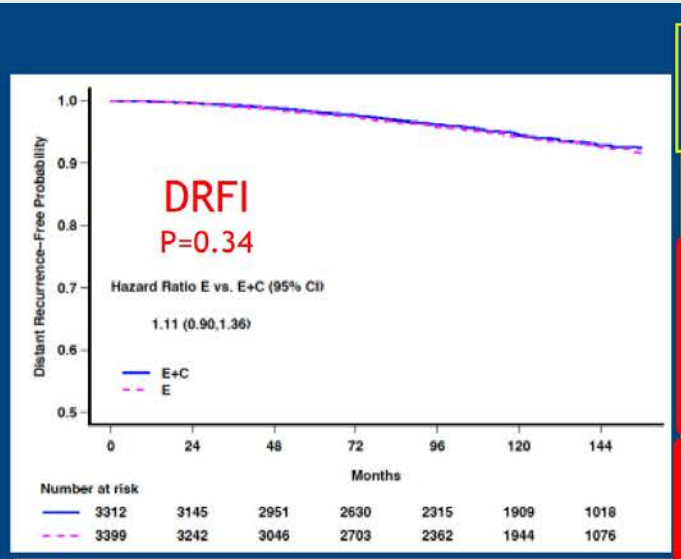
Joseph A. Sparano, Robert J. Gray, Della F. Makower, Kathy S. Albain, Daniel F. Hayes, Charles E. Geyer, Elizabeth Claire Dees, Matthew P. Goetz, John A. Olson, Jr., Tracy G. Lively, Sunil Badve, Thomas J. Saphner, Timothy J. Whelan, Virginia Kaklamani, & George W. Sledge, Jr.

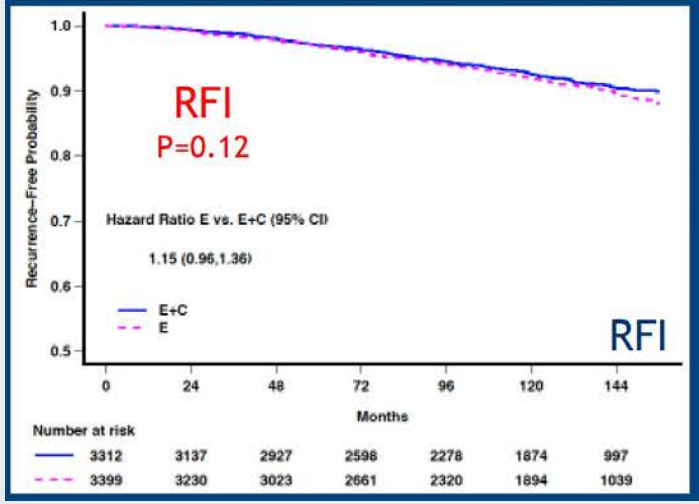
on behalf of the TAILORx Investigators

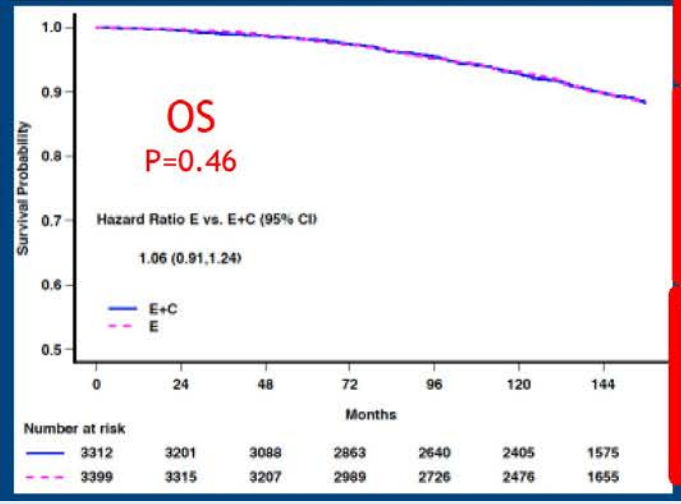
Funding: U.S. NIH/NCI U10CA180820, U10CA180794, UG1CA189859, UG1CA190140, UG1CA233160, UG1CA23337, UG1CA189869; U.S. Postal Service Breast Cancer Stamp Fund; Canadian Cancer Society Research Institute grants 015469, 021039; Breast Cancer Research Foundation, Komen Foundation.

