

13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Breast Cancer

**Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET**

Medical Oncologists

**Carey K Anders, MD
Kathy D Miller, MD
Sara M Tolaney, MD, MPH**

Oncology Nurse Practitioners

**Gretchen Santos Fulgencio, MSN, FNP-BC
Allie Hershey, MSN, RN, ANP-BC, AOCNP
Kelly Leonard, MSN, FNP-BC**

Moderator

Neil Love, MD

Medical Oncologists



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Duke Cancer Institute
Durham, North Carolina



Kathy D Miller, MD
The Indiana University Melvin and Bren
Simon Cancer Center
Indianapolis, Indiana



Sara M Tolaney, MD, MPH
Dana-Farber Cancer Institute
Associate Professor of Medicine
Boston, Massachusetts

Oncology Nurse Practitioners



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Berkeley, California



Allie Hershey, MSN, RN, ANP-BC, AOCNP
Dana-Farber Cancer Institute
Boston, Massachusetts



Kelly Leonard, MSN, FNP-BC
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Boston, Massachusetts

Commercial Support

This activity is supported by educational grants from Lilly, Novartis 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, 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, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, Genentech, a member of the Roche Group, 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, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, Turning Point Therapeutics Inc and Verastem Inc.

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

Dr Anders — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Athenex, Eisai Inc, Elucida Oncology Inc, Genentech, a member of the Roche Group, Immunomedics Inc, Ipsen Biopharmaceuticals Inc, Novartis, Seagen Inc
Contracted Research	G1 Therapeutics, Lilly, Merck, Nektar, Novartis, Pfizer Inc, Puma Biotechnology Inc, Seagen Inc, Tesaro, A GSK Company, The Zion Pharma
Royalties	Jones and Bartlett Learning

Dr Miller — Disclosures

Consulting Agreements	AbbVie Inc, Athenex
Contracted Research	Astex Pharmaceuticals, BBI Solutions, CytomX Therapeutics, Pfizer Inc
Data and Safety Monitoring Board/Committee	AstraZeneca Pharmaceuticals LP, Merck, Roche Laboratories Inc

Dr Tolaney — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Athenex, Bristol-Myers Squibb Company, Certara, CytomX Therapeutics, Daiichi Sankyo Inc, Eisai Inc, G1 Therapeutics, Genentech, a member of the Roche Group, Gilead Sciences Inc, Immunomedics Inc, Kyowa Kirin Co Ltd, Lilly, Merck, Mersana Therapeutics, NanoString Technologies, Nektar, Novartis, Odonate Therapeutics, OncoPep, OncoSec Medical, Pfizer Inc, Puma Biotechnology Inc, Samsung Bioepis, Sanofi Genzyme, Seagen Inc
Contracted Research	AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Cyclacel Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Immunomedics Inc, Lilly, Merck, NanoString Technologies, Nektar, Novartis, Odonate Therapeutics, Pfizer Inc, Sanofi Genzyme, Seagen Inc
Data and Safety Monitoring Board/Committee	Odonate Therapeutics

Ms Fulgencio — Disclosures

No relevant conflicts of interest to disclose.

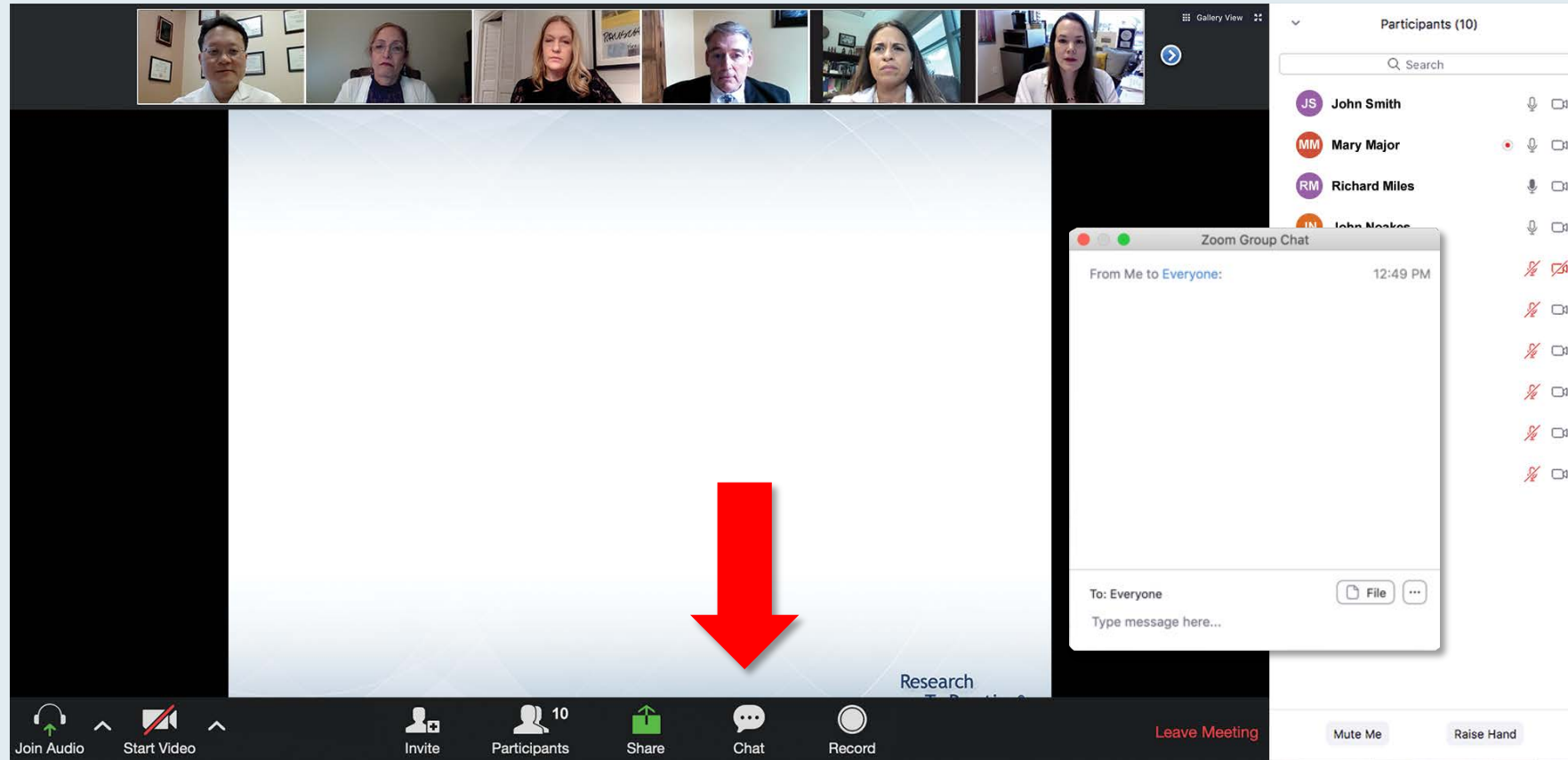
Ms Hershey — Disclosures

No relevant conflicts of interest to disclose.

Ms Leonard — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



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

Familiarizing Yourself with the Zoom Interface

How to answer poll questions

The screenshot displays a Zoom meeting interface. At the top, a gallery view shows six participants. The main screen displays a poll question: "What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?". Below the question is a list of ten treatment options, each preceded by a number. A "Quick Poll" overlay is visible, showing a list of radio button options corresponding to the numbered list. The bottom of the screen features a toolbar with icons for "Join Audio", "Start Video", "Invite", "Participants" (showing 10), "Share", "Chat", "Record", and a "Leave Meeting" button. On the right side, a "Participants (10)" list is visible, showing names and status icons.

What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?

Quick Poll

- ☐ Carfilzomib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Carfilzomib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Ixazomib + Rd
- ☐ Other

Submit

Co-provided by USF Health Research To Practice®

Join Audio Start Video Invite Participants 10 Share Chat Record Leave Meeting Mute Me Raise Hand

Participants (10)

Search

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

When a poll question pops up, click your answer choice from the available options.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a 'Recording...' button. The main content area displays a slide titled 'Meet The Professor Program Steering Committee' with six members listed:

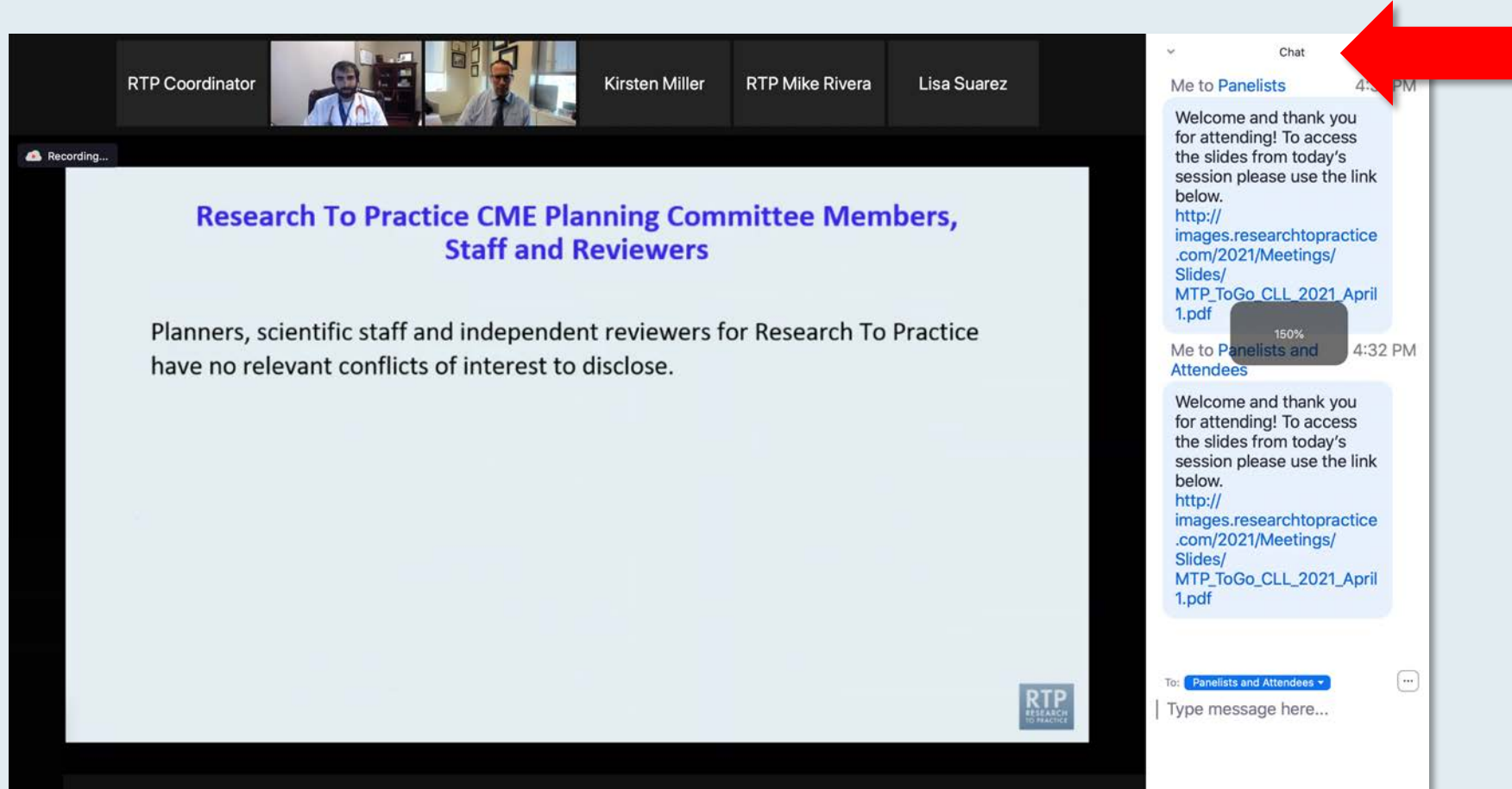
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Director of Lymphoma Research Program
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee
- Steven Coutre, MD**
Professor of Medicine (Hematology)
Stanford University School of Medicine
Stanford, California
- Prof John G Gribben, MD, DSc, FMedSci**
Chair of Medical Oncology
Barts Cancer Institute
Queen Mary University of London
Charterhouse Square
London, United Kingdom
- Matthew S Davids, MD, MMSc**
Associate Professor of Medicine
Harvard Medical School
Division of Lymphoma
Dana-Farber Cancer Institute
Boston, Massachusetts
- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

The right side of the interface shows a chat window titled 'Chat'. It contains two messages from 'Me to Panelists' at 4:31 PM and 'Me to Panelists and Attendees' at 4:32 PM, both welcoming attendees and providing a link to a PDF of slides. At the bottom of the chat window, there is a 'To:' dropdown menu set to 'Panelists and Attendees' and a text input field labeled 'Type message here...'. A large red arrow points to this input field.

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

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.**

ONCOLOGY TODAY

WITH DR NEIL LOVE

Newly Approved Agents in HER2-Positive Metastatic Breast Cancer



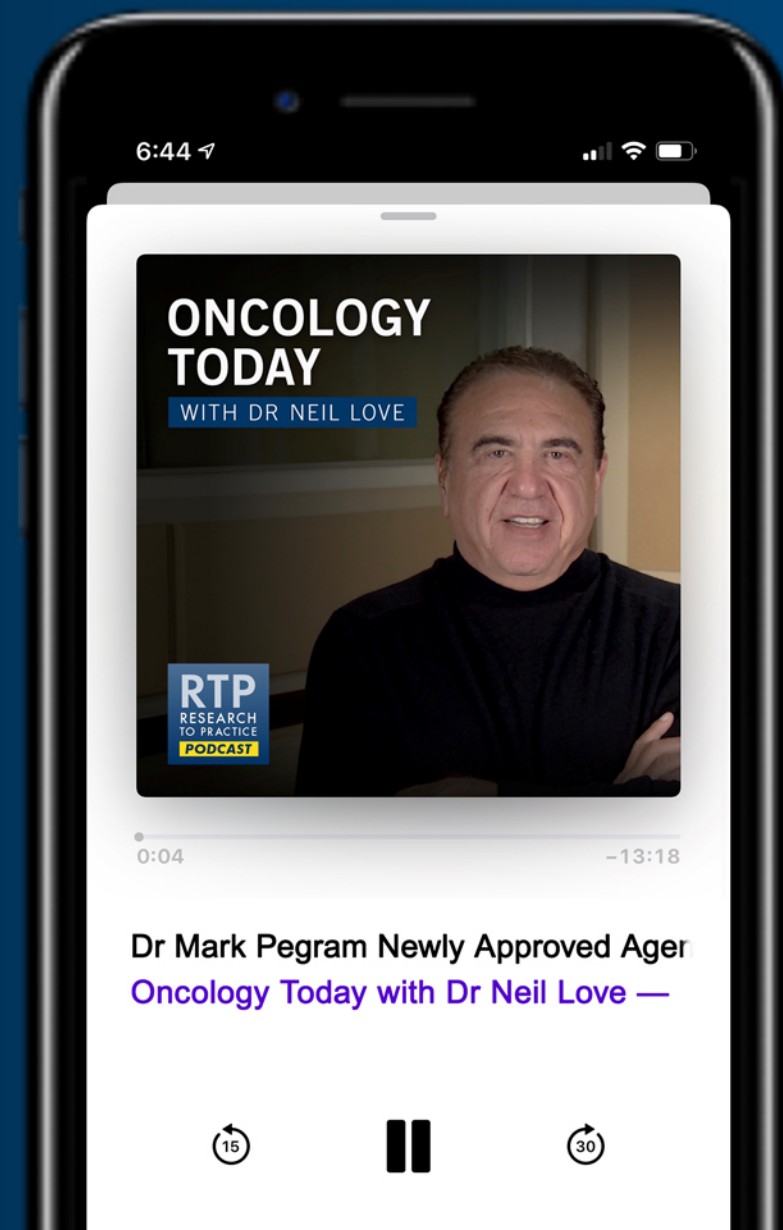
DR MARK PEGRAM
STANFORD UNIVERSITY SCHOOL OF MEDICINE



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Wednesday, April 21, 2021

12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers

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4:45 PM – 5:45 PM ET

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Chronic Lymphocytic Lymphoma

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8:30 AM – 10:00 AM ET

Chimeric Antigen Receptor T-Cell Therapy

Thursday, April 29, 2021

5:00 PM – 6:30 PM ET

Exploring the Multidisciplinary Management of Localized Non-Small Cell Lung Cancer with EGFR Mutation

*A CME/MOC Virtual Satellite Symposia
Offering During the AATS 101st Annual Meeting*

Faculty

Chung-Han Lee, MD, PhD
David I Quinn, MBBS, PhD
Walter Stadler, MD

Moderator

Neil Love, MD

Activity Dates and Times

Tuesday, May 4, 2021 – 5:00 PM – 6:00 PM – Dr Lee

Wednesday, June 2, 2021 – 5:00 PM – 6:00 PM – Dr Stadler

Tuesday, July 6, 2021 – 5:00 PM – 6:00 PM – Dr Quinn

All times noted are Eastern Daylight Time

Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo® and Florida Cancer Specialists

**Tuesday, May 4, 2021
5:00 PM – 6:00 PM ET**

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

*A Daylong Clinical Summit Hosted in
Partnership with Medical Oncology
Association of Southern California (MOASC)*

**Saturday, May 15, 2021
10:30 AM – 6:30 PM ET**

Saturday, May 15, 2021

10:30 AM — Breast Cancer

Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma

Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas

Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers

Joaquim Bellmunt, Sumanta Kumar Pal

Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers

Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes

Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer

D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

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2:00 PM — Multiple Myeloma

Irene M Ghobrial, Sagar Lonial

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Virginia Kaklamani, Nancy U Lin

Thank you for joining us!

