Fall Oncology Nursing Series

A Complimentary NCPD-Accredited Virtual Curriculum

Breast Cancer

Tuesday, August 31, 2021
5:00 PM – 6:00 PM ET

Faculty

Carey K Anders, MD
Jamie Carroll, APRN, MSN, CNP

Moderator

Neil Love, MD

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Faculty

Carey K Anders, MD
Professor of Medicine
Medical Director of the Duke Center of Brain and Spine Metastases
Duke Cancer Institute
Durham, North Carolina

Jamie Carroll, APRN, MSN, CNP
Mayo Clinic
Rochester, Minnesota

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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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, 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, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, 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, TG Therapeutics Inc, Turning Point Therapeutics Inc and Verastem Inc.

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Research To Practice CME Planning Committee Members, Staff and Reviewers

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

Dr 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

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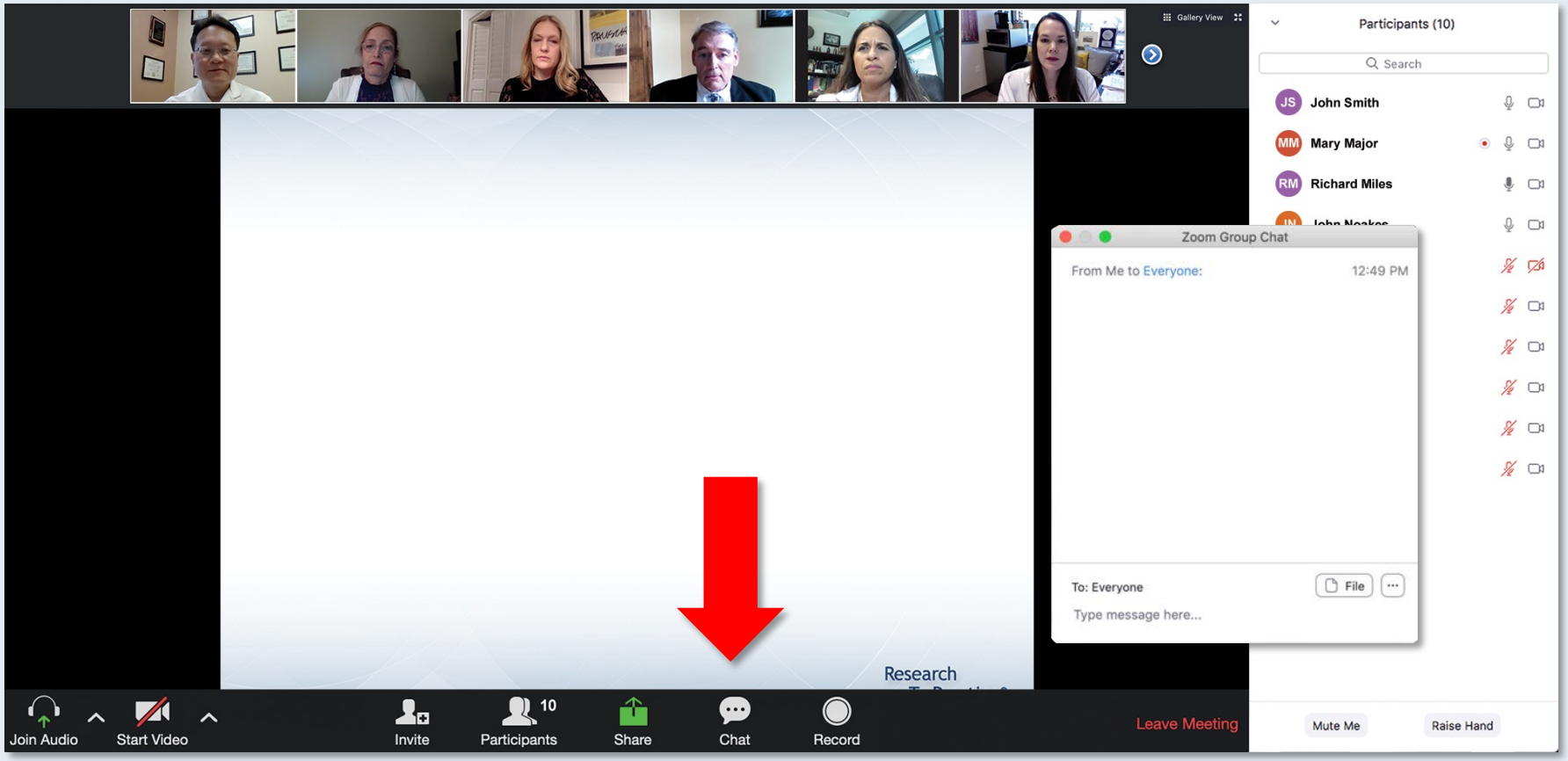
Ms Carroll — Disclosures

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.

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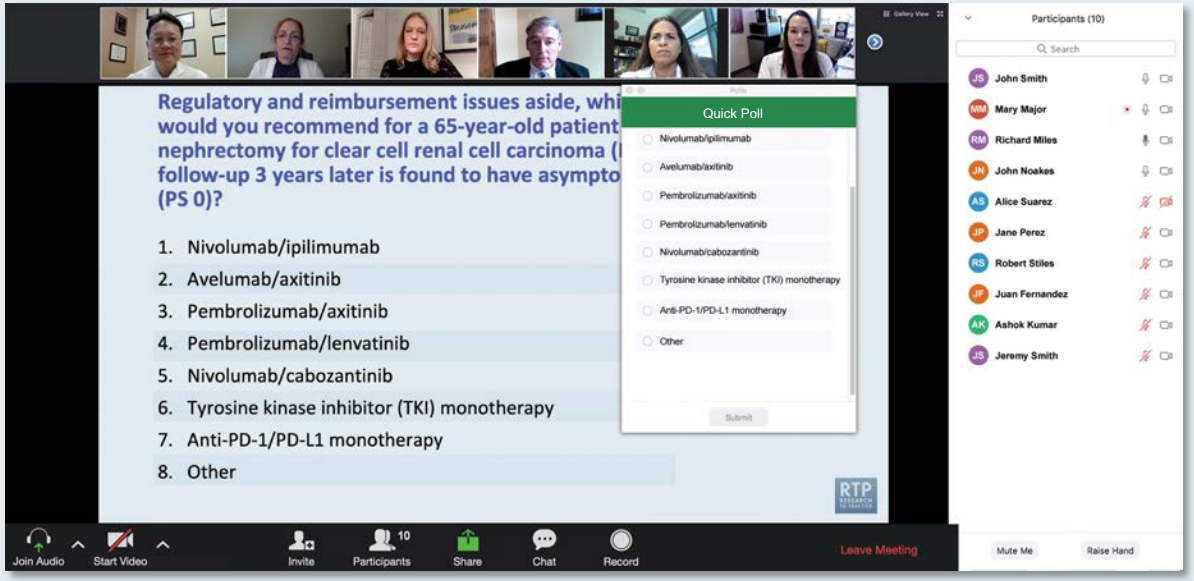
Familiarizing Yourself with the Zoom Interface

How to answer survey or poll questions



Clinicians in the audience, please click your answer choice for the premeeting survey as well as the live polling questions.

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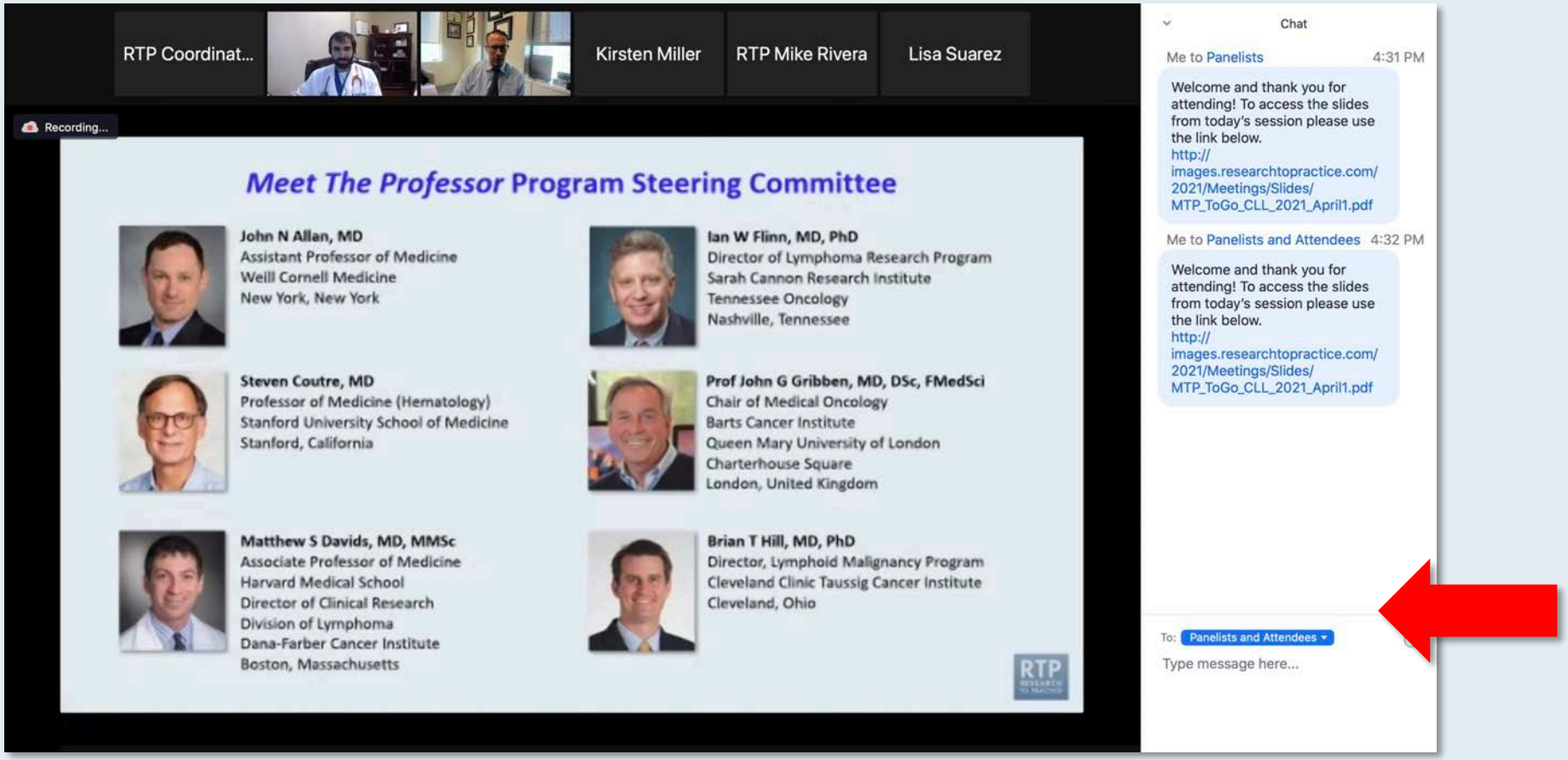
Expand chat submission box



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

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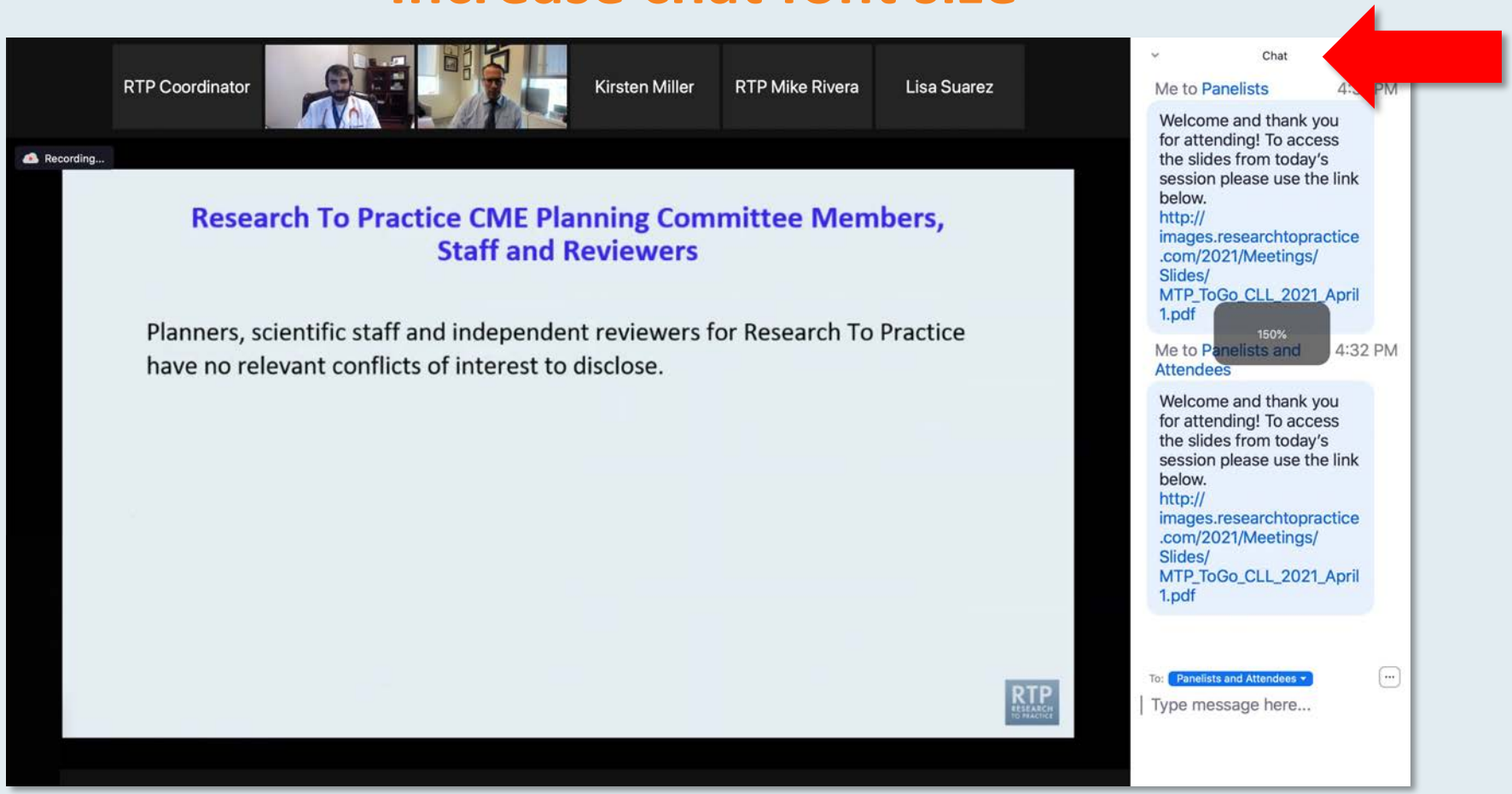
Increase chat font size



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

ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Breast Cancer from the 2021 ASCO Annual Meeting

