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

Breast Cancer

Thursday, January 6, 2022
5:00 PM – 6:00 PM ET

Faculty

Harold J Burstein, MD, PhD
Professor Peter Schmid, FRCP, MD, PhD

Moderator

Neil Love, MD

RTP Year in Review 2022

YiR Breast Cancer Faculty

Harold J Burstein, MD, PhD
Institute Physician, Dana-Farber Cancer Institute
Professor of Medicine, Harvard Medical School
Boston, Massachusetts

Professor Peter Schmid, FRCP, MD, PhD
Centre Lead
Centre for Experimental Cancer Medicine
Barts Cancer Institute
London, United Kingdom

Commercial Support

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Dr Love — Disclosures

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Dr Burstein — Disclosures

No relevant conflicts of interest to disclose.

Prof Schmid — Disclosures

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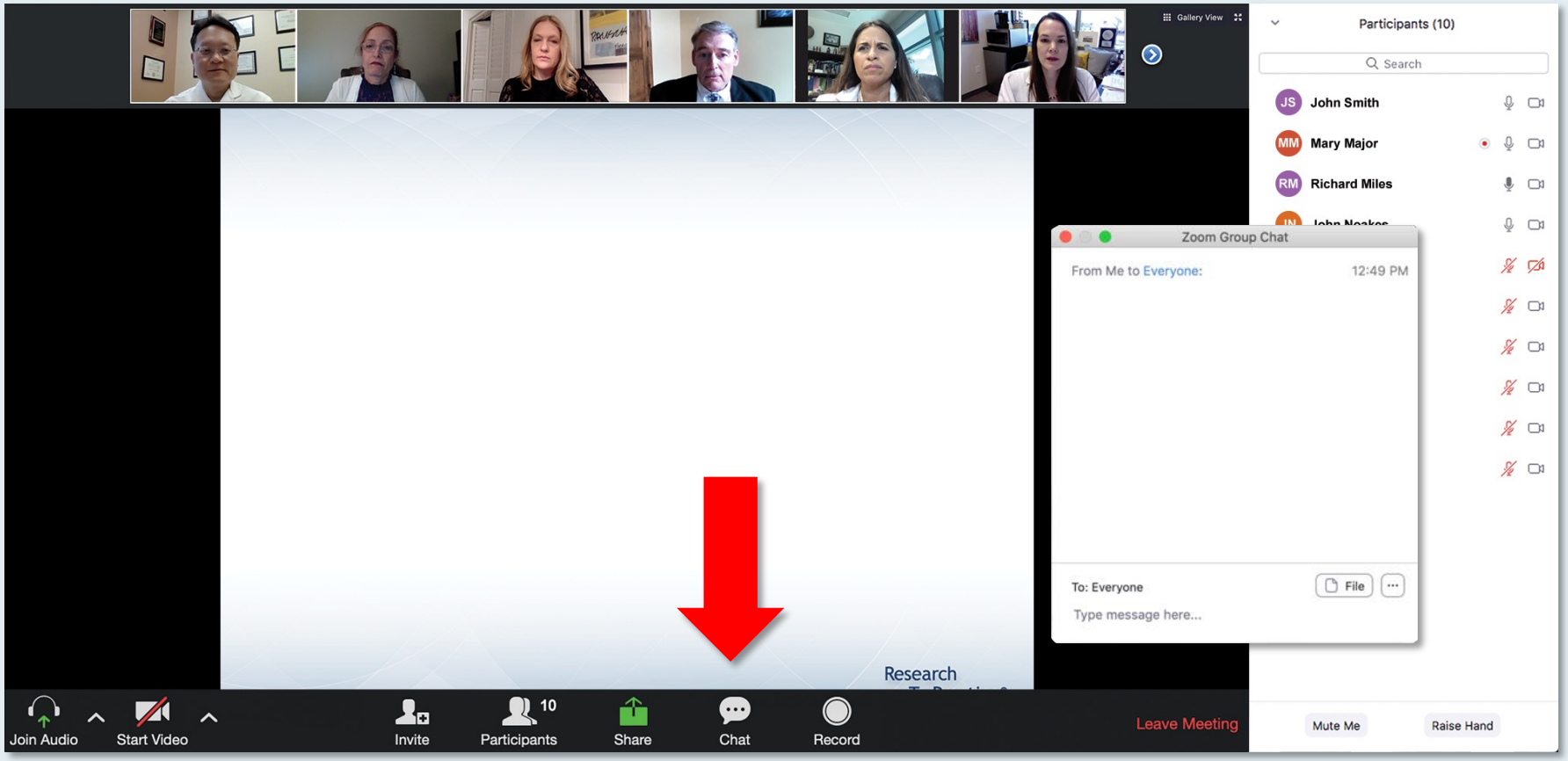
We Encourage Clinicians in Practice to Submit Questions



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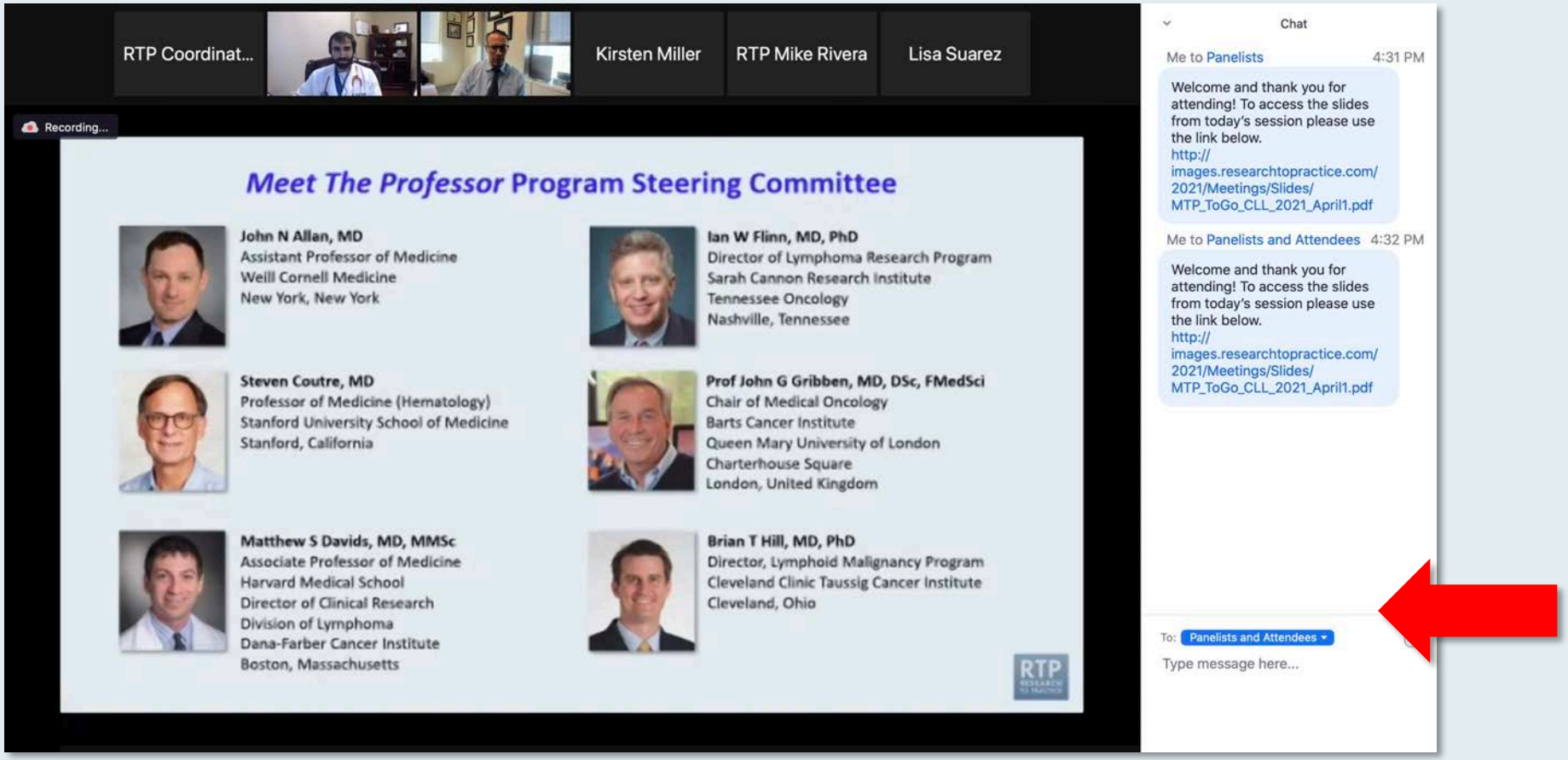

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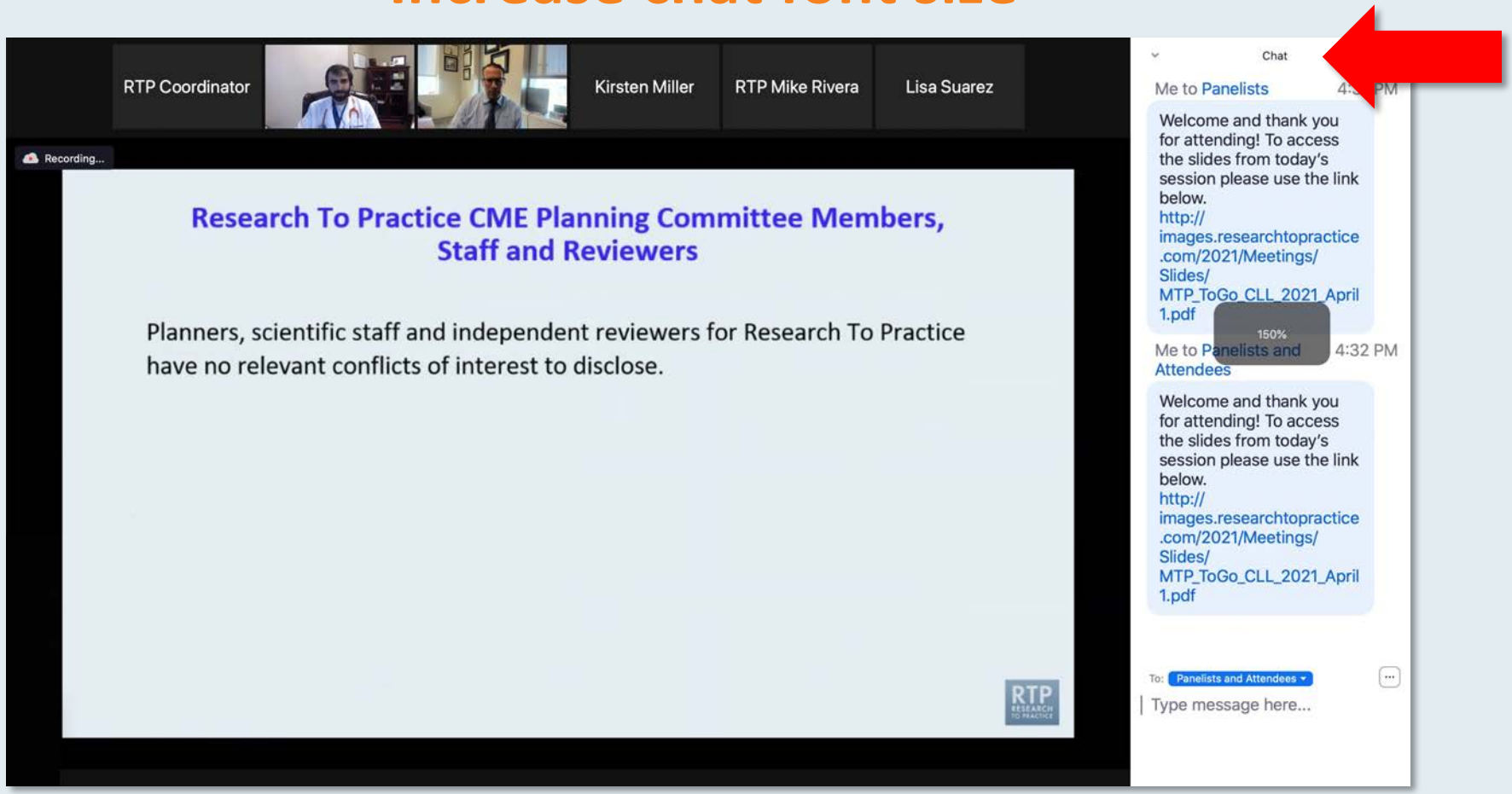

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ONCOLOGY TODAY

WITH DR NEIL LOVE

Management of HER2-Low Breast Cancer

DR IAN KROP

DANA-FARBER CANCER INSTITUTE

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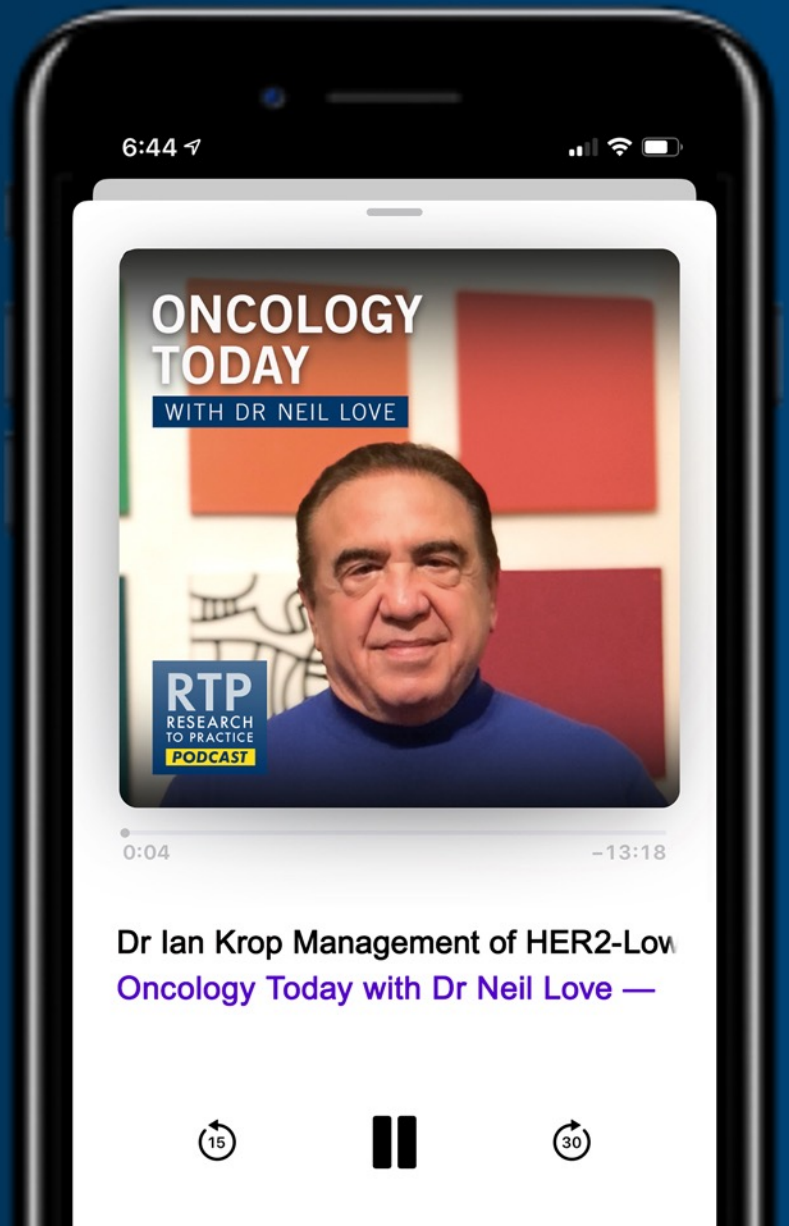