NCPD credit information will be emailed to each participant within 3 business days.

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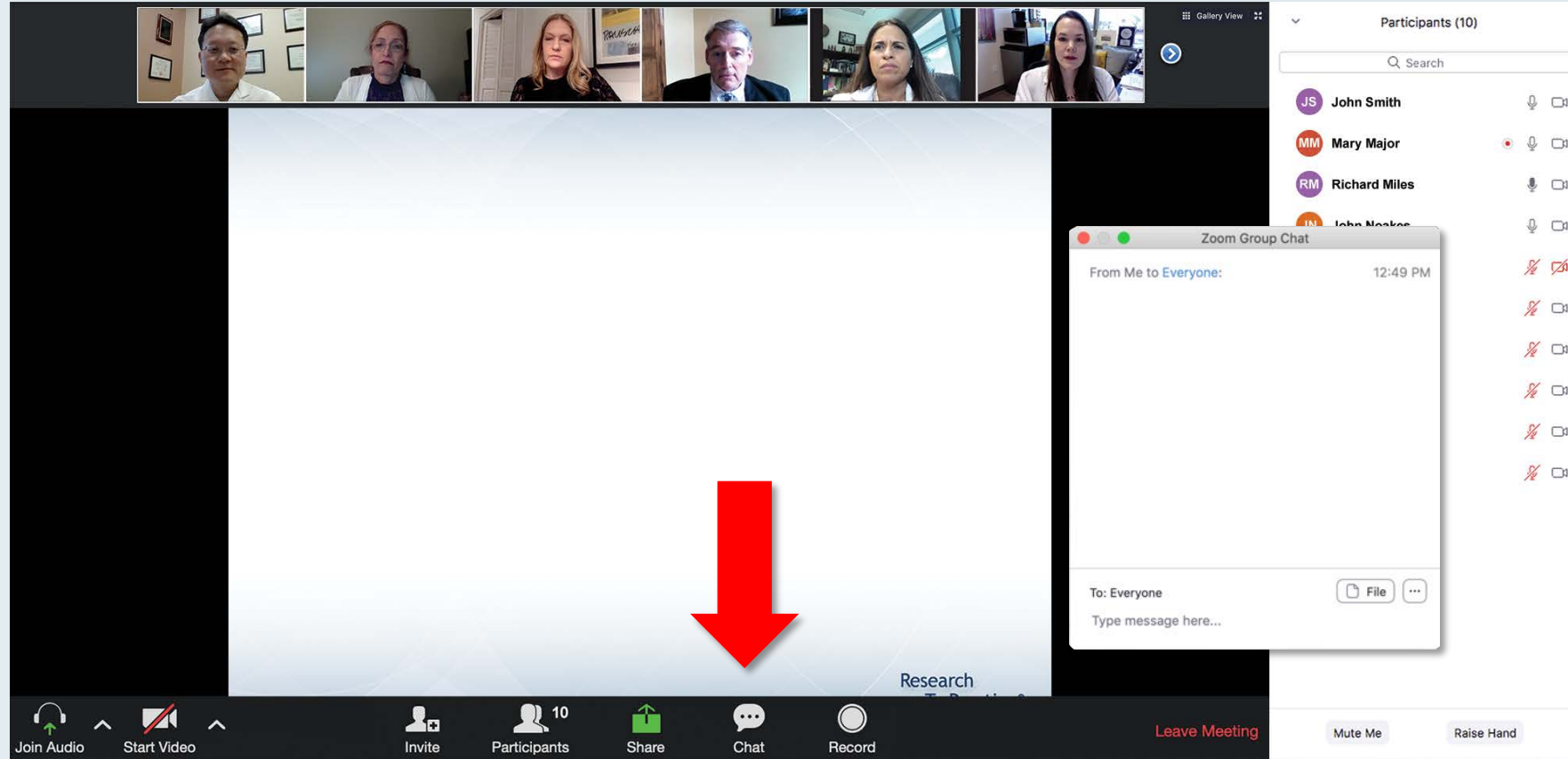


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Medical Oncologists



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Hematopoietic Cellular Therapy Program
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Columbus, Ohio

Oncology Nurse Practitioners



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Jessica Mitchell, APRN, CNP, MPH
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Patricia Mangan, RN, MSN, CRNP, APN, BC
Nurse Lead, Hematologic Malignancies and
Stem Cell Transplant Programs
Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania



Mollie Moran, APRN-CNP, AOCNP
The James Cancer Hospital and Solove
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The Ohio State University
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Tara Plues, APRN, MSN
Hematology and Medical Oncology
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Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC
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Victoria Sherry, DNP, CRNP, AOCNP
Oncology Nurse Practitioner for Thoracic
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Perelman Center for Advanced Medicine
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Faculty, University of Pennsylvania School of Nursing
Philadelphia, Pennsylvania



Elizabeth Zerante, MS, AGACNP-BC
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University of Chicago Medicine
Chicago, Illinois

Oncology Grand Rounds Nursing Webinar Series

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM	21 AML 12:00 PM	22 Prostate Ca 8:30 AM	23
	Lung Ca 5:00 PM	CRC and GI Ca 4:45 PM	Lymphomas 5:00 PM	
26	27 Multiple Myeloma 8:30 AM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM	30
	GYN 5:00 PM		CAR-T 5:00 PM	





The Core Oncology Triad

Developing an Individualized Oncology Strategy



13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
 - Family/loved ones
 - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

Research To Practice's 2019 San Antonio Breast Cancer Symposia

DATA + PERSPECTIVES

Clinical Investigators Explore the Current and Future Management of ER-Positive Breast Cancer

Wednesday, December 11, 2019

7:30 PM – 9:00 PM

San Antonio, Texas

Moderator
Neil Love, MD

Faculty

Harold J Burstein, MD, PhD
Matthew Goetz, MD

Stephen RD Johnston, MA, PhD
Joseph A Sparano, MD

DATA + PERSPECTIVES

Clinical Investigators Explore the Current and Future Management of HER2-Positive Breast Cancer

Friday, December 13, 2019

7:30 PM – 9:00 PM

San Antonio, Texas

Moderator
Neil Love, MD

Faculty

Adam M Brufsky, MD, PhD
Lisa A Carey, MD

Sara Hurvitz, MD
Martine J Piccart-Gebhart, MD, PhD

Research
To Practice®

DATA + PERSPECTIVES

Clinical Investigators Explore the Current and Future Management of Triple-Negative Breast Cancer

Thursday, December 12, 2019

7:30 PM – 9:00 PM

San Antonio, Texas

Moderator
Neil Love, MD

Faculty

Erika Hamilton, MD
Professor Sherene Loi, MBBS, PhD

Mark E Robson, MD
Hope S Rugo, MD

Research
To Practice®

13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Breast Cancer

**Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET**

Medical Oncologists

**Carey K Anders, MD
Kathy D Miller, MD
Sara M Tolaney, MD, MPH**

Oncology Nurse Practitioners

**Gretchen Santos Fulgencio, MSN, FNP-BC
Allie Hershey, MSN, RN, ANP-BC, AOCNP
Kelly Leonard, MSN, FNP-BC**

Moderator

Neil Love, MD



Kelly Leonard, MSN, FNP-BC



Gretchen Santos Fulgencio, MSN, FNP-BC



Allie Hershey, MSN, RN, ANP-BC, AOCNP

Agenda

Cases from the Practices of Ms Fulgencio, Ms Hershey and Ms Leonard

Module 1: ER-Positive

- **Case 1 (Ms Fulgencio):** A 31-year-old woman with localized ER/PR-positive, HER2-negative breast cancer and 3 positive nodes
- **Case 2 (Ms Leonard):** A 53-year-old woman with ER-positive, HER2-negative metastatic breast cancer and a PIK3CA tumor mutation

Module 2: HER2-Positive

- **Case 3 (Ms Leonard):** A 33-year-old woman with localized ER/PR-positive, HER2-positive breast cancer and residual disease after neoadjuvant treatment
- **Case 4 (Ms Fulgencio):** A 70-year-old woman with metastatic HER2-positive breast cancer
- **Case 5 (Ms Hershey):** A 44-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer
- **Case 6 (Ms Leonard):** A 64-year-old woman with ER-positive, HER2-positive metastatic breast cancer and brain metastases

Module 3: Triple-Negative

- **Case 7 (Ms Hershey):** A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive

Ms Leonard: Reflections on Being an Oncology Nurse



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- **Case 7 (Ms Hershey): A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive**

Case Presentation – A 31-year-old woman with localized ER/PR-positive, HER2-negative breast cancer and 3 positive nodes (Part 1)



Ms Fulgencio

- Systems engineer diagnosed with Stage IIB breast cancer with 3 of 8 positive nodes
- Experienced noticeable fatigue and cognitive issues associated with adjuvant chemotherapy

Case Presentation – A 31-year-old woman with localized ER/PR-positive, HER2-negative breast cancer and 3 positive nodes (Part 2)



Ms Fulgencio

- Systems engineer diagnosed with Stage IIB breast cancer with 3 of 8 positive nodes
- Experienced noticeable fatigue and cognitive issues associated with adjuvant chemotherapy
- ***Started on chemotherapy, LHRH agonist, aromatase inhibitor, zoledronic acid and considering abemaciclib***

Which of the following toxicities is more common with palbociclib and ribociclib than with abemaciclib?

1. Gastrointestinal toxicity
2. Neutropenia
3. Anemia
4. Peripheral neuropathy
5. I don't know

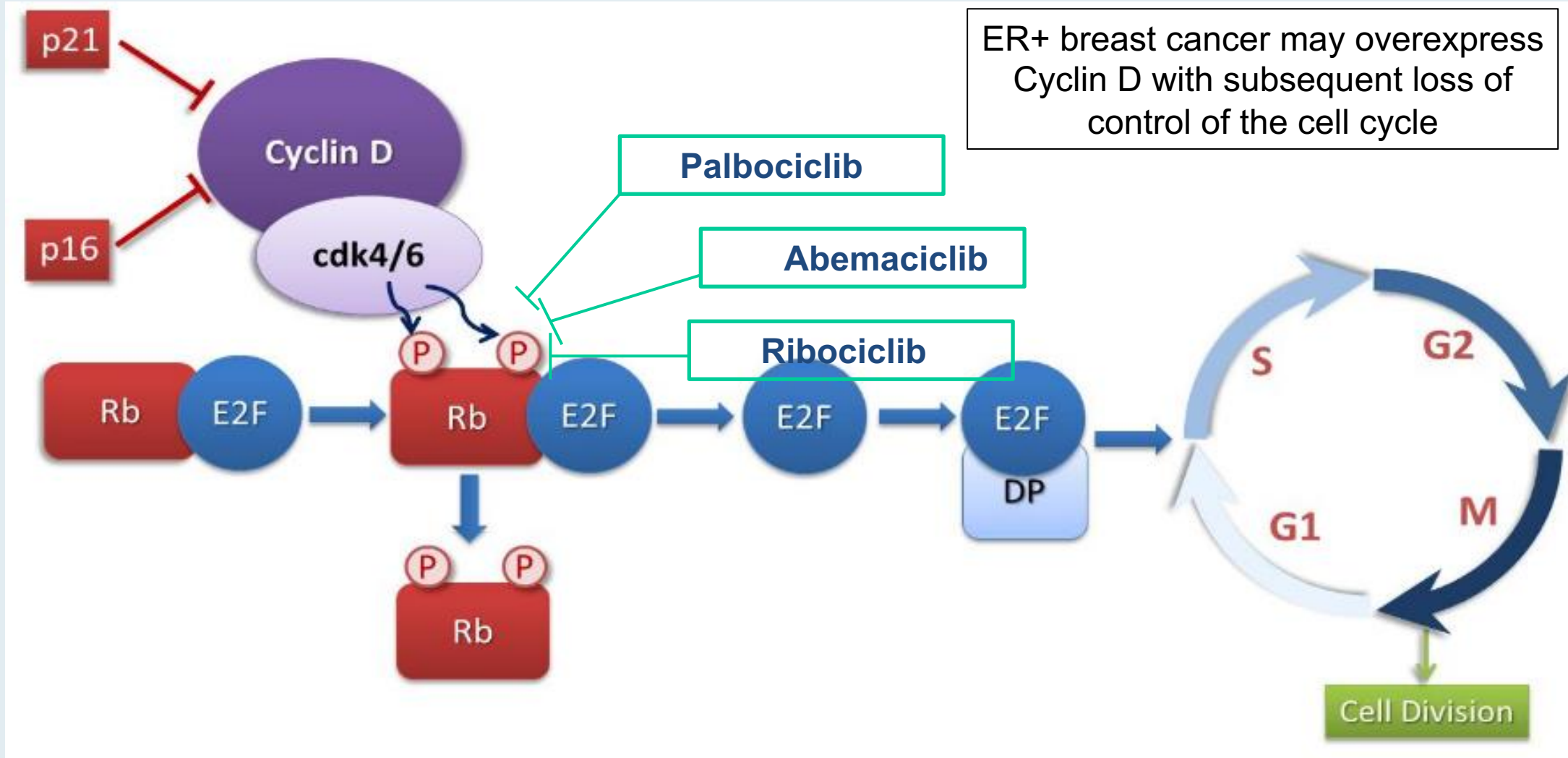
Which of the following toxicities is more common with abemaciclib than with palbociclib and ribociclib?

1. Diarrhea
2. Neutropenia
3. Anemia
4. Peripheral neuropathy
5. I don't know

Which CDK4/6 inhibitor requires that an electrocardiogram be conducted prior to the initiation of treatment?

1. Palbociclib
2. Ribociclib
3. Abemaciclib
4. I don't know

CDK4/6 Regulates Cell Cycle Progression



What effect was observed in the Phase III trial of adjuvant abemaciclib?

1. Fewer recurrences
2. Fewer deaths
3. Both

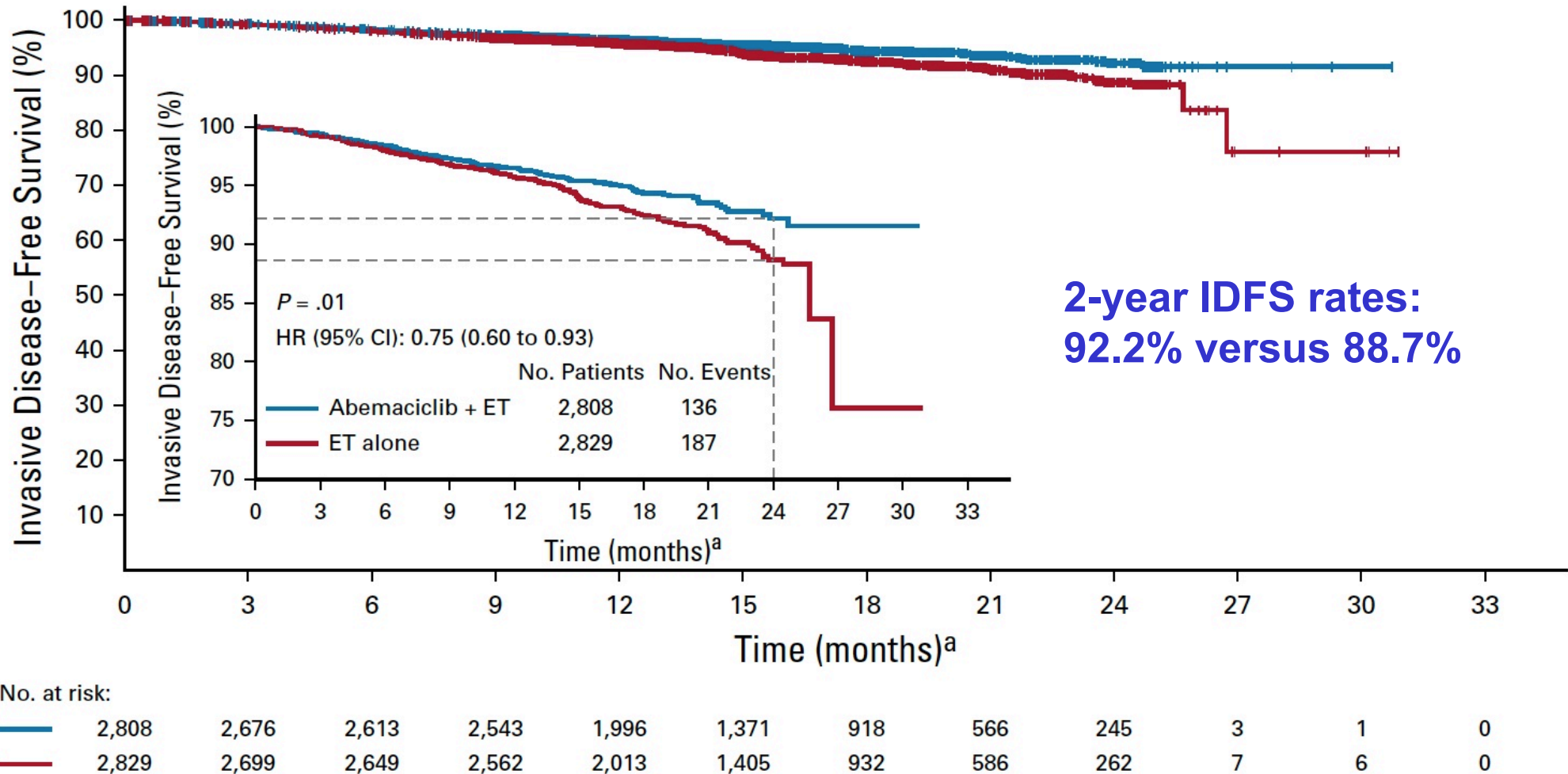
J Clin Oncol 2020;38(34):3987-98.