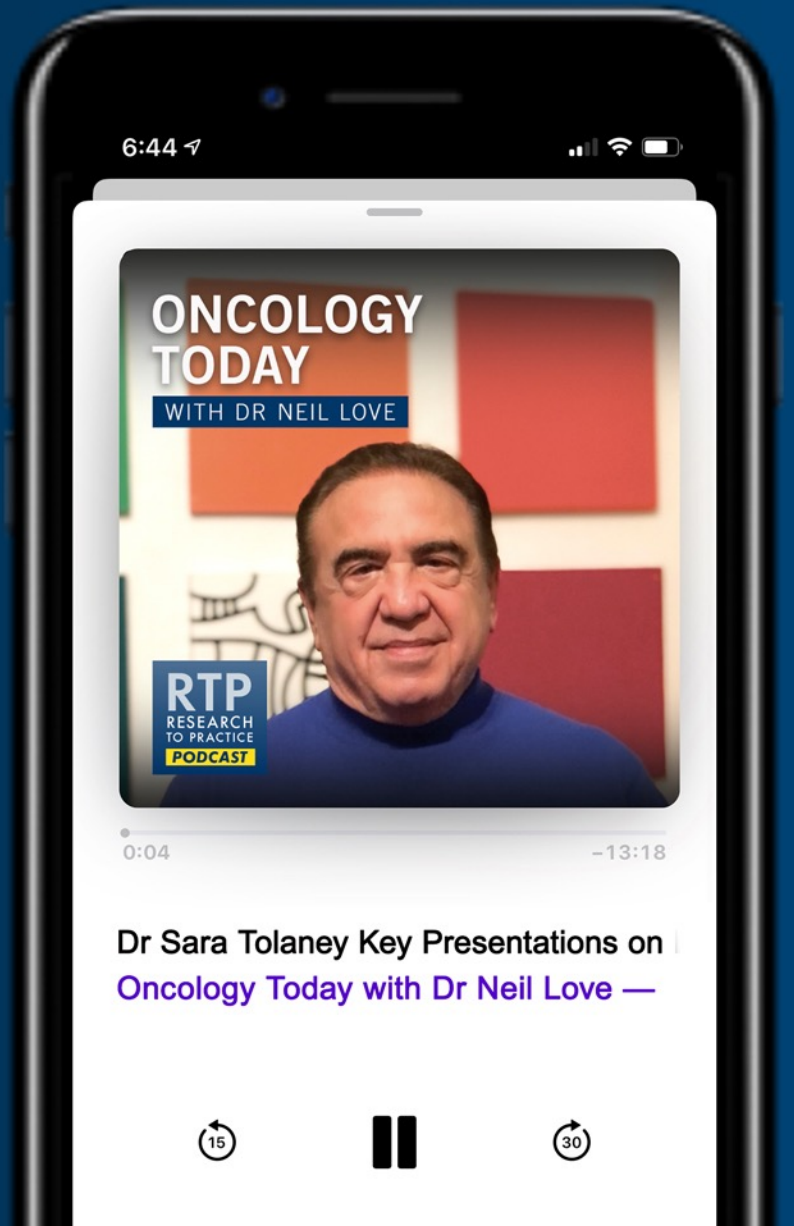
DR SARA TOLANEY

DANA-FARBER CANCER INSTITUTE

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts



Data + Perspectives: Clinical Investigators Discuss the Current and Future Management of Non-Hodgkin Lymphoma

A Virtual CME Satellite Symposium Series in Conjunction with the Society of Hematologic Oncology 2021 Annual Meeting

Tuesday, August 31, 2021
7:00 PM – 8:00 PM ET

Faculty

Andrew M Evens, DO, MSc
Ian W Flinn, MD, PhD
Gilles Salles, MD, PhD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Meet The Professor

Immunotherapy and Novel Agents in Gynecologic Cancers

Wednesday, September 1, 2021
5:00 PM – 6:00 PM ET

Faculty

Joyce F Liu, MD, MPH

Moderator

Neil Love, MD

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Fall Oncology Nursing Series

A Complimentary NCPD-Accredited Virtual Curriculum

Prostate Cancer

Thursday, September 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Mary-Ellen Taplin, MD
Kathy D Burns, RN, MSN, AGACNP-BC, OCN

Moderator

Neil Love, MD

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TO PRACTICE

Data + Perspectives: Clinical Investigators Discuss the Current and Future Management of Acute Myeloid Leukemia and Myelodysplastic Syndromes

A Virtual CME Satellite Symposium During the Society of Hematologic Oncology 2021 Annual Meeting

Wednesday, September 8, 2021
7:30 PM – 9:00 PM Central Time

Faculty

Courtney D DiNardo, MD, MSCE
Daniel A Pollyea, MD, MS
David Sallman, MD
Eunice S Wang, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Exploring Key Issues Affecting the Care of Patients with Metastatic Colorectal Cancer with BRAF Mutations

A CME/MOC-Accredited Virtual Event

Thursday, September 9, 2021
5:00 PM – 6:00 PM ET

Faculty
Scott Kopetz, MD, PhD

Consulting Clinical Investigator
Wells A Messersmith, MD

Moderator
Neil Love, MD

RTP RESEARCH TO PRACTICE

Expert Second Opinion: Investigators Discuss Available Clinical Research in the Care of Patients with Early-Stage Non-Small Cell Lung Cancer

A Live Webinar Held as a Satellite CME/MOC Symposium During the IASLC 2021 World Conference on Lung Cancer Worldwide Virtual Event

Sunday, September 12, 2021
9:15 PM – 10:15 PM MDT / 11:15 PM – 12:15 AM ET

Faculty

Edward B Garon, MD, MS
Harvey I Pass, MD
Heather Wakelee, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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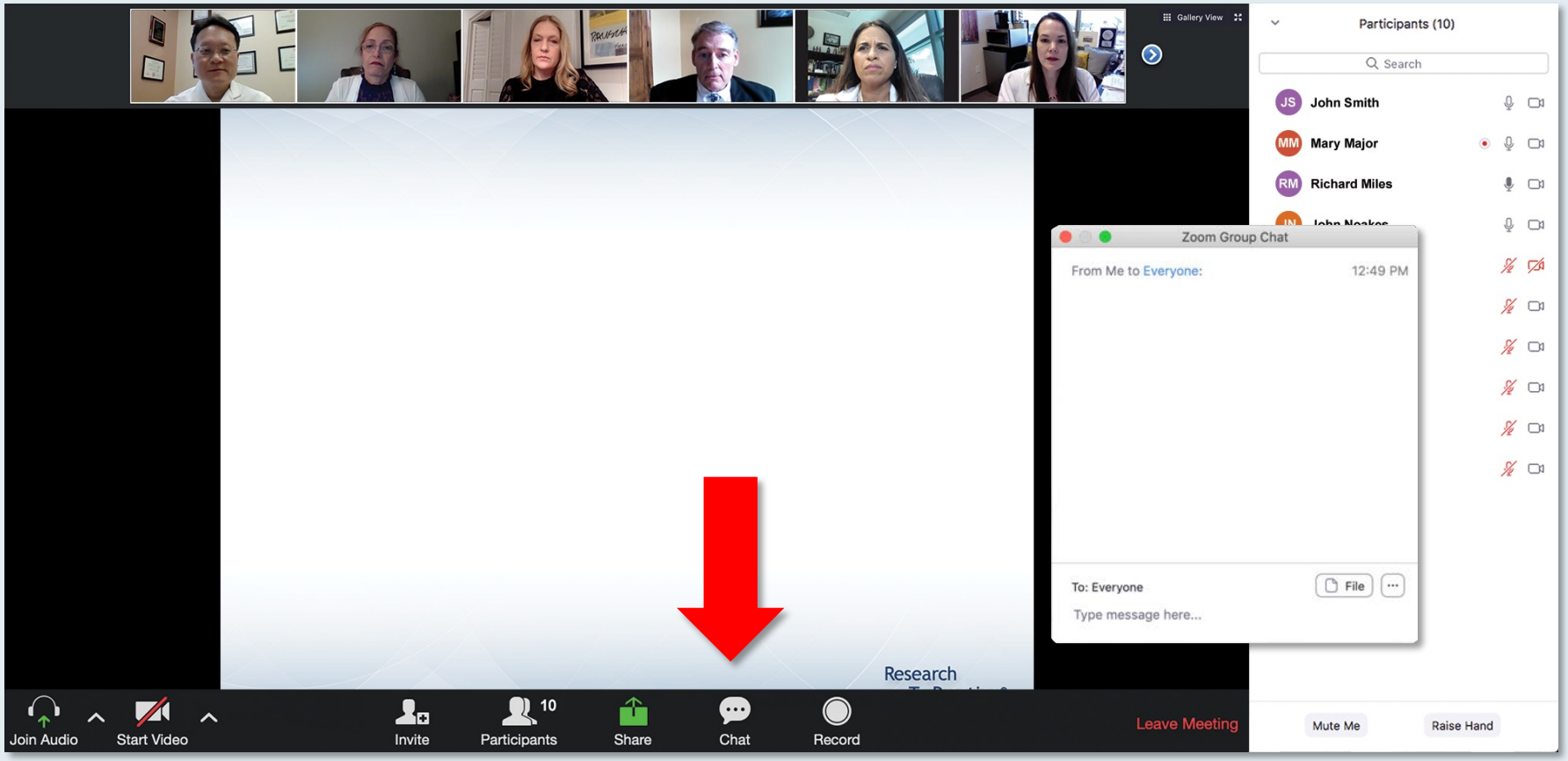

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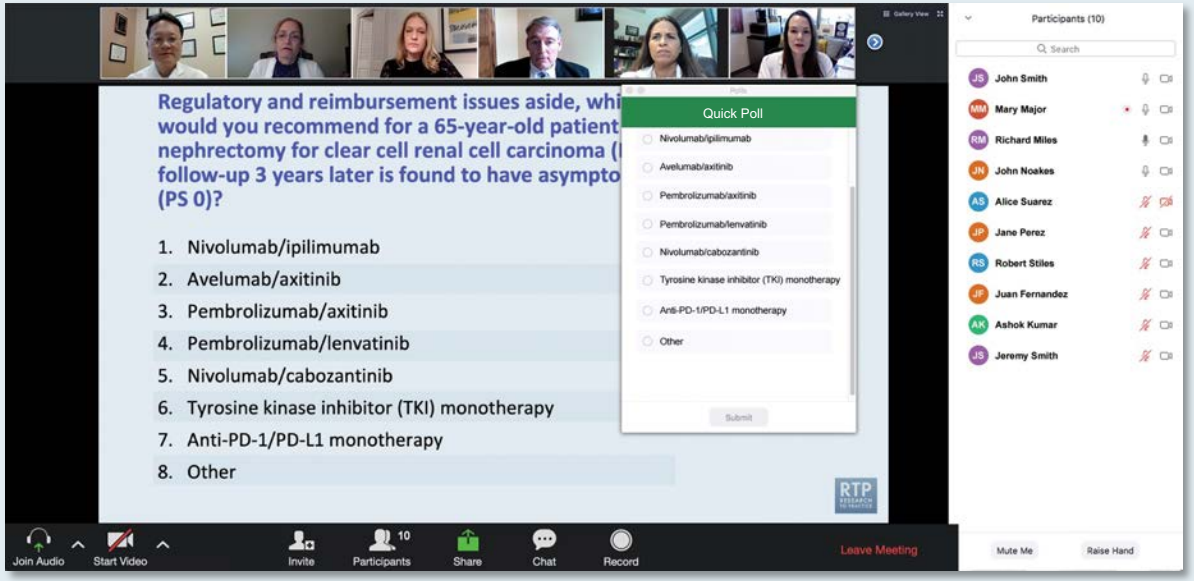

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Oncology Grand Rounds Nursing Webinar Series

April 2021

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

RTP 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

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Kelly Leonard, MSN, FNP-BC

Gretchen Santos Fulgencio, MSN, FNP-BC

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

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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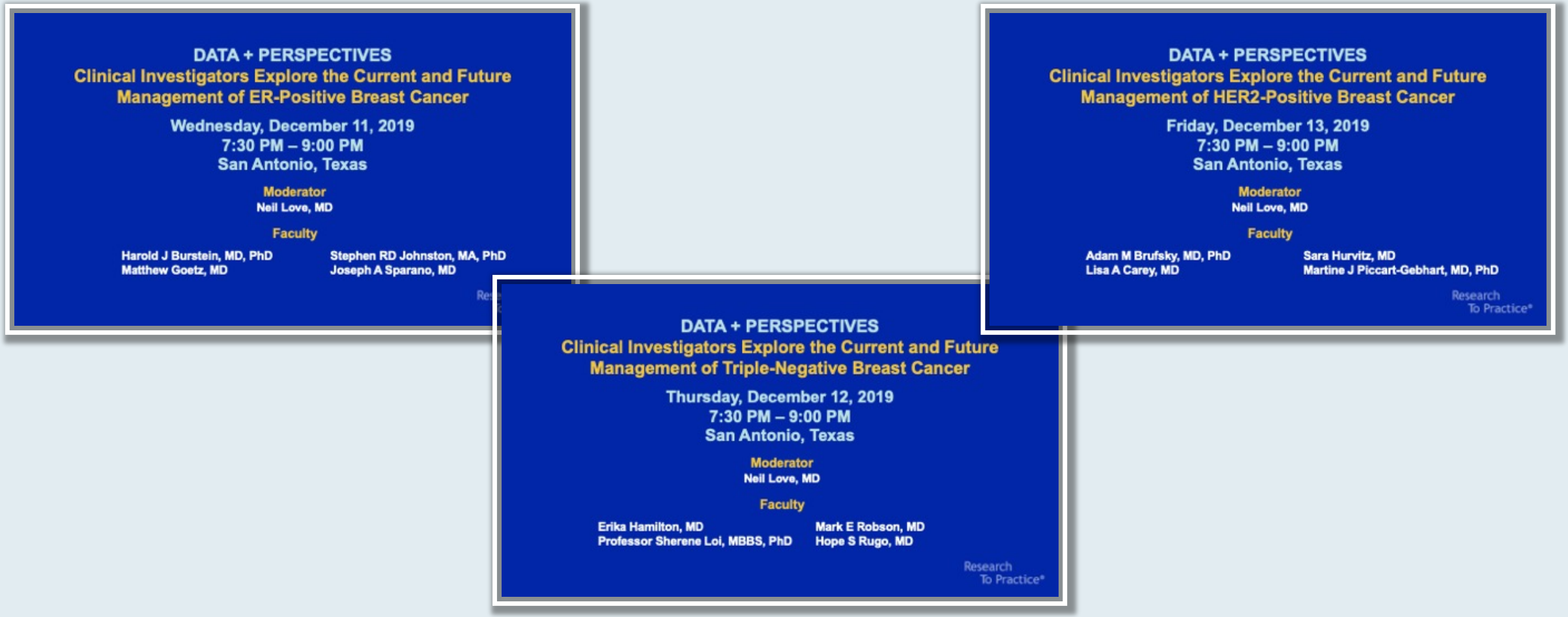
Research To Practice's 2019 San Antonio Breast Cancer Symposia



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Agenda

Prologue: The Summer of 2021 – Immunotherapy and PARP inhibitors enter the adjuvant/neoadjuvant settings

Case Scenario 1: A woman with ER-positive, HER2-positive breast cancer and brain metastases

Case Presentation – Ms Carroll: A 61-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer

Case Scenario 2: A woman with ER-positive, HER2-negative breast cancer and bone metastases

Case Presentation – Ms Carroll: A 38-year-old woman with high-risk ER/PR-positive, HER2-negative, node-positive localized breast cancer

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FDA Approval for High-Risk Early-Stage TNBC of Pembrolizumab Combined with Chemotherapy as Neoadjuvant Treatment, Then Continued as Single-Agent Adjuvant Treatment After Surgery

Press Release – July 27, 2021

The US Food and Drug Administration has approved pembrolizumab for the treatment of high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment and then continued as single-agent adjuvant treatment after surgery, based on the Phase III KEYNOTE-522 trial. KEYNOTE-522 demonstrated that pembrolizumab in combination with chemotherapy before surgery and continued as a single agent after surgery significantly prolonged event-free survival in comparison to the same neoadjuvant chemotherapy regimens alone for patients with previously untreated Stage II or Stage III TNBC.