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Targeted Therapy for Non-Small Cell Lung Cancer

Tuesday, January 11, 2022
5:00 PM – 6:00 PM ET

Faculty

John V Heymach, MD, PhD
Zofia Piotrowska, MD, MHS

Moderator

Neil Love, MD

RTP Year in Review 2022

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with HER2-Positive Breast Cancer

Wednesday, January 12, 2022
6:00 PM – 7:00 PM ET

Faculty

Tiffany A Traina, MD

Moderator

Neil Love, MD

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Immunotherapy and Other Nontargeted Approaches for Lung Cancer

Thursday, January 13, 2022
5:00 PM – 6:00 PM ET

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Corey J Langer, MD

Anne S Tsao, MD, MBA

Moderator

Neil Love, MD

RTP Year in Review 2022

Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Colorectal Cancer (Part 1 of a 3-Part Series)

Wednesday, January 19, 2022
10:15 PM – 11:45 PM ET

Faculty

Cathy Eng, MD
Christopher Lieu, MD
Alan P Venook, MD

Moderator

Kristen K Ciombor, MD, MSCI

RTP RESEARCH TO PRACTICE

Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Gastroesophageal Cancers (Part 2 of a 3-Part Series)

Thursday, January 20, 2022
9:15 PM – 10:45 PM ET

Faculty

Yelena Y Janjigian, MD
Eric Van Cutsem, MD, PhD
Harry H Yoon, MD

Moderator

Samuel J Klempner, MD

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Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Hepatobiliary Cancers (Part 3 of a 3-Part Series)

Friday, January 21, 2022
9:15 PM – 10:45 PM ET

Faculty

Ghassan Abou-Alfa, MD, MBA
Richard S Finn, MD
Robin K Kelley, MD

Moderator

Tanios Bekaii-Saab, MD

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Thank you for joining us!

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

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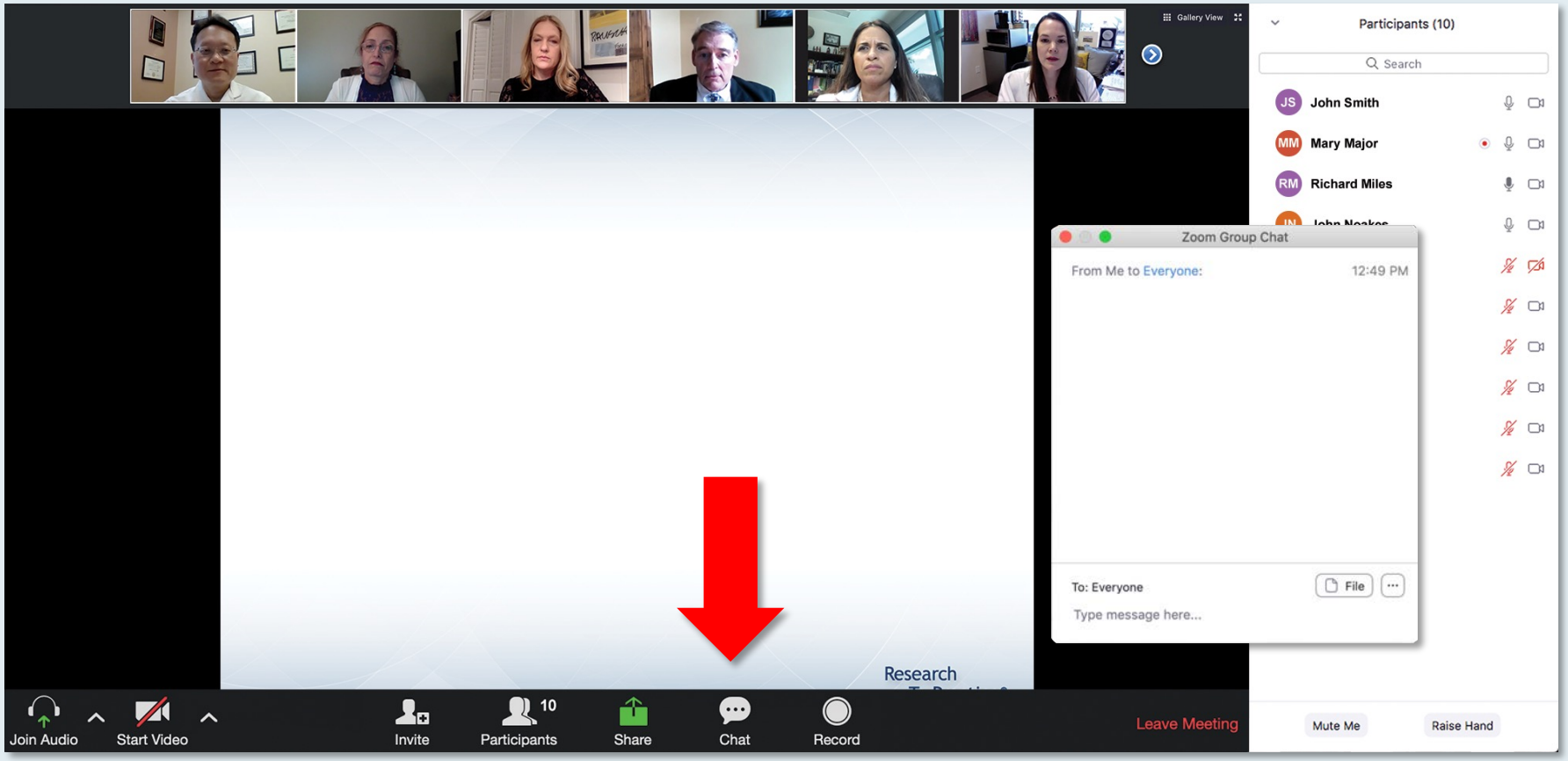

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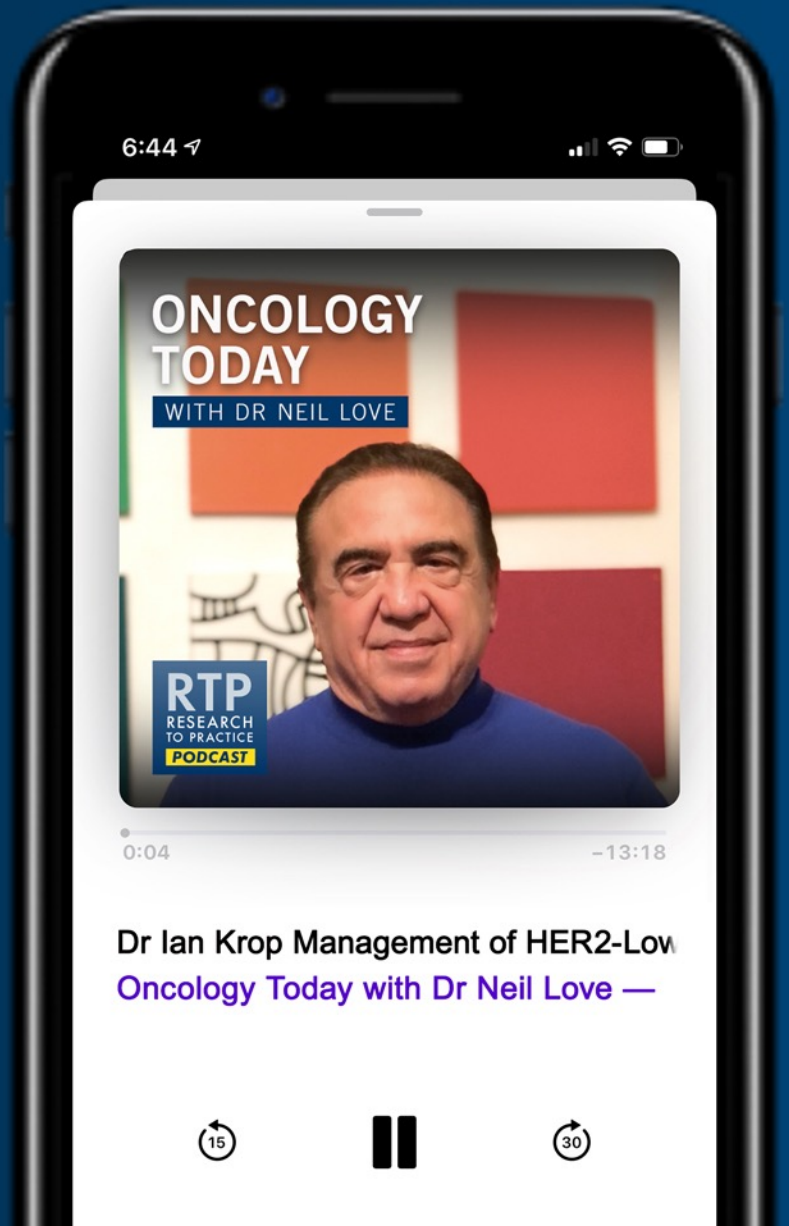

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RTP RESEARCH TO PRACTICE

Agenda

Module 1: HER2-Positive Breast Cancer

- DESTINY-Breast03
- HER2CLIMB
- SUMMIT, ExteNET, CONTROL

Module 2: Triple-Negative Breast Cancer

- ASCENT, TROPION-PanTumor01
- KEYNOTE-522
- OlympiA, NEOTALA

Module 3: ER-Positive Breast Cancer

- RxPONDER
- monarchE
- SOLAR-1, BYLieve
- EMERALD

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Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with HER2-Positive Breast Cancer

September 22, 2021

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Self-Assessment Questions

As second-line treatment for metastatic HER2-positive breast cancer, the overall response rate observed with T-DM1 was 34%. What is the response rate with trastuzumab deruxtecan in the same setting?

a. 35%
b. 50%
c. 60%
d. 70%
e. 80%
f. I'm not sure

Self-Assessment Questions

Outside of a clinical trial, what is your most likely third-line treatment for metastatic HER2-positive breast cancer after first-line taxane/pertuzumab/trastuzumab and second-line trastuzumab deruxtecan?

Objective response rates have been observed with trastuzumab deruxtecan in patients with IHC 0, FISH-negative breast cancer.

a. Agree
b. Disagree
c. I'm not sure

Self-Assessment Questions

Have you administered adjuvant endocrine therapy in combination with anti-HER2 treatment without chemotherapy in older patients or those with comorbidities?

a. Yes, frequently
b. Yes, occasionally
c. No

The drug-to-antibody ratio of trastuzumab deruxtecan is approximately double that of T-DM1.

a. Agree
b. Disagree
c. I'm not sure

Self-Assessment Questions

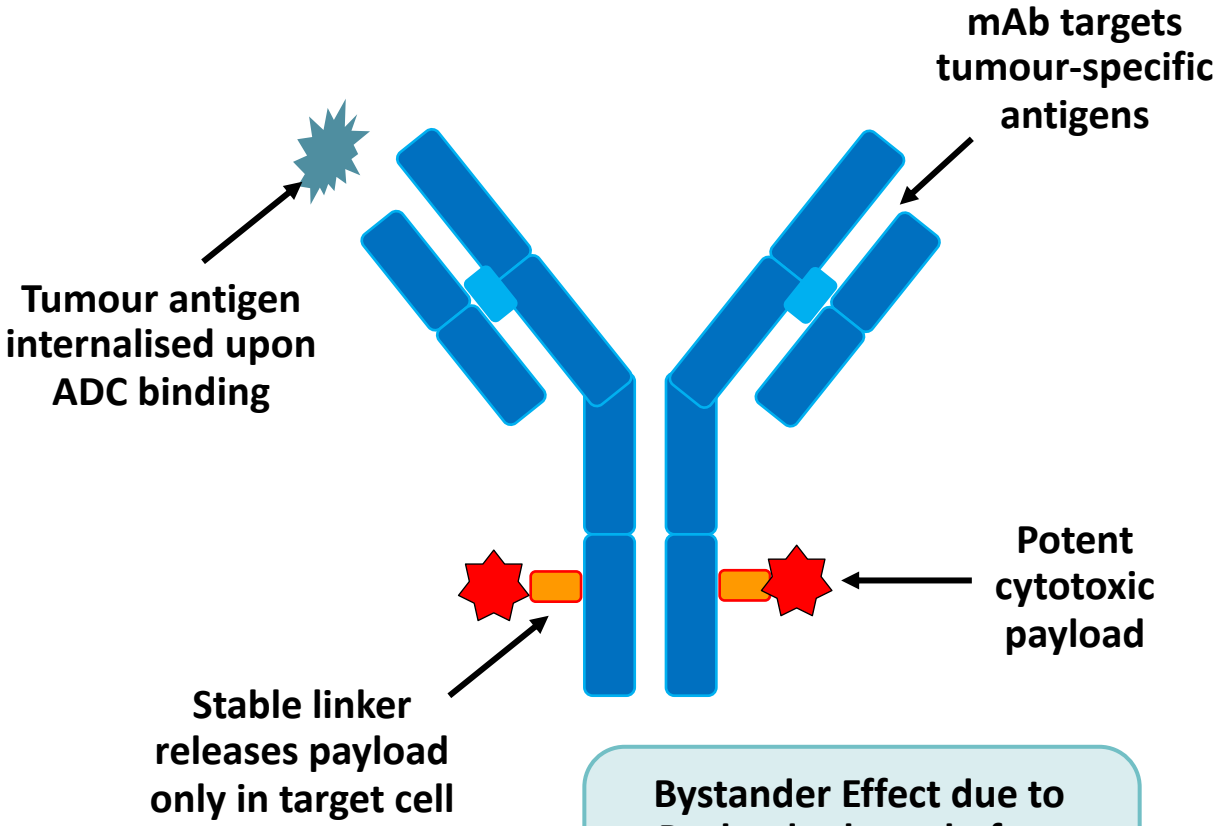
The use of postadjuvant neratinib in patients with HER2-positive, ER/PR-positive tumors was associated with a reduced incidence of brain metastases.

a. Agree
b. Disagree
c. I'm not sure

With dose-escalation and preemptive antidiarrheal medications, most patients are able to tolerate postadjuvant neratinib.

a. Agree
b. Disagree
c. I'm not sure

HER2-targeting Antibody Drug Conjugates (ADCs)