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Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2–, Node-Positive, High-Risk, Early Breast Cancer (monarchE)

Stephen R. D. Johnston, MD, PhD¹; Nadia Harbeck, MD, PhD²; Roberto Hegg, MD, PhD³; Masakazu Toi, MD, PhD⁴; Miguel Martin, MD, PhD⁵; Zhi Min Shao, MD⁶; Qing Yuan Zhang, MD, PhD⁷; Jorge Luis Martinez Rodriguez, MD⁸; Mario Campone, MD, PhD⁹; Erika Hamilton, MD¹⁰; Joohyuk Sohn, MD, PhD¹¹; Valentina Guarneri, MD, PhD¹²; Morihito Okada, MD, PhD¹³; Frances Boyle, MD, MBBS, PhD¹⁴; Patrick Neven, MD, PhD¹⁵; Javier Cortés, MD, PhD¹⁶; Jens Huober, MD¹⁷; Andrew Wardley, MD, MBChB¹⁸; Sara M. Tolaney, MD, MPH¹⁹; Irfan Cicin, MD²⁰; Ian C. Smith, MD^{21,22}; Martin Frenzel, PhD²²; Desirée Headley, MSc²²; Ran Wei, PhD²²; Belen San Antonio, PhD²²; Maarten Hulstijn, PhD²²; Joanne Cox, MD²²; Joyce O'Shaughnessy, MD²³; and Priya Rastogi, MD²⁴; on behalf of the monarchE Committee Members and Investigators

monarchE: Invasive Disease-Free Survival (IDFS) (Zoomed in to better show separation of curves)





Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study

Erica L Mayer, Amylou C Dueck, Miguel Martin, Gabor Rubovszky, Harold J Burstein, Meritxell Bellet-Ezquerria, Kathy D Miller, Nicholas Zdenkowski, Eric P Winer, Georg Pfeiler, Matthew Goetz, Manuel Ruiz-Borrego, Daniel Anderson, Zbigniew Nowecki, Sibylle Loibl, Stacy Moulder, Alistair Ring, Florian Fitzal, Tiffany Traina, Arlene Chan, Hope S Rugo, Julie Lemieux, Fernando Henao, Alan Lyss, Silvia Antolin Novoa, Antonio C Wolff, Marcus Vetter, Daniel Egle, Patrick G Morris, Eleftherios P Mamounas, Miguel J Gil-Gil, Aleix Prat, Hannes Fohler, Otto Metzger Filho, Magdalena Schwarz, Carter DuFrane, Debora Fumagalli, Kathy Puyana Theall, Dongrui Ray Lu, Cynthia Huang Bartlett, Maria Koehler, Christian Fesl, Angela DeMichele*, Michael Gnant*

Therapy for premenopausal women with ER-positive metastatic breast cancer who undergo ovarian suppression or ablation is generally approached in the same manner as is therapy for postmenopausal patients.

1. Agree
2. Disagree
3. I don't know

Randomized Trials of Endocrine Therapy +/- CDK4/6 Inhibition

Line	Trial	Schema	PFS HR compared to endocrine alone	OS HR compared to endocrine alone
First line	PALOMA-1	Letrozole ± palbociclib	0.49	0.897
	PALOMA-2	Letrozole ± palbociclib	0.58	NR
	MONALEESA-2	Letrozole ± ribociclib	0.56	0.75
	MONALEESA-3	Fulvestrant ± ribociclib	0.55	0.72
	MONALEESA-7 (premenopausal)	Goserelin + AI or tamoxifen ± ribociclib	0.55	0.71
	MONARCH 3	Letrozole or anastrozole, ± abemaciclib	0.54	NR
Second line	PALOMA-3	Fulvestrant ± palbociclib	0.46	0.75
	MONARCH 2	Fulvestrant ± abemaciclib	0.55	0.757

Common Side Effects and Dosing of CDK4/6 Inhibitors

	Palbociclib		Abemaciclib		Ribociclib	
Dosing	125 mg qd 3 wk on, 1 wk off		200 mg BID continuously		600 mg qd 3 wk on, 1 wk off	
Common adverse events	All grades	Grade 3/4	All grades	Grade 3/4	All grades	Grade 3/4
Neutropenia	95%	54%	88%	27%	46%	29%
Thrombocytopenia	76%	19%	42%	2%	37%	10%
Diarrhea	16%	0	90%	20%	22%	3%
Nausea	23%	0	65%	5%	46%	2%
Vomiting	5%	0	35%	2%	25%	0

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Module 3: Triple-Negative

- Case 7 (Ms Hershey): A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive

Case Presentation – A 53-year-old woman with ER-positive, HER2-negative metastatic breast cancer and a PIK3CA tumor mutation



Ms Leonard

- Married mother of 2 teenage children whose disease has progressed on CDK4/6 inhibitors, everolimus and multiple chemotherapies
- Treated with alpelisib with fulvestrant
- Management of hyperglycemia associated with alpelisib

Ms Fulgencio: Patient Education on Alpelisib (Part 1)



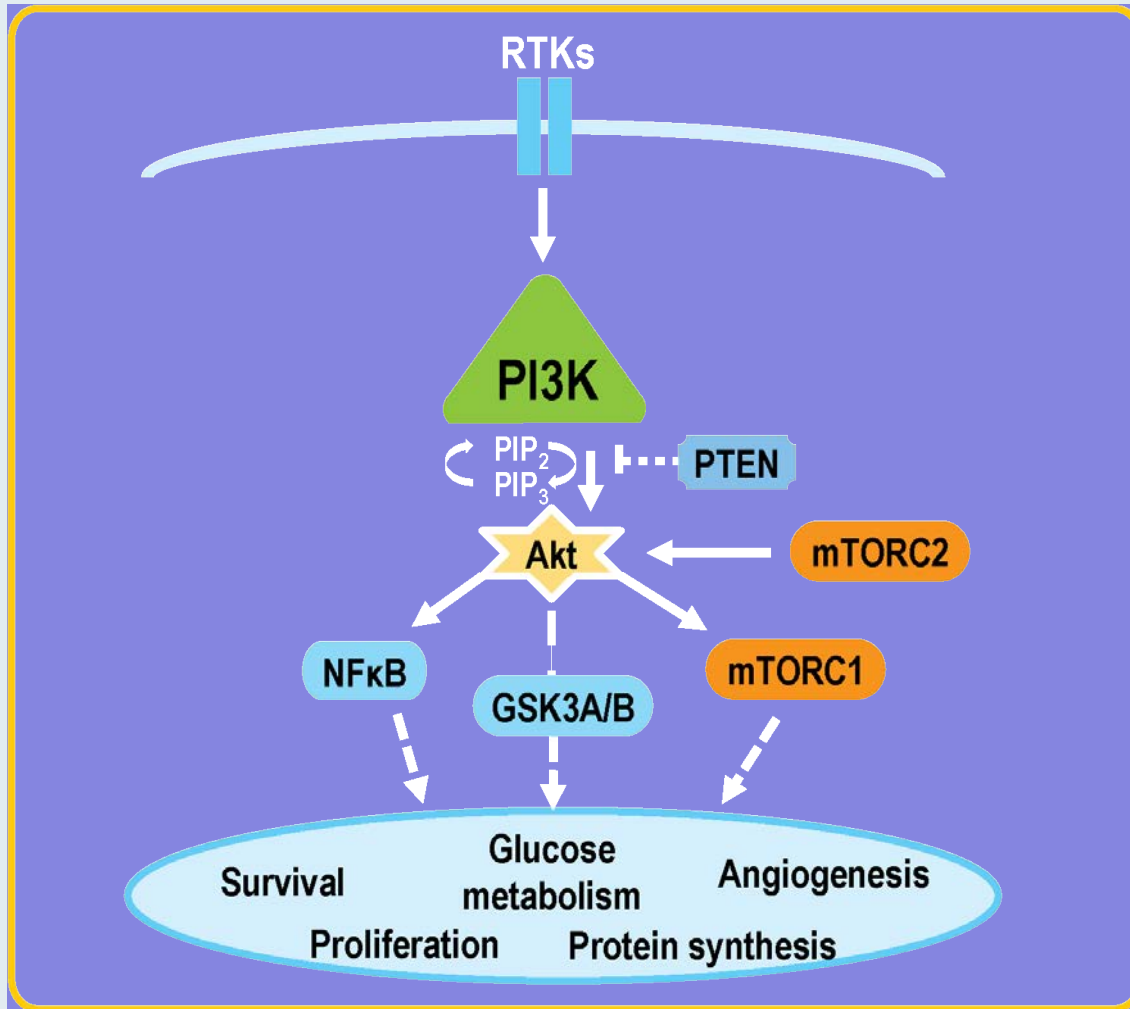
Ms Fulgencio: Patient Education on Alpelisib (Part 2)



The PI3 kinase inhibitor alpelisib is used for patients with metastatic ER-positive, HER2-negative breast cancer with a...

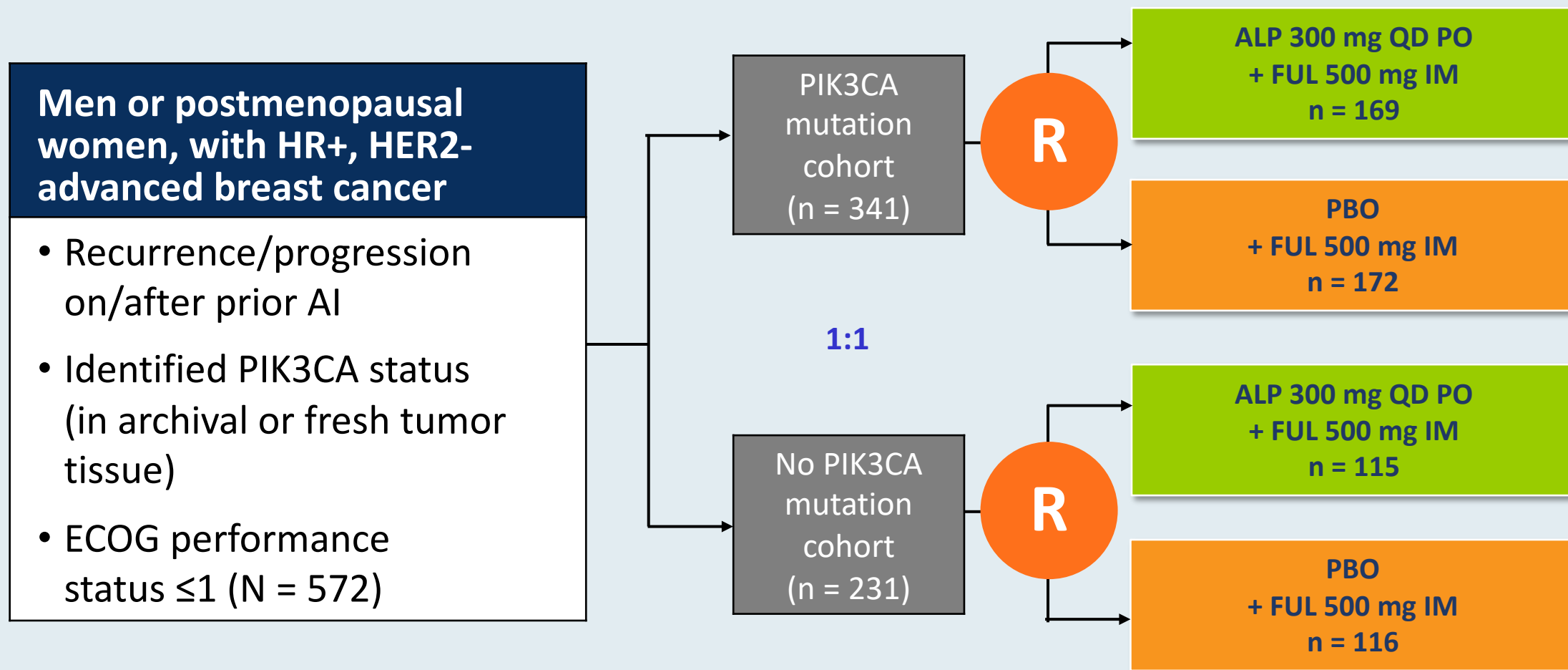
1. PIK3CA germline mutation
2. PIK3CA somatic mutation
3. PIK3CA amplification
4. All of the above
5. I don't know

PI3K Inhibitors: Mechanism of Action



- PI3K is involved in the activation of Akt.
- Hyperactivation of the PI3K pathway is implicated in malignant transformation, cancer progression and endocrine therapy resistance.
- PIK3CA encodes the alpha isoform of the PI3K catalytic subunit.
- Around 40% of patients with HR+, HER- BC present with an activating PIK3CA tumor mutation.
- Alpelisib is a specific inhibitor of the PI3K alpha isoform.