Additionally, the FDA converted the accelerated approval of pembrolizumab in combination with chemotherapy for patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) to a full approval based on confirmatory data from KEYNOTE-522. This approval was originally granted in November 2020 based on results from the Phase III KEYNOTE-355 trial.

https://www.merck.com/news/fda-approves-keytruda-pembrolizumab-for-treatment-of-patients-with-high-risk-early-stage-triple-negative-breast-cancer-in-combination-with-chemotherapy-as-neoadjuvant-treatment-then-continued/

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ESMO VIRTUAL PLENARY

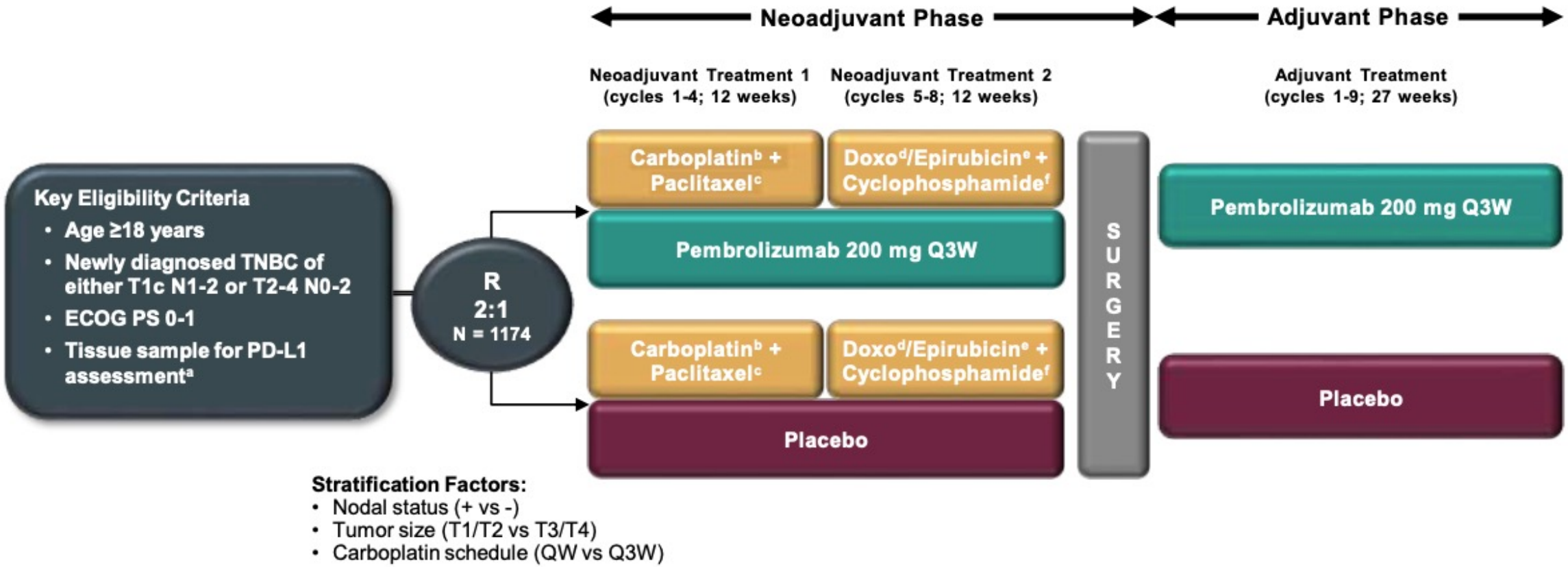
KEYNOTE-522: Phase 3 Study of Neoadjuvant Pembrolizumab + Chemotherapy versus Placebo + Chemotherapy, Followed by Adjuvant Pembrolizumab versus Placebo for Early-Stage Triple-Negative Breast Cancer

Peter Schmid[1], Javier Cortes[2], Rebecca Dent[3], Lajos Pusztai[4], Heather McArthur[5], Sherko Kümmel[6], Jonas Bergh[7], Carsten Denkert[8], Yeon Hee Park[9], Rina Hui[10], Nadia Harbeck[11], Masato Takahashi[12], Michael Untch[13], Peter A. Fasching[14], Fatima Cardoso[15], Yu Ding[16], Konstantinos Tryfonidis[17], Gursel Aktan[17], Vassiliki Karantza[17], Joyce O'Shaughnessy[18]

1. Centre for Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University London, London, UK; 2. International Breast Cancer Center, Quirón Group, Madrid and Barcelona, Spain and Vall d'Hebron Institute of Oncology, Barcelona, Spain; 3. National Cancer Center Singapore, Duke–National University of Singapore Medical School, Singapore; 4. Yale School of Medicine, Yale Cancer Center, New Haven, CT, USA; 5. Breast Oncology, Cedars-Sinai Medical Center, Los Angeles, CA, USA; 6. Breast Unit, Kliniken Essen-Mitte, Essen, Germany; 7. Department of Oncology-Pathology, Karolinska Institutet and Breast Cancer Centre, Cancer theme, Karolinska University Hospital, Solna, Sweden; 8. Institute of Pathology, Philipps-University Marburg and University Hospital Marburg (UKGM), Marburg, Germany; 9. Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; 10. Westmead Breast Cancer Institute, Westmead Hospital and the University of Sydney, Sydney, NSW, Australia; 11. Breast Center, LMU University Hospital, Munich, Germany; 12. Department of Breast Surgery, Hokkaido Cancer Center, Sapporo, Japan; 13. Breast Cancer Center, Helios Klinikum Berlin-Buch, Berlin, Germany; 14. University Hospital Erlangen, Comprehensive Cancer Center Erlangen-EMN, Erlangen, Germany; 15. Breast Unit, Champalimaud Clinical Center/Champalimaud Foundation, Lisbon, Portugal; 16. Biostatistics, Merck & Co., Inc., Kenilworth, NJ, USA; 17. Merck Research Laboratories, Merck & Co., Inc., Kenilworth, NJ, USA; 18. Baylor University Medical Center, Texas Oncology, US Oncology, Dallas, TX, USA

Schmid P et al. ESMO 2021;Abstract VP7.

KEYNOTE-522 Study Design (NCT03036488)



Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post treatment included)

Adjuvant phase: starts from the first adjuvant treatment and includes radiation therapy as indicated (post treatment included)

Schmid P et al. ESMO 2021;Abstract VP7.

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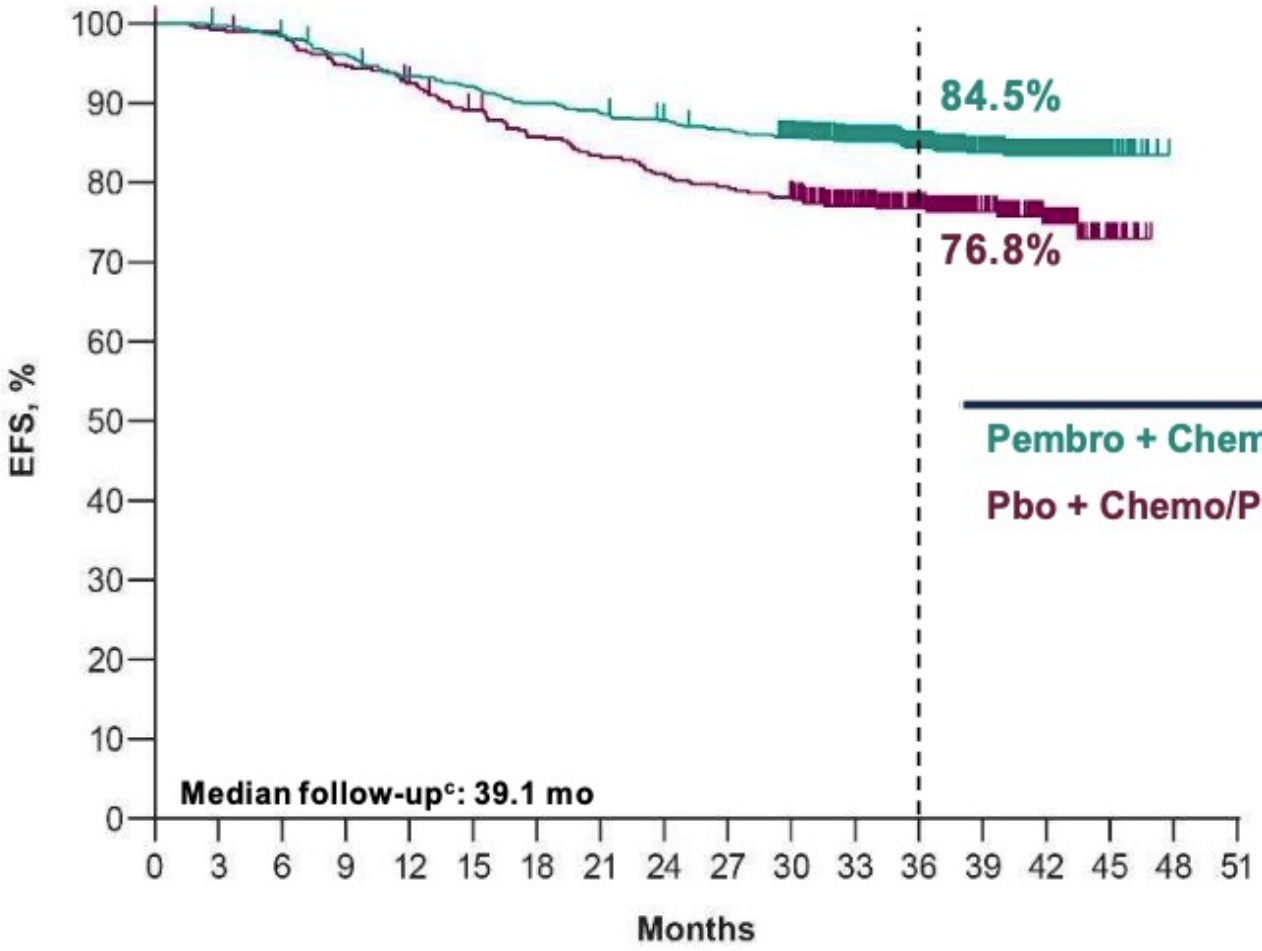
Statistically Significant and Clinically Meaningful EFS at IA4



	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	15.7%	0.63[a] (0.48-0.82)	0.00031[b]
Pbo + Chemo/Pbo	23.8%		

Schmid P et al. ESMO 2021;Abstract VP7.

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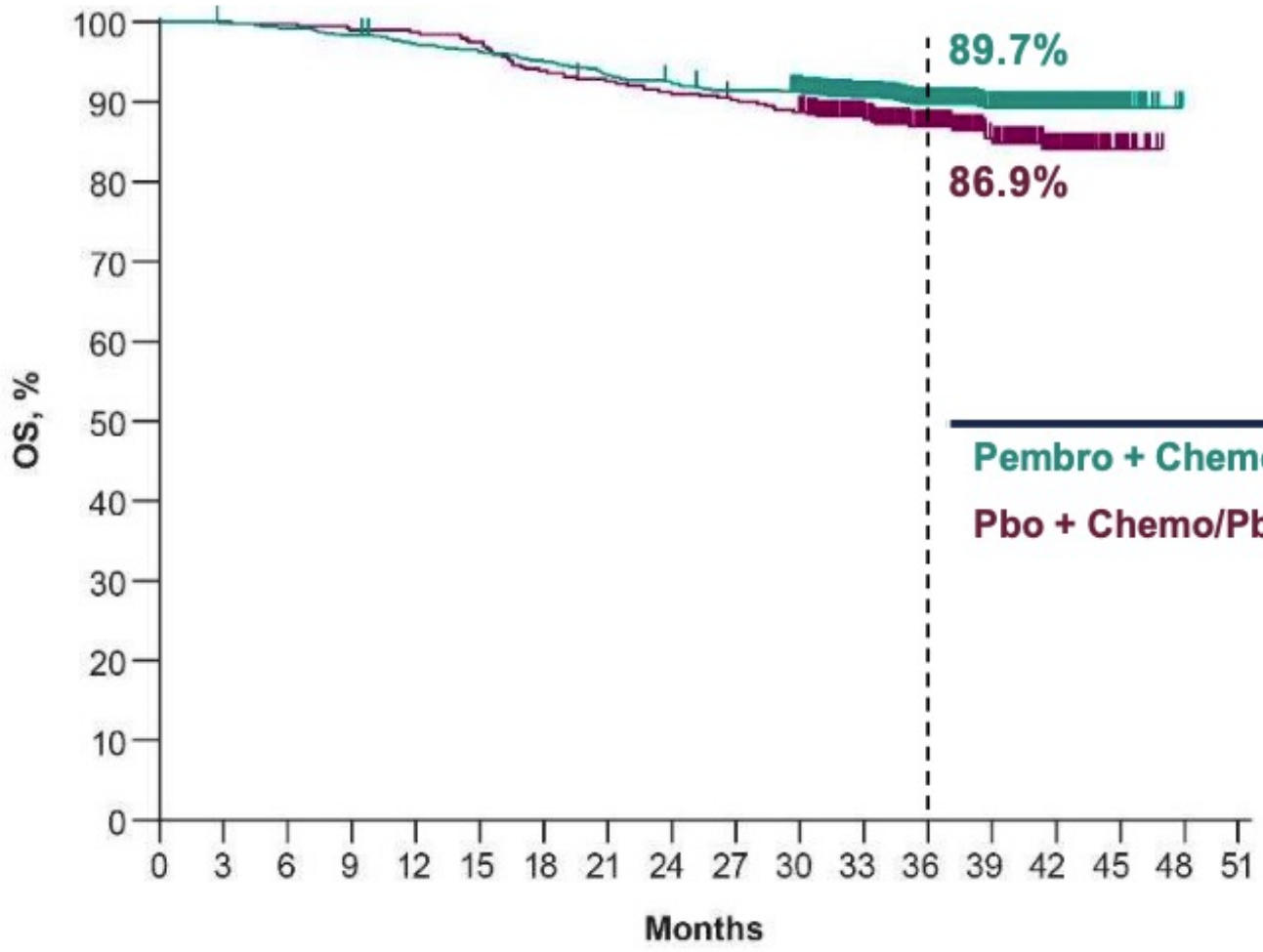
Overall Survival

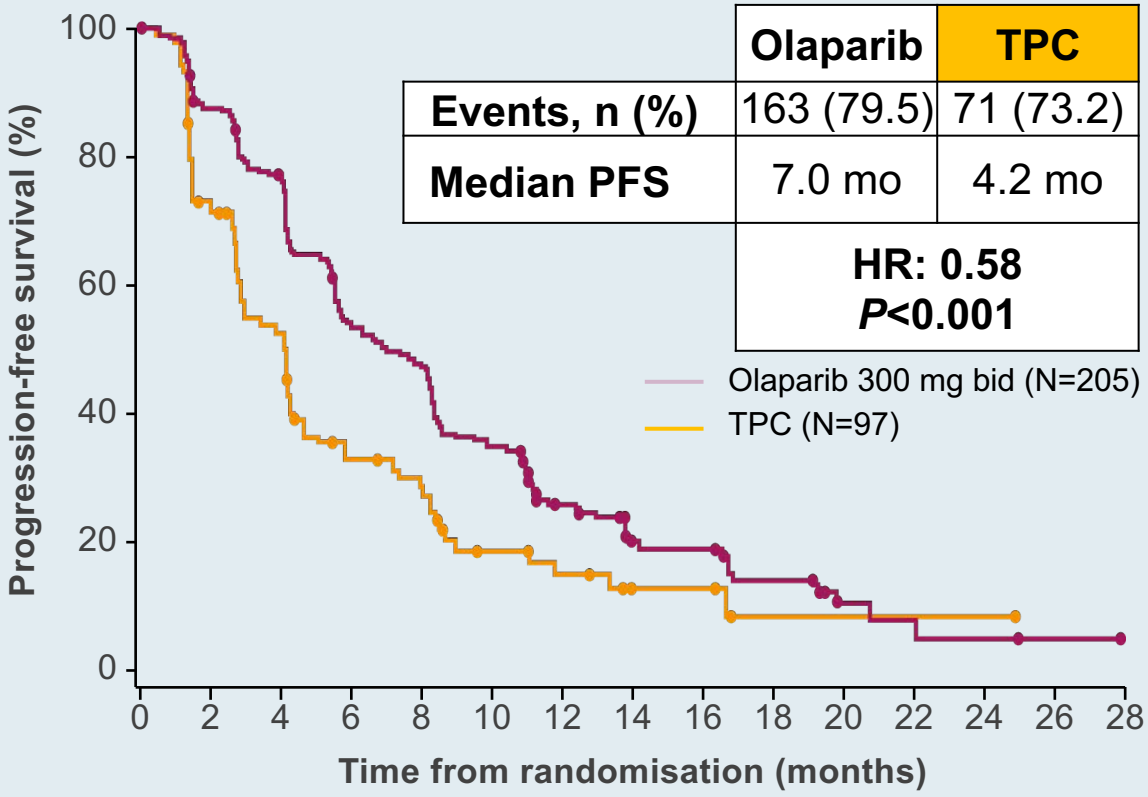


	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	10.2%	0.72[a] (0.51-1.02)	0.03214[b]
Pbo + Chemo/Pbo	14.1%		

Schmid P et al. ESMO 2021;Abstract VP7.