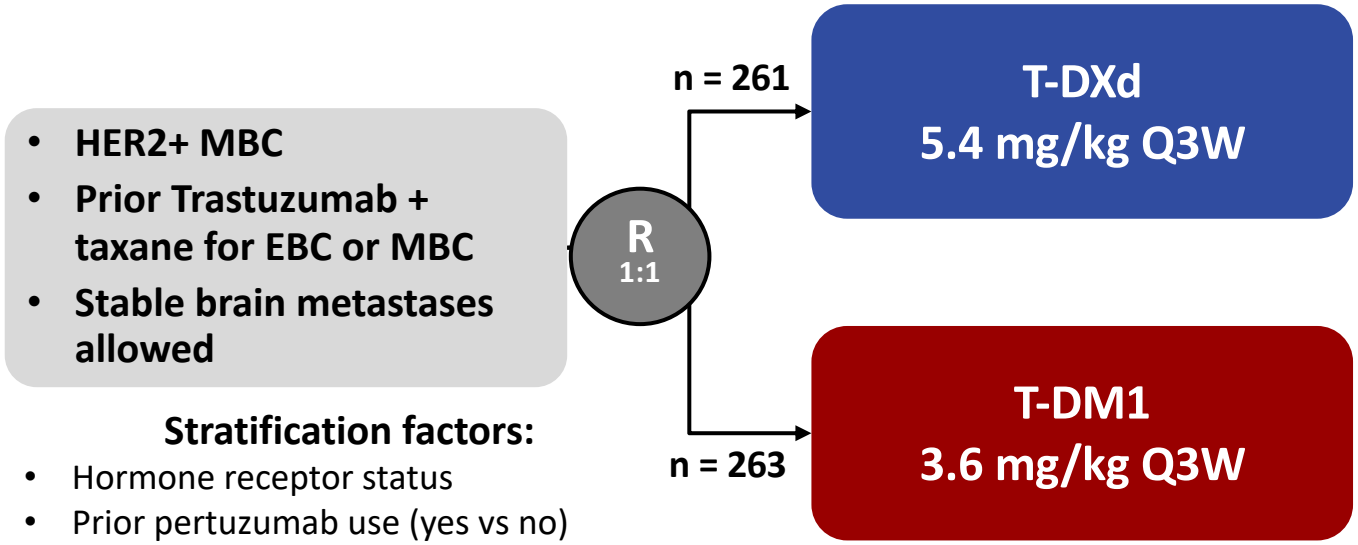


ADC Attributes	T-DM1[3-5]	T-DXd[1-4,a]
Payload MoA	Anti-microtubule	Topoisomerase I inhibitor
Drug-to-antibody ratio	~3.5:1	~8:1
Tumor-selective cleavable linker?	No	Yes
Evidence of bystander anti-tumor effect?	No	Yes

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

Trastuzumab-Deruxtecan (T-DXd) in HER2+ MBC

Destiny-Breast03 Trial



Primary endpoint: PFS (BICR)

Key Secondary endpoint: OS

Stratification factors:

- Hormone receptor status
- Prior pertuzumab use (yes vs no)
- Visceral disease(yes vs no)

Study Population:

- **ER+ 51%, HR- 49%**
- **Brain metastases, 22%**
- **Visceral disease, 70%**
- **1L, 10%; 2L, 39%, 3L+, 51%**
- **Pertuzumab, 61%; HER2 TKI, 15%**

Interim analysis for PFS (data cutoff: May 21, 2021)

- Efficacy boundary for superiority: $P < 0.000204$ (245 events)
- IDMC recommendation to unblind study (July 30, 2021)

Interim analysis for OS: boundary for efficacy: $P < 0.000265$ (86 events)

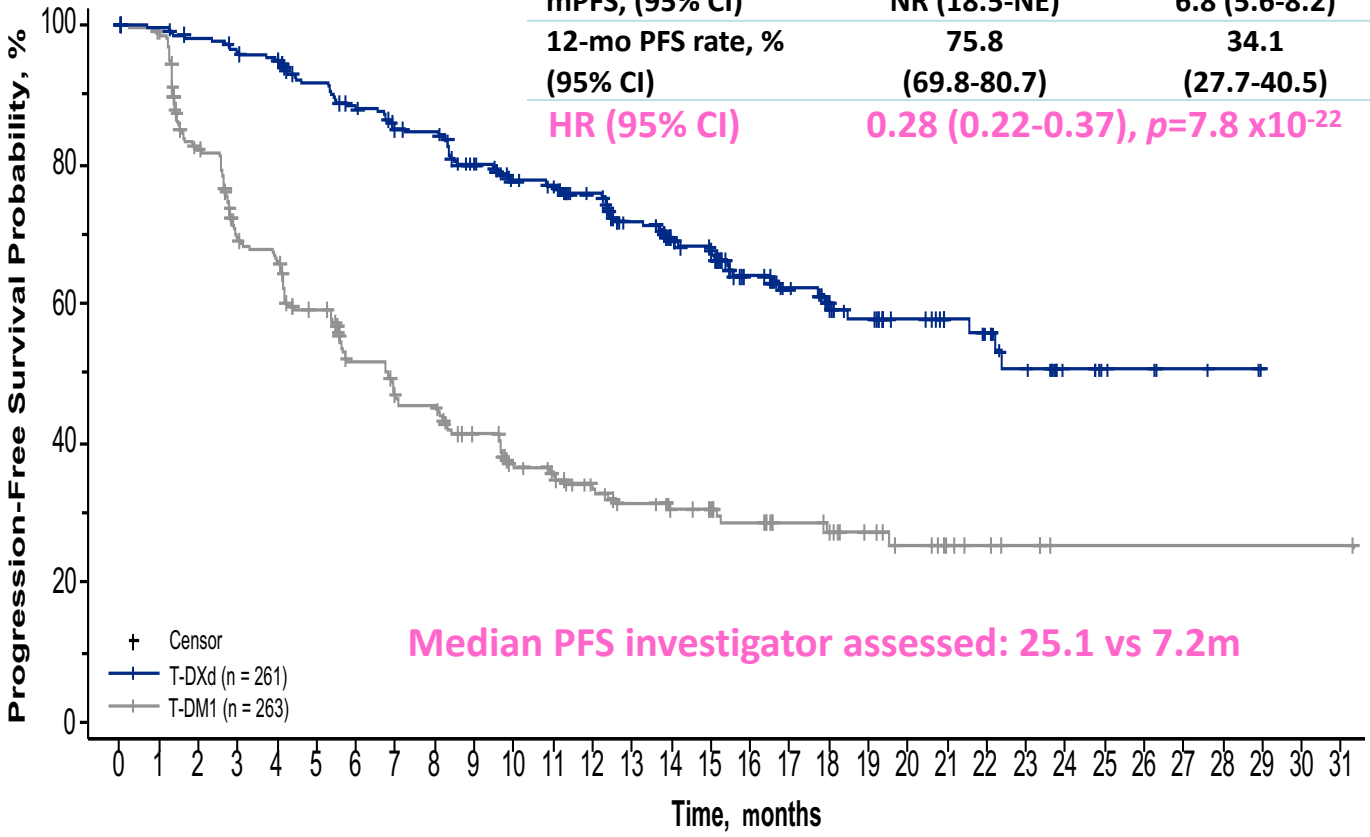
Cortes, ESMO 2021

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

Destiny-Breast03: Progression-free Survival

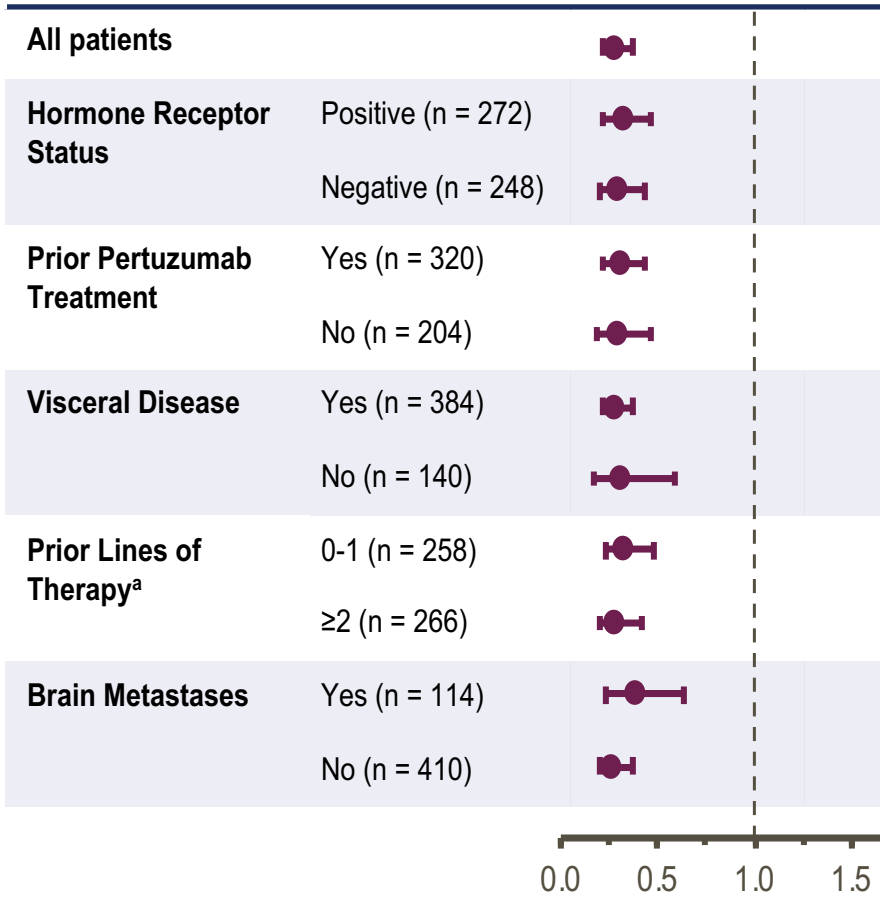
Primary Endpoint: PFS by BICR

	T-DXd	T-DM1
mPFS, (95% CI)	NR (18.5-NE)	6.8 (5.6-8.2)
12-mo PFS rate, % (95% CI)	75.8 (69.8-80.7)	34.1 (27.7-40.5)
HR (95% CI)	0.28 (0.22-0.37), p=7.8 x10^{-22}	



Median PFS investigator assessed: 25.1 vs 7.2m

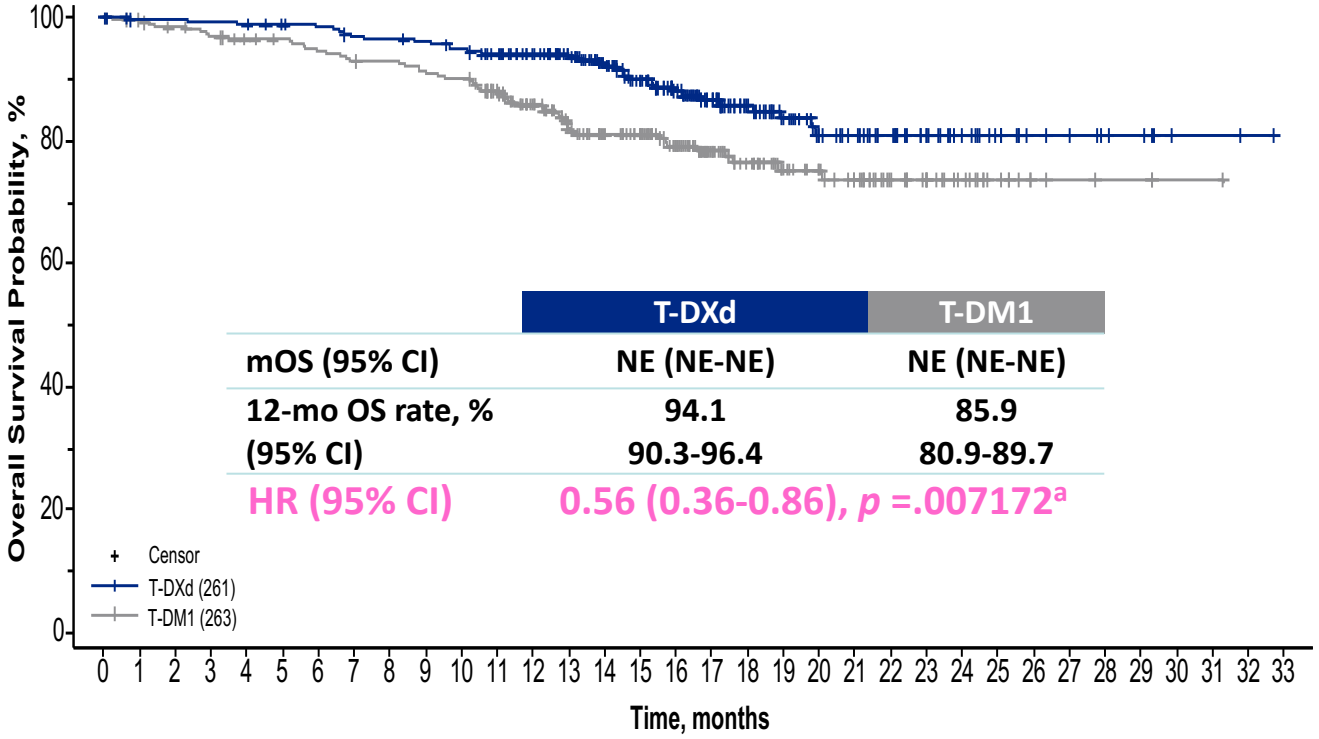
PFS in Subgroups



Courtesy of Professor Peter Schmid, FRCP, MD, PhD

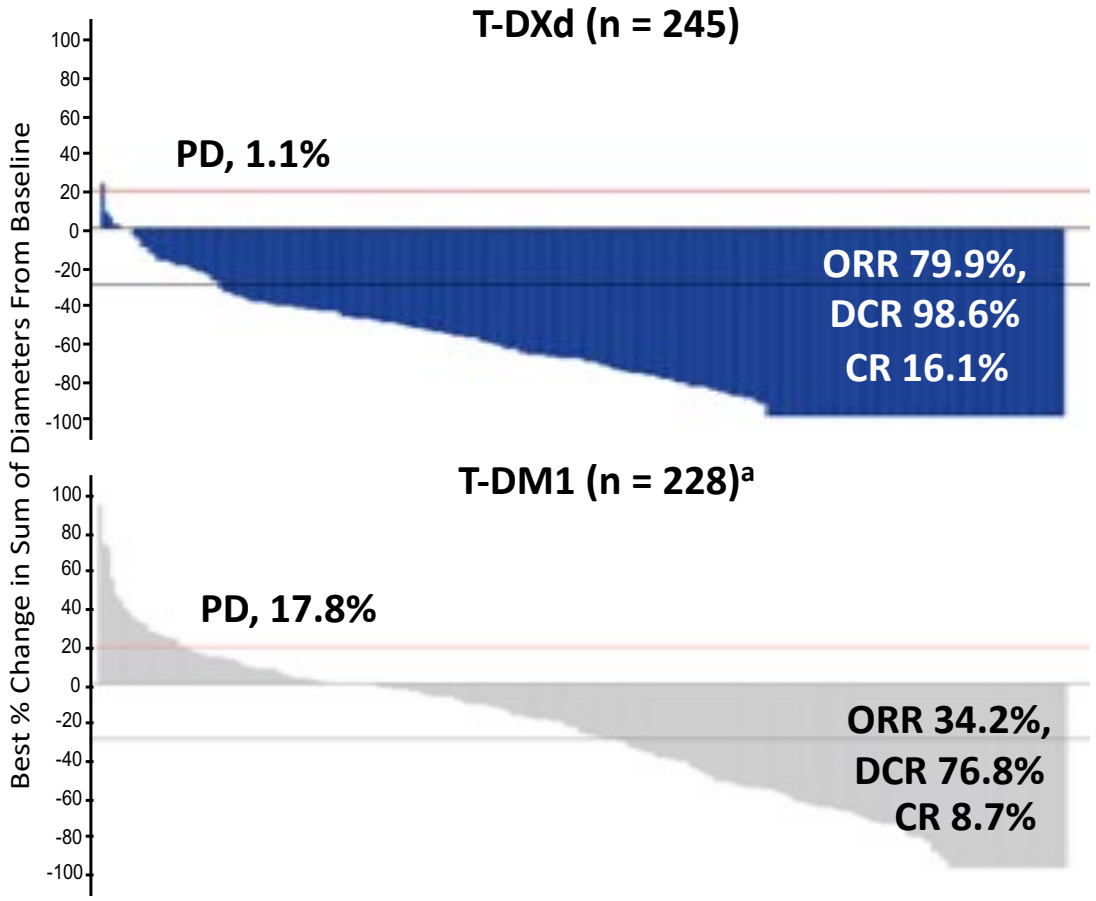
Destiny-Breast03: Overall Survival & Response