# TAILORx Updated Analysis: Kaplan-Meier Curves in RS 11-25 Arms (ITT Population)




**Primary trial conclusions unchanged:**
**ET non-inferior to CET (N=6711)**

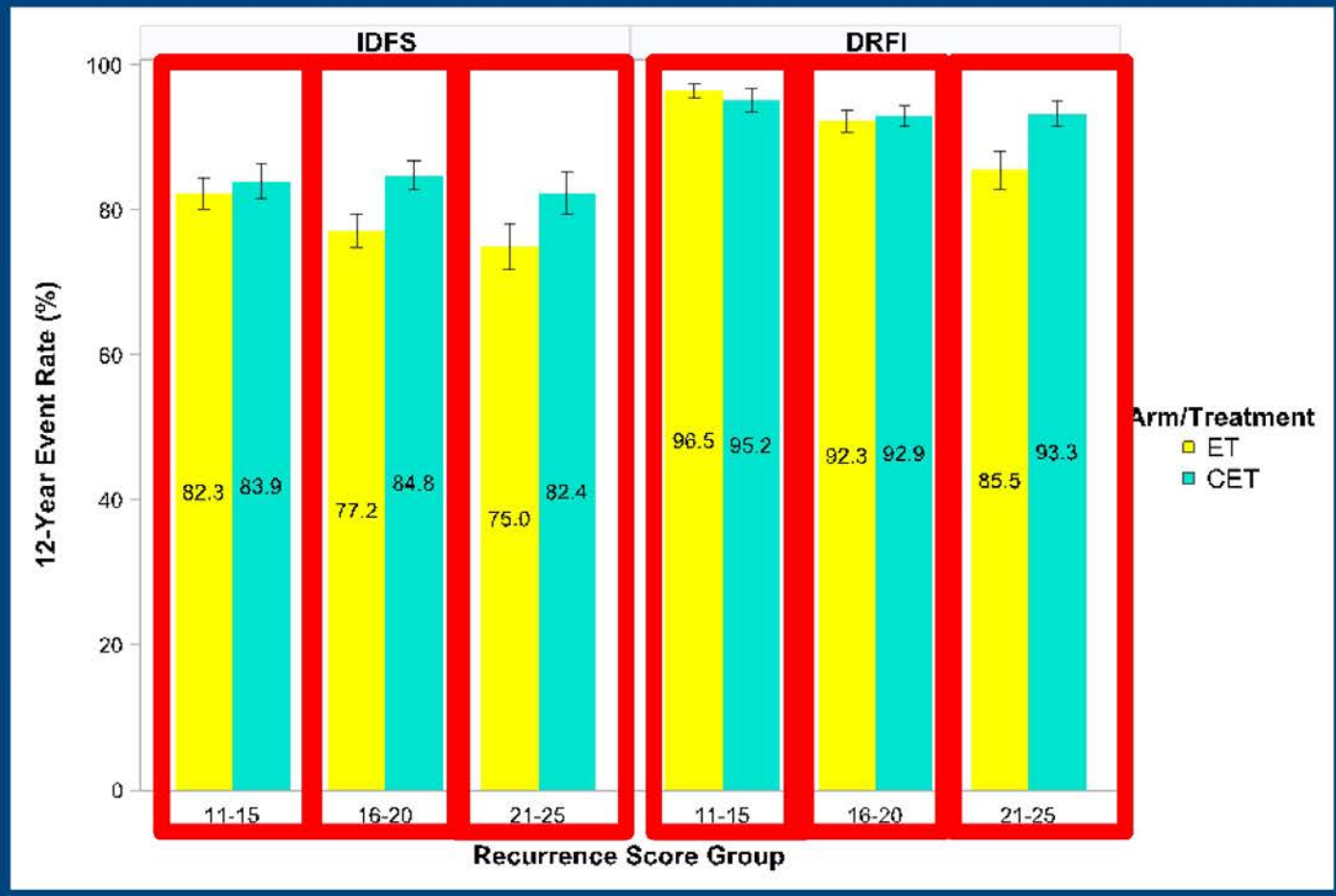
| Event | Hazard Ratio: Arm B vs. C (95% CI) |
|---|---|
| IDFS | Primary analysis: 1.08 (0.94, 1.24, p=0.26)<br>Updated analysis: 1.08 (0.96, 1.20) |
| DRFI | Primary analysis: 1.10 (0.85,1.41, p=0.48)<br>Updated analysis: 1.11 (0.90, 1.36) |
| RFI | Primary analysis: 1.11 (0.90, 1.37, p=0.33)<br>Updated analysis: 1.15 (0.96, 1.36) |
| OS | Primary analysis: 0.99 (0.79, 1.22, p=0.89)<br>Updated analysis: 1.06 (0.91, 1.24) |

IDFS = invasive disease-free survival; DRFI = distant recurrence-free interval; RFI = recurrence-free interval; OS = overall survival

Sparano JA et al. SABCS 2022;Abstract GS1-05.

# TAILORx Updated Analysis: Event Rates in RS 11-25 Arms for Age ≤50 Years (ITT Population)

- No chemo benefit for RS 11-15
- Marginal benefit for RS 16-20
- Evident benefit for RS 21-25




Sparano JA et al. SABCS 2022;Abstract GS1-05.

*J Clin Oncol* 2021 September 10;39(26):2959-61.

ASCO rapid recommendations

# Adjuvant PARP Inhibitors in Patients With High-Risk Early-Stage HER2-Negative Breast Cancer and Germline *BRCA* Mutations: ASCO Hereditary Breast Cancer Guideline Rapid Recommendation Update

**Nadine M. Tung, MD[1]; Dana Zakalik, MD[2]; and Mark R. Somerfield, PhD[3]; for the Hereditary Breast Cancer Guideline Expert Panel**

*ASCO Rapid Recommendations Updates highlight revisions to select ASCO guideline recommendations as a response to the emergence of new and practice-changing data. The rapid updates are supported by an evidence review and follow the guideline development processes outlined in the ASCO Guideline Methodology Manual. The goal of these articles is to disseminate updated recommendations, in a timely manner, to better inform health practitioners and the public on the best available cancer care options.*

# ASCO 2021 Adjuvant PARP Inhibitor Updated Recommendations

- **For patients with localized, HER2-negative breast cancer** with high risk of recurrence and germline BRCA1 or BRCA2 pathogenic or likely pathogenic variants, 1 year of adjuvant olaparib should be offered after completion of (neo)adjuvant chemotherapy and local treatment, including radiation therapy.
- **For those who underwent surgery first**, 1 year of adjuvant olaparib should be offered for patients with triple-negative breast cancer and tumor size >2 cm or any involved axillary nodes.
- **For those with hormone receptor (HR)-positive disease**, 1 year of adjuvant olaparib should be offered to those with at least 4 involved axillary lymph nodes.
- **For patients who received neoadjuvant chemotherapy**, 1 year of adjuvant olaparib should be offered to patients with triple-negative breast cancer and any residual cancer; **for patients with HR-positive disease**, 1 year of adjuvant olaparib should be offered to patients with residual disease and a clinical stage, pathologic stage, estrogen receptor and tumor grade score ≥3.

Tung NM et al. *J Clin Oncol* 2021 September 10;39(26):2959-61.