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

OlympiAD: Olaparib PFS[1,2]

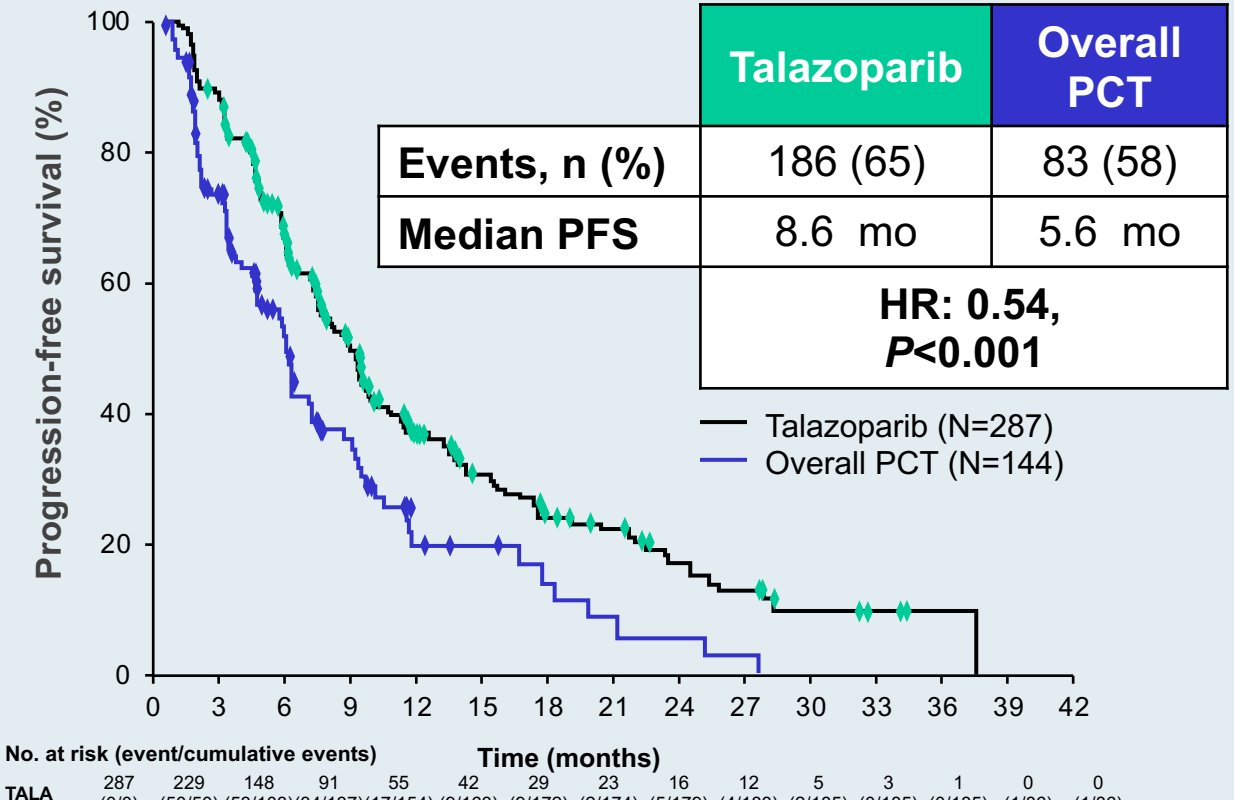


	Olaparib	TPC
Events, n (%)	163 (79.5)	71 (73.2)
Median PFS	7.0 mo	4.2 mo
	HR: 0.58 *P*<0.001	

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	0	0	0	0

EMBRACA: Talazoparib PFS[3]



	Talazoparib	Overall PCT
Events, n (%)	186 (65)	83 (58)
Median PFS	8.6 mo	5.6 mo
	HR: 0.54, *P*<0.001	

No. at risk (event/cumulative events)

TALA	287 (0/0)	229 (50/50)	148 (53/103)	91 (34/137)	55 (17/154)	42 (9/163)	29 (9/172)	23 (2/174)	16 (5/179)	12 (4/183)	5 (2/185)	3 (0/185)	1 (0/185)	0 (1/86)	0 (1/86)
PCT	144 (0/0)	68 (41/41)	34 (20/61)	22 (8/69)	9 (7/76)	8 (0/76)	4 (3/79)	2 (2/81)	2 (0/81)	1 (1/82)	0 (1/83)	0 (0/83)	0 (0/83)	0 (0/83)	0 (0/83)

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)

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Adjuvant Olaparib for Patients with *BRCA1*- or *BRCA2*-Mutated Breast Cancer

A.N.J. Tutt, J.E. Garber, B. Kaufman, G. Viale, D. Fumagalli, P. Rastogi, R.D. Gelber, E. de Azambuja, A. Fielding, J. Balmaña, S.M. Domchek, K.A. Gelmon, S.J. Hollingsworth, L.A. Korde, B. Linderholm, H. Bandos, E. Senkus, J.M. Suga, Z. Shao, A.W. Pippas, Z. Nowecki, T. Huzarski, P.A. Ganz, P.C. Lucas, N. Baker, S. Loibl, R. McConnell, M. Piccart, R. Schmutzler, G.G. Steger, J.P. Costantino, A. Arahmani, N. Wolmark, E. McFadden, V. Karantza, S.R. Lakhani, G. Yothers, C. Campbell, and C.E. Geyer, Jr., for the OlympiA Clinical Trial Steering Committee and Investigators*

***N Engl J Med* 2021;384(25):2394-405.**

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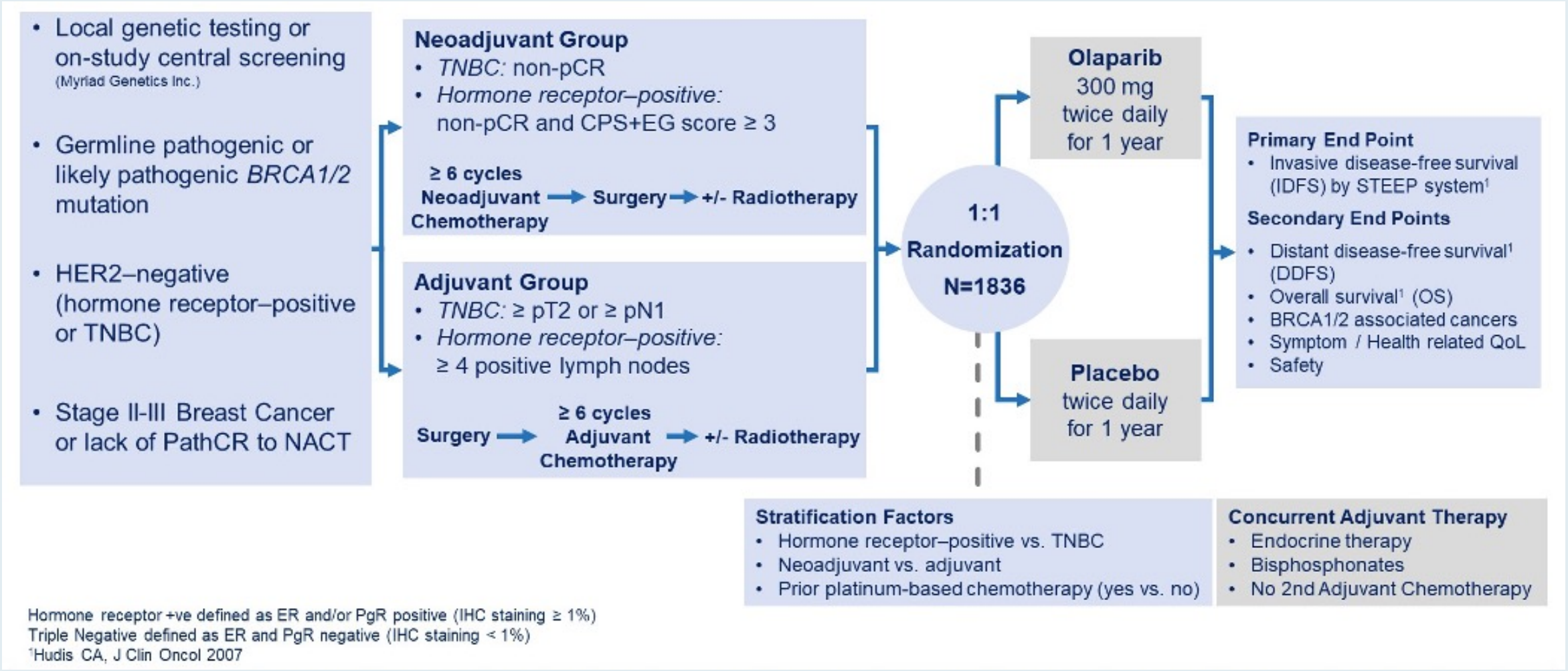
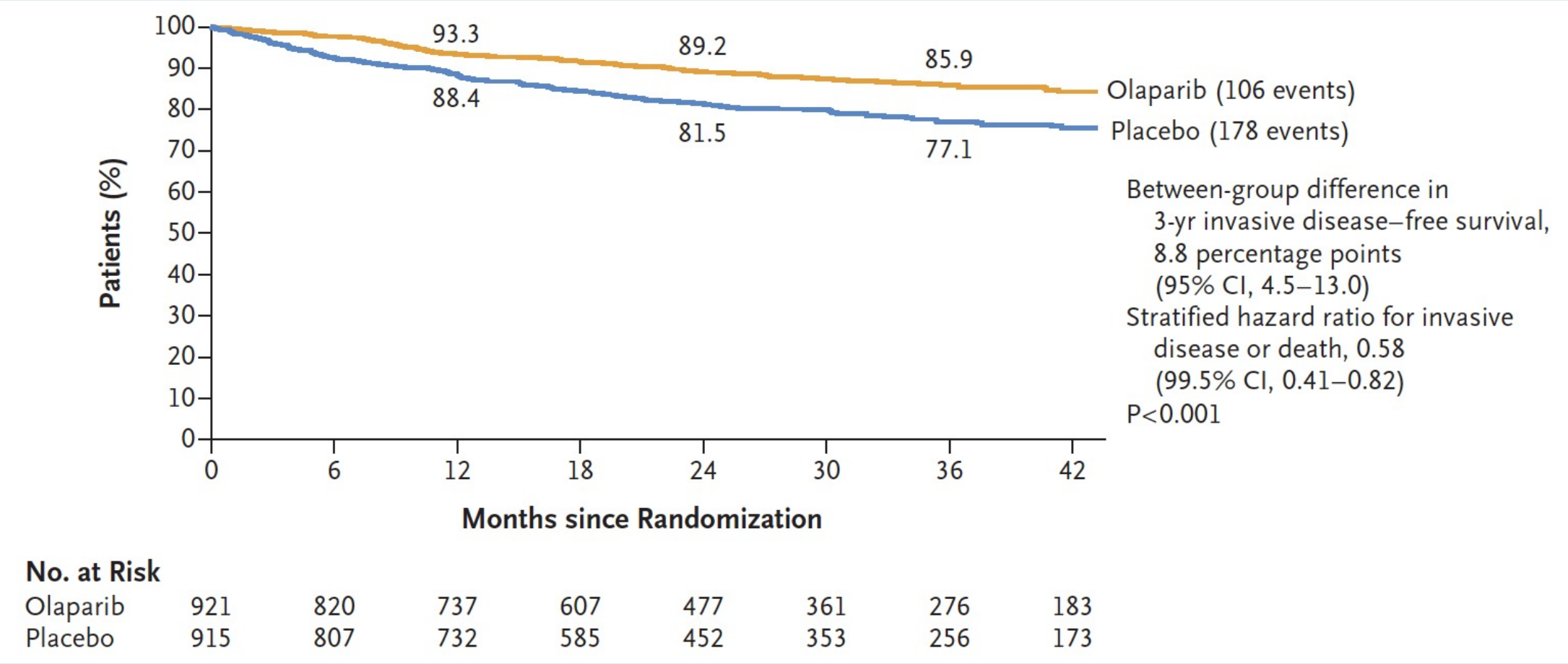
OlympiA: Trial Design



Hormone receptor +ve defined as ER and/or PgR positive (IHC staining ≥ 1%)
Triple Negative defined as ER and PgR negative (IHC staining < 1%)
[1]Hudis CA, J Clin Oncol 2007

Tutt ANJ et al. ASCO 2021;Abstract LBA1.

OlympiA: Invasive Disease-Free Survival

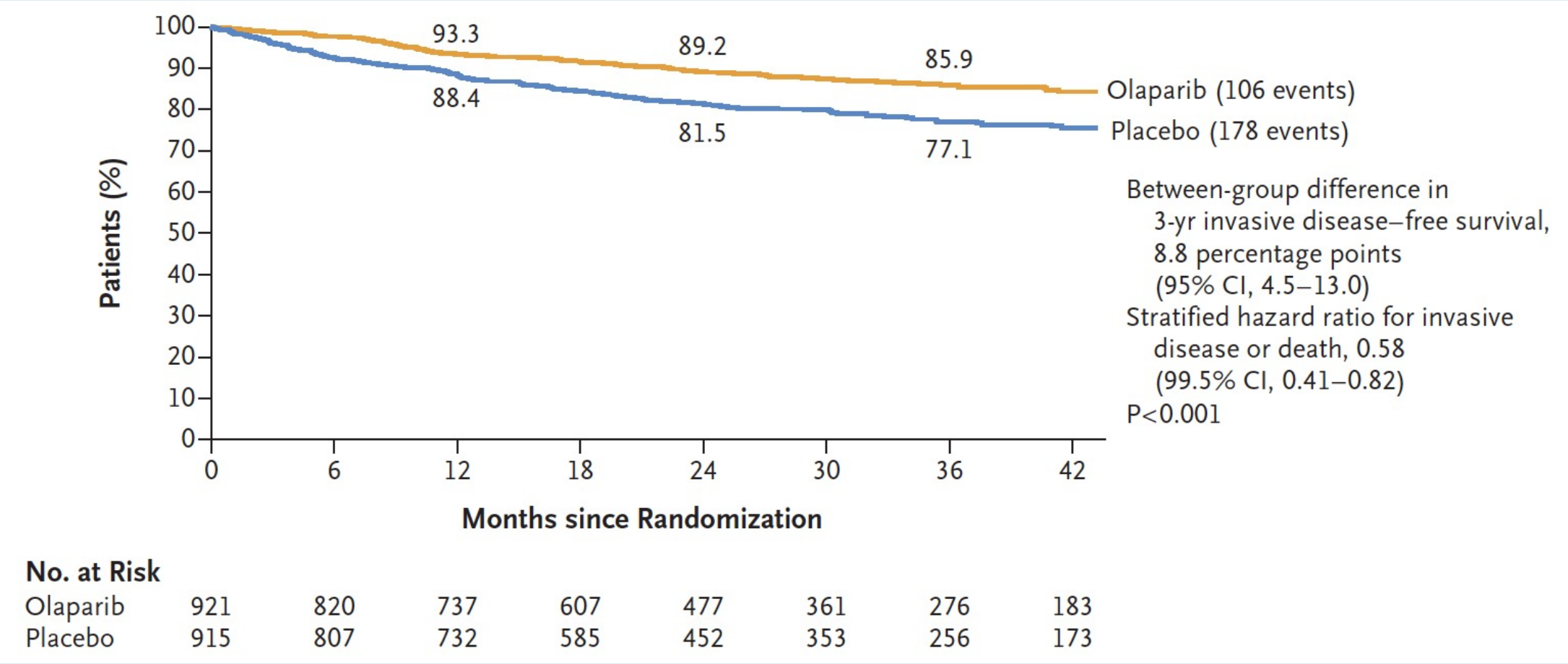


No. at Risk

Olaparib	921	820	737	607	477	361	276	183
Placebo	915	807	732	585	452	353	256	173

Tutt ANJ et al. *N Engl J Med* 2021;384(25):2394-405.