Overall Survival



	T-DXd	T-DM1
mOS (95% CI)	NE (NE-NE)	NE (NE-NE)
12-mo OS rate, % (95% CI)	94.1 (90.3-96.4)	85.9 (80.9-89.7)
HR (95% CI)	0.56 (0.36-0.86), *p* =.007172[a]	

Response Rate



Cortes, ESMO 2021

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

DESTINY-Breast03: PFS and Overall Response Rate (ORR) with T-DXd versus T-DM1 by Subgroup

	PFS by BICR, HR (95% CI)	Absolute ORR difference T-DXd, T-DM1 (95% CI)
All patients (N = 524)	0.28 (0.22-0.37)	45.5 (37.6-53.4)
Hormone receptor		
Positive (n = 272)	0.32 (0.22-0.46)	47.3 (36.1-58.4)
Negative (n = 248)	0.30 (0.20-0.44)	43.2 (31.5-55.0)
Prior pertuzumab		
Yes (n = 320)	0.31 (0.22-0.43)	46.7 (36.5-56.9)
No (n = 204)	0.30 (0.19-0.47)	43.6 (30.5-56.7)
Prior lines of therapy		
0-1 (n = 258)	0.33 (0.23-0.48)	39.3 (27.3-51.2)
≥2 (n = 266)	0.28 (0.19-0.41)	51.6 (40.9-62.4)
Visceral disease		
Yes (n = 384)	0.28 (0.21-0.38)	48.3 (39.1-57.6)
No (n = 140)	0.32 (0.17-0.58)	39.1 (23.6-54.6)
Brain metastases at baseline		
Yes (n = 82)	0.25 (0.13-0.45)	46.9 (25.6-68.3)
No (n = 442)	0.30 (0.22-0.40)	45.5 (36.9-54.1)

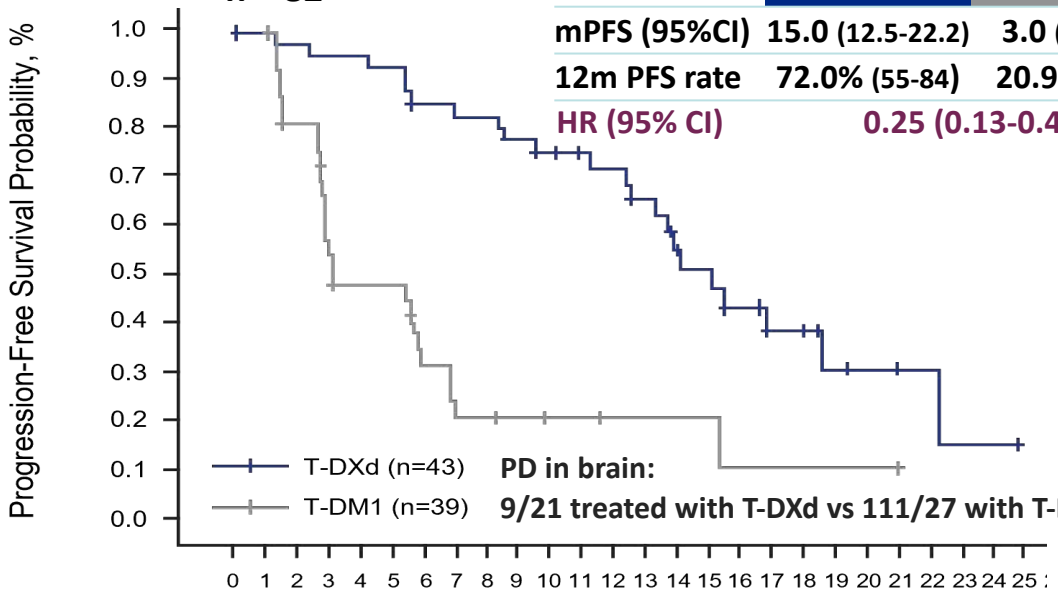
Hurvitz S et al. SABCS 2021;Abstract GS3-01.

Efficacy of T-DXd and Tucatinib against brain metastases

T-DXd (Destiny Breast03): Brain Metastases at Baseline

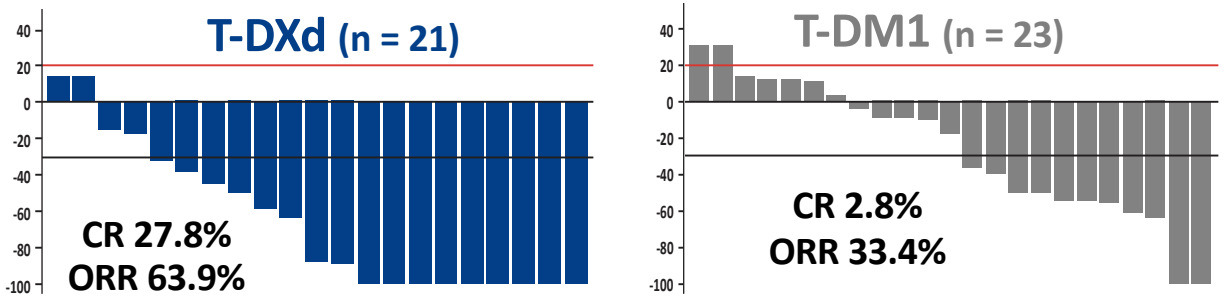
n = 82

	T-DXd	T-DM1
mPFS (95%CI)	15.0 (12.5-22.2)	3.0 (2.8-5.8)
12m PFS rate	72.0% (55-84)	20.9% (9-37)
HR (95% CI)	0.25 (0.13-0.45)	



PD in brain:
9/21 treated with T-DXd vs 111/27 with T-DM1

T-DXd (Destiny Breast03): Intracranial response(BICR)

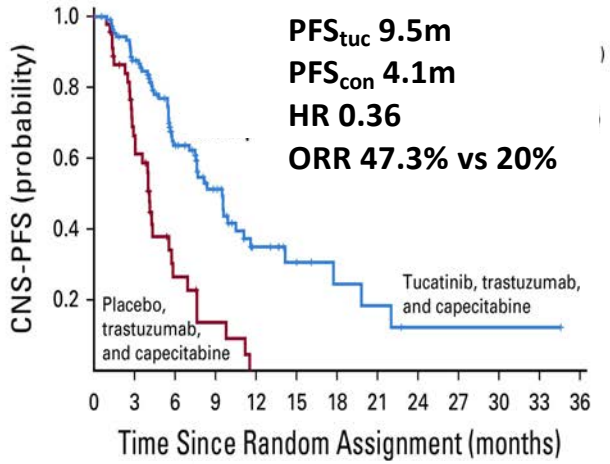


Tucatinib (HER2Climb): Brain Metastases Subgroup

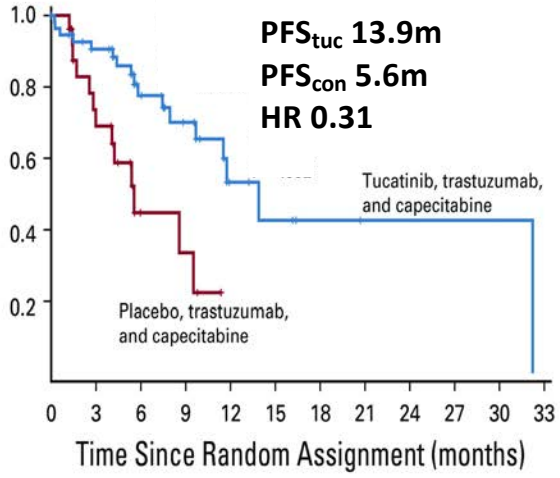
n = 291 (48% of ITT)

Stable: Treated & stable (40.2%),
Active: Treated & progressing (37.1%), untreated (22.7%).

Active BM



Stable BM



Courtesy of Professor Peter Schmid, FRCP, MD, PhD

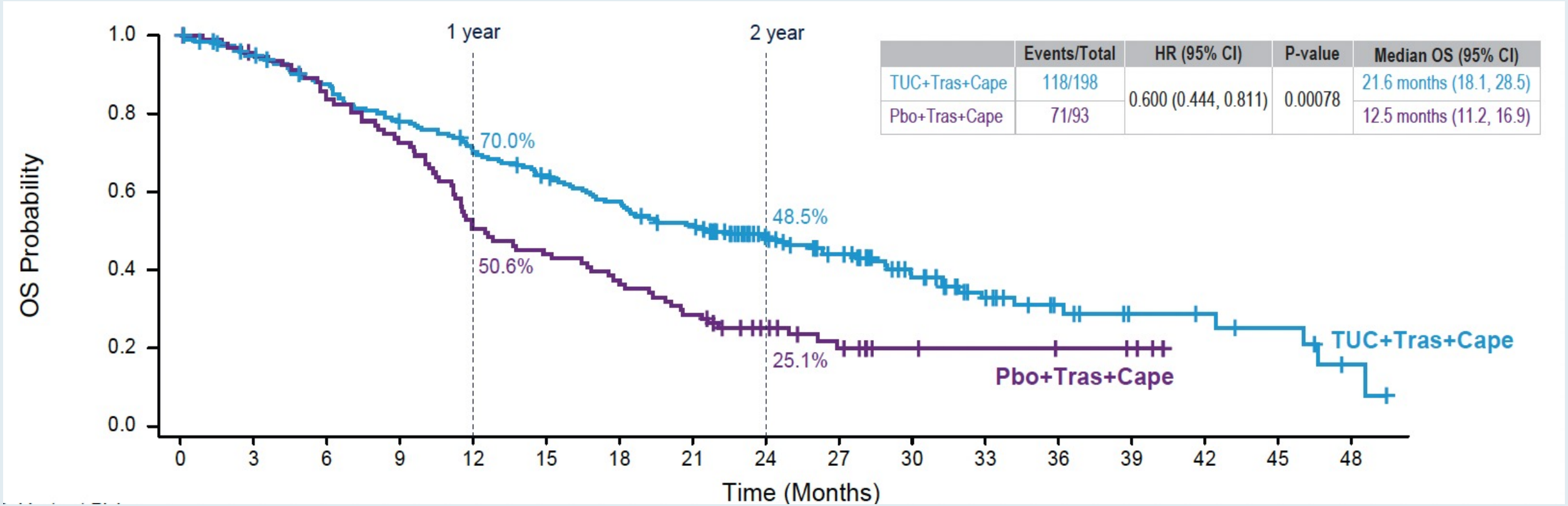
Hurvitz, SABCS 2021, Lin, JCO 2021

Updated Results of Tucatinib vs Placebo Added to Trastuzumab and Capecitabine for Patients with Previously Treated HER2+ Metastatic Breast Cancer with Brain Metastases (HER2CLIMB)

Lin NU et al.

SABCS 2021;Abstract PD4-04.

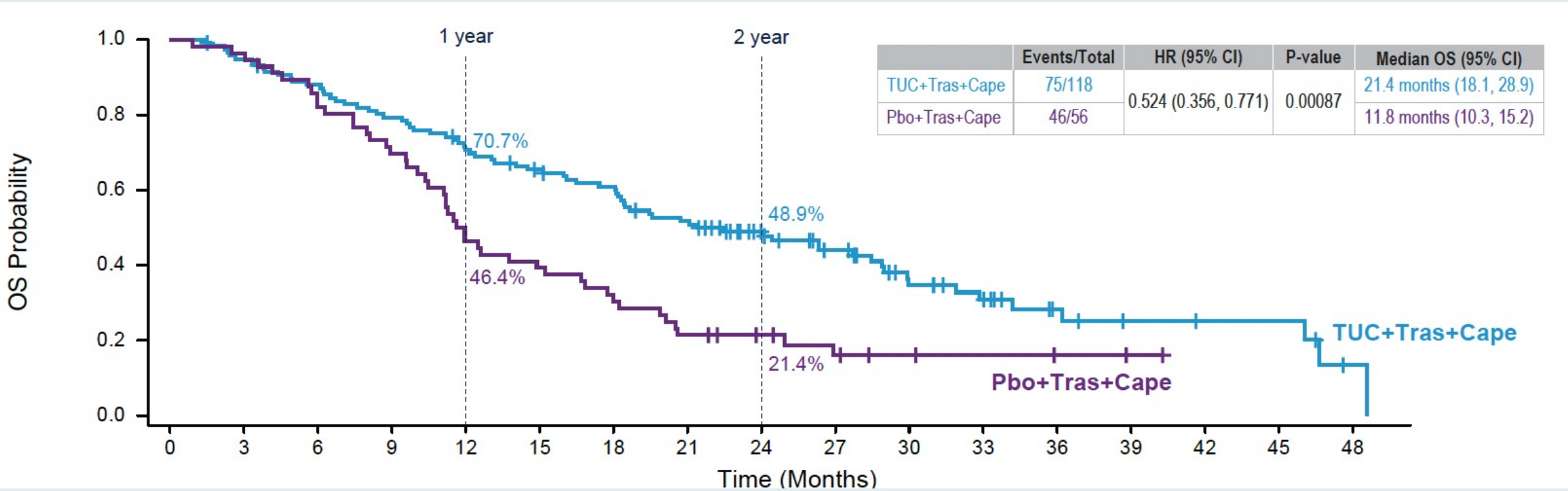
HER2CLIMB: OS for All Patients with Brain Metastases



	Events/Total	HR (95% CI)	P-value	Median OS (95% CI)
TUC+Tras+Cape	118/198	0.600 (0.444, 0.811)	0.00078	21.6 months (18.1, 28.5)
Pbo+Tras+Cape	71/93			12.5 months (11.2, 16.9)

Lin NU et al. SABCS 2021;Abstract PD4-04.