SOLAR-1 Phase III Study Design



Primary endpoint: Locally assessed PFS in PIK3CA mutation cohort

ORIGINAL ARTICLE

Alpelisib plus fulvestrant for *PIK3CA*-mutated, hormone receptor-positive, human epidermal growth factor receptor-2—negative advanced breast cancer: final overall survival results from SOLAR-1

F. André^{1*}, E. M. Ciruelos², D. Juric³, S. Loibl⁴, M. Campone⁵, I. A. Mayer⁶, G. Rubovszky⁷, T. Yamashita⁸, B. Kaufman⁹, Y.-S. Lu¹⁰, K. Inoue¹¹, Z. Pápai¹², M. Takahashi¹³, F. Ghaznawi¹⁴, D. Mills¹⁵, M. Kaper¹⁴, M. Miller¹⁴, P. F. Conte¹⁶, H. Iwata¹⁷ & H. S. Rugo¹⁸

¹Department of Medical Oncology, Institut Gustave Roussy, Villejuif and Paris Saclay University, Orsay, France; ²Medical Oncology, Hospital Universitario 12 de Octubre, Madrid, Spain; ³Department of Medicine, Massachusetts General Hospital Cancer Center, Boston, USA; ⁴Department of Medicine and Research, German Breast Group, GBG Forschungs GmbH, Neu-Isenburg, Germany; ⁵Medical Oncology, Institut de Cancerologie de l'Ouest, Saint-Herblain, Nantes Cedex, France; ⁶Hematology/Oncology, Vanderbilt University, Nashville, USA; ⁷Department of Medical Oncology and Clinical Pharmacology, National Institute of Oncology, Budapest, Hungary; ⁸Department of Breast and Endocrine Surgery, Kanagawa Cancer Center, Yokohama, Japan; ⁹Medical Oncology, Tel Aviv University, Sheba Medical Centre, Tel Hashomer, Israel; ¹⁰Medical Oncology, National Taiwan University Hospital, Taipei, Taiwan; ¹¹Breast Surgery, Saitama Cancer Center, Saitama, Japan; ¹²Medical Oncology, Hungarian Defence Forces Medical Centre, Budapest, Hungary; ¹³Breast Surgery, NHO Hokkaido Cancer Center, Sapporo, Japan; ¹⁴Novartis Pharmaceuticals Corporation, East Hanover, USA; ¹⁵Novartis Pharma AG, Basel, Switzerland; ¹⁶Medical Oncology, Università di Padova and Oncologia Medica 2, Istituto Oncologico Veneto IRCCS, Padua, Italy; ¹⁷Breast Oncology, Aichi Cancer Center Hospital, Aichi, Japan; ¹⁸Breast Department, UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, USA



Available online 25 November 2020

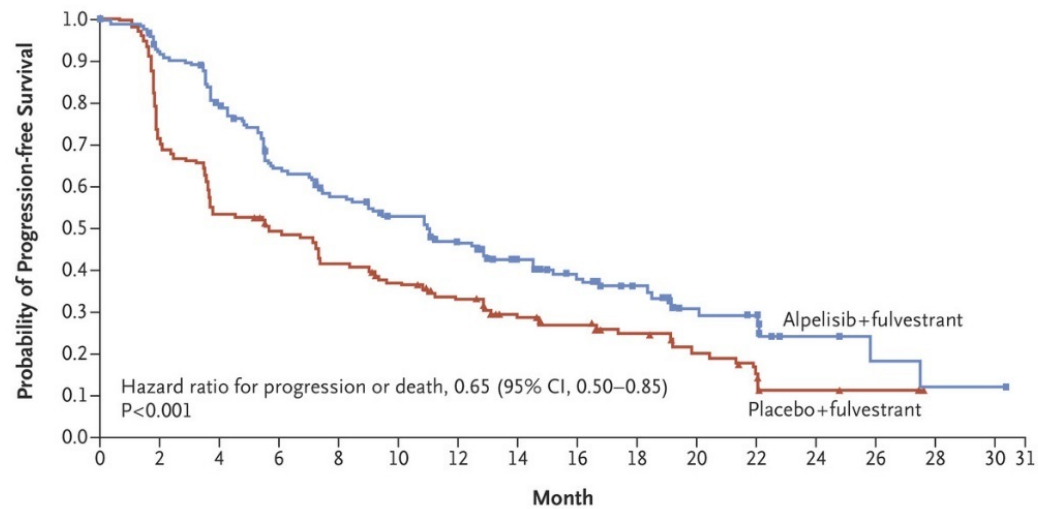
***Ann Oncol* 2021;32(2):208-17.**

SOLAR-1: Response

Response	Alpelisib–Fulvestrant Group	Placebo–Fulvestrant Group
All patients		
No. of patients	169	172
Confirmed best overall response — no. (%)		
Complete response	1 (0.6)	2 (1.2)
Partial response	44 (26.0)	20 (11.6)
Stable disease	58 (34.3)	63 (36.6)
Neither complete response nor progressive disease*	38 (22.5)	25 (14.5)
Progressive disease	16 (9.5)	53 (30.8)
Unknown status	12 (7.1)	9 (5.2)
Overall response†		
No. of patients	45	22
Percentage of patients (95% CI)	26.6 (20.1–34.0)	12.8 (8.2–18.7)
Clinical benefit‡		
No. of patients	104	78
Percentage of patients (95% CI)	61.5 (53.8–68.9)	45.3 (37.8–53.1)

SOLAR-1: PFS Outcomes by PIK3CA Mutation Status

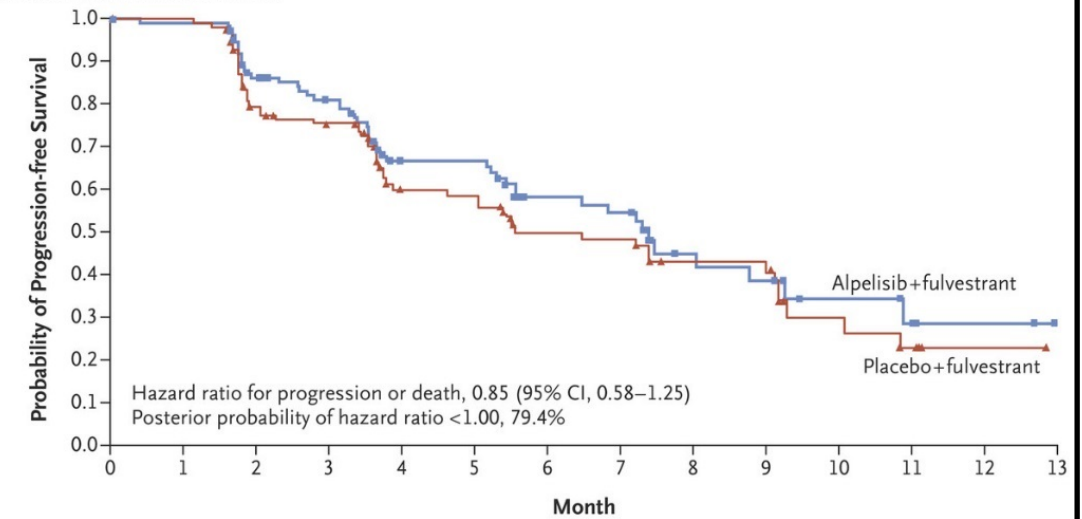
Cohort with *PIK3CA*-Mutated Cancer



No. at Risk

Alpelisib+fulvestrant	169	145	123	97	85	75	62	50	39	30	17	14	5	3	1	1	0
Placebo+fulvestrant	172	120	89	80	67	58	48	37	29	20	14	9	3	2	0	0	0

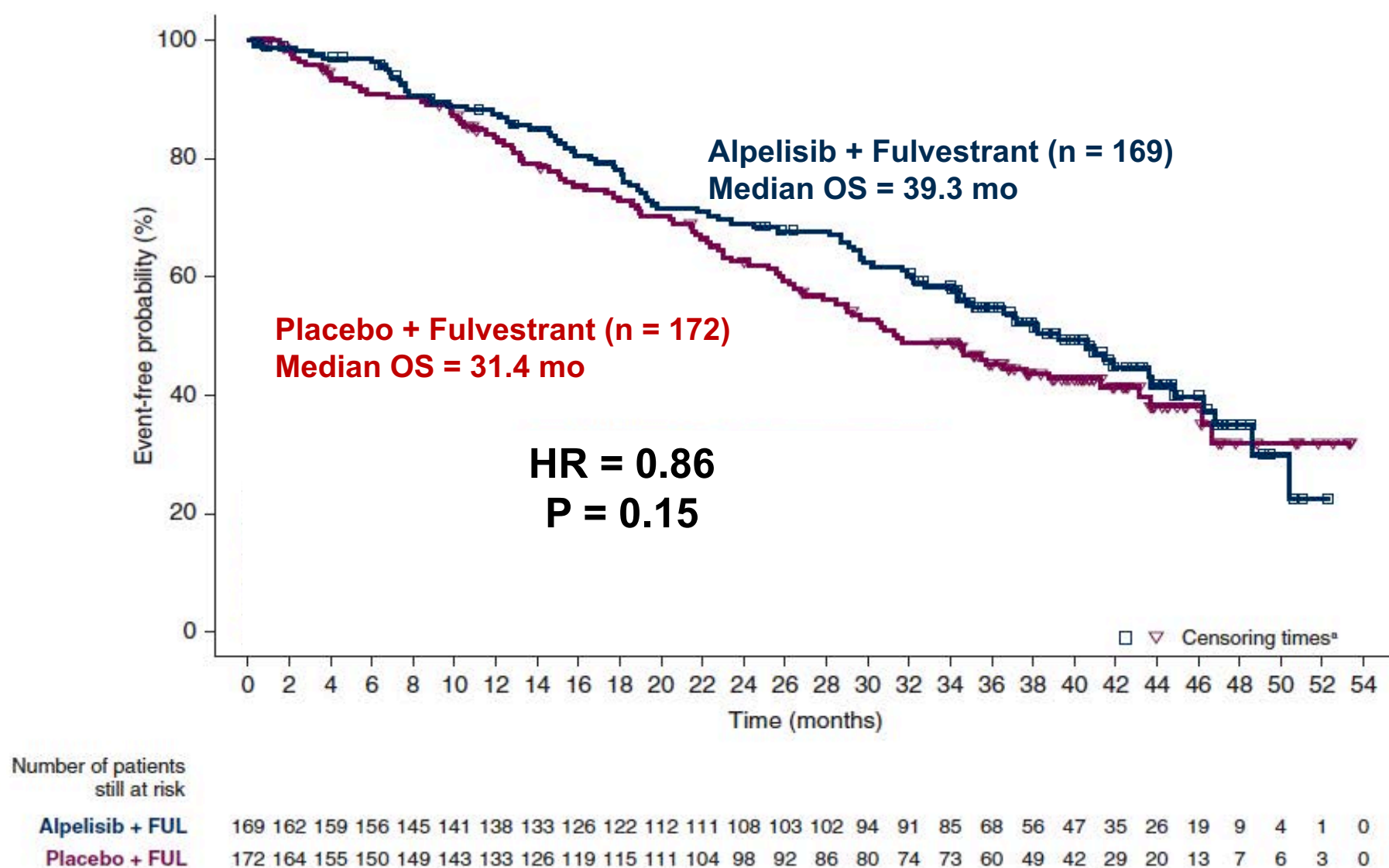
Cohort without *PIK3CA*-Mutated Cancer



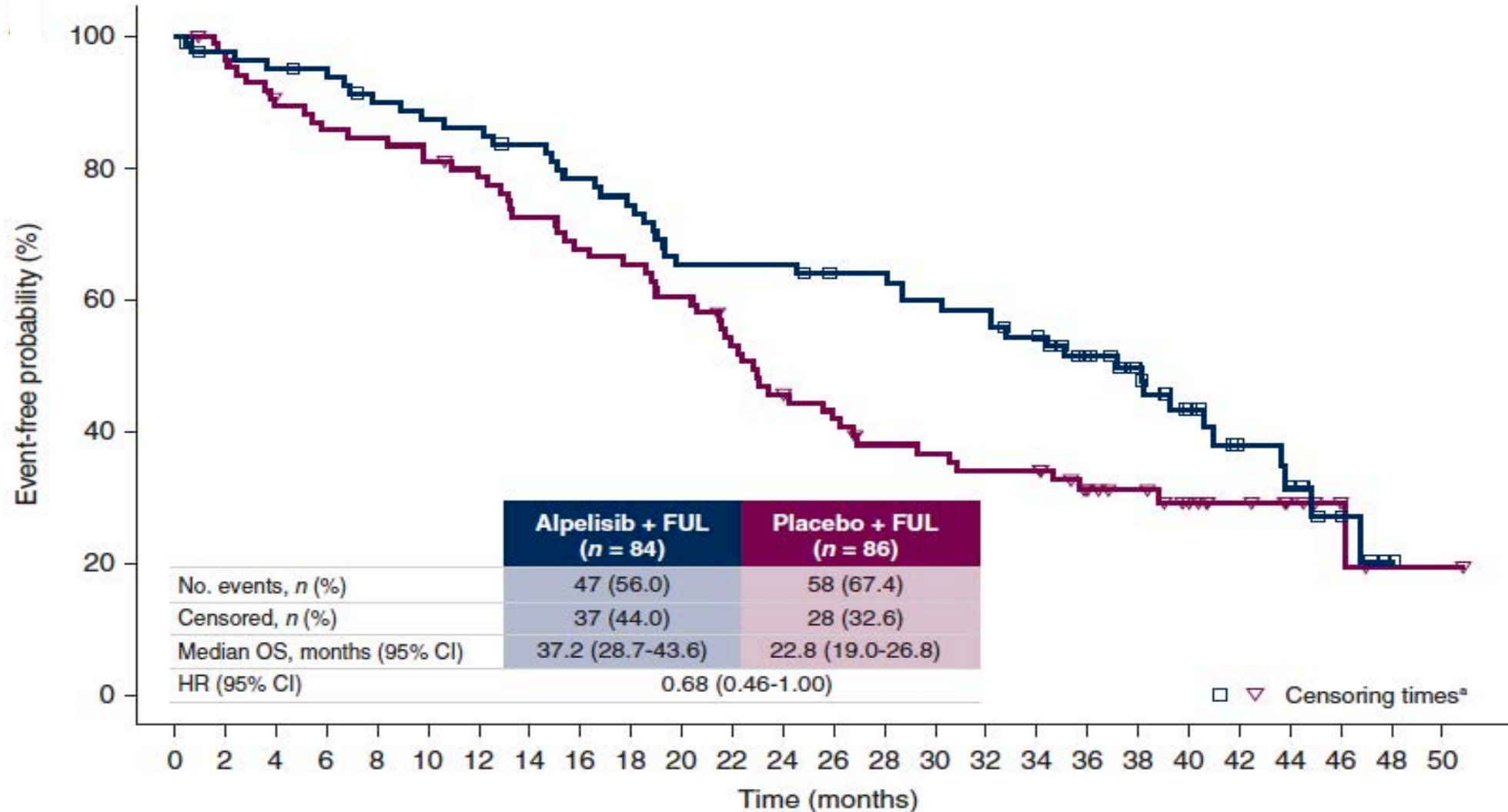
No. at Risk

Alpelisib+fulvestrant	115	110	86	76	48	48	31	29	14	12	7	5	3	0
Placebo+fulvestrant	116	110	79	72	43	42	31	30	20	20	8	5	1	0

SOLAR-1: OS in Patients with Advanced BC with a PIK3CA Mutation



SOLAR-1: OS in Patients with BC with PIK3CA Mutations and Lung/Liver Metastases

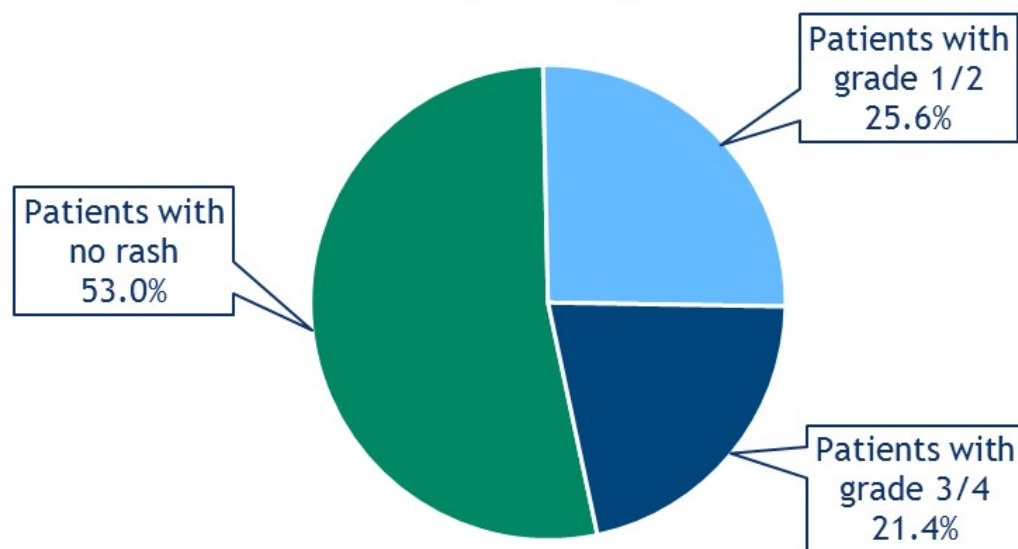


SOLAR-1: Select Adverse Events in Overall Patient Population

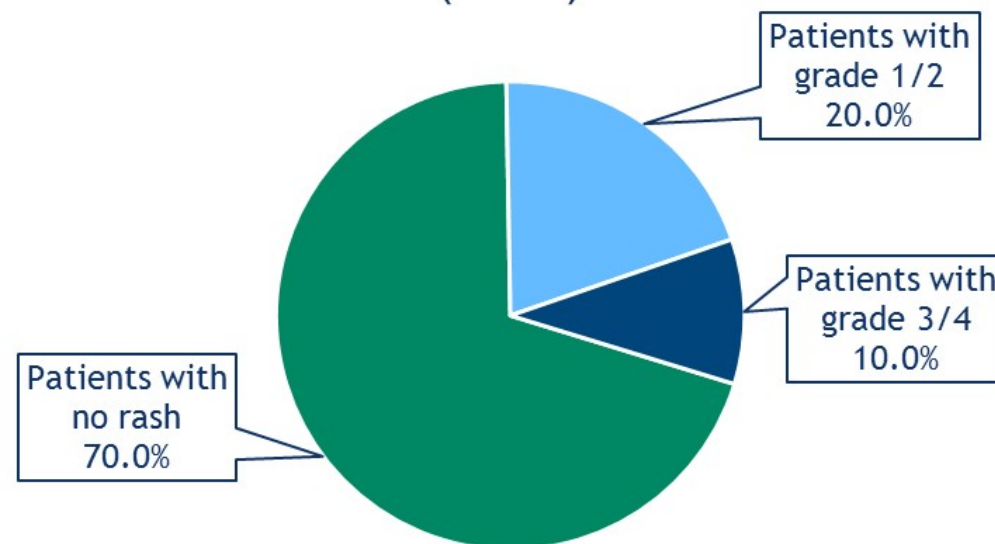
Adverse Event	Alpelisib–Fulvestrant Group (N = 284)			Placebo–Fulvestrant Group (N = 287)		
	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4
	<i>number of patients (percent)</i>					
Any adverse event	282 (99.3)	183 (64.4)	33 (11.6)	264 (92.0)	87 (30.3)	15 (5.2)
Hyperglycemia	181 (63.7)	93 (32.7)	11 (3.9)	28 (9.8)	1 (0.3)	1 (0.3)
Diarrhea	164 (57.7)	19 (6.7)	0	45 (15.7)	1 (0.3)	0
Nausea	127 (44.7)	7 (2.5)	0	64 (22.3)	1 (0.3)	0
Decreased appetite	101 (35.6)	2 (0.7)	0	30 (10.5)	1 (0.3)	0
Rash	101 (35.6)	28 (9.9)	0	17 (5.9)	1 (0.3)	0