OlympiA: Overall Survival



No. at Risk

Olaparib	921	820	737	607	477	361	276	183
Placebo	915	807	732	585	452	353	256	173

Tutt ANJ et al. *N Engl J Med* 2021;384(25):2394-405.

Agenda

Prologue: The Summer of 2021 – Immunotherapy and PARP inhibitors enter the adjuvant/neoadjuvant settings

Case Scenario 1: A woman with ER-positive, HER2-positive breast cancer and brain metastases

Case Presentation – Ms Carroll: A 61-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer

Case Scenario 2: A woman with ER-positive, HER2-negative breast cancer and bone metastases

Case Presentation – Ms Carroll: A 38-year-old woman with high-risk ER/PR-positive, HER2-negative, node-positive localized breast cancer

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Case Scenario 1: A woman with ER-positive, HER2-positive breast cancer and brain metastases

- A woman seeks care for back pain and workup reveals a breast mass which biopsy confirms to be ER-positive, HER2-positive breast cancer. Imaging shows extensive bone metastases.
- What strategies can be used to protect her bones from the risk of fracture and the patient from other complications?
- What systemic treatment is likely to be recommended and why?

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Case Scenario 1: A woman with ER-positive, HER2-positive breast cancer and brain metastases (continued)

- The patient receives paclitaxel/trastuzumab/pertuzumab and responds for 18 months but then presents with headache and is found to have multiple bilateral brain metastases with no evidence of edema.
- What local treatment (radiation, surgery) is likely to be considered?
- What systemic therapy is likely to be recommended?

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Case Presentation – Ms Carroll: A 61-year-old woman with ER/PR-positive, HER2-positive metastatic breast cancer

Treatments received for multiply relapsed metastatic disease

- FEC/trastuzumab and tamoxifen
- Trastuzumab/palbociclib/letrozole
- T-DM1/fulvestrant
- Abemaciclib/fulvestrant
- Capecitabine/lapatinib/trastuzumab
  - Capecitabine discontinued due to toxicity
- Tucatinib/trastuzumab/capecitabine
- Olaparib/trastuzumab

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How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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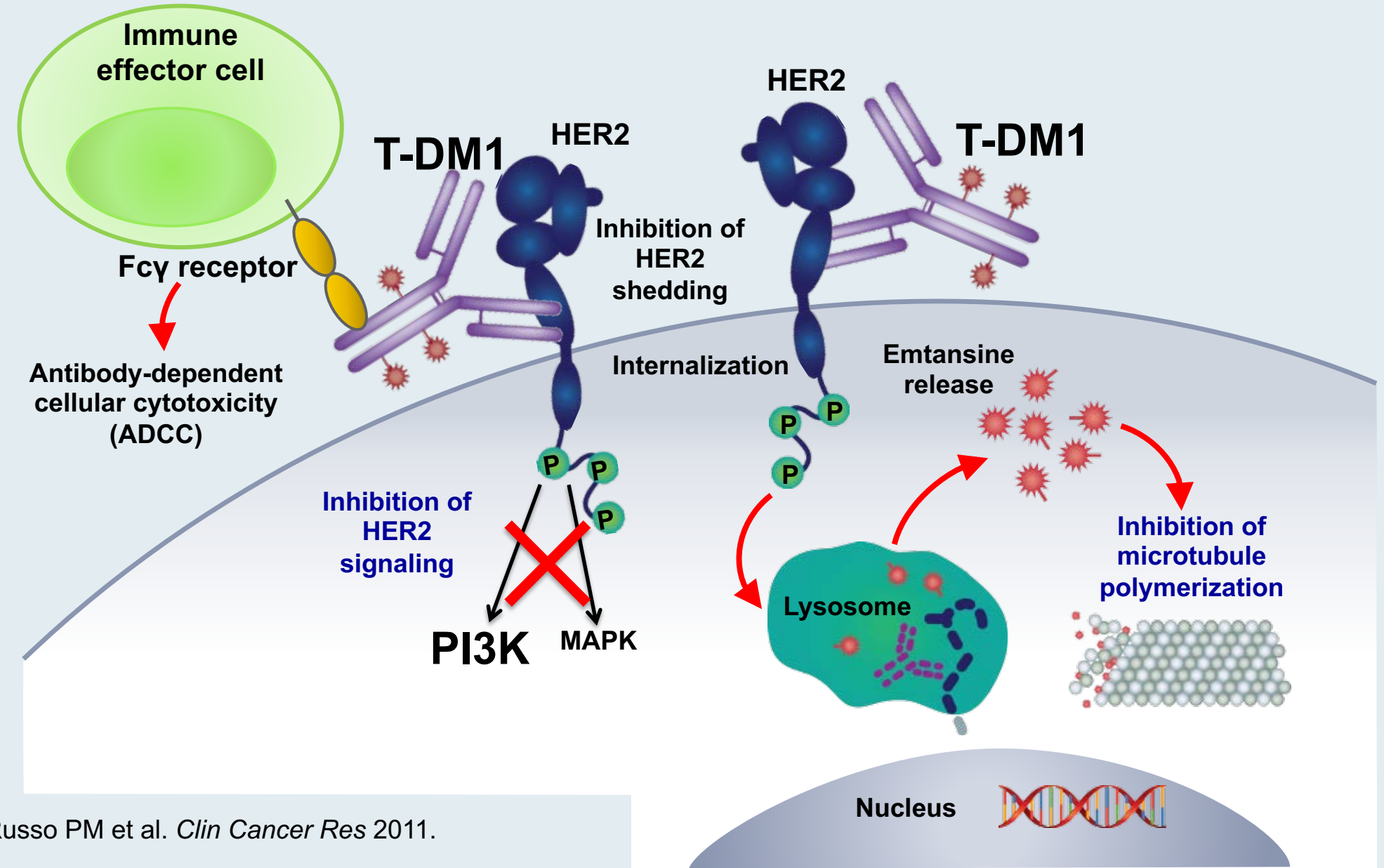
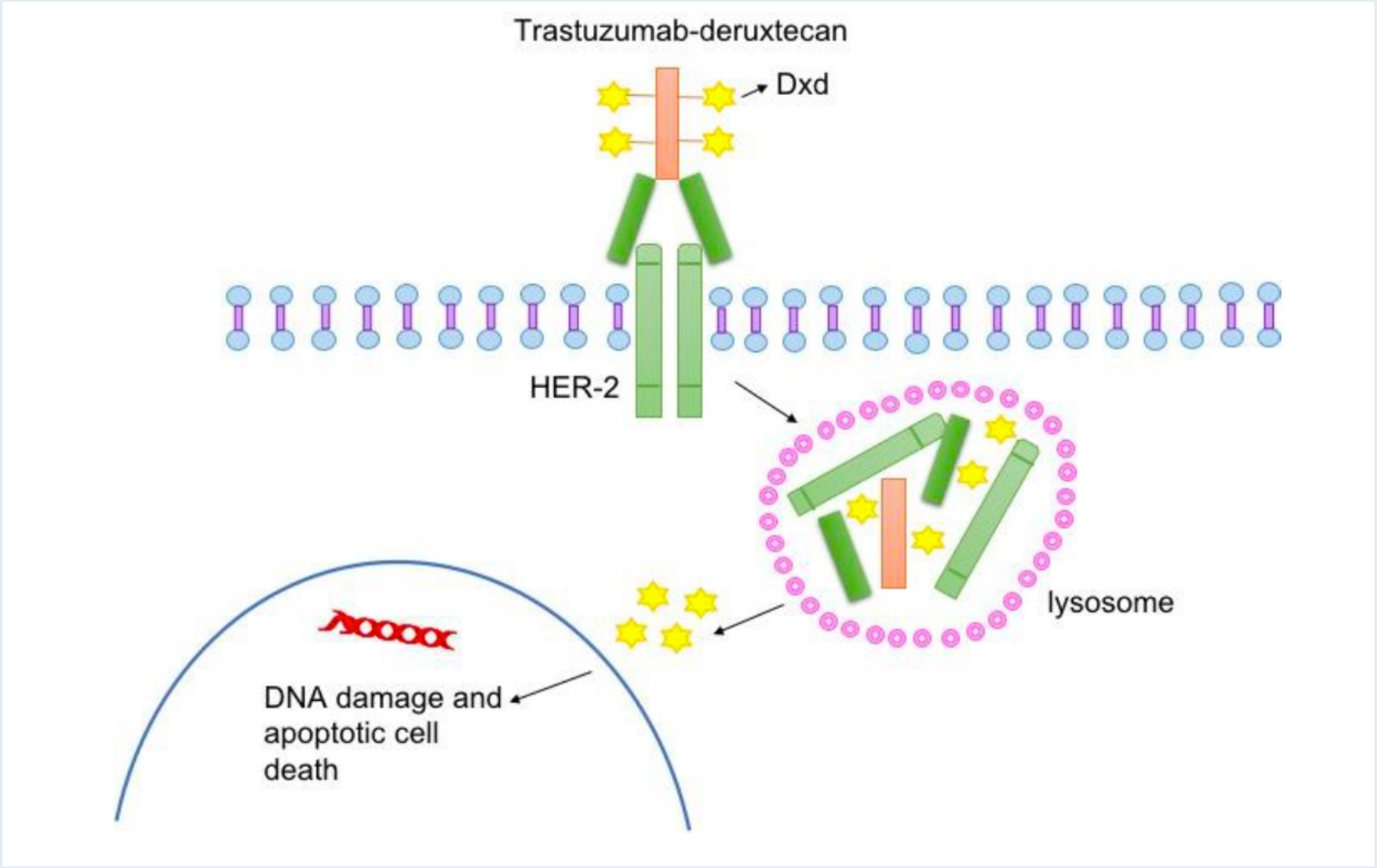
Trastuzumab Emtansine (T-DM1): Mechanisms of Action



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

RTP RESEARCH TO PRACTICE

Trastuzumab Deruxtecan: Mechanism of Action



Indini A et al. *Int J Mol Sci* 2021;22:474.

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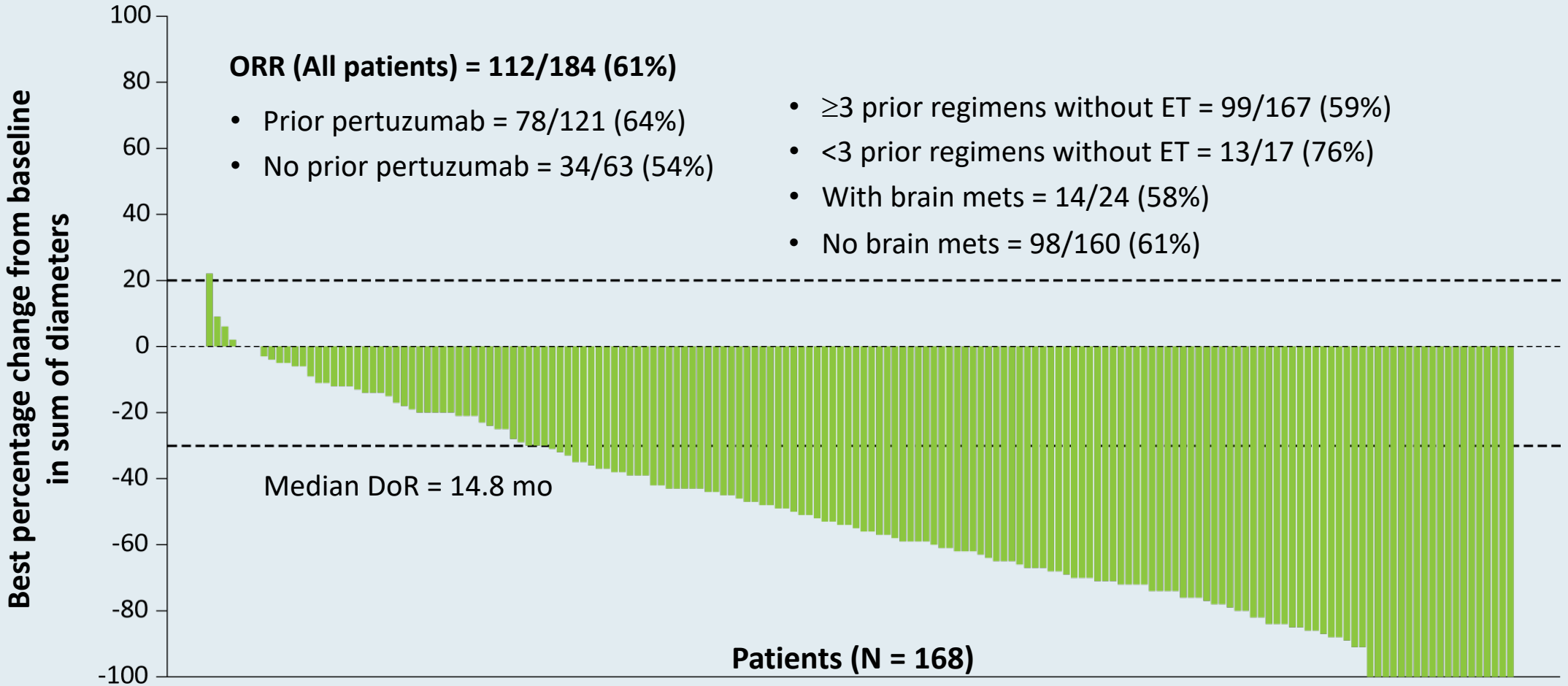
DESTINY-Breast01: Response According to Tumor Size and Subgroup Analyses



Modi S et al. *N Engl J Med* 2020;382(7):610-21.