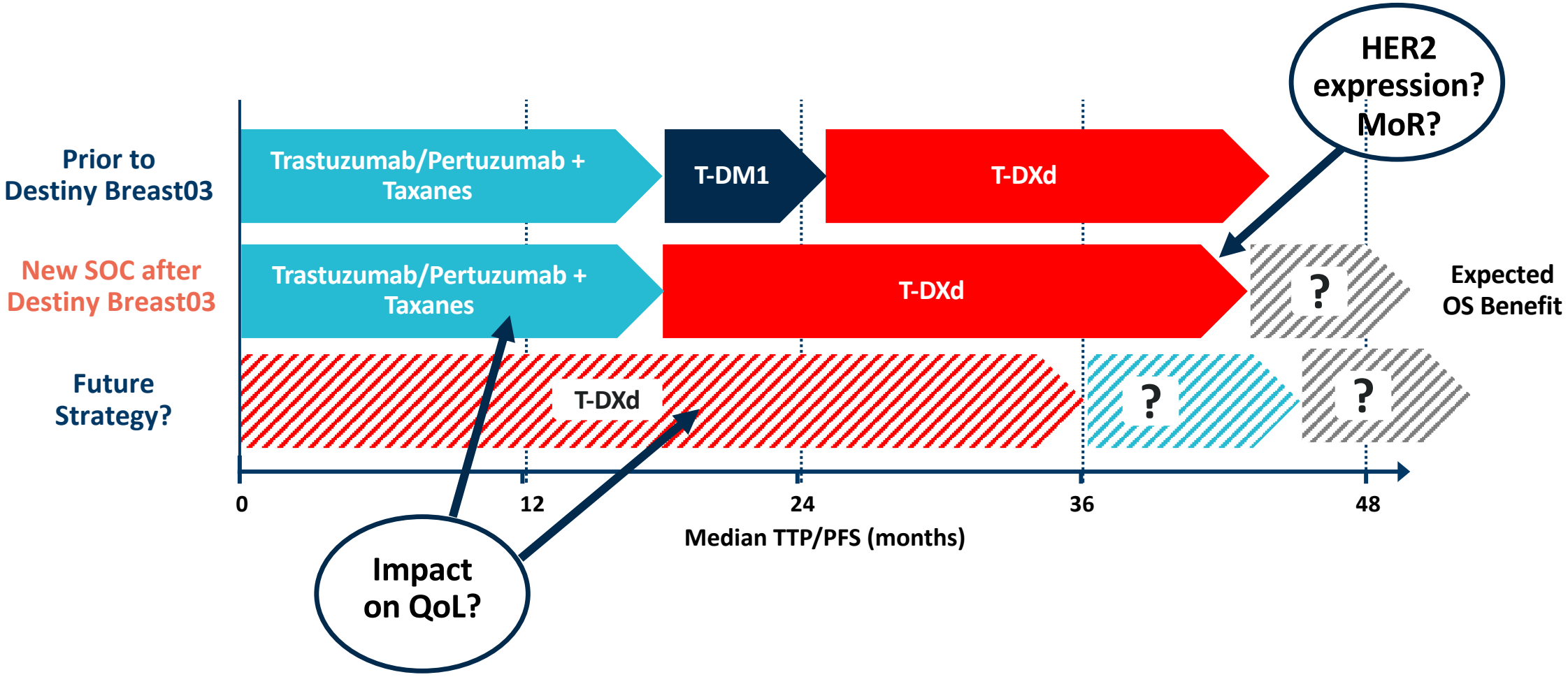
HER2CLIMB: OS for Patients with Active Brain Metastases



	Events/Total	HR (95% CI)	P-value	Median OS (95% CI)
TUC+Tras+Cape	75/118	0.524 (0.356, 0.771)	0.00087	21.4 months (18.1, 28.9)
Pbo+Tras+Cape	46/56			11.8 months (10.3, 15.2)

Lin NU et al. SABCS 2021;Abstract PD4-04.

Evolution of HER2-targeted therapy for HER2 MBC



Courtesy of Professor Peter Schmid, FRCP, MD, PhD

San Antonio Breast Cancer Symposium®, December 7-10, 2021

Abstract GS4-10

Neratinib + fulvestrant + trastuzumab for hormone-receptor positive, *HER2*-mutant metastatic breast cancer, and neratinib + trastuzumab for *HER2*-mutant metastatic triple-negative disease: latest updates from the SUMMIT trial

Komal Jhaveri,[1] Haeseong Park,[2] James Waisman,[3] Jonathan W. Goldman,[4] Angel Guerrero-Zotano,[5] Valentina Boni,[6] Barbara Haley,[7] Ingrid A. Mayer,[8] Adam Brufsky,[9] Eddy Yang,[10] José A. García-Sáenz,[11] Francois-Clement Bidard,[12] John Crown,[13] Bo Zhang,[14] Aimee Frazier,[14] Irmina Diala,[14] Brian Barnett,[14] Lisa D Eli,[14] Hans Wildiers[15]

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SUMMIT: Neratinib, Fulvestrant and Trastuzumab for HR-Positive, HER2-Negative Metastatic Breast Cancer with a HER2 Mutation – All Patients

Characteristics	All N+F+T (n=33)	N+F (subset, prior CDK4/6i) (n=14)
Objective response (confirmed CR/PR)[a], n (%) CR PR	14 (42.4) 1 (3.0) 13 (39.4)	4 (28.6) 0 4 (28.6)
Best overall response (confirmed or unconfirmed PR or CR), n (%)	18 (54.5)	4 (28.6)
Median DOR[b], months (95% CI)	14.4 (6.4–NE)	NE
Clinical benefit[c], n (%)	17 (51.5)	5 (35.7)
Median PFS, months (95% CI)	7.0 (4.2–12.7)	2.9 (1.7–11.9)
Median duration of treatment, months (range)	6.5 (0.7–22.1)	3.7 (0.5–48.3)

Jhaveri K et al. SABCS 2021;Abstract GS4-10.

Improved Central Nervous System Outcomes in Patients with Early-Stage HER2-Positive Breast Cancer Who Receive Neratinib for the Recommended Duration: Findings from the Phase 3 ExteNET Trial

Holmes FH et al.

SABCS 2021;Abstract P2-13-21.

ExteNET: CNS-DFS and Cumulative Incidence of CNS Events

Population or subgroup	N		CNS-DFS rate at 5 years	
	Neratinib	Placebo	Difference (%)	Hazard ratio
Intent-to-treat population	1,420	1,420	+ 1.1	0.73
Completed therapy	872	1,420	+ 1.2	0.70
ER-positive ≤1 year	670	664	+ 2.7	0.41
Completed therapy	402	664	+ 3.2	0.27
ER-positive ≤1 year no pCR	131	164	+ 6.4	0.24
Completed therapy	92	164	+ 6.9	0.16

	First site of CNS recurrence at 5 years					
	N		Events (n)		Cumulative incidence of CNS recurrence	
Population or subgroup	Neratinib	Placebo	Neratinib	Placebo	Neratinib	Placebo
Intent-to-treat population	1,420	1,420	16	23	1.3	1.8
Completed therapy	872	1,420	12	23	1.4	1.8
ER-positive ≤1 year	670	664	4	12	0.7	2.1
Completed therapy	402	664	3	12	0.8	2.1

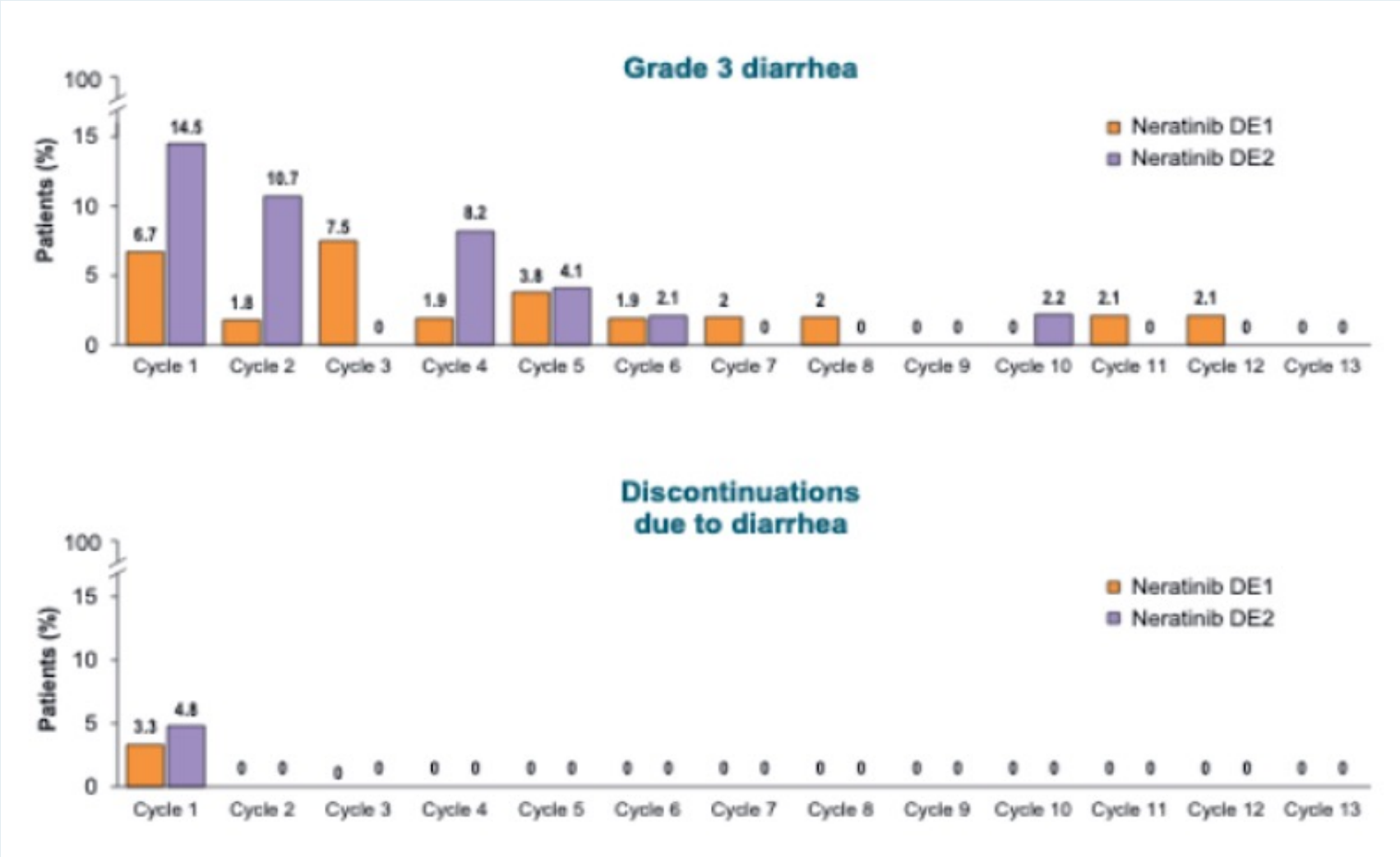
Holmes FH et al. SABCS 2021;Abstract P2-13-21.

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

Chan S et al.

SABCS 2021;Abstract P5-18-02.

CONTROL: Final Data for 2-Week (DE1) and 4-Week (DE2) Escalation Cohorts



Chan S et al. SABCS 2021;Abstract P5-18-02.

Agenda

Module 1: HER2-Positive Breast Cancer

- DESTINY-Breast03
- HER2CLIMB
- SUMMIT, ExteNET, CONTROL

Module 2: Triple-Negative Breast Cancer

- ASCENT, TROPION-PanTumor01
- KEYNOTE-522
- OlympiA, NEOTALA

Module 3: ER-Positive Breast Cancer

- RxPONDER
- monarchE
- SOLAR-1, BYLieve
- EMERALD

Self-Assessment Questions

Quality-of-life data from the OlympiA trial suggest a lack of significant adverse events with adjuvant olaparib.

a. Agree
b. Disagree
c. I'm not sure

The pCR rate with a neoadjuvant PARP inhibitor in a patient with a BRCA mutation is…

a. 10%
b. 20%
c. 50%
d. >50%
e. There are no data
f. I'm not sure

Self-Assessment Questions

Adjuvant olaparib is…

a. More effective in ER-positive breast cancer than TNBC
b. Less effective in ER-positive breast cancer than TNBC
c. Equally effective in both

In the KEYNOTE-522 trial a benefit with pembrolizumab was seen in all patients regardless of PD-L1 status.

a. Agree
b. Disagree
c. I'm not sure

Self-Assessment Questions

In general, what is your usual approach to a patient with Stage III or higher-risk Stage II TNBC?

a. KEYNOTE-522 regimen (neoadjuvant chemo/pembrolizumab → adjuvant pembrolizumab)
b. KEYNOTE-522 neoadjuvant but no adjuvant if pCR
c. Other

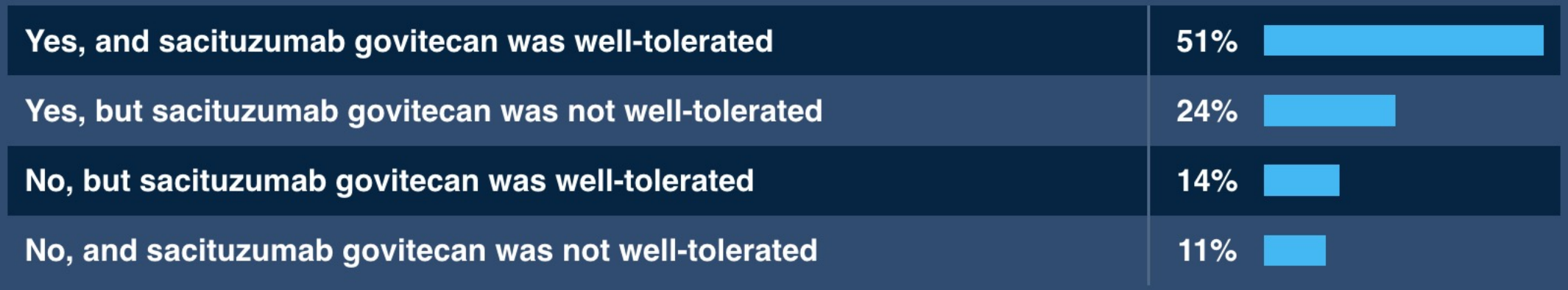
Questions About Sacituzumab Govitecan

What percent of patients benefit?

Is there a correlation between response and TROP-2 levels?