Abstract VP1-2022

ESMO VIRTUAL PLENARY

# PRE-SPECIFIED EVENT DRIVEN ANALYSIS OF OVERALL SURVIVAL (OS) IN THE OLYMPIA PHASE III TRIAL OF ADJUVANT OLAPARIB (OL) IN GERMLINE *BRCA1/2* MUTATION (*gBRCAm*) ASSOCIATED BREAST CANCER

**Andrew Nicholas James Tutt[1], Judy Garber[2], Richard D. Gelber[2], Kelly-Anne Phillips[3], Andrea Eisen[4], Oskar Thor Jóhannsson[5], Priya Rastogi[6], Karen Yongzhi Cui[7], Seock-Ah Im[8], Rinat Yerushalmi[9], Adam Matthew Brufsky[10], Maria Taboada[11], Giovanna Rossi[12], Greg Yothers[13], Christian Singer[14], Luis E. Fein[15], Niklas Loman[16], David Cameron[17], Christine Campbell[18], Charles Edward Geyer Jr[19]**

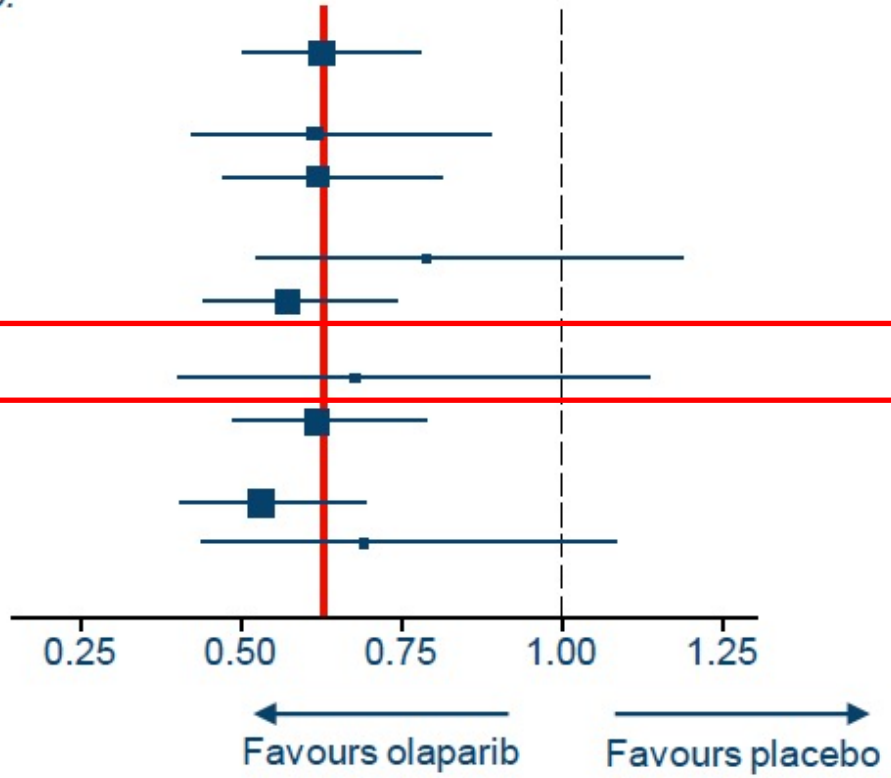
[1]Breast Cancer Now Research Unit, Institute of Cancer Research, London, United Kingdom; [2]Dana Farber Cancer Institute, Boston, MA, USA; [3]Department of Medical Oncology, Peter MacCallum Cancer Center, Melbourne, Australia; [4]Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, Canada; [5]Landspitali – The National University Hospital of Iceland, Reykjavik, Iceland; [6]Department of Oncology, NSABP Foundation, Pittsburgh, PA, USA; [7]Global Medicine Development, AstraZeneca US, Gaithersburg, MD, USA; [8]Department of Internal Medicine, Seoul National University Hospital, Seoul, Korea; [9]Department of Oncology, Clalit Health Services, Petah Tikva, Israel; [10]Department of Hematology-Oncology, Magee-Womens Hospital of UPMC, Pittsburgh, PA, USA; [11]AstraZeneca, Royston, United Kingdom; [12]Department of R&D, Breast International Group (BIG) – AISBL, Brussels, Belgium; [13]Department of Biostatistics, University of Pittsburgh, Pittsburgh, PA, USA;

[14]Center for Breast Health, Medical University of Vienna, Vienna, Austria; [15]Department of Oncology, Instituto de Oncología de Rosario, Rosario, Santa Fe, Argentina; [16]Skane University Hospital, Lund, Sweden; [17]Department of Oncology, Edinburgh Cancer Centre, Edinburgh, United Kingdom; [18]Frontier Science Scotland, Kincraig, United Kingdom; [19]Department of Clinical Research, Houston Methodist Cancer Center, Houston, TX, USA

RTP RESEARCH TO PRACTICE

# OlympiA: IDFS (Primary Endpoint) – Subgroup Analysis

| Subgroup | Olaparib | Placebo | Stratified hazard ratio for invasive disease-free survival (95% CI) | P value for heterogeneity |
|---|---|---|---|---|
| | *No. of patients with an invasive disease event/total no.* | | | |
| **All patients** | 134 / 921 | 207 / 915 | 0.628 (0.504, 0.779) | NA |
| **Prior chemo** | | | | 0.977 |
| Adjuvant | 46 / 461 | 75 / 455 | 0.618 (0.425, 0.888) | |
| Neoadjuvant | 88 / 460 | 132 / 460 | 0.622 (0.473, 0.813) | |
| **Prior platinum** | | | | 0.197 |
| Yes | 42 / 247 | 51 / 238 | 0.791 (0.523, 1.187) | |
| No | 92 / 674 | 156 / 677 | 0.575 (0.443, 0.742) | |
| **HR status** | | | | 0.754 |
| HR+/HER2- | 25 / 168 | 34 / 157 | 0.680 (0.402, 1.134) | |
| TNBC | 109 / 751 | 173 / 758 | 0.620 (0.487, 0.787) | |
| **BRCA** | | | | 0.615 |
| BRCA1 | 83 / 579 | 149 / 588 | 0.533 (0.406, 0.695) | |
| BRCA2 | 34 / 235 | 44 / 216 | 0.693 (0.440, 1.082) | |
| BRCA1/2 both | 0 / 2 | 0 / 3 | NC | |




IDFS = invasive disease-free survival

Tutt ANJ et al. ESMO Virtual Plenary 2022;Abstract VP1-2022.