BYLieve: Incidence of Rash with and without Prophylactic Antihistamines

Patients who did not receive antihistamines
or received antihistamines after rash
(n=117)



Patients who received antihistamines
before rash or had no event
(n=10)



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Module 3: Triple-Negative

- **Case 7 (Ms Hershey): A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive**

Case Presentation – A 33-year-old woman with localized ER/PR-positive, HER2-positive breast cancer and residual disease after neoadjuvant treatment (Part 1)



Ms Leonard

- Veterinary technician with residual disease after treatment with neoadjuvant TCHP and surgery
- Currently treated with T-DM1 and tolerating treatment well

Case Presentation – A 33-year-old woman with localized ER/PR-positive, HER2-positive breast cancer and residual disease after neoadjuvant treatment (Part 2)



Ms Leonard

- Veterinary technician with residual disease after treatment with neoadjuvant TCHP and surgery
- Currently treated with T-DM1 and tolerating treatment well
- ***Fertility preservation***

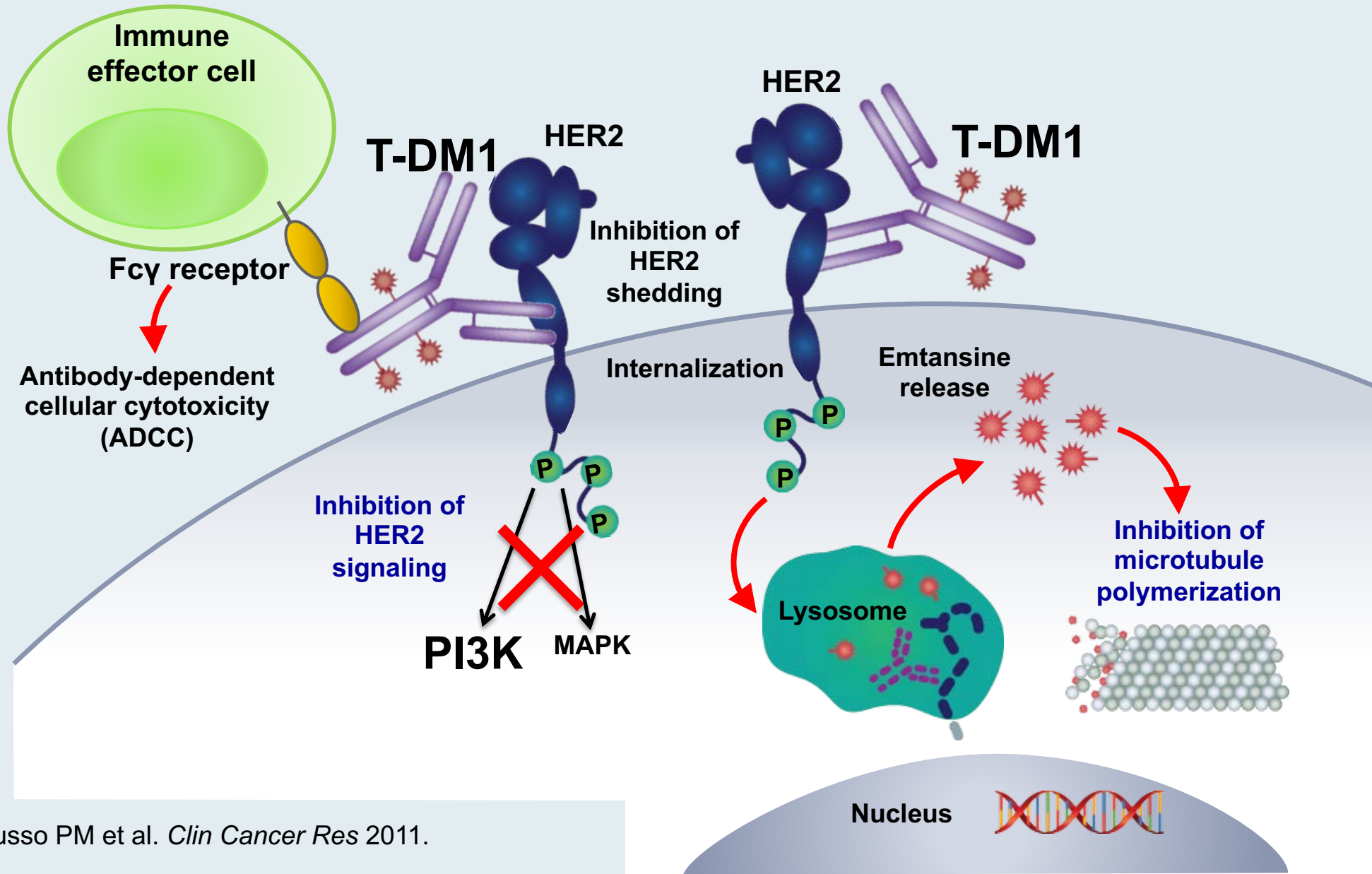
A 60-year-old woman presents with a palpable 2.5-cm breast mass that on biopsy is diagnosed as an ER-negative, HER2-positive infiltrating ductal carcinoma (IDC). Biopsy of a small axillary lymph node is positive. In general, the most common next step in this situation is...

1. Surgery to remove the primary tumor and axillary dissection followed by systemic therapy
2. Neoadjuvant systemic therapy followed by surgery
3. Either a or b
4. Neither a nor b
5. I don't know

A patient with a HER2-positive IDC responds to neoadjuvant chemotherapy and trastuzumab/pertuzumab, but at surgery residual disease is detected. In general, the most common next treatment is...

1. Trastuzumab
2. Trastuzumab/pertuzumab
3. T-DM1
4. Any of the above
5. I don't know

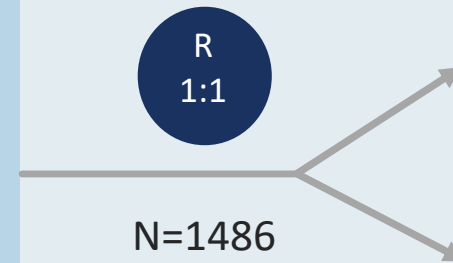
Trastuzumab Emtansine (T-DM1): Mechanisms of Action



Adapted from LoRusso PM et al. *Clin Cancer Res* 2011.

KATHERINE Study Design

- cT1-4/N0-3/M0 at presentation (cT1a-b/N0 excluded)
- Centrally confirmed HER2-positive breast cancer
- Neoadjuvant therapy must have consisted of
 - Minimum of 6 cycles of chemotherapy
 - Minimum of 9 weeks of taxane
 - Anthracyclines and alkylating agents allowed
 - All chemotherapy prior to surgery
 - Minimum of 9 weeks of trastuzumab
 - Second HER2-targeted agent allowed
- Residual invasive tumor in breast or axillary nodes
- Randomization within 12 weeks of surgery



T-DM1
3.6 mg/kg IV Q3W
14 cycles

Trastuzumab
6 mg/kg IV Q3W
14 cycles

Radiation and endocrine therapy
per protocol and local guidelines

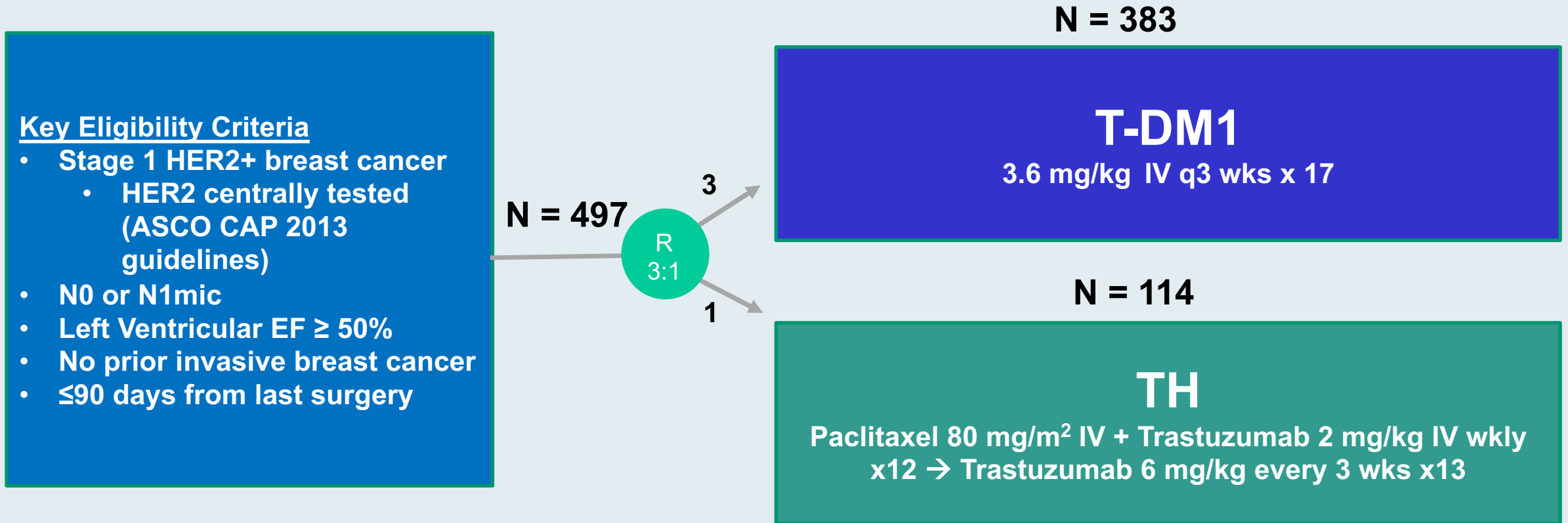
Stratification factors:

- Clinical presentation: Inoperable (stage cT4 or cN2–3) vs operable (stages cT1-3N0-1)
- Hormone receptor: ER or PR positive vs ER negative and PR negative/unknown
- Preoperative therapy: Trastuzumab vs trastuzumab plus other HER2-targeted therapy
- Pathological nodal status after neoadjuvant therapy: Positive vs negative/not done

KATHERINE: Invasive Disease-Free Survival (IDFS) Outcomes

IDFS	T-DM1 (n = 743)	Trastuzumab (n = 743)
IDFS events	12.2%	22.2%
3-year IDFS	88.3%	77.0%
	HR = 0.50; <i>p</i> < 0.0001	
Distant recurrence		
3-year event-free rate	89.7%	83.0%
	HR = 0.60	

ATEMPT Study Schema



*Radiation and endocrine therapy could be initiated after 12 weeks on study therapy

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Module 3: Triple-Negative

- **Case 7 (Ms Hershey): A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive**

Case Presentation – A 70-year-old woman with metastatic HER2-positive breast cancer



Ms Fulgencio

- Physicist initially diagnosed with metastatic disease in 2002
- Currently treated with tucatinib, capecitabine and trastuzumab
- Experiencing issues with fatigue, hair thinning, appetite changes and muscle cramps

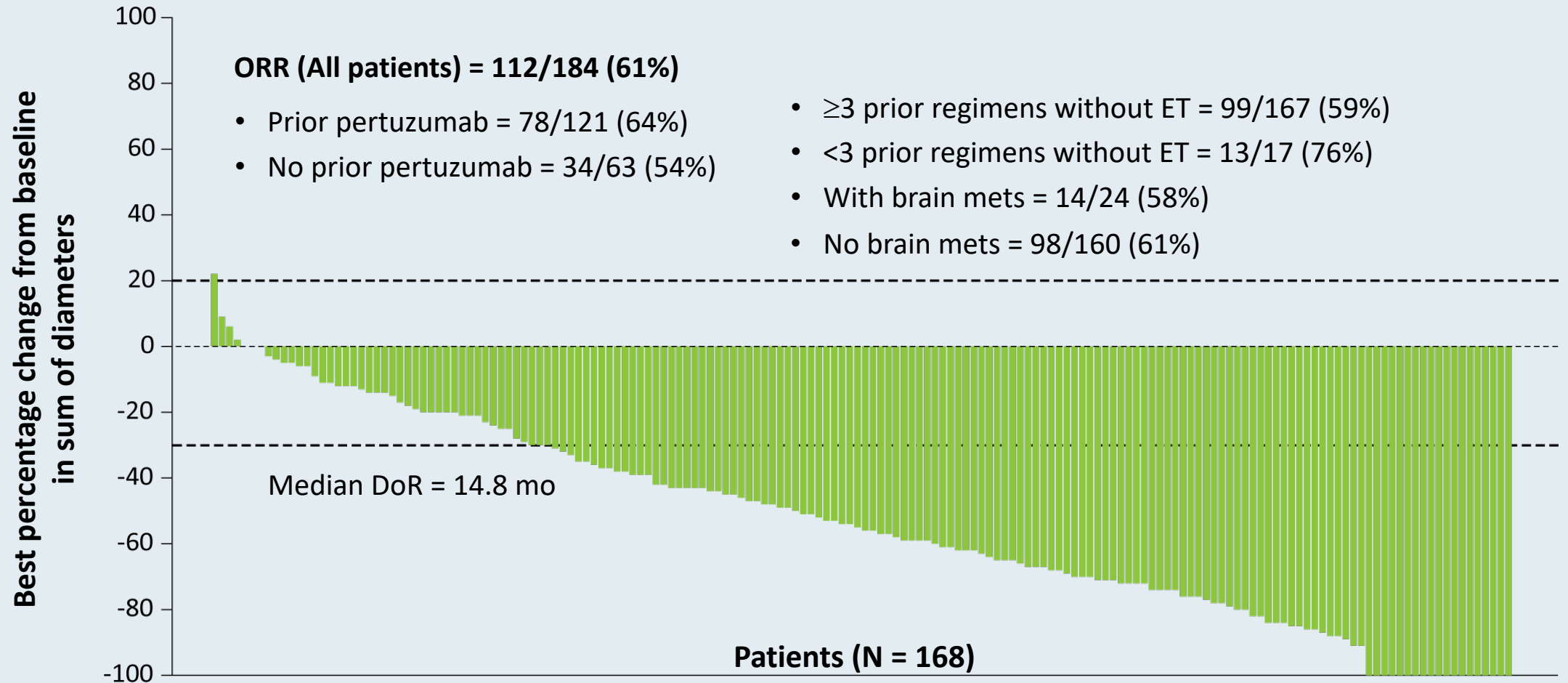
The recently approved trastuzumab deruxtecan is classified as which type of anti-HER2 agent?

1. Monoclonal antibody
2. Antibody-drug conjugate
3. Small molecule tyrosine kinase inhibitor
4. I don't know

Trastuzumab deruxtecan carries a black box warning for...