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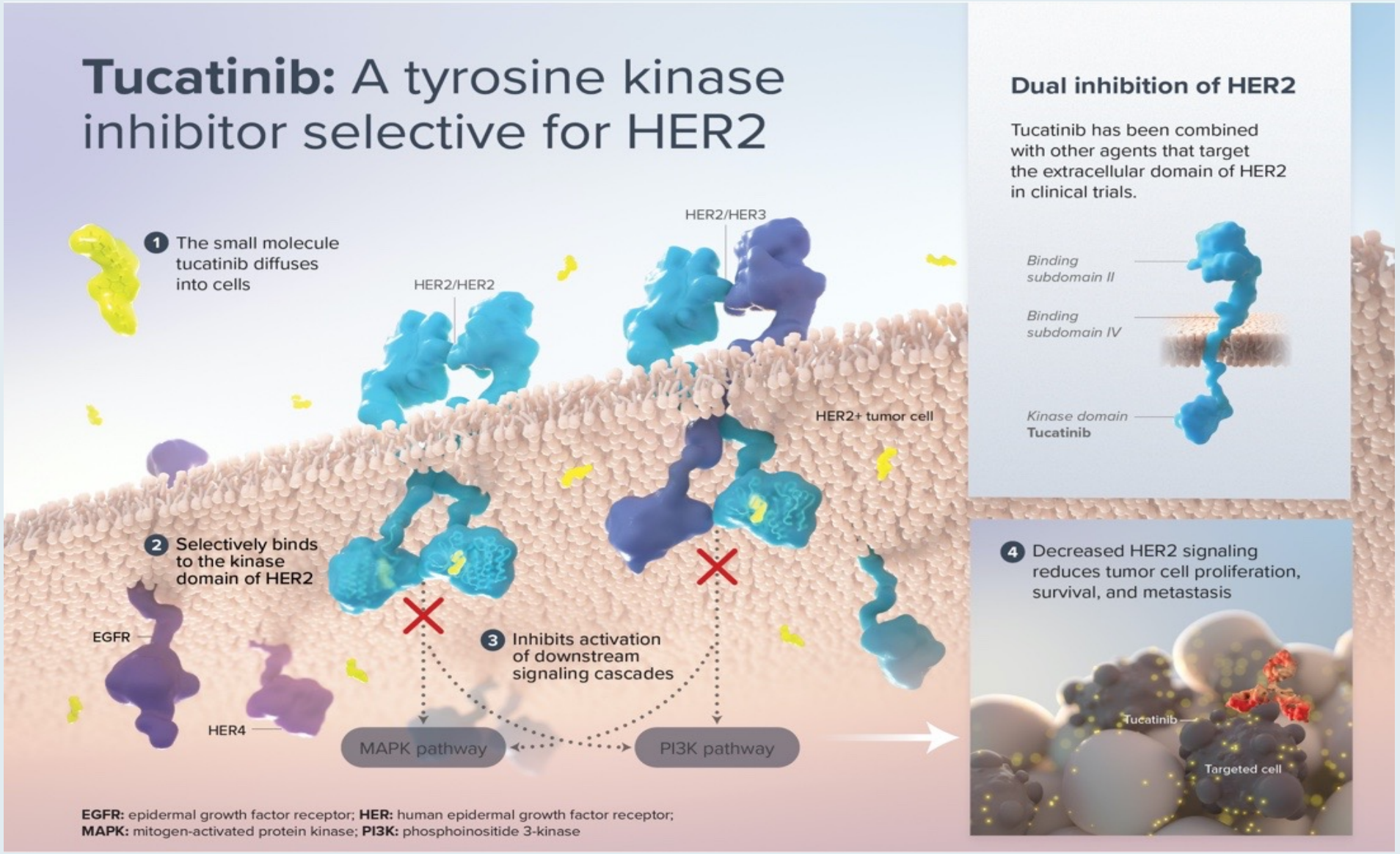
Tucatinib Mechanism of Action



www.seagen.com/science/pipeline/tucatinib

RTP RESEARCH TO PRACTICE

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 13, 2020 VOL. 382 NO. 7

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

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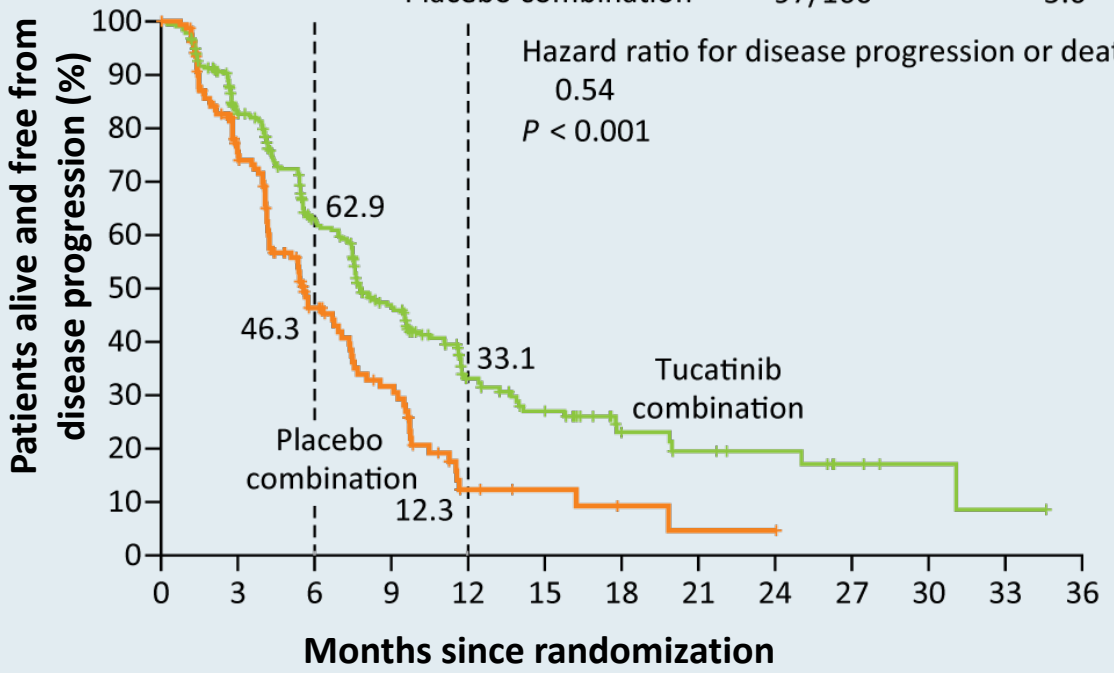
HER2CLIMB: Survival Outcomes

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)

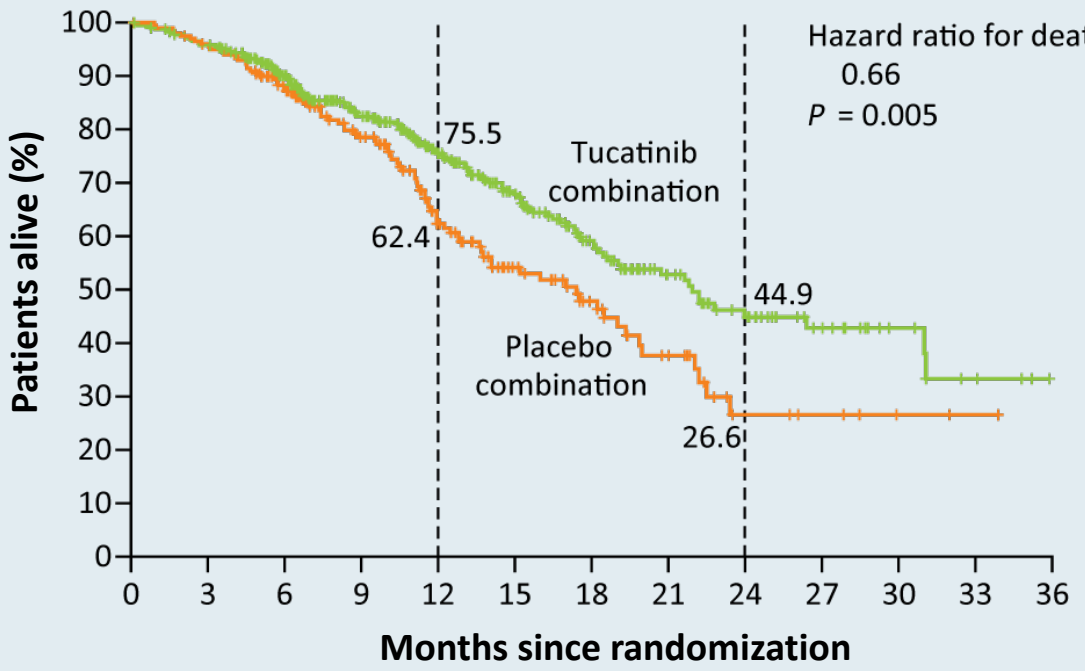
PFS

	No. of events/ No. of patients	Median duration *mo*
Tucatinib combination	178/320	7.8
Placebo combination	97/160	5.6



OS

	No. of deaths/ No. of patients	Median duration *mo*
Tucatinib combination	130/410	21.9
Placebo combination	85/202	17.4



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.

RTP RESEARCH TO PRACTICE

rapid communications

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, MD[1]; Virginia Borges, MMSc, MD[2]; Carey Anders, MD[3]; Rashmi K. Murthy, MD, MBE[4]; Elisavet Paplomata, MD[5]; Erika Hamilton, MD[6]; Sara Hurvitz, MD[7]; Sherene Loi, MD, PhD[8]; Alicia Okines, MBChB, MD[9]; Vandana Abramson, MD[10]; Philippe L. Bedard, MD[11]; Mafalda Oliveira, MD, PhD[12]; Volkmar Mueller, MD[13]; Amelia Zelnak, MD[14]; Michael P. DiGiovanna, MD, PhD[15]; Thomas Bachelot, MD[16]; A. Jo Chien, MD[17]; Ruth O'Regan, MD[5]; Andrew Wardley, MBChB, MSc, MD[18]; Alison Conlin, MD, MPH[19]; David Cameron, MD, MA[20]; Lisa Carey, MD[21]; Giuseppe Curigliano, MD, PhD[22]; Karen Gelmon, MD[23]; Sibylle Loibl, MD, PhD[24]; JoAl Mayor, PharmD[25]; Suzanne McGoldrick, MD, MPH[25]; Xuebei An, PhD[25]; and Eric P. Winer, MD[1]

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

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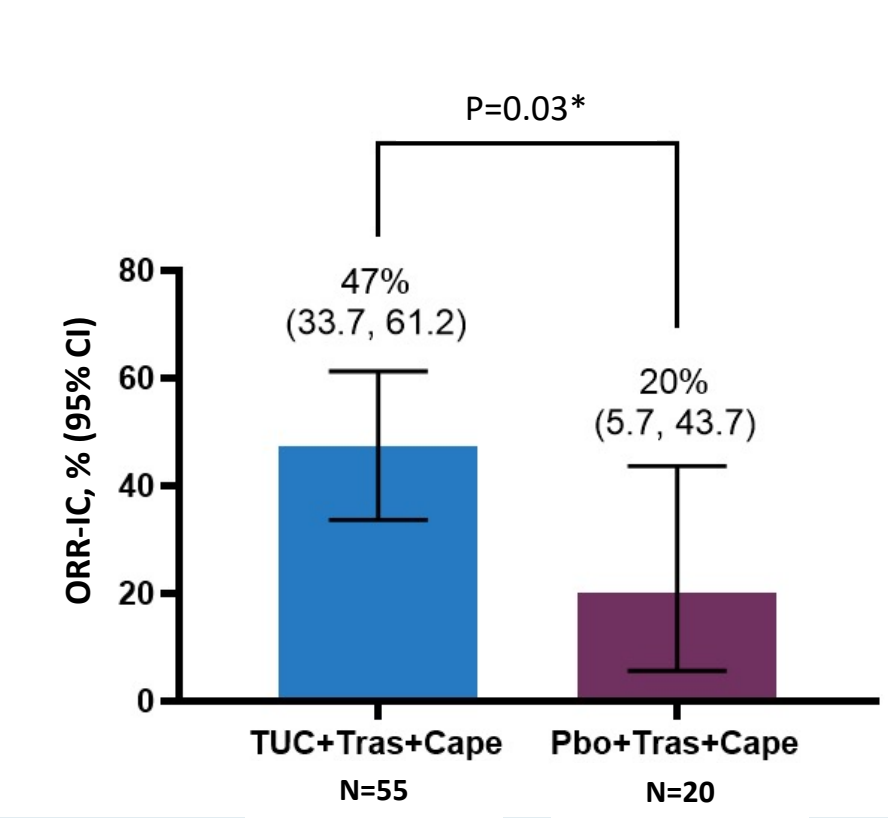
HER2CLIMB: Intracranial Response Rate (ORR-IC) for Patients with Active Brain Metastases and Measurable Intracranial Lesions at Baseline

Confirmed Objective Response Rate (RECIST 1.1)



*Stratified Cochran-Mantel-Haenszel P value

	TUC+Tras+Cape (N=55)	Pbo+Tras+Cape (N=20)
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).

Courtesy of Carey K Anders, MD

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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; Maaike 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].**

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Agenda

Prologue: The Summer of 2021 – Immunotherapy and PARP inhibitors enter the adjuvant/neoadjuvant settings

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Case Scenario 2: A woman with ER-positive, HER2-negative breast cancer and bone metastases

- A postmenopausal patient self palpates a 3-cm breast mass, and evaluation reveals an ER-positive, HER2-negative IDC with a biopsy-proven enlarged axillary lymph node.
- Neoadjuvant chemotherapy is administered, but at surgery there is significant residual disease.
- What adjuvant systemic treatment will be considered?

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Case Scenario 2: A woman with ER-positive, HER2-negative breast cancer and bone metastases (continued)

- The patient receives an aromatase inhibitor but 2 years later is found to have metastatic disease.
- What first-line systemic treatment will be considered?

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Case Scenario 2: A woman with ER-positive, HER2-negative breast cancer and bone metastases (continued)

- The patient receives fulvestrant and a CDK inhibitor but 18 months later is found to have disease progression.
- What next-line systemic treatment will be considered?

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Case Presentation – Ms Carroll: A 38-year-old woman with high-risk ER/PR-positive, HER2-negative, node-positive localized breast cancer

- Neoadjuvant AC → T → Surgery (ypT3N3)
- Adjuvant abemaciclib/exemestane

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How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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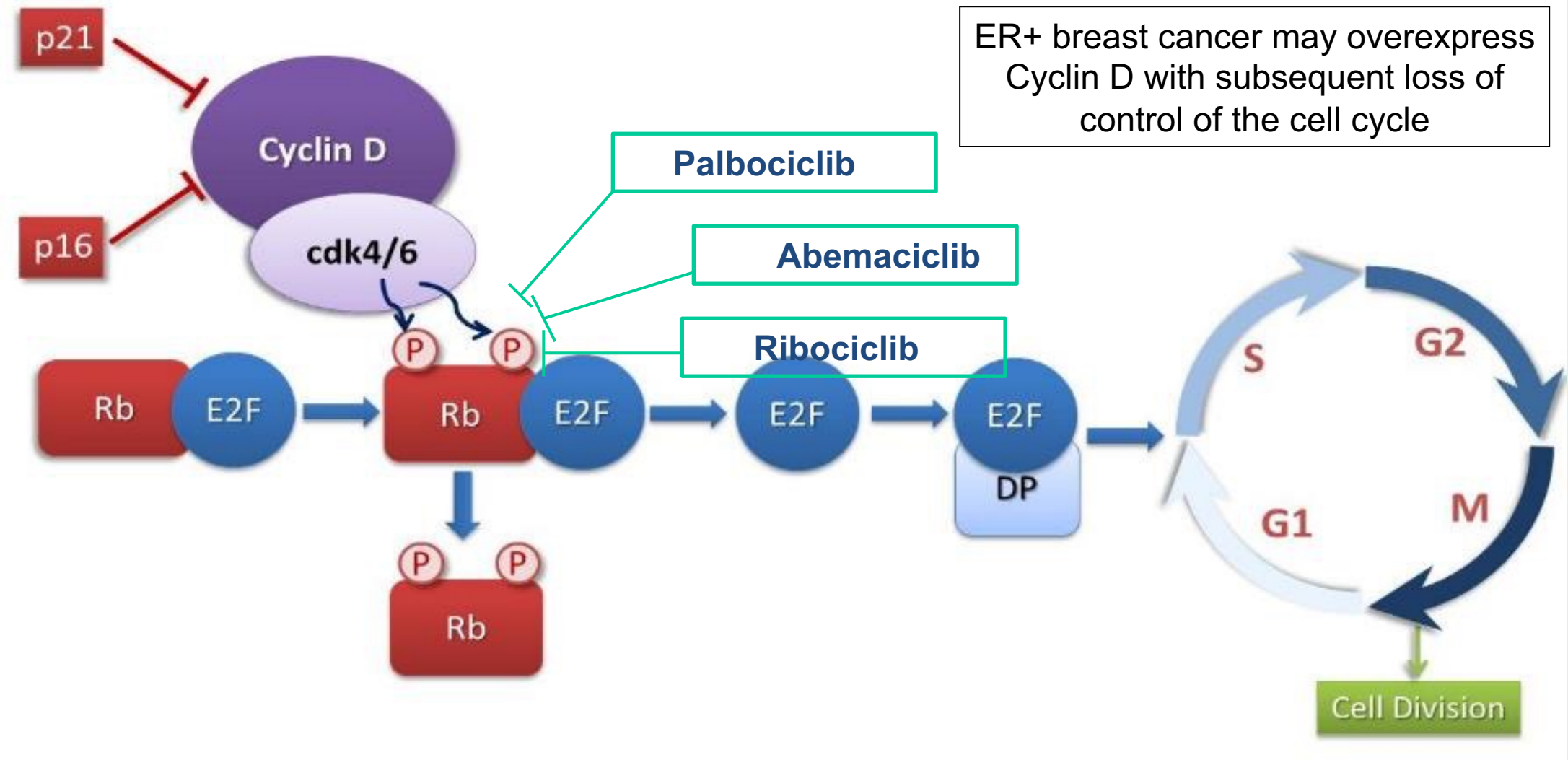
CDK4/6 Regulates Cell Cycle Progression



Adapted from Finn et al, 2016.