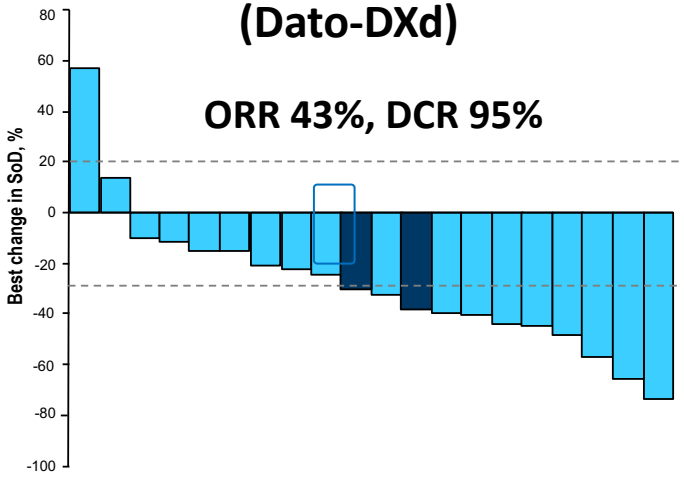
What are the tolerability issues?

(For physicians who have used sacituzumab govitecan for mTNBC) Think about the last patient in your practice with mTNBC to whom you administered sacituzumab govitecan for whom you have adequate follow-up. Did the patient derive antitumor benefit?



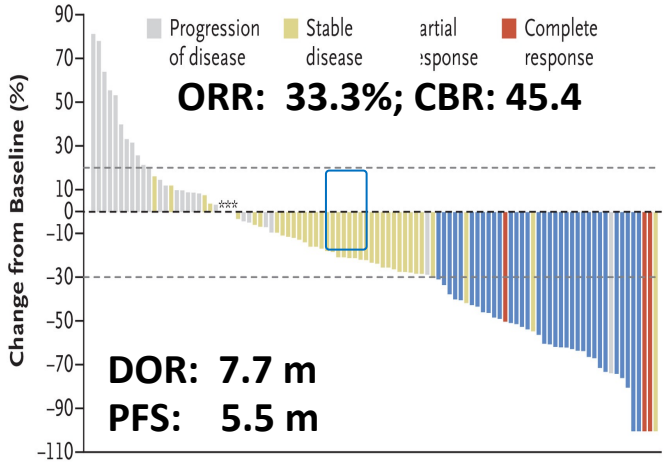
Targets for Antibody-Drug Conjugates in TNBC

Datopotamab Deruxtecan (Dato-DXd)



ORR 43%, DCR 95%

Sacituzumab



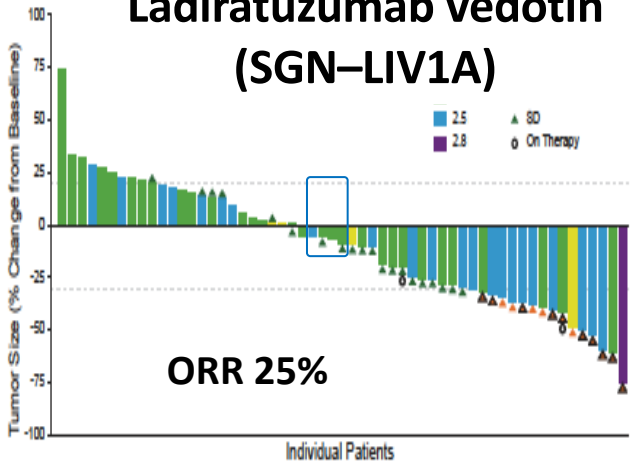
ORR: 33.3%; CBR: 45.4

DOR: 7.7 m
PFS: 5.5 m

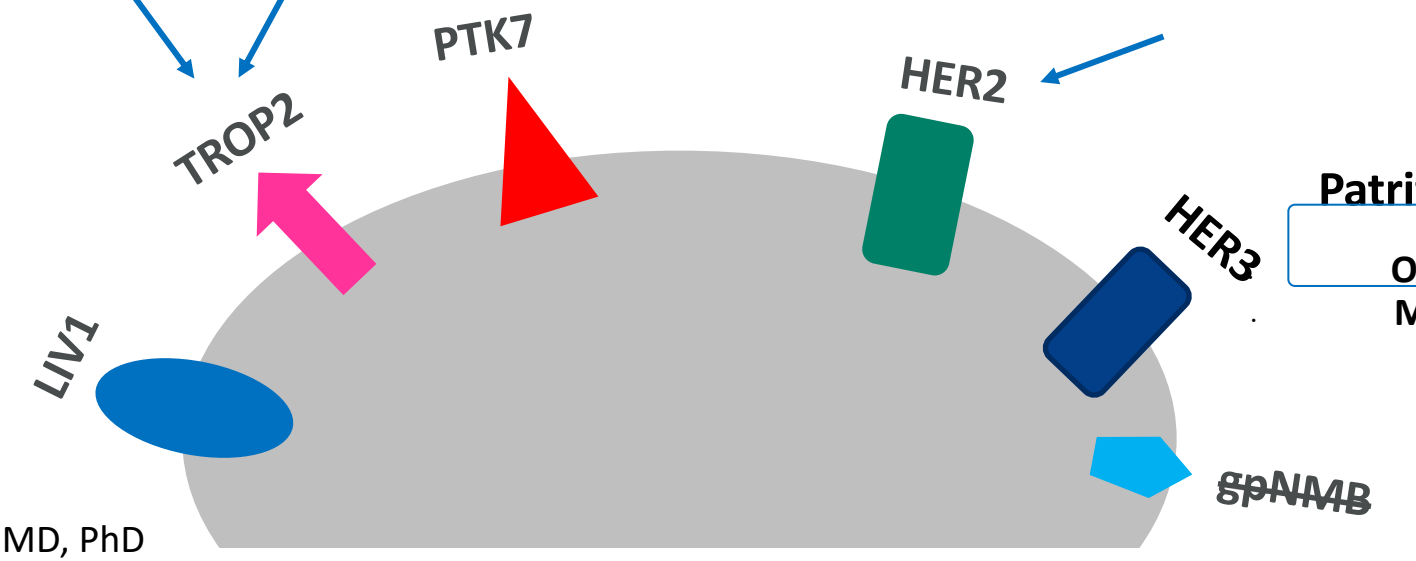
T-DXd

ORR 37%

Ladiratuzumab vedotin (SGN–LIV1A)



ORR 25%



Patritumab Deruxtecan

ORR 16.1%, SD 67.7%
Median PFS 5.5 mths

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

FDA Grants Regular Approval to Sacituzumab Govitecan for Triple-Negative Breast Cancer

Press Release: April 7, 2021

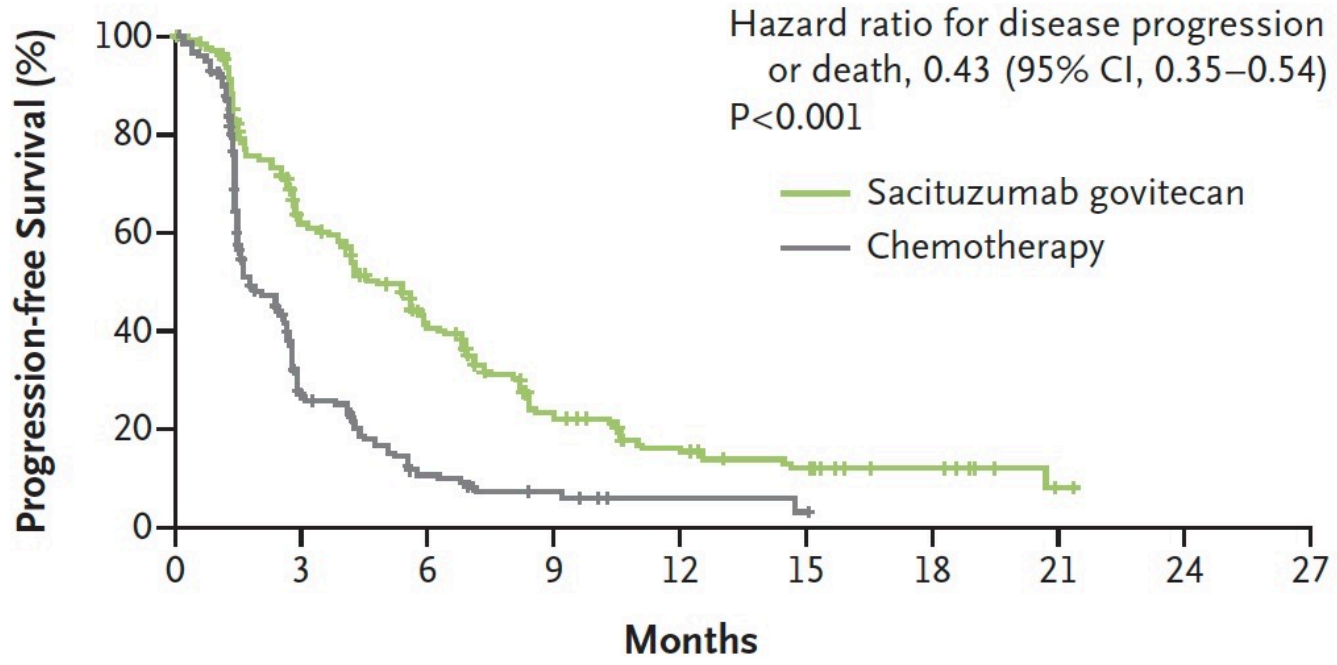
"The Food and Drug Administration granted regular approval to sacituzumab govitecan for patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Efficacy and safety were evaluated in a multicenter, open-label, randomized trial (ASCENT; NCT02574455) conducted in 529 patients with unresectable locally advanced or mTNBC who had relapsed after at least two prior chemotherapies, one of which could be in the neoadjuvant or adjuvant setting, if progression occurred within 12 months. Patients were randomized (1:1) to receive sacituzumab govitecan, 10 mg/kg as an intravenous infusion, on days 1 and 8 of a 21-day (n = 267) cycle or physician's choice of single agent chemotherapy (n = 262)."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-regular-approval-sacituzumab-govitecan-triple-negative-breast-cancer

ASCENT: PFS (Overall Population)

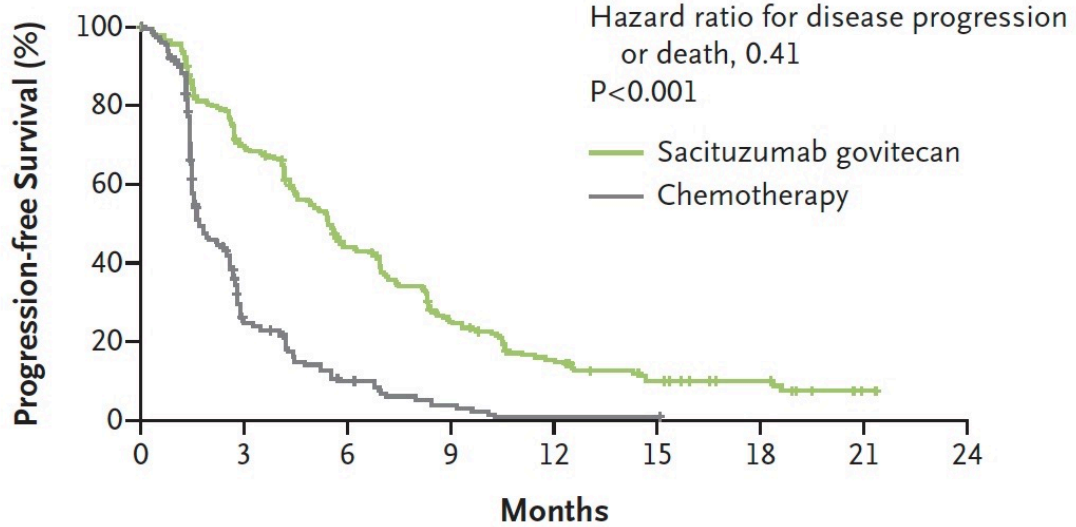
	No. of Patients	No. of Events	Median Progression-free Survival
			mo
Sacituzumab Govitecan	267	190	4.8
Chemotherapy	262	171	1.7



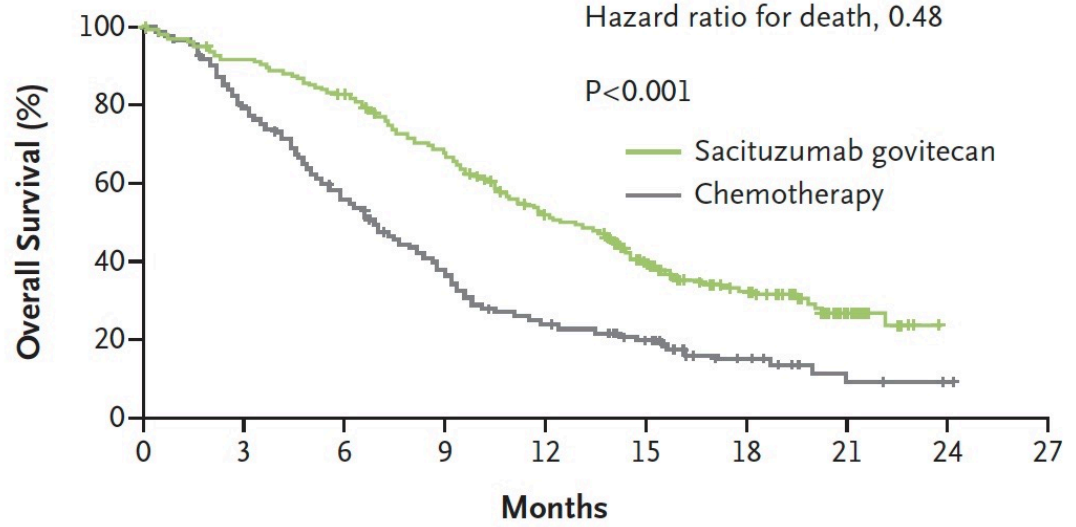
Bardia A et al. *N Engl J Med* 2021;384:1529-41.