1. QT interval prolongation
2. Interstitial lung disease
3. Cardiovascular events
4. I don't know

DESTINY-Breast01: Response According to Tumor Size and Subgroup Analyses



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Cases from the Practices of Ms Fulgencio, Ms Hershey and Ms Leonard

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- **Case 1 (Ms Fulgencio): A 31-year-old woman with localized ER/PR-positive, HER2-negative breast cancer and 3 positive nodes**
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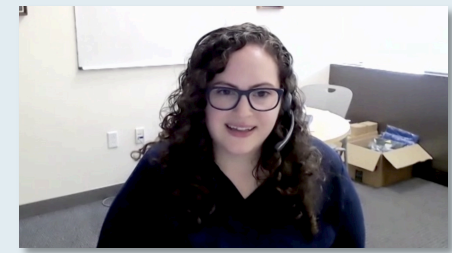
Module 2: HER2-Positive

- **Case 3 (Ms Leonard): A 33-year-old woman with localized ER/PR-positive, HER2-positive breast cancer and residual disease after neoadjuvant treatment**
- **Case 4 (Ms Fulgencio): A 70-year-old woman with metastatic HER2-positive breast cancer**
- **Case 5 (Ms Hershey): A 44-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer**
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Module 3: Triple-Negative

- **Case 7 (Ms Hershey): A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive**

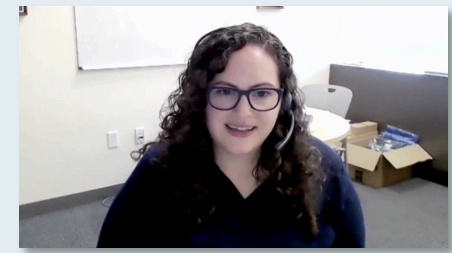
Case Presentation – A 44-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer (Part 1)



Ms Hershey

- Former research scientist with recurrence and multiple symptomatic brain metastases in 2014
- Treated with multiple lines of therapy and has experienced many complications, including substantial vision decline (legally blind)
- Currently treated with trastuzumab deruxtecan

Case Presentation – A 44-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer (Part 2)

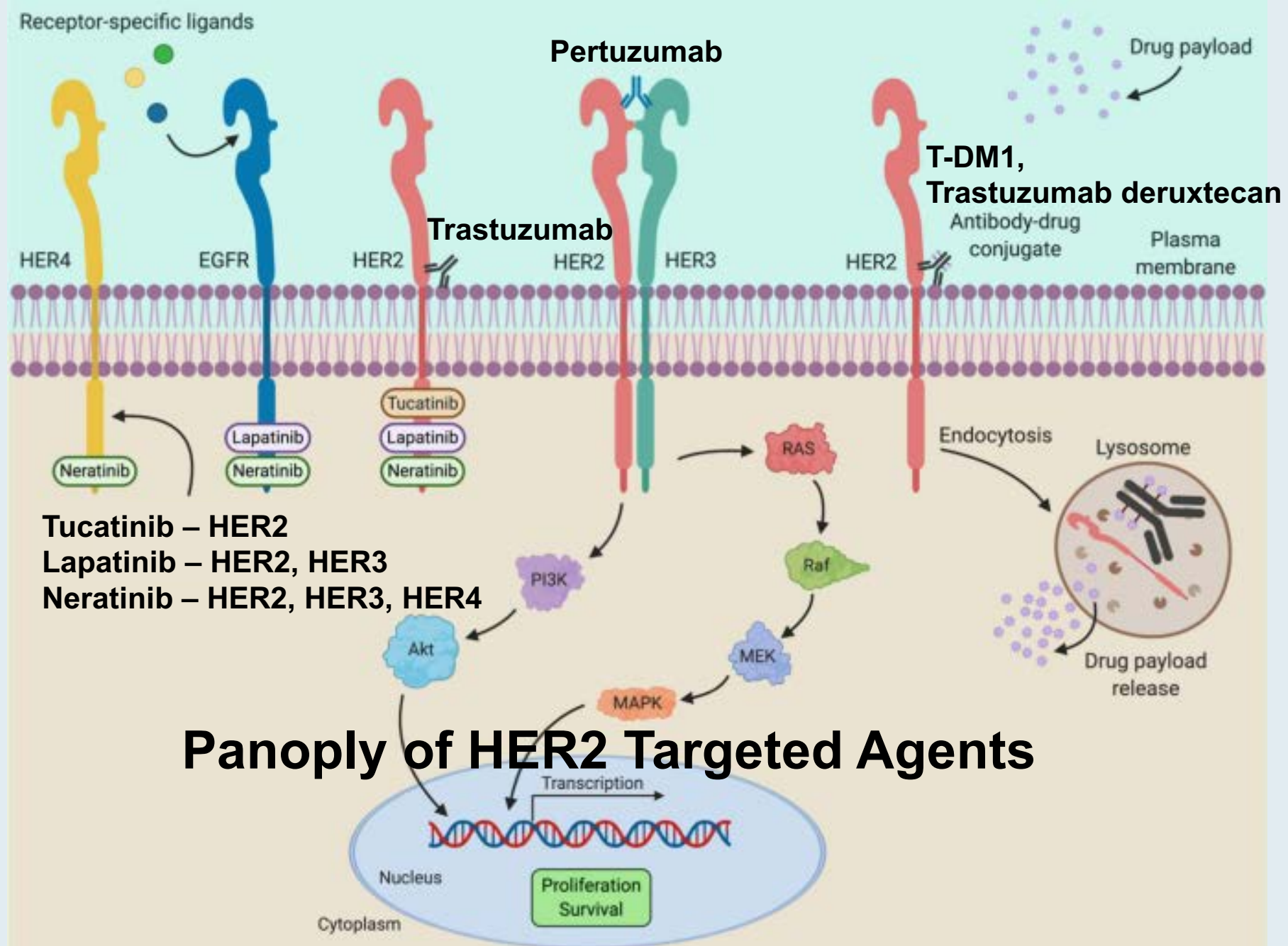


Ms Hershey

- Former research scientist with recurrence and multiple symptomatic brain metastases in 2014
- Treated with multiple lines of therapy and has experienced many complications, including substantial vision decline (legally blind)
- Currently treated with trastuzumab deruxtecan
 - ***Tolerating treatment well***

A Phase III trial evaluating the addition of tucatinib to trastuzumab/capecitabine for metastatic HER2-positive breast cancer resulted in an improvement in overall survival for all patients, including those with brain metastases.

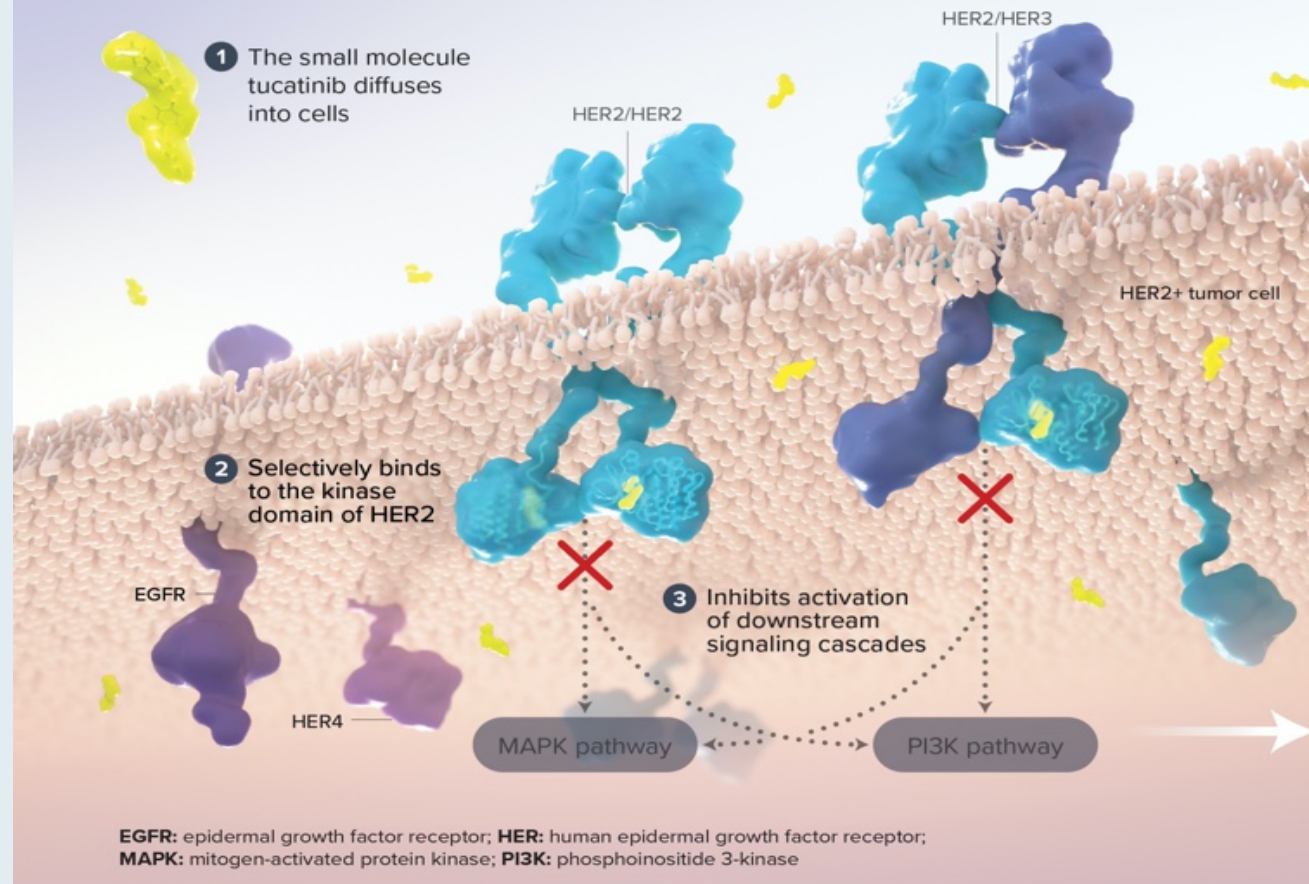
1. Agree
2. Disagree
3. I don't know



Tesch ME, Gelmon KA. Drugs 2020;80:1811-30.

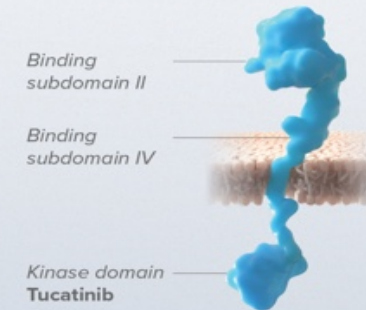
Tucatinib Mechanism of Action

Tucatinib: A tyrosine kinase inhibitor selective for HER2

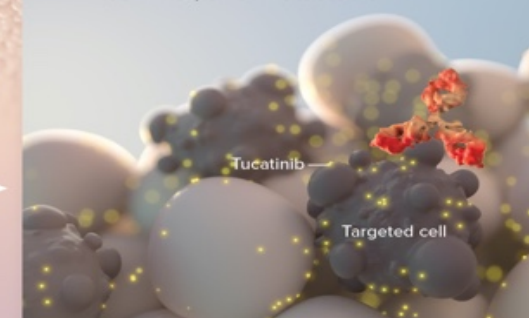


Dual inhibition of HER2

Tucatinib has been combined with other agents that target the extracellular domain of HER2 in clinical trials.



4 Decreased HER2 signaling reduces tumor cell proliferation, survival, and metastasis



The NEW ENGLAND JOURNAL *of* MEDICINE

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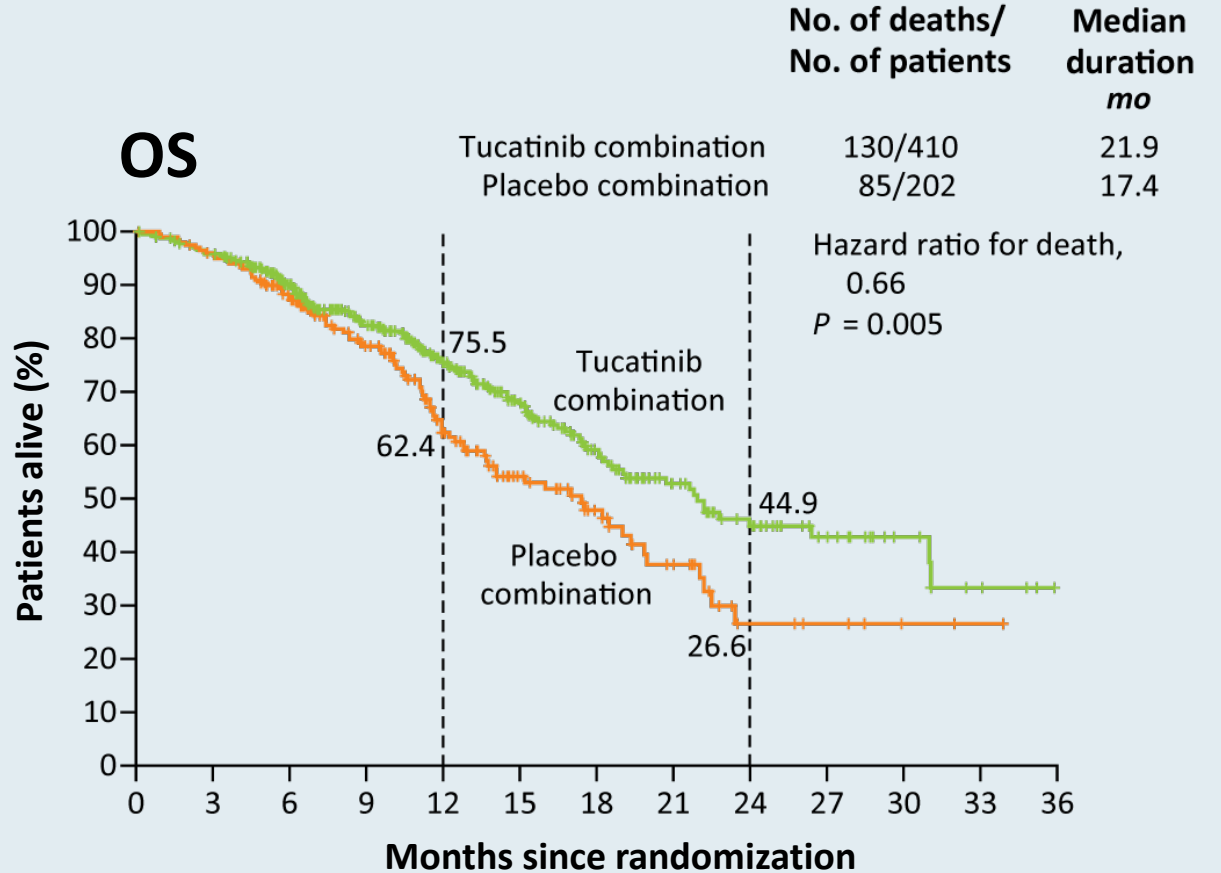
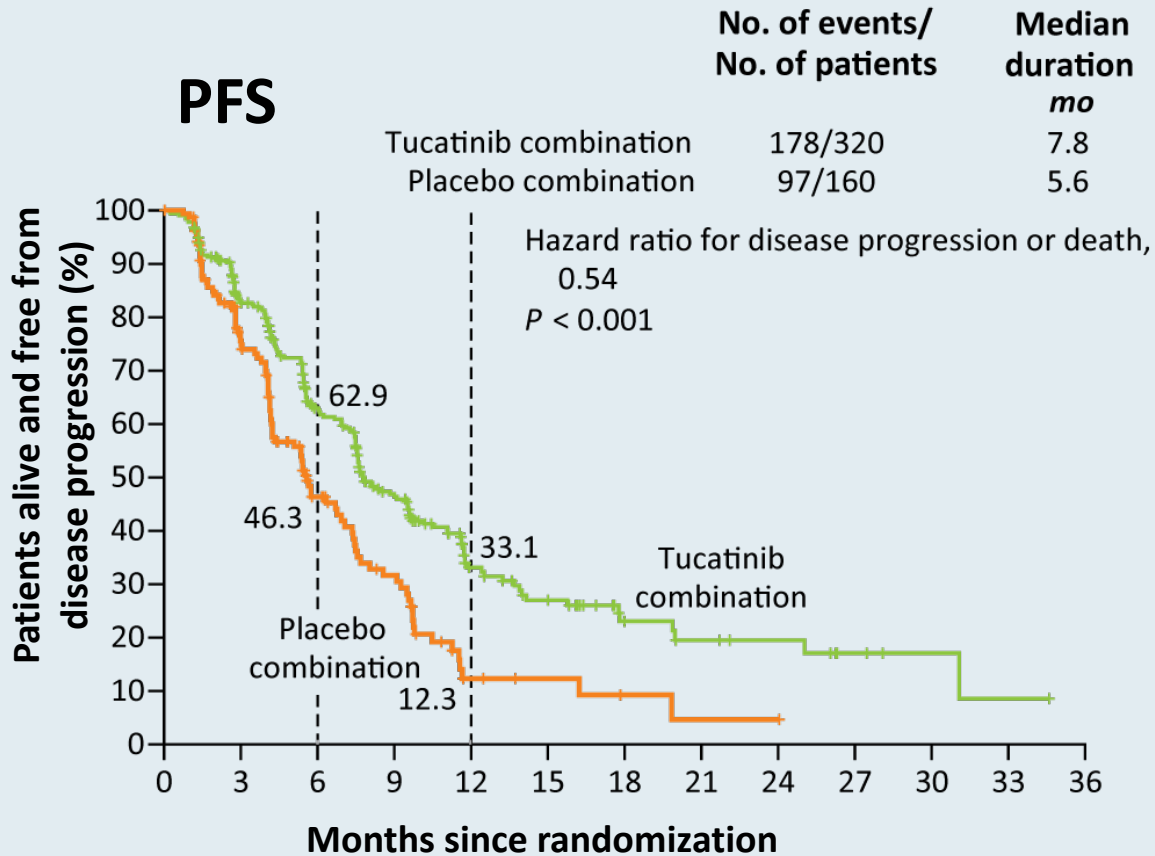
Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer

R.K. Murthy, S. Loi, A. Okines, E. Paplomata, E. Hamilton, S.A. Hurvitz, N.U. Lin, V. Borges, V. Abramson, C. Anders, P.L. Bedard, M. Oliveira, E. Jakobsen, T. Bachelot, S.S. Shachar, V. Müller, S. Braga, F.P. Duhoux, R. Greil, D. Cameron, L.A. Carey, G. Curigliano, K. Gelmon, G. Hortobagyi, I. Krop, S. Loibl, M. Pegram, D. Slamon, M.C. Palanca-Wessels, L. Walker, W. Feng, and E.P. Winer

HER2CLIMB: Survival Outcomes

Among the patients with brain metastases:

- Median PFS = 7.6 mo (tucatinib) vs 5.4 mo (placebo)
 - HR = 0.48; $p < 0.001$
- 1-year PFS = 24.9% (tucatinib) vs 0% (placebo)



Murthy R et al. San Antonio Breast Cancer Symposium 2019;Abstract GS1-01;
Murthy RK et al. *N Engl J Med* 2020;382(7):597-609.