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

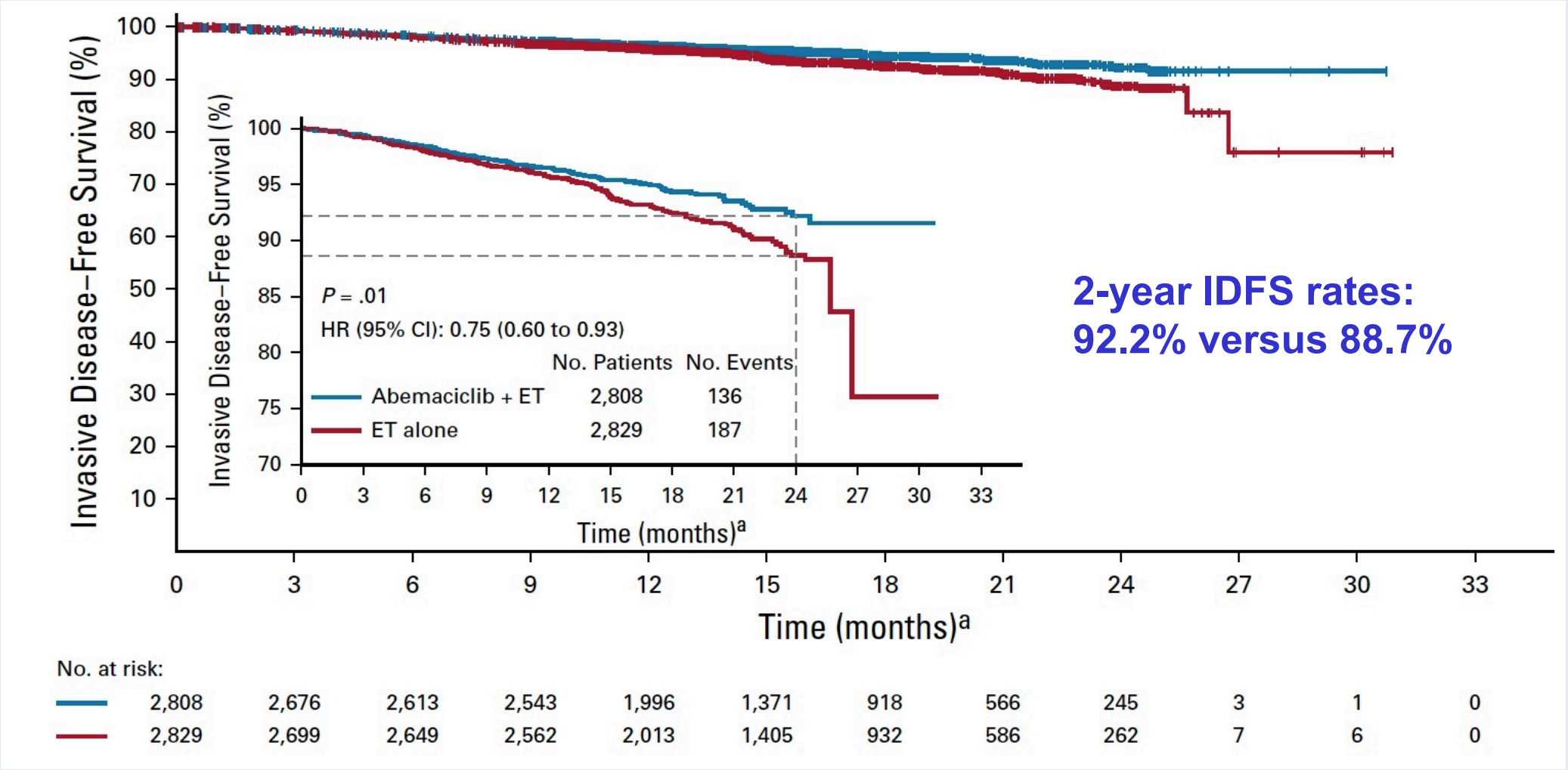
rapid communications

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, PhD[1]; Nadia Harbeck, MD, PhD[2]; Roberto Hegg, MD, PhD[3]; Masakazu Toi, MD, PhD[4]; Miguel Martin, MD, PhD[5]; Zhi Min Shao, MD[6]; Qing Yuan Zhang, MD, PhD[7]; Jorge Luis Martinez Rodriguez, MD[8]; Mario Campone, MD, PhD[9]; Erika Hamilton, MD[10]; Joohyuk Sohn, MD, PhD[11]; Valentina Guarneri, MD, PhD[12]; Morihito Okada, MD, PhD[13]; Frances Boyle, MD, MBBS, PhD[14]; Patrick Neven, MD, PhD[15]; Javier Cortés, MD, PhD[16]; Jens Huober, MD[17]; Andrew Wardley, MD, MBChB[18]; Sara M. Tolaney, MD, MPH[19]; Irfan Cicin, MD[20]; Ian C. Smith, MD[21,22]; Martin Frenzel, PhD[22]; Desirée Headley, MSc[22]; Ran Wei, PhD[22]; Belen San Antonio, PhD[22]; Maarten Hulstijn, PhD[22]; Joanne Cox, MD[22]; Joyce O'Shaughnessy, MD[23]; and Priya Rastogi, MD[24]; on behalf of the monarchE Committee Members and Investigators

RTP RESEARCH TO PRACTICE

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



Johnston SRD et al. *J Clin Oncol* 2020;38(34):3987-98.

Articles

Lancet Oncol 2021;22:212-22

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-Ezquerra, 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*

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Randomized Trials of Endocrine Therapy with and without 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

Courtesy of Dr Harold Burstein; Updated with MONALEESA-3 and MONALEESA-7

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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 Thrombocytopenia	95% 76%	54% 19%	88% 42%	27% 2%	46% 37%	29% 10%
Diarrhea Nausea Vomiting	16% 23% 5%	0 0 0	90% 65% 35%	20% 5% 2%	22% 46% 25%	3% 2% 0

Barroso-Sousa R et al. *Breast Care* 2016;11:167-73.

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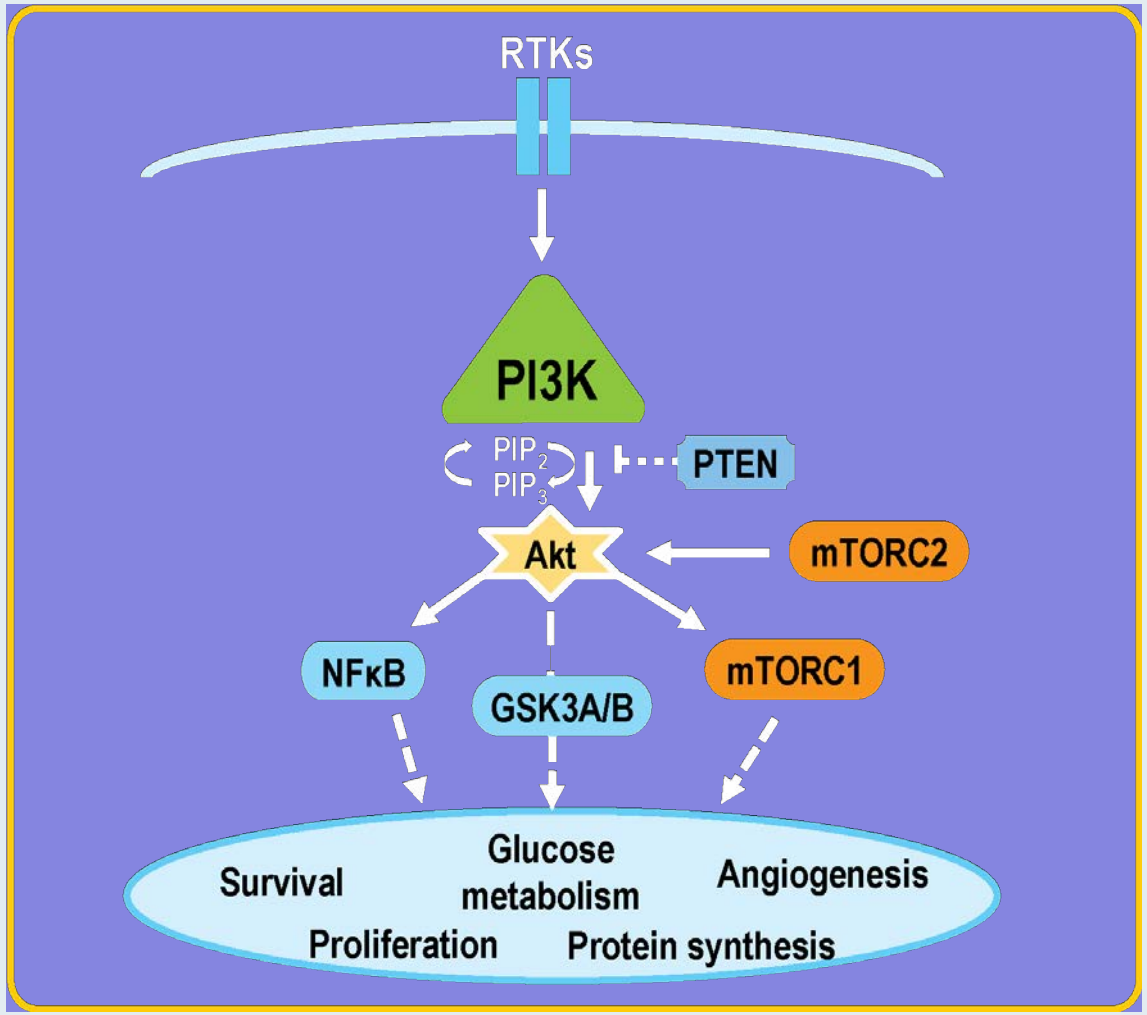
PI3K Inhibitors: Mechanism of Action



- 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.

André F et al. ESMO 2018;Abstract LBA3_PR.

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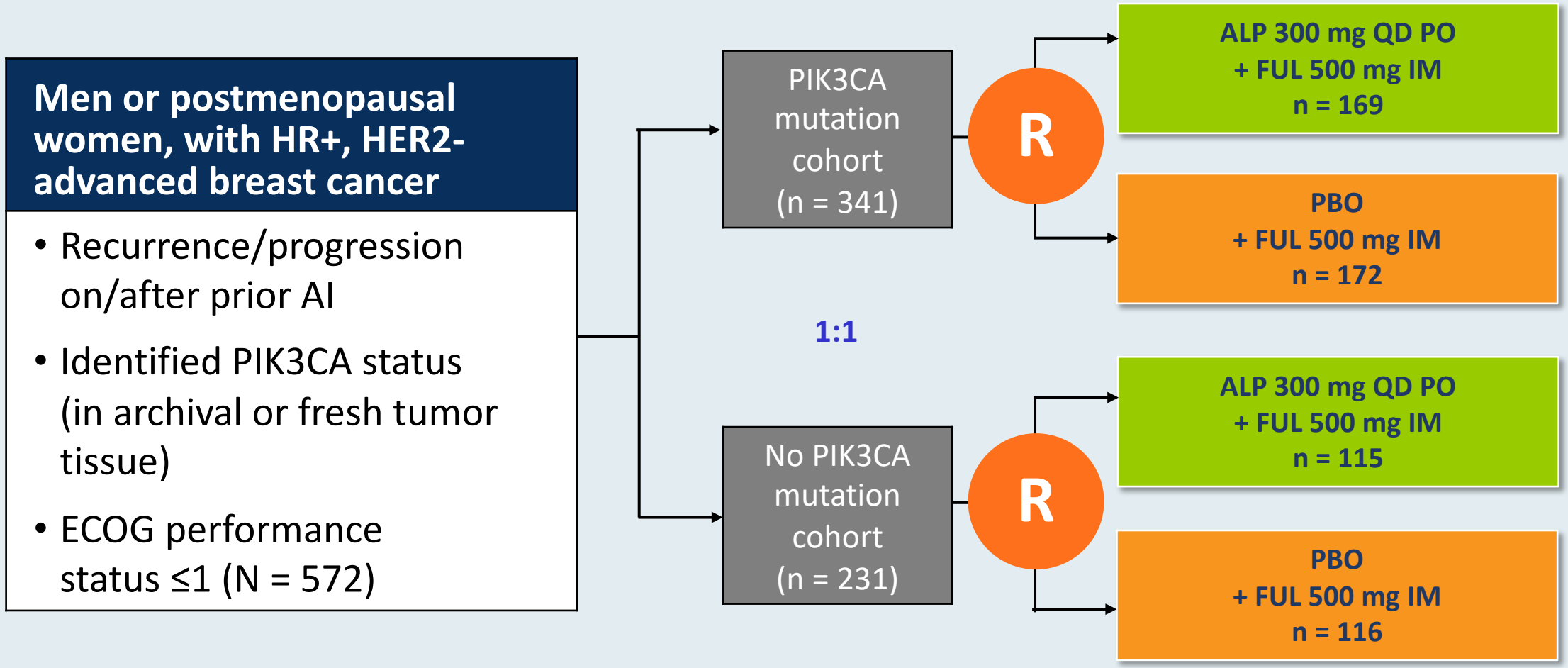
SOLAR-1 Phase III Study Design



Primary endpoint: Locally assessed PFS in PIK3CA mutation cohort

André F et al. ESMO 2018;Abstract LBA3_PR.