ASCENT: PFS and OS Among Patients without Brain Metastases

	No. of Patients	No. of Events	Median Progression-free Survival
			mo
Sacituzumab Govitecan	235	166	5.6
Chemotherapy	233	150	1.7



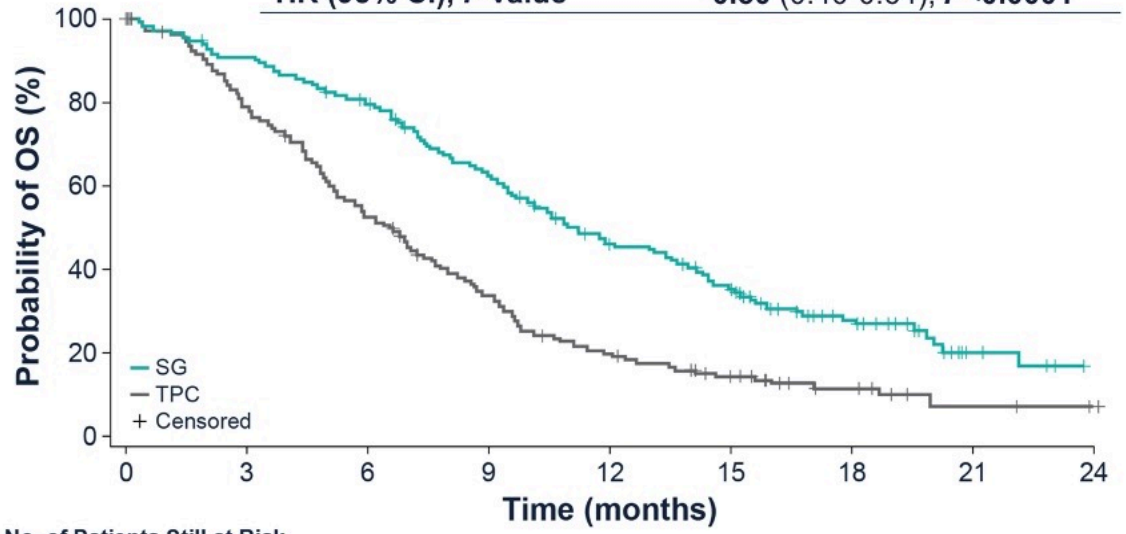
	No. of Patients	No. of Events	Median Overall Survival
			mo
Sacituzumab Govitecan	235	155	12.1
Chemotherapy	233	185	6.7



Bardia A et al. *N Engl J Med* 2021;384:1529-41.

ASCENT: OS for Young and Older Patients with mTNBC Treated with Sacituzumab Govitecan

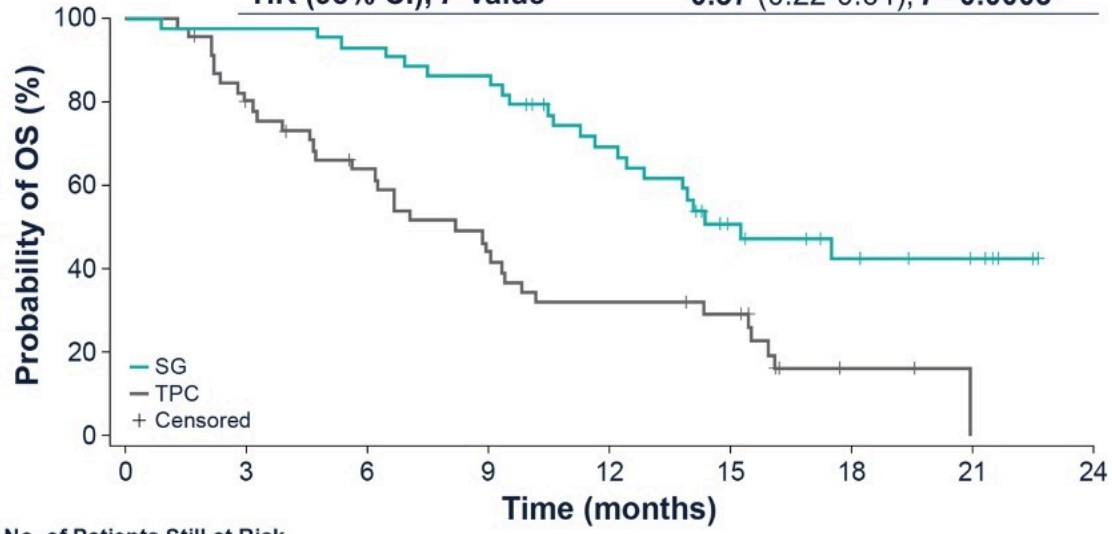
	<65 y	
	SG (n=191)	TPC (n=187)
No. of events	133	150
Median OS—mo (95% CI)	11.2 (9.9-13.4)	6.6 (5.3-7.4)
HR (95% CI), *P* value	**0.50** (0.40-0.64), ***P*<0.0001**	



No. of Patients Still at Risk

SG	191	185	177	171	163	155	149	135	123	115	102	89	80	77	68	56	40	32	28	22	14	7	6	1	0
TPC	187	168	157	138	125	106	91	77	66	56	42	37	32	28	25	19	14	11	9	5	3	3	3	2	1

	≥65 y	
	SG (n=44)	TPC (n=46)
No. of events	22	35
Median OS—mo (95% CI)	15.3 (12.4-NE)	8.2 (5.6-9.8)
HR (95% CI), *P* value	**0.37** (0.22-0.64), ***P*=0.0003**	



No. of Patients Still at Risk

SG	44	43	43	43	43	42	41	39	38	38	33	29	27	24	22	14	12	11	9	8	7	6	2	0
TPC	46	46	43	35	31	28	26	22	21	18	14	13	13	13	12	11	6	3	2	2	1	0	0	0

- In patients aged ≥65 years, improvement in median OS with SG vs TPC treatment was comparable with that of the overall population (12.1 vs 6.7 months)[1]

Kalinsky K et al. ASCO 2021;Abstract 1011.

ASCENT: Selected Adverse Events

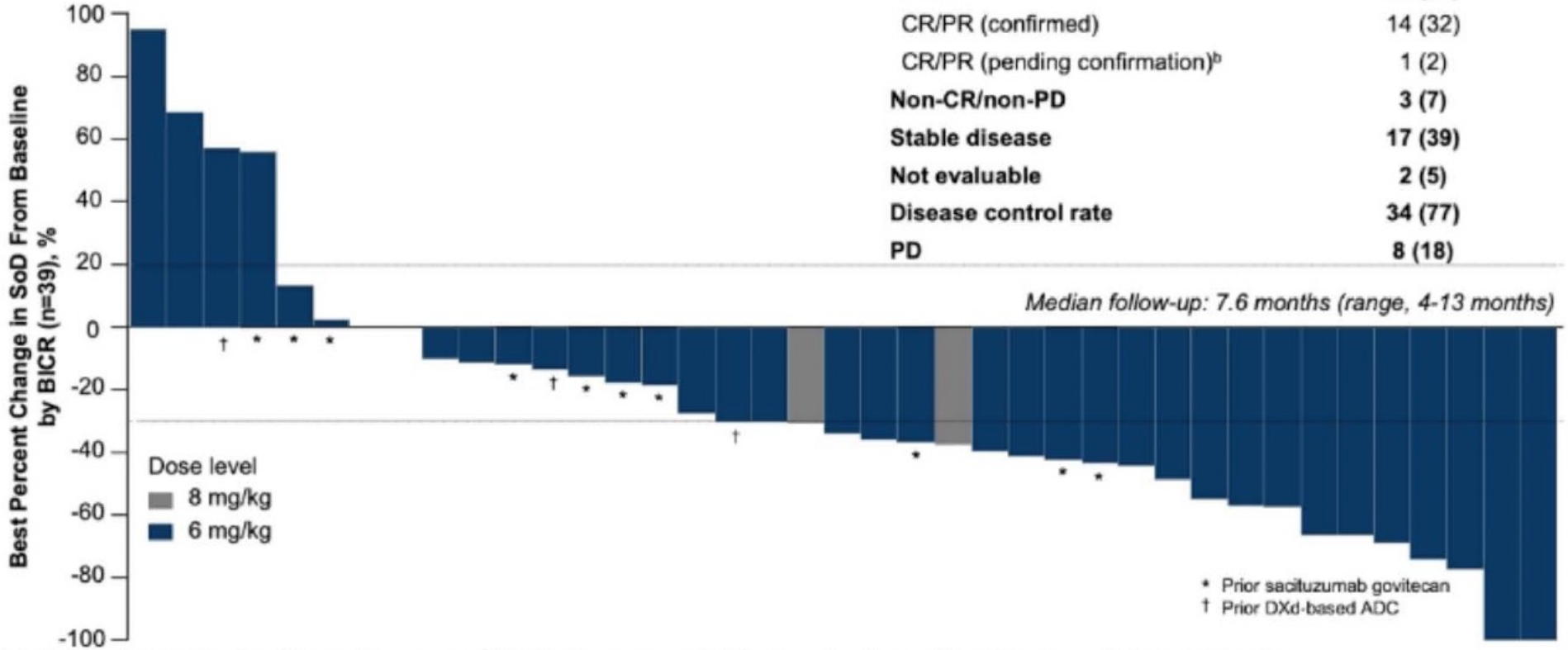
Adverse event	Patients (N = 108)		
	Any grade	Grade 3	Grade 4
Gastrointestinal disorders			
Nausea	67%	6%	0
Diarrhea	62%	8%	0
Vomiting	49%	6%	0
Blood and lymphatic system disorders			
Neutropenia	64%	26%	16%
Anemia	50%	11%	0
Abnormal values			
Decrease white blood cell counts	21%	8%	3%

Bardia A et al. *N Engl J Med* 2021;384:1529-41.

TROPION-PanTumor01 (TNBC Cohort): Antitumor Response with Dato-DXd by BICR

All patients with TNBC

Patients, n (%)[a]	All Patients (n=44)
ORR	**15 (34)**
CR/PR (confirmed)	14 (32)
CR/PR (pending confirmation)[b]	1 (2)
Non-CR/non-PD	**3 (7)**
Stable disease	**17 (39)**
Not evaluable	**2 (5)**
Disease control rate	**34 (77)**
PD	**8 (18)**

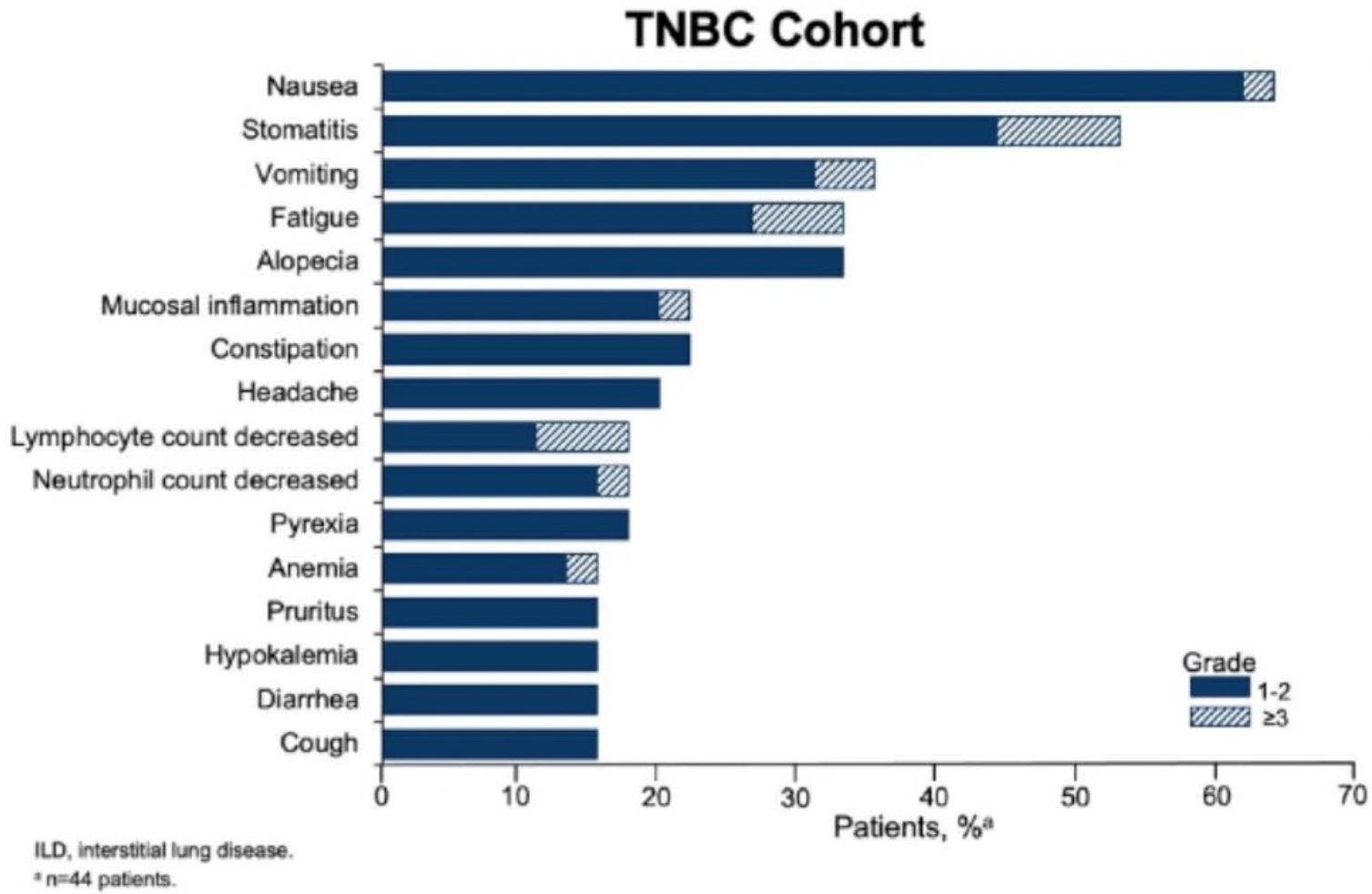


BICR, blinded independent central review; CR, complete response; ORR, objective response rate; PD, progressive disease; PR, partial response; SoD, sum of diameters.
[a] Includes response evaluable patients who had ≥1 postbaseline tumor assessment or discontinued treatment. Postbaseline tumor assessments were not yet available for 2 patients at the data cutoff. Three patients were not confirmed to have a target lesion per BICR and therefore had a best overall response of non-CR/non-PD.
[b] Includes patients with an unconfirmed response but are ongoing treatment.

Data cutoff: July 30, 2021

Krop I et al. SABCS 2021;Abstract GS1-05.