VOLUME 36 · NUMBER 19 · JULY 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

# Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update

*Kutluk Oktay, Brittany E. Harvey, Ann H. Partridge, Gwendolyn P. Quinn, Joyce Reinecke, Hugh S. Taylor, W. Hamish Wallace, Erica T. Wang, and Alison W. Loren*

- Sperm, oocyte and embryo cryopreservation are considered standard practice and are widely available
- There is conflicting evidence to recommend gonadotrophin-releasing hormone agonists (GnRHa) and other means of ovarian suppression for fertility preservation
- The panel recognizes that, when proven fertility preservation methods are not feasible, and in the setting of young women with breast cancer, GnRHa may be offered to patients in the hope of reducing the likelihood of chemotherapy-induced ovarian insufficiency
- GnRHa should not be used in place of proven fertility preservation methods

RTP RESEARCH TO PRACTICE

The NEW ENGLAND JOURNAL of MEDICINE

2015;372(10):923-32

ORIGINAL ARTICLE

# Goserelin for Ovarian Protection during Breast-Cancer Adjuvant Chemotherapy

Halle C.F. Moore, M.D., Joseph M. Unger, Ph.D., Kelly-Anne Phillips, M.D., Frances Boyle, M.B., B.S., Ph.D., Erika Hitre, M.D., David Porter, M.D., Prudence A. Francis, M.D., Lori J. Goldstein, M.D., Henry L. Gomez, M.D., Carlos S. Vallejos, M.D., Ann H. Partridge, M.D., M.P.H., Shaker R. Dakhil, M.D., Agustin A. Garcia, M.D., Julie Gralow, M.D., Janine M. Lombard, M.D., John F. Forbes, M.B., B.S., Silvana Martino, D.O., William E. Barlow, Ph.D., Carol J. Fabian, M.D., Lori Minasian, M.D., Frank L. Meyskens, Jr., M.D., Richard D. Gelber, Ph.D., Gabriel N. Hortobagyi, M.D., and Kathy S. Albain, M.D., for the POEMS/S0230 Investigators

- Among 135 patients with complete primary endpoint data, the ovarian failure rate was 8% in the goserelin group and 22% in the chemotherapy-alone group (odds ratio 0.30, two-sided $p = 0.04$)
- Due to missing primary endpoint data, sensitivity analyses were performed; the results were consistent with the main findings

RTP RESEARCH TO PRACTICE

VOLUME 36 · NUMBER 19 · JULY 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

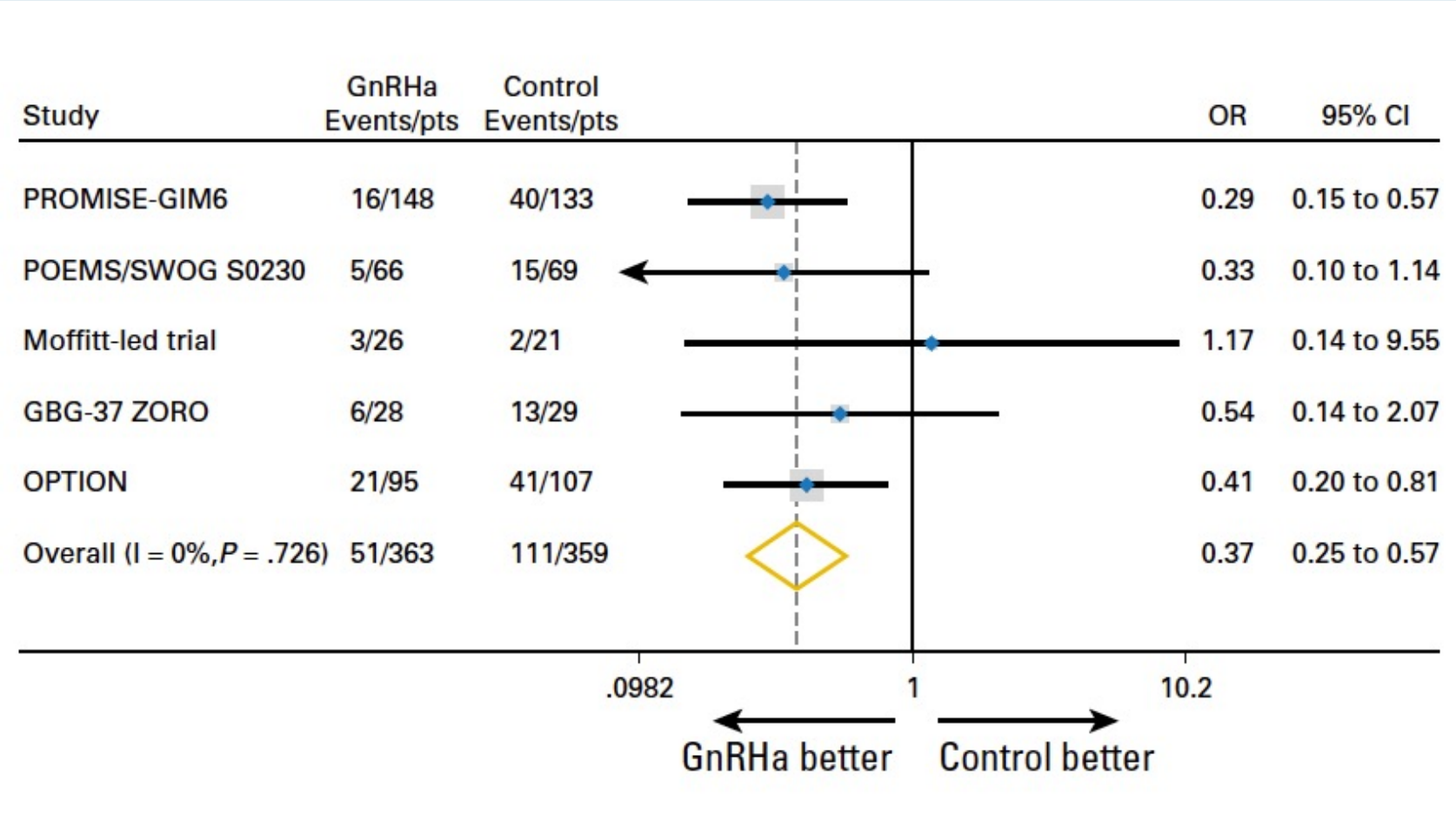
REVIEW ARTICLE

# Gonadotropin-Releasing Hormone Agonists During Chemotherapy for Preservation of Ovarian Function and Fertility in Premenopausal Patients With Early Breast Cancer: A Systematic Review and Meta-Analysis of Individual Patient–Level Data