HER2CLIMB: Safety Outcomes

Select AE	Tucatinib (n = 404)		Placebo (n = 197)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any	99.3%	55.2%	97.0%	48.7%
Diarrhea	80.9%	12.9%	53.3%	8.6%
PPE syndrome	63.4%	13.1%	52.8%	9.1%
Nausea	58.4%	3.7%	43.7%	3.0%
Fatigue	45.0%	4.7%	43.1%	4.1%
Vomiting	35.9%	3.0%	25.4%	3.6%
Stomatitis	25.5%	2.5%	14.2%	0.5%
Increased AST	21.3%	4.5%	11.2%	0.5%
Increased ALT	20.0%	5.4%	6.6%	0.5%

Research

JAMA Oncology | **Original Investigation**

Efficacy of Margetuximab vs Trastuzumab in Patients With Pretreated ERBB2-Positive Advanced Breast Cancer A Phase 3 Randomized Clinical Trial

Hope S. Rugo, MD; Seock-Ah Im, MD, PhD; Fatima Cardoso, MD; Javier Cortés, MD, PhD; Giuseppe Curigliano, MD, PhD; Antonino Musolino, MD, PhD, MSc; Mark D. Pegram, MD; Gail S. Wright, MD; Cristina Saura, MD, PhD; Santiago Escrivá-de-Romaní, MD; Michelino De Laurentiis, MD, PhD; Christelle Levy, MD; Ursa Brown-Glaberman, MD; Jean-Marc Ferrero, MD; Maaïke de Boer, MD, PhD; Sung-Bae Kim, MD, PhD; Katarína Petráková, MD, PhD; Denise A. Yardley, MD; Orit Freedman, MD, MSc; Erik H. Jakobsen, MD; Bella Kaufman, MD; Rinat Yerushalmi, MD; Peter A. Fasching, MD; Jeffrey L. Nordstrom, PhD; Ezio Bonvini, MD; Scott Koenig, MD, PhD; Sutton Edlich, MS, PA; Shengyan Hong, PhD; Edwin P. Rock, MD, PhD; William J. Gradishar, MD; for the SOPHIA Study Group

***JAMA Oncol* 2021;[Online ahead of print].**

Agenda

Cases from the Practices of Ms Fulgencio, Ms Hershey and Ms Leonard

Module 1: ER-Positive

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- **Case 7 (Ms Hershey):** A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive

Case Presentation – A 64-year-old woman with ER-positive, HER2-positive metastatic breast cancer and brain metastases (Part 1)



Ms Leonard

- Progression of metastatic disease on multiple HER2-targeted therapies, including:
 - Neratinib/capecitabine
 - Tucatinib
- Patient education on typical toxicities associated with capecitabine and tucatinib

Case Presentation – A 64-year-old woman with ER-positive, HER2-positive metastatic breast cancer and brain metastases (Part 2)



Ms Leonard

- Progression of metastatic disease on multiple HER2-targeted therapies, including:
 - Neratinib/capecitabine
 - Tucatinib
- Patient education on typical toxicities associated with capecitabine and tucatinib
- ***Impact of CNS involvement on patient's quality of life***

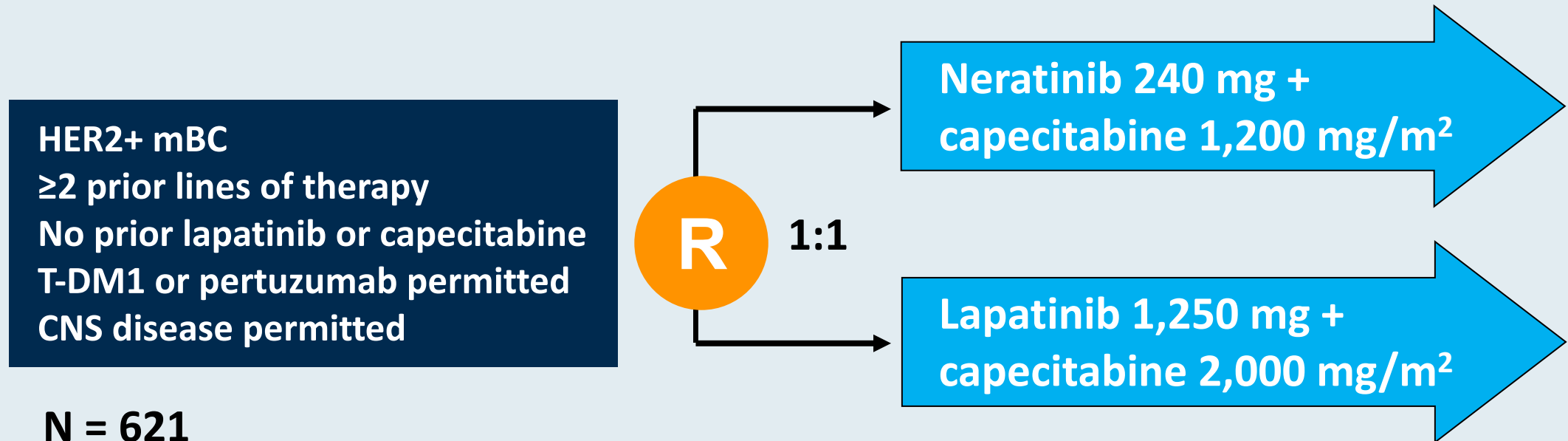
Ms Leonard: Challenges and Rewards of Being an Oncology Nurse



Brain Metastases Are Common in Advanced Cancers

Primary site	Incidence rate
Lung cancer – overall	16%-20%
SCLC	~30%
NSCLC	~13%
Breast cancer – overall	10%-15%
HER2-positive	25%-50%
Triple-negative	20%

NALA: Phase III Trial Design



Coprimary endpoints: PFS (central) and OS

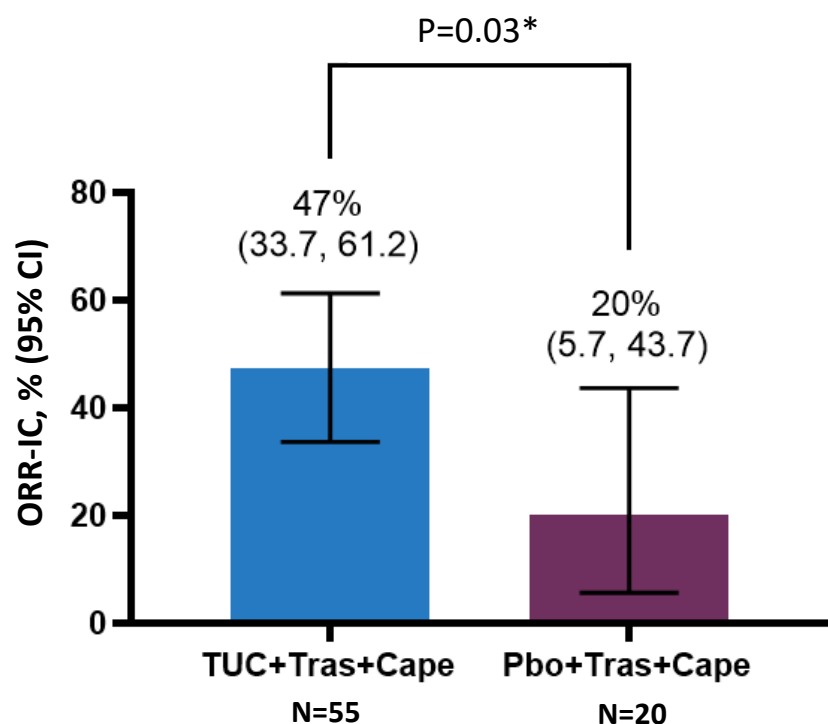
Intracranial Efficacy and Survival With Tucatinib Plus Trastuzumab and Capecitabine for Previously Treated HER2-Positive Breast Cancer With Brain Metastases in the HER2CLIMB Trial

Nancy U. Lin, MD¹; Virginia Borges, MMSc, MD²; Carey Anders, MD³; Rashmi K. Murthy, MD, MBE⁴; Elisavet Paplomata, MD⁵; Erika Hamilton, MD⁶; Sara Hurvitz, MD⁷; Sherene Loi, MD, PhD⁸; Alicia Okines, MBChB, MD⁹; Vandana Abramson, MD¹⁰; Philippe L. Bedard, MD¹¹; Mafalda Oliveira, MD, PhD¹²; Volkmar Mueller, MD¹³; Amelia Zelnak, MD¹⁴; Michael P. DiGiovanna, MD, PhD¹⁵; Thomas Bachelot, MD¹⁶; A. Jo Chien, MD¹⁷; Ruth O'Regan, MD⁵; Andrew Wardley, MBChB, MSc, MD¹⁸; Alison Conlin, MD, MPH¹⁹; David Cameron, MD, MA²⁰; Lisa Carey, MD²¹; Giuseppe Curigliano, MD, PhD²²; Karen Gelmon, MD²³; Sibylle Loibl, MD, PhD²⁴; JoAl Mayor, PharmD²⁵; Suzanne McGoldrick, MD, MPH²⁵; Xuebei An, PhD²⁵; and Eric P. Winer, MD¹

J Clin Oncol 2020;38(23):2610-9.

HER2CLIMB: Intracranial Response Rate (ORR-IC) in Patients with Active Brain Metastases and Measurable Intracranial Lesions at Baseline

Confirmed Objective Response Rate (RECIST 1.1)



*Stratified Cochran-Mantel-Haenszel P value

Courtesy of Carey K Anders, MD

Best Overall Intracranial Response ^a , n (%)		
Complete Response (CR)	3 (5.5)	1 (5.0)
Partial Response (PR)	23 (41.8)	3 (15.0)
Stable Disease (SD)	24 (43.6)	16 (80.0)
Progressive Disease (PD)	2 (3.6)	0
Not Available ^b	3 (5.5)	0
Subjects with Objective Response of Confirmed CR or PR, n	26	4
Duration of Intracranial Response (DOR-IC) ^e (95% CI) ^f , months	6.8 (5.5, 16.4)	3.0 (3.0, 10.3)

(a) Confirmed Best overall response assessed per RECIST 1.1. (b) Subjects with no post-baseline response assessments. (c) Two-sided 95% exact confidence interval, computed using the Clopper-Pearson method (1934). (d) Cochran-Mantel-Haenszel test controlling for stratification factors (ECOG performance status: 0/1, and Region of world: North America/Rest of World) at randomization. (e) As estimated using Kaplan-Meier methods. (f) Calculated using the complementary log-log transformation method (Collett, 1994).

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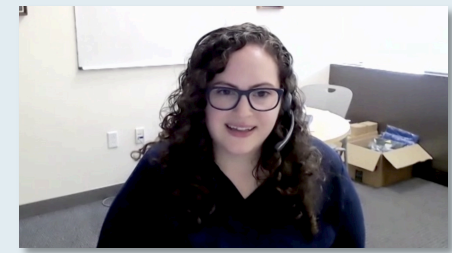
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Case Presentation – A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive (Part 1)



Ms Hershey

- Former school teacher with progression after first-line atezolizumab/*nab* paclitaxel
- Currently treated with sacituzumab govitecan
- Coping with anxieties and uncertainties of having metastatic disease

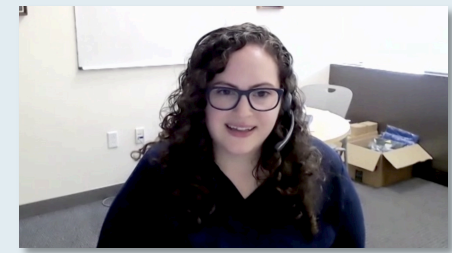
October 2020 – Widespread Erythema



January 2021 – Disease Progression



Case Presentation – A 52-year-old woman with metastatic BRCA wild-type TNBC, PD-L1-positive (Part 2)



Ms Hershey

- Former school teacher with progression after first-line atezolizumab/*nab* paclitaxel
- Currently treated with sacituzumab govitecan
- Coping with anxieties and uncertainties of having metastatic disease
 - ***Initially hesitant to take prescription pain medicine***

Ms Hershey: Reflections on Being an Oncology Nurse



Ms Fulgencio: Personal Experiences with Caregiving for a Loved One with Breast Cancer



The anti-PD-L1 antibody atezolizumab is currently FDA approved in combination with *nab* paclitaxel as first-line treatment for...

1. All patients with metastatic breast cancer
2. Metastatic triple-negative breast cancer
3. Metastatic PD-L1-positive triple-negative breast cancer
4. I don't know

A germline mutation is found in every cell in the body and a somatic mutation is found in the tumor.

1. Agree
2. Disagree
3. I don't know

The PARP inhibitors olaparib and talazoparib are FDA approved for patients with metastatic breast cancer and a germline BRCA mutation...

1. As maintenance therapy after platinum chemotherapy
2. As monotherapy
3. Both a and b
4. I don't know

Sacituzumab Govitecan (SG) Is a First-in-Class Trop-2–Directed ADC

- SG is distinct from other ADCs¹⁻⁴
 - Antibody highly specific for Trop-2
 - High drug-to-antibody ratio (7.6:1)
 - Internalization and enzymatic cleavage by tumor cell not required for SN-38 liberation from antibody
 - Hydrolysis of the linker also releases SN-38 extracellularly in the tumor microenvironment (bystander effect)
- Granted FDA accelerated approval for mTNBC⁵
- Landmark ASCENT study demonstrated a significant survival improvement of SG over chemotherapy, with a tolerable safety profile in pretreated mTNBC⁶
 - Median PFS of 5.6 vs 1.7 months (HR 0.41, $P < 0.0001$)
 - Median OS of 12.1 vs 6.7 months (HR 0.48, $P < 0.0001$)

Linker for SN-38

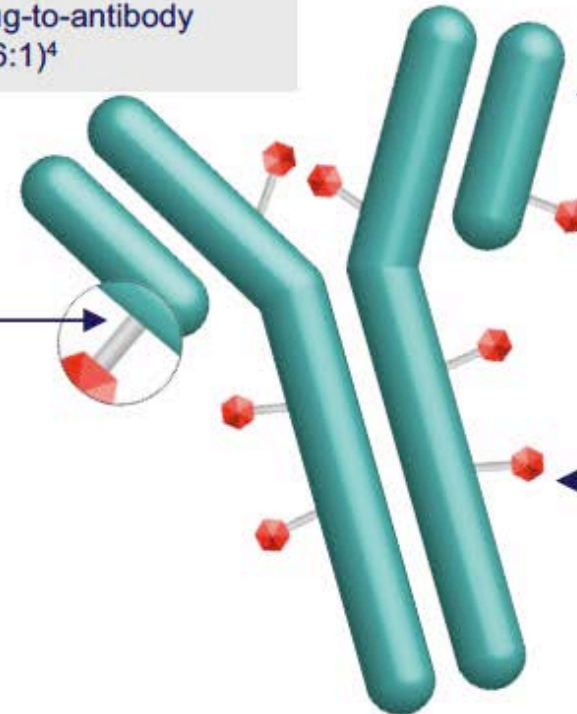
- Hydrolyzable linker for payload release
- High drug-to-antibody ratio (7.6:1)⁴