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

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. Ciruelos[2], D. Juric[3], S. Loibl[4], M. Campone[5], I. A. Mayer[6], G. Rubovszky[7], T. Yamashita[8], B. Kaufman[9], Y.-S. Lu[10], K. Inoue[11], Z. Pápai[12], M. Takahashi[13], F. Ghaznawi[14], D. Mills[15], M. Kaper[14], M. Miller[14], P. F. Conte[16], H. Iwata[17] & H. S. Rugo[18]

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

Available online 25 November 2020

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

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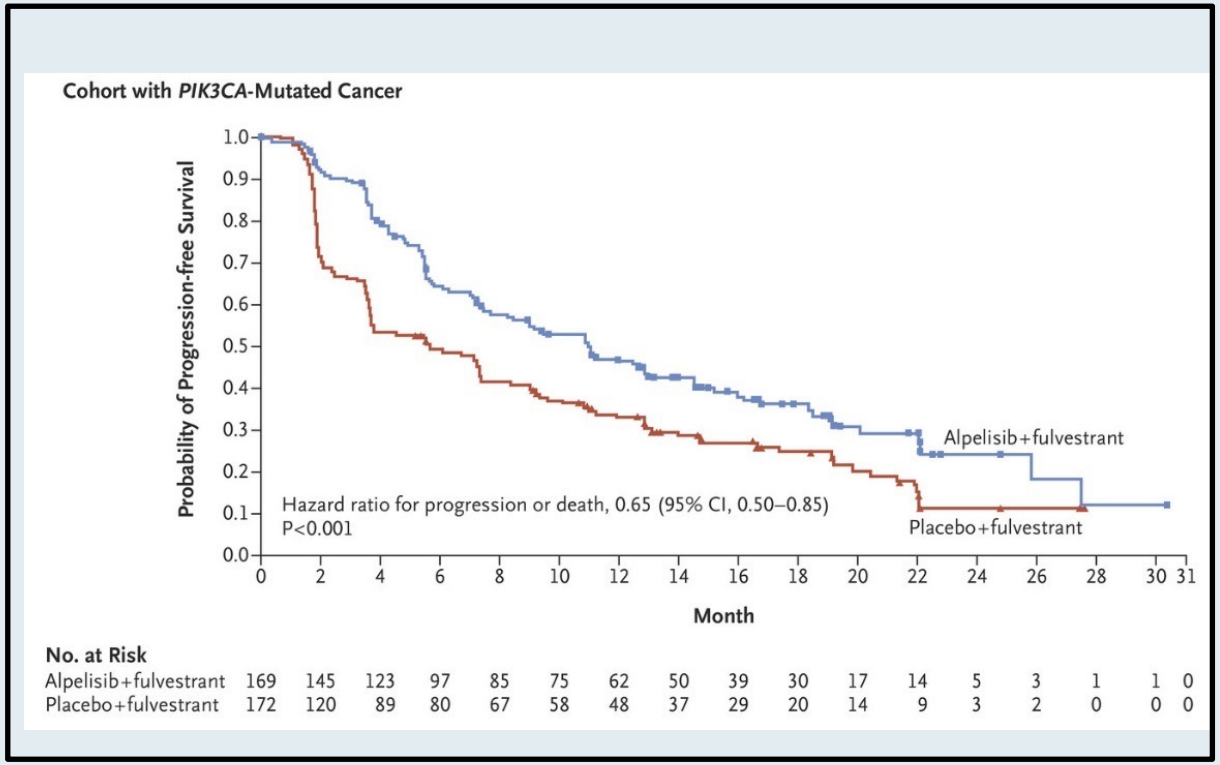
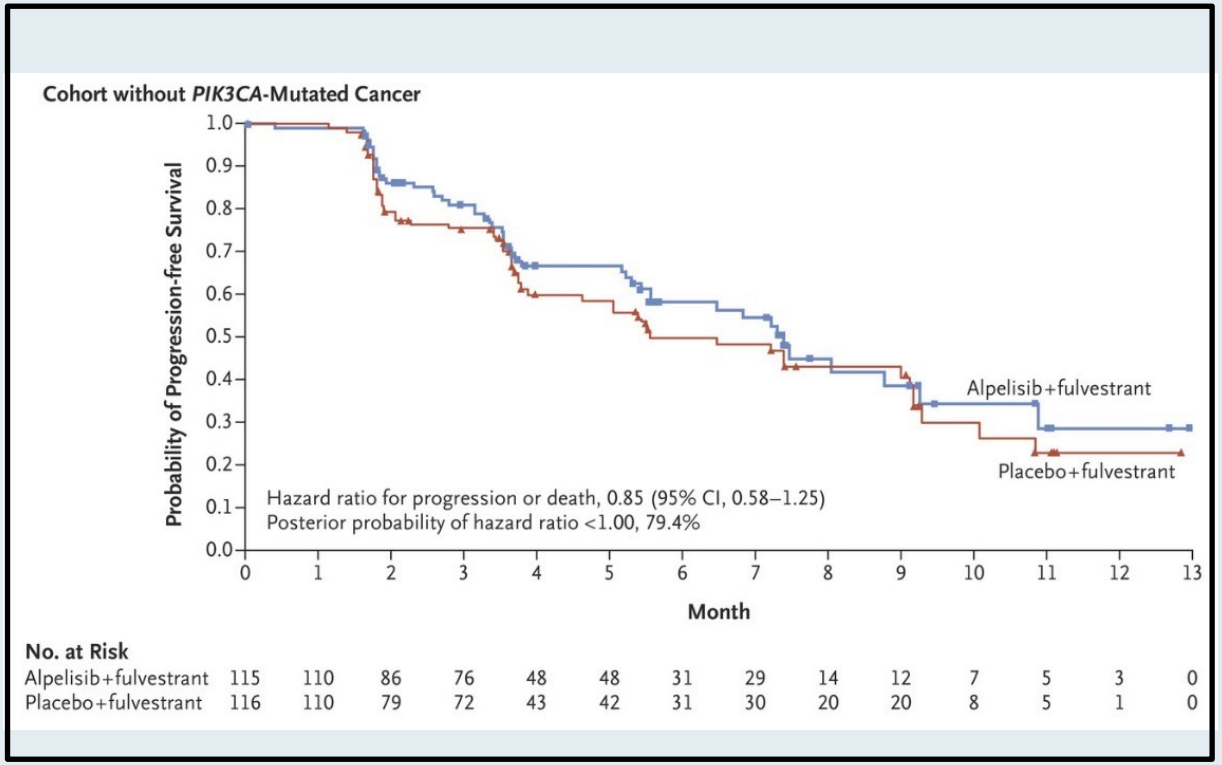
SOLAR-1: PFS Outcomes by PIK3CA Mutation Status

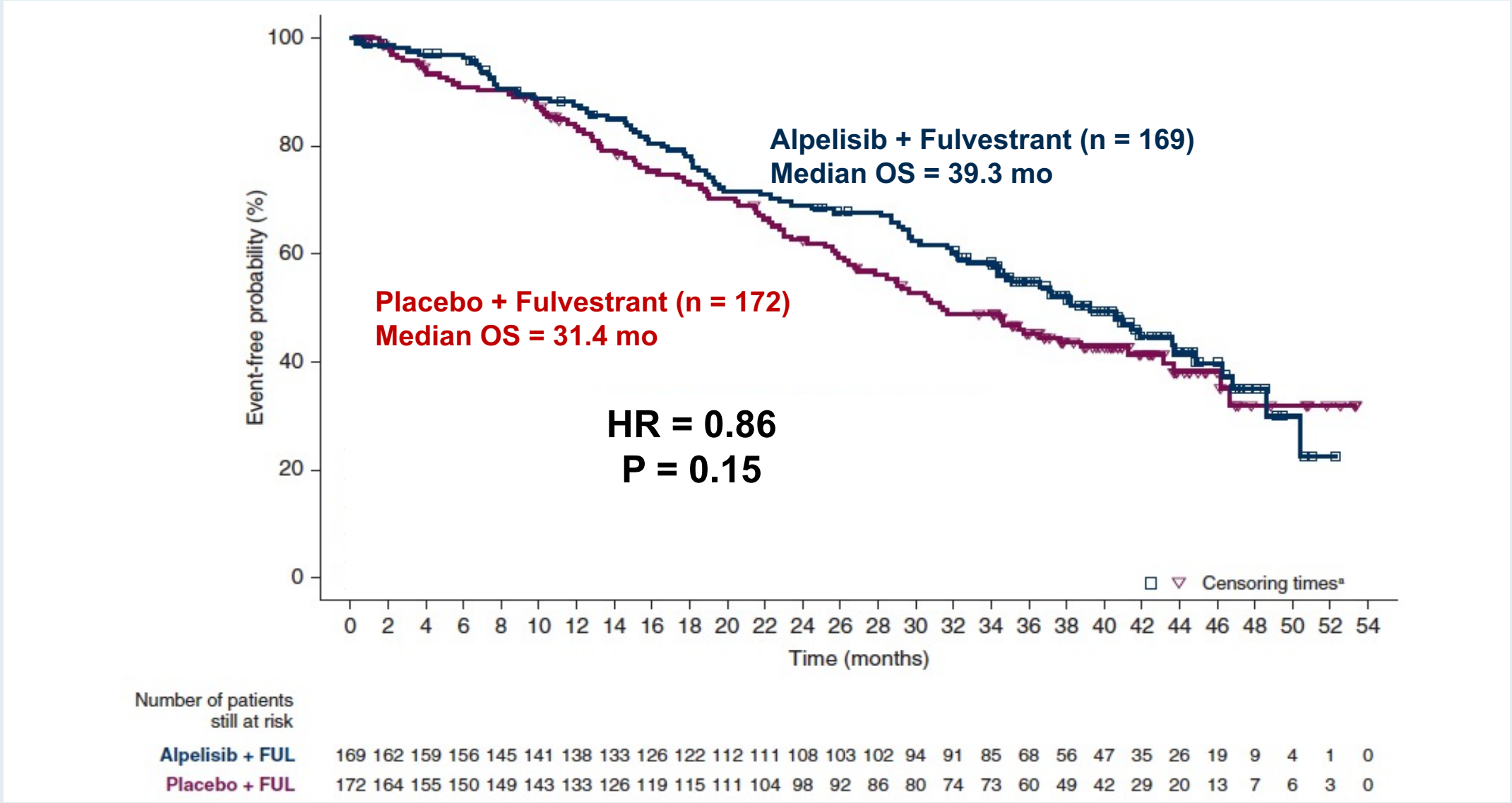




André F et al. *N Engl J Med* 2019;380:1929-40.

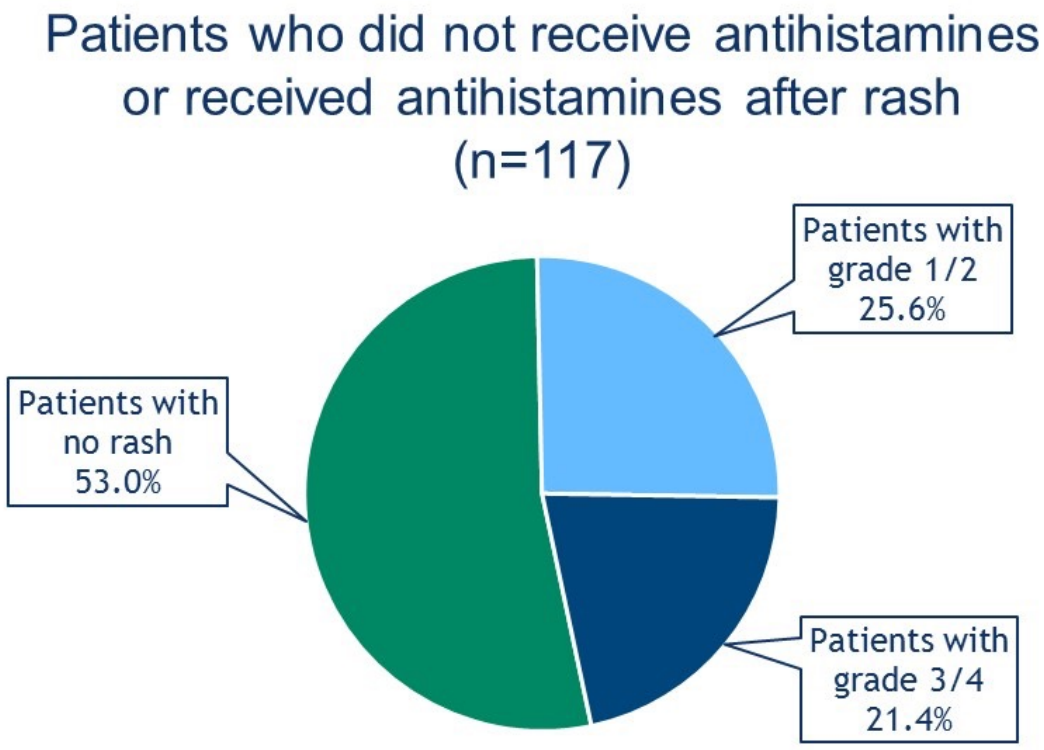
RTP RESEARCH TO PRACTICE

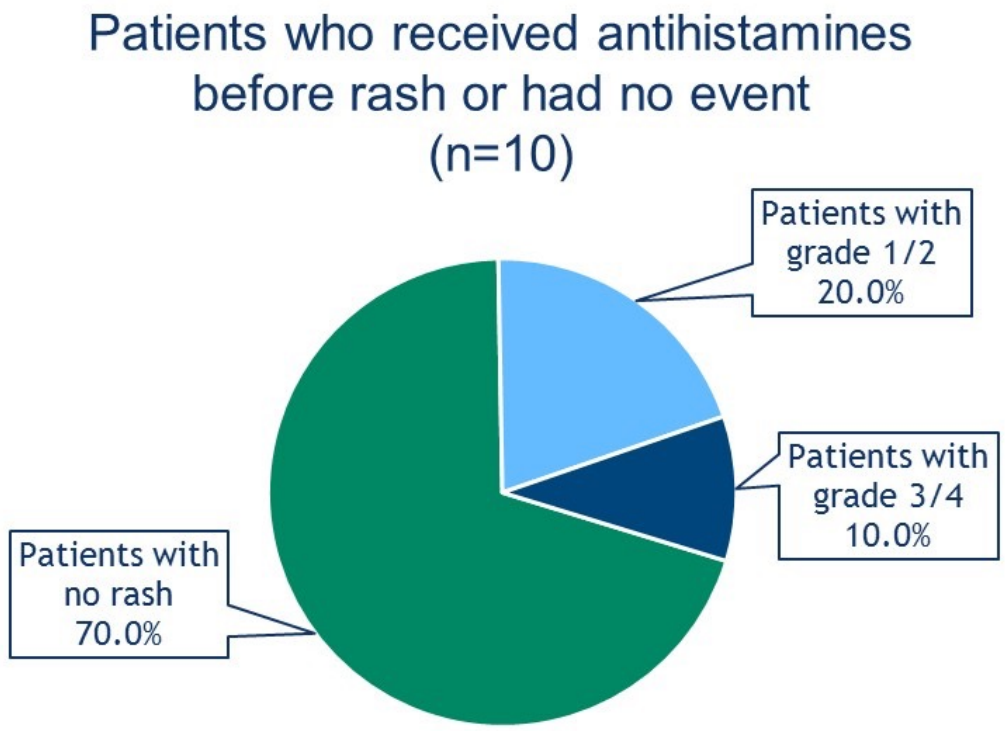
SOLAR-1: OS in Patients with Advanced BC with a PIK3CA Mutation



André F et al. *Ann Oncol* 2021;32(2):208-17.

BYLieve: Incidence of Rash with and without Prophylactic Antihistamines





Rugo HS et al. ASCO 2020;Abstract 1006.

RTP RESEARCH TO PRACTICE

Data + Perspectives: Clinical Investigators Discuss the Current and Future Management of Non-Hodgkin Lymphoma

A Virtual CME Satellite Symposium Series in Conjunction with the Society of Hematologic Oncology 2021 Annual Meeting

Tuesday, August 31, 2021
7:00 PM – 8:00 PM ET

Faculty

Andrew M Evens, DO, MSc
Ian W Flinn, MD, PhD
Gilles Salles, MD, PhD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.