*Matteo Lambertini, Halle C.F. Moore, Robert C.F. Leonard, Sibylle Loibl, Pamela Munster, Marco Bruzzone, Luca Boni, Joseph M. Unger, Richard A. Anderson, Keyur Mehta, Susan Minton, Francesca Poggio, Kathy S. Albain, Douglas J.A. Adamson, Bernd Gerber, Amy Cripps, Gianfilippo Bertelli, Sabine Seiler, Marcello Ceppi, Ann H. Partridge, and Lucia Del Mastro*

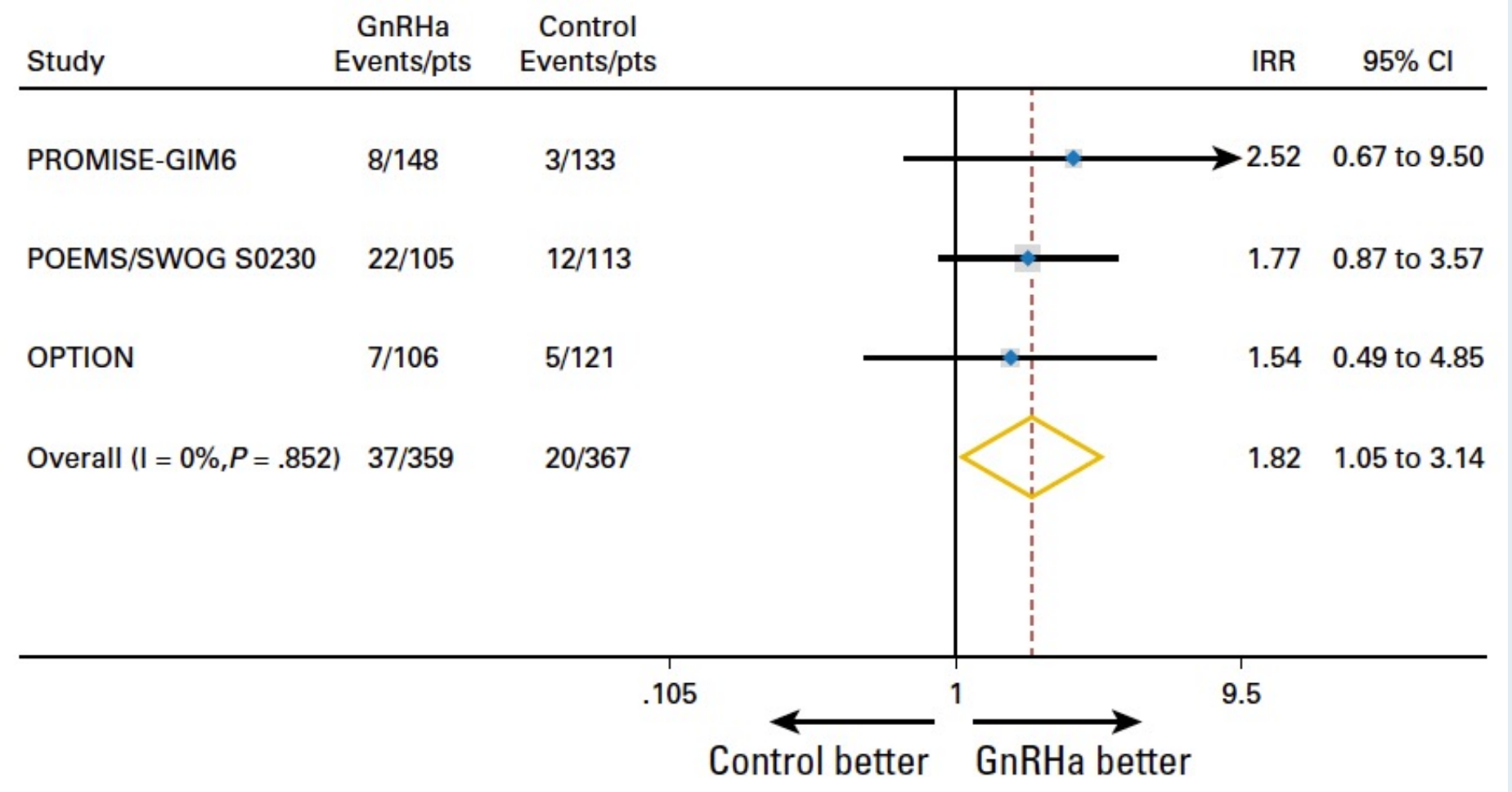
# Meta-analysis of Gonadotropin-Releasing Hormone Analogues During Chemotherapy for Localized Breast Cancer: Premature Ovarian Insufficiency by Trial

- 873 randomized patients from 5 major trials were included in the meta-analysis




Lambertini M et al. *J Clin Oncol* 2018;36(19):1981-90.

# Meta-analysis of Gonadotropin-Releasing Hormone Analogues During Chemotherapy for Localized Breast Cancer: Post-treatment Pregnancies by Trial




Lambertini M et al. *J Clin Oncol* 2018;36(19):1981-90.