Humanized anti-Trop-2 antibody

- Directed toward Trop-2, an epithelial antigen expressed on many solid cancers

SN-38 payload

- SN-38 more potent than parent compound, irinotecan

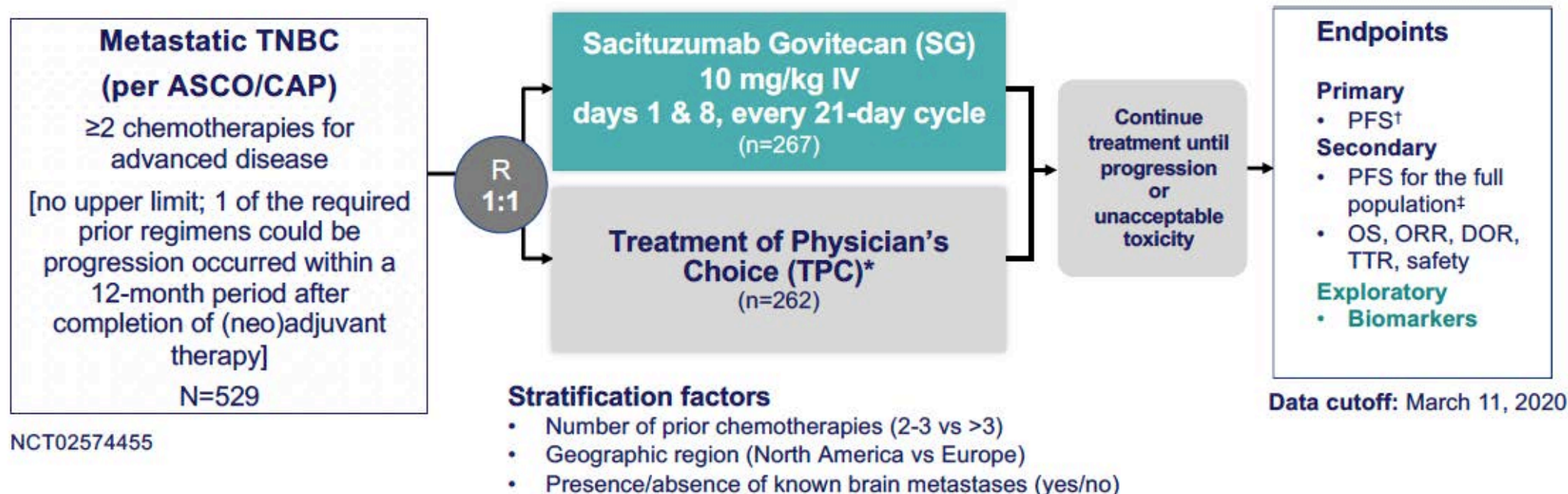


ADC, antibody-drug conjugate; FDA, US Food and Drug Administration; OS, overall survival; PFS, progression-free survival; TNBC, triple-negative breast cancer; Trop-2, trophoblast cell surface antigen 2.

1. Goldenberg DM, et al. *Expert Opin Biol Ther*. 2020;20:871-885. 2. Nagayama A, et al. *Ther Adv Med Oncol*. 2020;12:1758835920915980. 3. Cardillo TM, et al. *Bioconjugate Chem*. 2015;26:919-931. 4. Goldenberg DM, et al. *Oncotarget*. 2015;6:22496-224512. 5. Press Release. <https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-sacituzumab-govitecan-hzly-metastatic-triple-negative-breast-cancer>. Accessed August 26, 2020. 6. Bardia A, et al. ESMO 2020. Abstract LBA17.

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ASCENT: A Phase 3 Confirmatory Study of Sacituzumab Govitecan in Refractory/Relapsed mTNBC

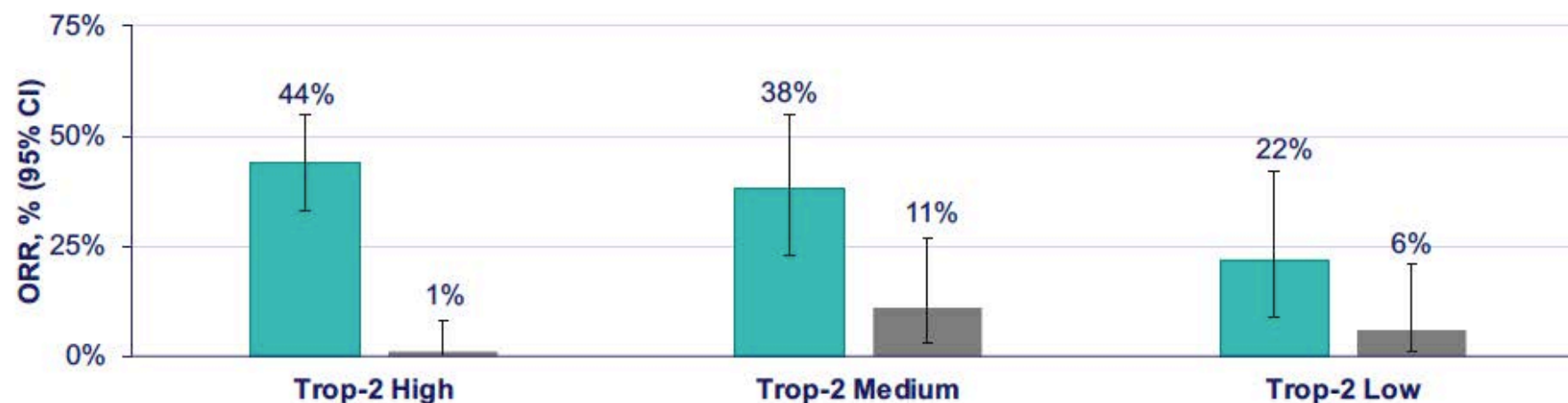


We report the exploratory biomarker analysis in the brain metastases-negative (Brain Mets-Negative) population

*TPC: eribulin, vinorelbine, gemcitabine, or capecitabine. [†]PFS measured by an independent, centralized, and blinded group of radiology experts who assessed tumor response using RECIST 1.1 criteria in patients without brain metastasis. [‡]The full population includes all randomized patients (with and without brain metastases). Baseline brain MRI only required for patients with known brain metastasis. ASCO/CAP, American Society of Clinical Oncology/College of American Pathologists; DOR, duration of response; DSMC, Data Safety Monitoring Committee; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; TTR, time to response. National Institutes of Health. <https://clinicaltrials.gov/ct2/show/NCT02574455>.

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ORR by Trop-2 Expression



	Trop-2 High H-score: 200-300 (n=157)		Trop-2 Medium H-score: 100-200 (n=74)		Trop-2 Low H-score: <100 (n=59)	
	SG (n=85)	TPC (n=72)	SG (n=39)	TPC (n=35)	SG (n=27)	TPC (n=32)
ORR—% (no.)	44% (37)	1% (1)	38% (15)	11% (4)	22% (6)	6% (2)
95% CI	33-55	0-8	23-55	3-27	9-42	1-21

Assessed in the brain metastases-negative population. ORR and PFS are assessed by BICR. Trop-2 expression determined in archival samples by validated immunohistochemistry assay and H-scoring. BICR, blind independent central review; H-score, histochemical-score; ORR, objective response rate; SG, sacituzumab govitecan; TPC, treatment of physician's choice; Trop-2, trophoblast cell surface antigen-2.

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Phase III Trials of PARP Inhibitors in gBRCA HER2-Negative Metastatic Breast Cancer

OlympiAD¹

gBRCAm HER2- mBC

≤2 prior chemotherapy lines for mBC

Previous treatment with anthracycline and taxane in either the (neo)adjuvant or metastatic setting

Randomise 2:1

Olaparib
300mg *po* bid

**Treatment of
Physician's
Choice (TPC)**

Primary endpoint
PFS (BICR)

EMBRACA²

gBRCAm HER2- LABC or ABC

≤3 prior lines of chemotherapy

Previous treatment with a taxane, an anthracycline, or both, unless this treatment was contraindicated

Randomise 2:1

Talazoparib
1mg *po* qd

**Treatment of
Physician's
Choice (TPC)**

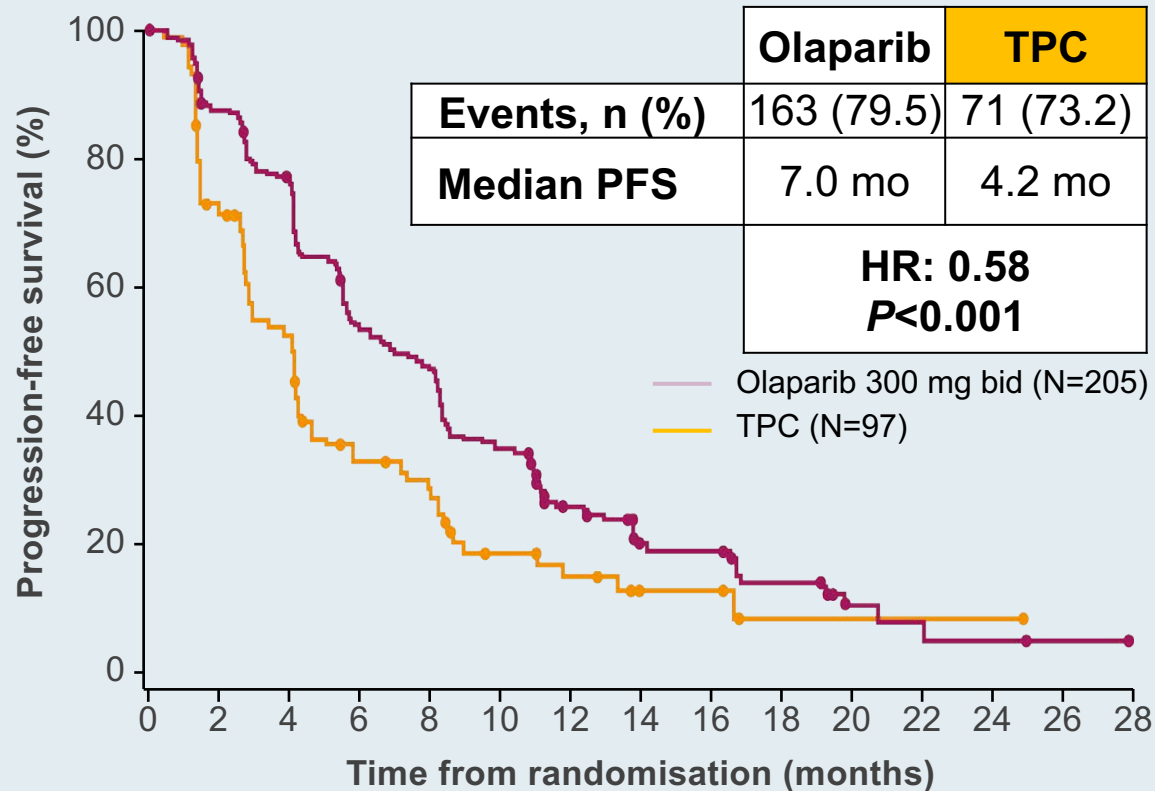
Primary endpoint
PFS (BICR)

1. Robson et al. *N Engl J Med* 2017; 377:523-33;

2. Litton J et al. *N Engl J Med* 2018; 379:753-63.

Phase III Trials of PARP Inhibitors in gBRCA HER2-Negative Metastatic Breast Cancer

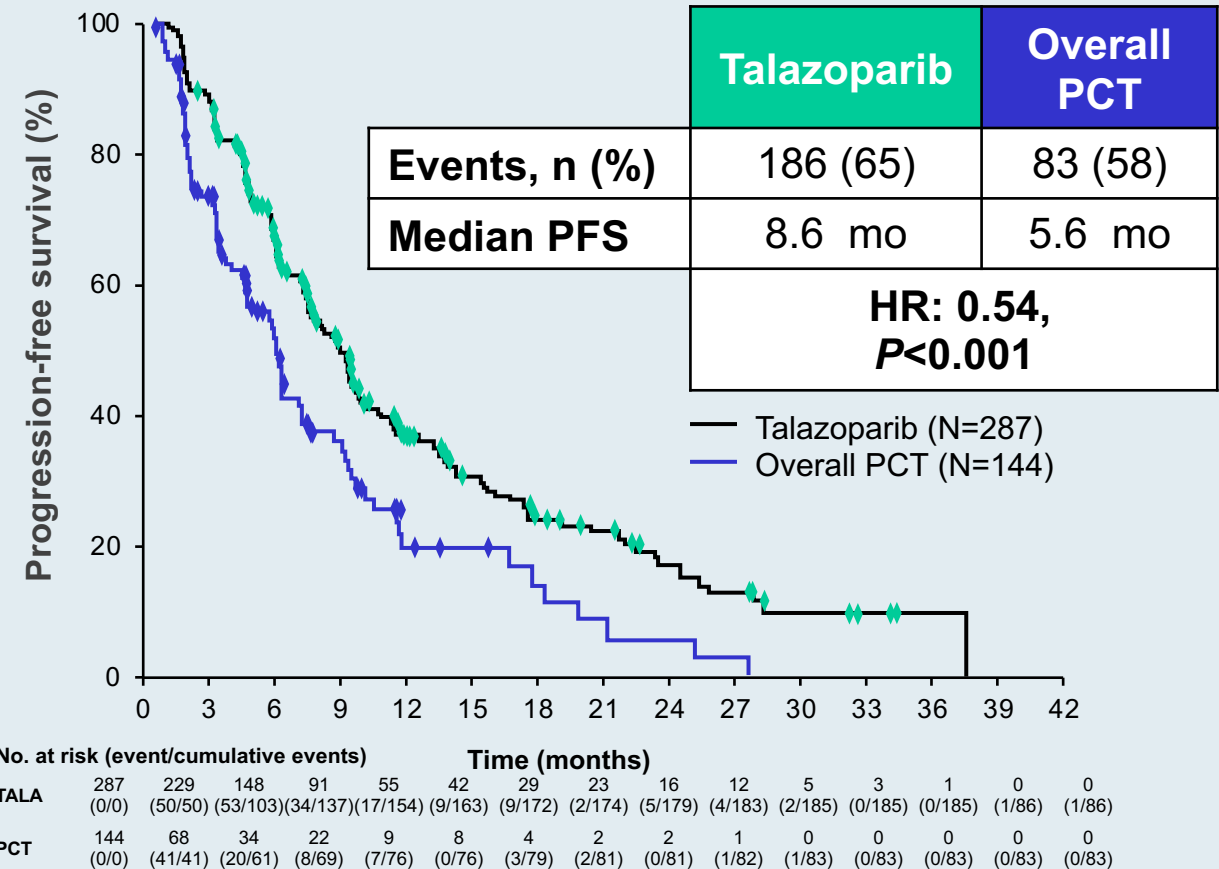
OlympiAD: Olaparib PFS^{1,2}



Number at risk

Olaparib	205	201	177	159	154	129	107	100	94	73	69	61	40	36	23	21	21	11	11	11	4	3	3	2	2	1	1	1	0
TPC	97	88	83	46	44	29	25	24	21	13	11	11	8	7	4	4	4	1	1	1	1	1	1	1	1	1	0	0	0

EMBRACA: Talazoparib PFS³



1. Robson M, et al. *N Engl J Med* 2017;377:523-33; 2. Olaparib 150mg Film-Coated Tablets, SmPC. 2019;
3. Litton JK, et al. *N Engl J Med* 2018;379:753-63 (supplementary appendix)

Phase III OlympiA Trial of Adjuvant Olaparib for High-Risk HER2-Negative Localized Breast Cancer with a BRCA Mutation Crossed the Superiority Boundary for Invasive Disease-Free Survival

Press Release – February 17, 2021

“The OlympiA Phase III trial of [olaparib] will move to early primary analysis and reporting following a recommendation from the Independent Data Monitoring Committee (IDMC).

Based on the planned interim analysis, the IDMC concluded that the trial crossed the superiority boundary for its primary endpoint of invasive disease-free survival (iDFS) and demonstrated a sustainable, clinically relevant treatment effect for olaparib versus placebo for patients with germline BRCA-mutated (gBRCAm) high-risk human epidermal growth factor receptor 2 (HER2)-negative early breast cancer, and recommend primary analysis now take place.

In its communication, the IDMC did not raise any new safety concerns. The trial will continue to assess the key secondary endpoints of overall survival and distant disease-free survival.”

13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Non-Small Cell Lung Cancer

Tuesday, April 20, 2021

5:00 PM – 6:30 PM ET

Medical Oncologists

John V Heymach, MD, PhD

Paul K Paik, MD

Zofia Piotrowska, MD, MHS

Oncology Nurse Practitioners

Kelly EH Goodwin, MSN, RN, ANP-BC

Tara Plues, APRN, MSN

Victoria Sherry, DNP, CRNP, AOCNP

Moderator

Neil Love, MD

Thank you for joining us!

NCPD credit information will be emailed to each participant within 3 business days.