San Antonio Breast Cancer Symposium®, December 6-10, 2022

## Abstract GS3-01

# EMERALD phase 3 trial of elacestrant versus standard of care endocrine therapy in patients with ER+/HER2- metastatic breast cancer: updated results by duration of prior CDK4/6i in metastatic setting

Bardia A,[1*] Bidard FC,[2*] Neven P,[3] Streich G,[4] Montero AJ,[5] Forget F,[6] Mouret-Reynier MA,[7] Sohn JH,[8] Taylor D,[9] Harnden KK,[10] Khong H,[11] Kocsis J,[12] Dalenc F,[13] Dillon P,[14] Babu S,[15] Waters S,[16] Deleu I,[17] Garcia-Saenz J,[18] Bria E,[19] Cazzaniga M,[20] Aftimos P,[21] Cortes J,[22] Tonini G,[23] Tarek Sahmoud,[24] Habboubi N,[24] Grzegorzewski KJ,[24] **Kaklamani V**[25**]

*=Co-first
**=Presenting author

1. Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA, USA; 2. Institut Curie, Paris and Saint Cloud, France 3. Universitaire Ziekenhuizen (UZ) - Leuven Cancer Institute, Leuven, Belgium; 4. Centro Médico Austral, Buenos Aires, Argentina; 5. University Hospitals Seidman Cancer Center- Case Western Reserve University, Cleveland, OH, USA; 6. Centre Hospitalier de l'Ardenne - Site de Libramont, Libramont-Chevigny, Belgium; 7. Centre Jean Perrin, Clermont-Ferrand, France; 8. Yonsei Cancer Center, Yonsei University Health System -Medical Oncology, Seoul, Republic of Korea; 9. Universite catholiqué de Louvain, CHU UCL Namur—Site Sainte-Elisabeth, Namur, Belgium; 10. Inova Schar Cancer Institute, Fairfax, VA, USA; 11. Moffit Cancer Center & Research Institute, Tampa, FL, USA; 12. Bács-Kiskun Megyei Kórház, Kecskemét, Hungary; 13. Institut Claudius Regaud, IUCT-Oncopole, Toulouse, France; 14. University of Virginia Cancer Center, Charlottesville, VA, USA; 15. Fort Wayne Medical Oncology and Hematology, Fort Wayne, IN, USA; 16. Velindre Cancer Centre, Cardiff, UK; 17. AZ Nikolaas, Sint-Niklaas, Belgium; 18. Instituto de Investigación Sanitaria Hospital Clinico San Carlos (IdISSC), Madrid, Spain; 19. Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Università Cattolica del Sacro Cuore, Roma, Italy; 20. Ospedale San Gerardo-ASST Monza, Monza, Italy; 21. Institut Jules Bordet – Université Libre de Bruxelles, Brussels, Belgium; 22. International Breast Cancer Center (IBCC), Quiron Group, Barcelona, Spain; 23. Menarini Group, Florence, Italy; 24. Stemline Therapeutics/Menarini Group, New York, NY, USA; 25. University of Texas Health Sciences Center, San Antonio, TX, USA

# EMERALD: PFS Analyses by CDK4/6 Inhibitor Duration

| Duration of CDK4/6i | <6 months | | 6-12 months | | 12-18 months | | ≥18 months | |
|---|---|---|---|---|---|---|---|---|
| **All patients** | **Elacestrant (n = 29)** | **SOC ET (n = 29)** | **Elacestrant (n = 52)** | **SOC ET (n = 46)** | **Elacestrant (n = 52)** | **SOC ET (n = 40)** | **Elacestrant (n = 98)** | **SOC ET (n = 119)** |
| Median PFS | 3.6 mo | 1.9 mo | 1.9 mo | 1.9 mo | 3.5 mo | 1.8 mo | 5.5 mo | 3.3 mo |
| **Patients with ESR1 mutations** | **Elacestrant (n = 9)** | **SOC ET (n = 8)** | **Elacestrant (n = 25)** | **SOC ET (n = 21)** | **Elacestrant (n = 23)** | **SOC ET (n = 25)** | **Elacestrant (n = 55)** | **SOC ET (n = 56)** |
| Median PFS | 1.9 mo | 1.9 mo | 1.9 mo | 1.8 mo | 5.5 mo | 1.8 mo | 8.6 mo | 2.1 mo |

Bardia A et al. SABCS 2022;Abstract GS3-01.

San Antonio Breast Cancer Symposium®, December 6-10, 2022

## Abstract GS3-02

# Camizestrant, a next-generation oral SERD *vs* fulvestrant in post-menopausal women with advanced ER-positive HER2-negative breast cancer: Results of the randomized, multi-dose Phase 2 SERENA-2 trial

*Mafalda Oliveira, MD, PhD[1], Denys Pominchuk, PhD[2], Zbigniew Nowecki MD[3], Erika Hamilton, MD[4], Yaroslav Kulyaba, MD[5], Timur Andabekov, PhD[6], Yevhen Hotko, MD[7], Tamar Melkadze, MD[8], Gia Nemsadze, MD, PhD[9], Patrick Neven, MD[10], Yuriy Semegen, MD[11], Vladimir Vladimirov, MD[12], Claudio Zamagni, MD[13], Hannelore Denys, MD, PhD[14], Frédéric Forget, MD[15], Zsolt Horvath, MD, PhD[16], Alfiya Nesterova, MD, PhD[17], Maxine Bennett, PhD[18], Bistra Kirova, MBChB, MSc[19], Teresa Klinowska, PhD[20], Justin P O Lindemann, MBChB, MB[18], Delphine Lissa, PharmD, PhD[18], Alastair Mathewson, PhD[18], Christopher J Morrow, PhD[18], Zuzana Traugottova, MD[21], Ruaan van Zyl, PhD[22], Ekaterine Arkania, MD[23]*

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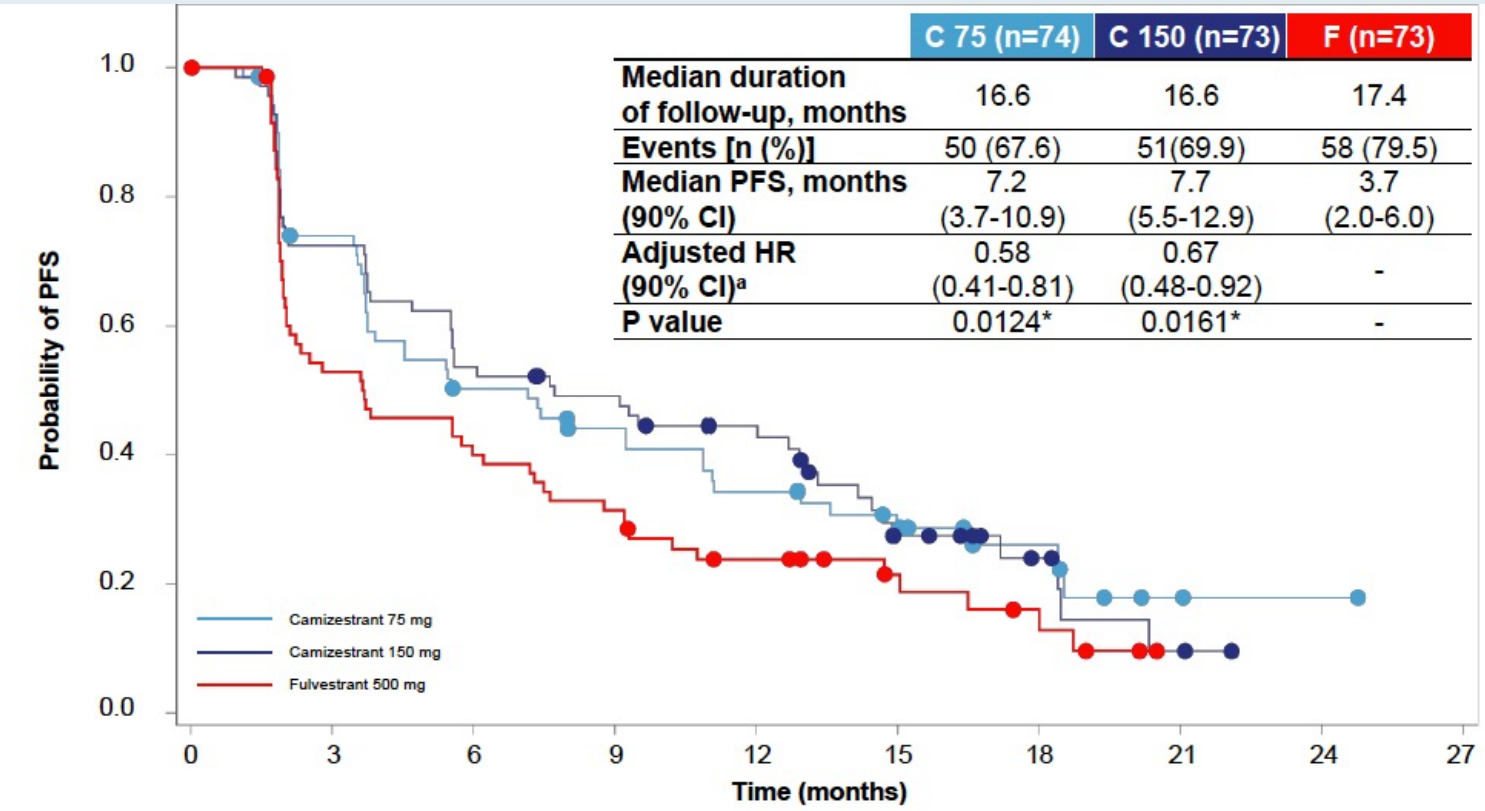
# SERENA-2 Primary Endpoint: PFS by Investigator Assessment




| | C 75 (n=74) | C 150 (n=73) | F (n=73) |
|---|---|---|---|
| Median duration of follow-up, months | 16.6 | 16.6 | 17.4 |
| Events [n (%)] | 50 (67.6) | 51(69.9) | 58 (79.5) |
| Median PFS, months (90% CI) | 7.2 (3.7-10.9) | 7.7 (5.5-12.9) | 3.7 (2.0-6.0) |
| Adjusted HR (90% CI)[a] | 0.58 (0.41-0.81) | 0.67 (0.48-0.92) | - |
| P value | 0.0124* | 0.0161* | - |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| C 75 | 74 | 50 | 33 | 27 | 21 | 14 | 7 | 2 | 1 | 0 |
| C 150 | 73 | 50 | 37 | 32 | 25 | 12 | 6 | 2 | 0 | |
| F | 73 | 37 | 28 | 22 | 14 | 8 | 5 | 0 | | |

*Statistically significant; [a]HRs adjusted for prior use of CDK4/6i and liver/lung metastases

CDK4/6i: CDK4/6 inhibitor; CI: confidence interval; HR: hazard ratio; PFS: progression-free survival

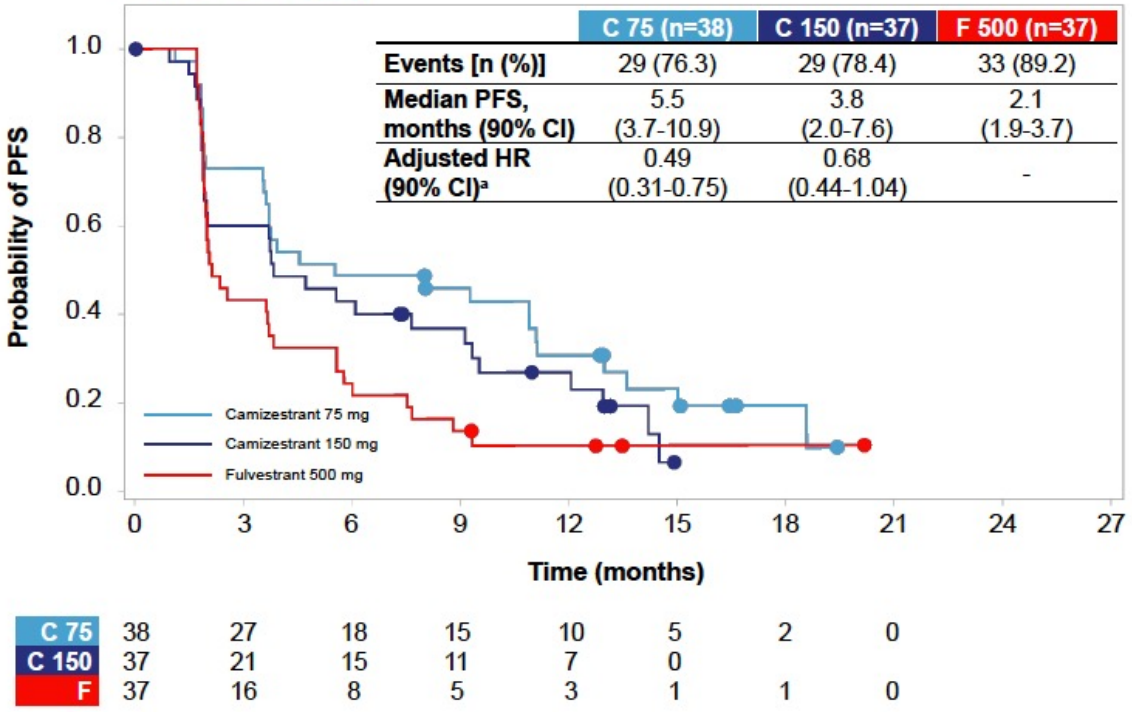
In the overall population, camizestrant produces a statistically significant and clinically meaningful improvement in PFS for both 75 and 150 mg camizestrant doses over fulvestrant

Oliveira M et al. SABCS 2022;Abstract GS3-02.

RTP RESEARCH TO PRACTICE

# SERENA-2: PFS by Prior CDK4/6 Inhibitor Use

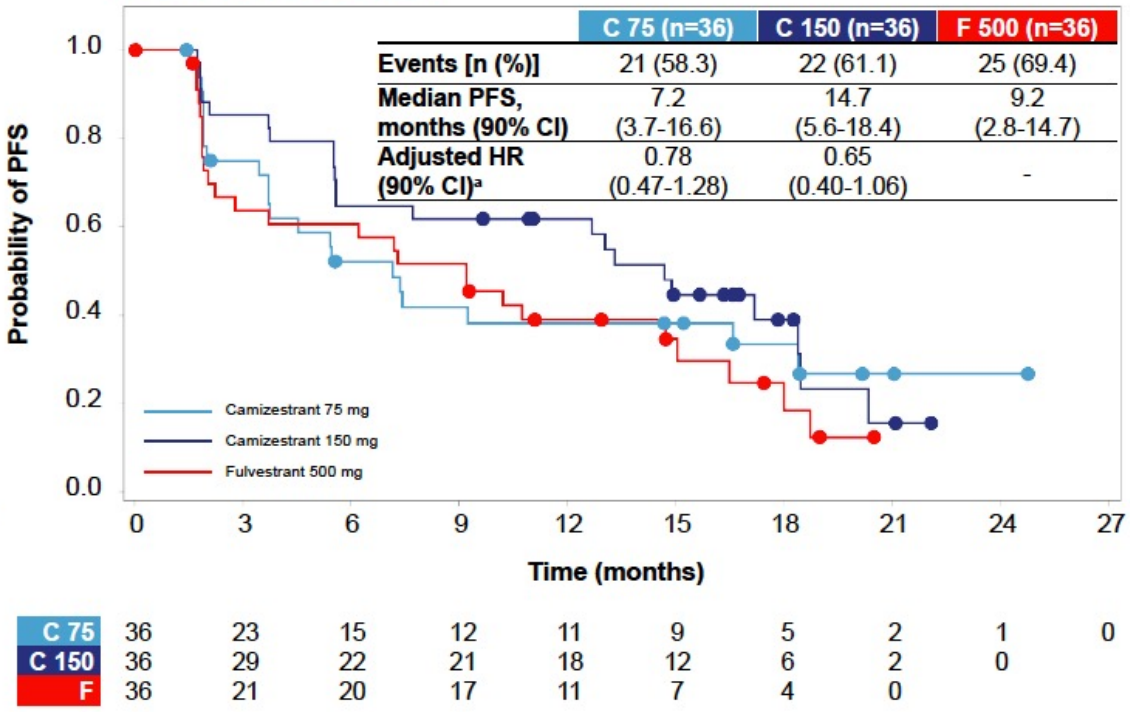
## Prior CDK4/6i




| | C 75 (n=38) | C 150 (n=37) | F 500 (n=37) |
|---|---|---|---|
| Events [n (%)] | 29 (76.3) | 29 (78.4) | 33 (89.2) |
| Median PFS, months (90% CI) | 5.5 (3.7-10.9) | 3.8 (2.0-7.6) | 2.1 (1.9-3.7) |
| Adjusted HR (90% CI)[a] | 0.49 (0.31-0.75) | 0.68 (0.44-1.04) | - |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| C 75 | 38 | 27 | 18 | 15 | 10 | 5 | 2 | 0 |
| C 150 | 37 | 21 | 15 | 11 | 7 | 0 | | |
| F | 37 | 16 | 8 | 5 | 3 | 1 | 1 | 0 |

## No prior CDK4/6i




| | C 75 (n=36) | C 150 (n=36) | F 500 (n=36) |
|---|---|---|---|
| Events [n (%)] | 21 (58.3) | 22 (61.1) | 25 (69.4) |
| Median PFS, months (90% CI) | 7.2 (3.7-16.6) | 14.7 (5.6-18.4) | 9.2 (2.8-14.7) |
| Adjusted HR (90% CI)[a] | 0.78 (0.47-1.28) | 0.65 (0.40-1.06) | - |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| C 75 | 36 | 23 | 15 | 12 | 11 | 9 | 5 | 2 | 1 | 0 |
| C 150 | 36 | 29 | 22 | 21 | 18 | 12 | 6 | 2 | 0 | |
| F | 36 | 21 | 20 | 17 | 11 | 7 | 4 | 0 | | |

- In the sub-population of patients previously treated with CDK4/6i + endocrine therapy, camizestrant at both doses produces a clinically meaningful improvement in PFS over fulvestrant

[a]HRs adjusted for liver/lung metastases

CI: confidence interval; CDK4/6i: CDK4/6 inhibitor; HR: hazard ratio; PFS: progression-free survival

Oliveira M et al. SABCS 2022;Abstract GS3-02.

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Charlotte, North Carolina

# Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

*A Multitumor CME/MOC-Accredited Live Webinar Series*

# Immunotherapy and Other Nontargeted Approaches for Lung Cancer

**Thursday, April 13, 2023**
**5:00 PM – 6:00 PM ET**

## Faculty

**Luis Paz-Ares, MD, PhD**

**Heather Wakelee, MD**

## Moderator

**Neil Love, MD**

RTP Year in Review 2023

*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 up to 5 minutes after the meeting ends.*

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

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