TROPION-PanTumor01 (TNBC Cohort): Treatment-Emergent Adverse Events in ≥15% of Patients



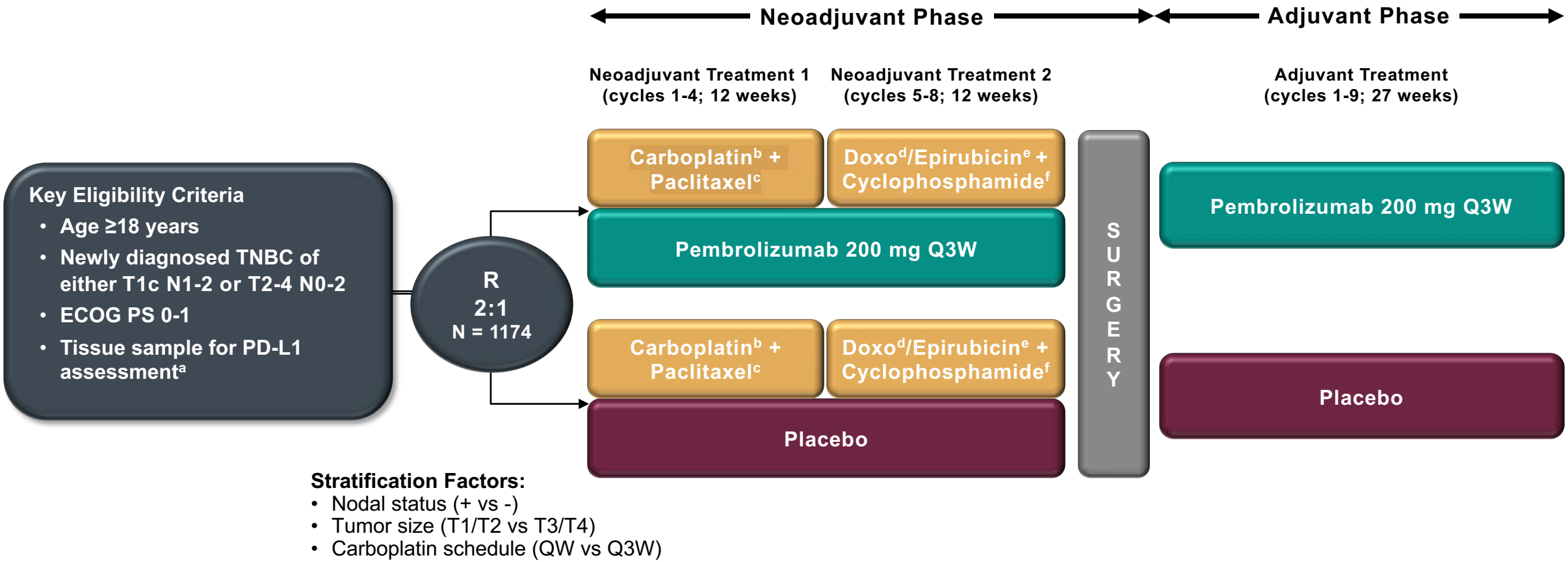
- Most common adverse events observed were nausea and stomatitis (predominantly grade 1-2)
- Low frequency of hematologic toxicity and diarrhea
- No cases adjudicated as drug-related ILD

ILD, interstitial lung disease.
[a] n=44 patients.

Data cutoff: July 30, 2021

Krop I et al. SABCS 2021;Abstract GS1-05.

KEYNOTE-522 Study Design (NCT03036488)



Stratification Factors:
- Nodal status (+ vs -)
- Tumor size (T1/T2 vs T3/T4)
- Carboplatin schedule (QW vs Q3W)

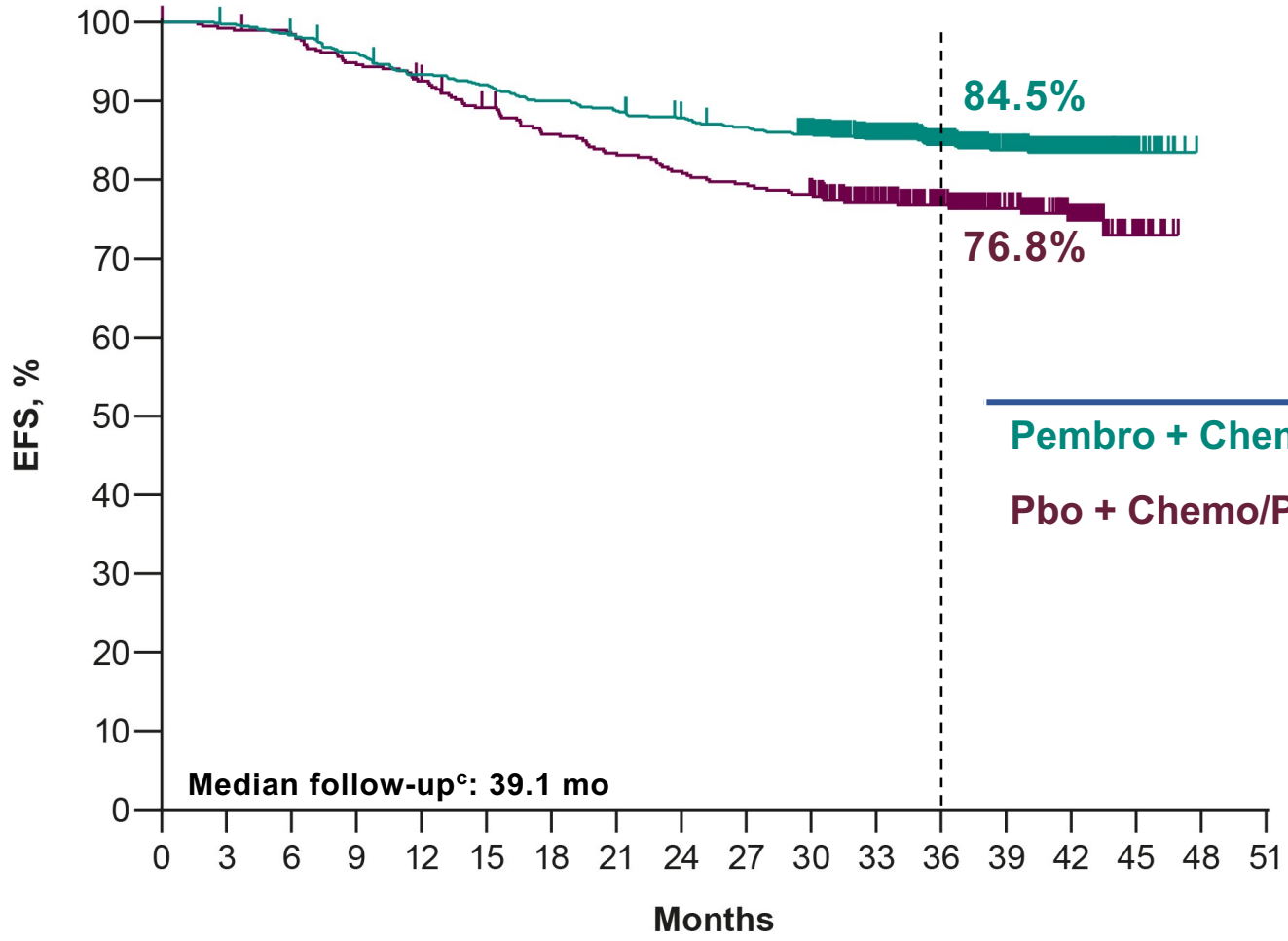
Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post treatment included)

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

[a]Must consist of at least 2 separate tumor cores from the primary tumor.
[b]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW.
[c]Paclitaxel dose was 80 mg/m^2 QW.
[d]Doxorubicin dose was 60 mg/m^2 Q3W.
[e]Epirubicin dose was 90 mg/m^2 Q3W.
[f]Cyclophosphamide dose was 600 mg/m^2 Q3W.

Courtesy of Harold J Burstein, MD, PhD

KEYNOTE-522: 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%		

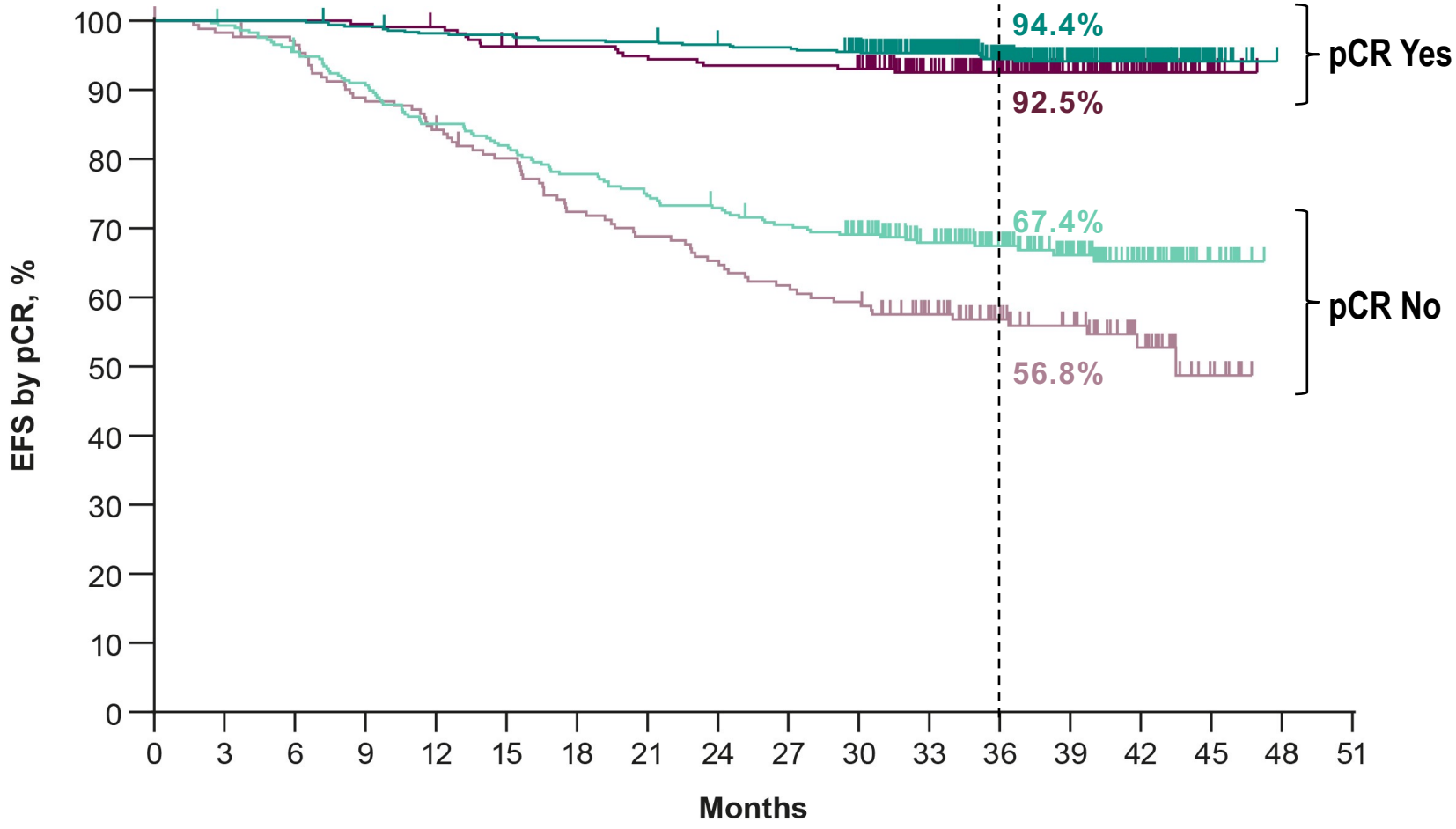
No. at Risk

Pembro + Chemo/Pembro	784	781	769	751	728	718	702	692	681	671	652	551	433	303	165	28	0	0
Pbo + Chemo/Pbo	390	386	382	368	358	342	328	319	310	304	297	250	195	140	83	17	0	0

[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [b]Prespecified *P*-value boundary of 0.00517 reached at this analysis.
[c]Defined as the time from randomization to the data cutoff date of March 23, 2021.

Courtesy of Harold J Burstein, MD, PhD

KEYNOTE-522: EFS by pCR (ypT0/Tis ypN0)

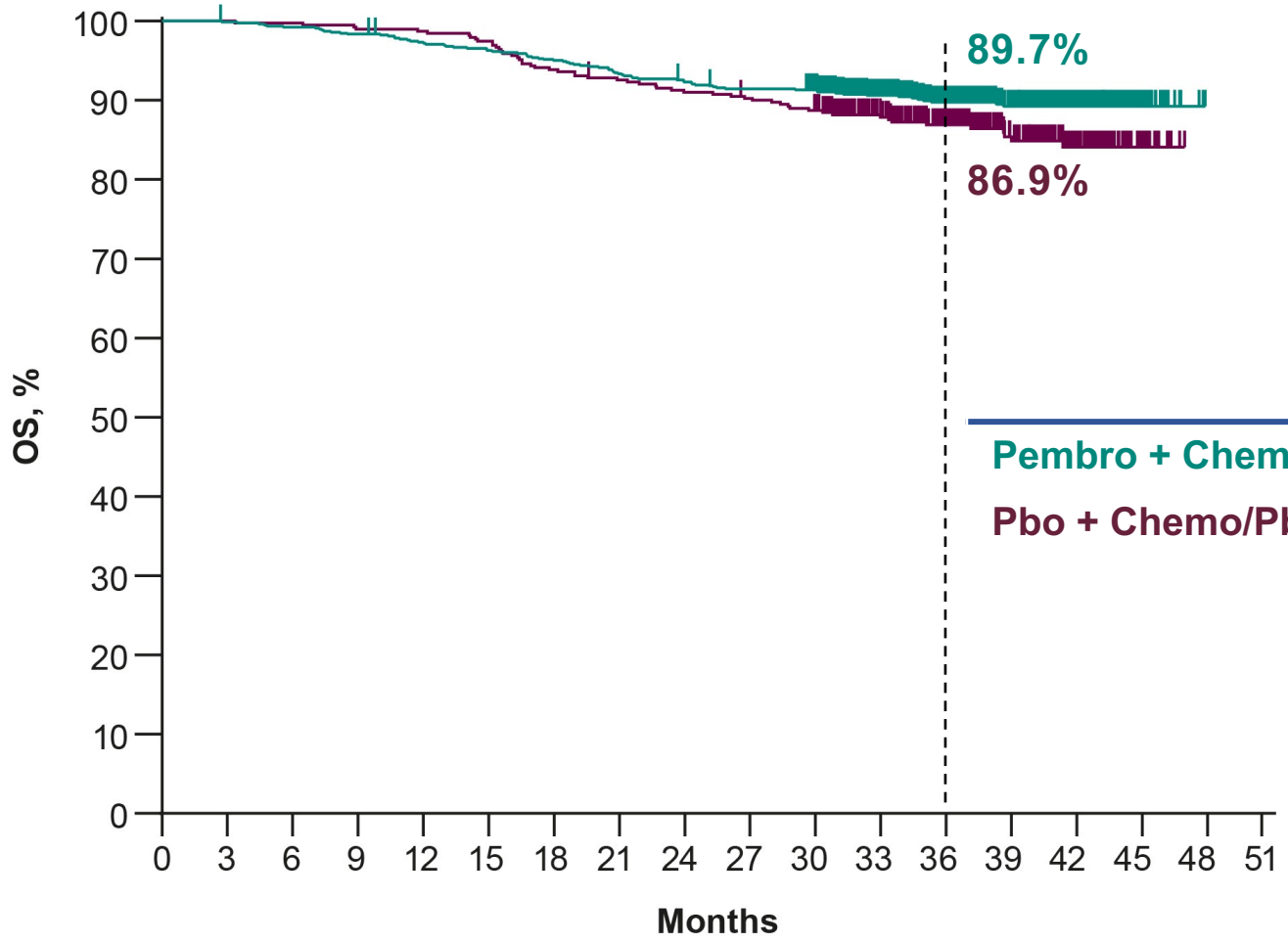


No. at Risk																		
Pembro + Chemo/Pembro Responder	494	494	494	489	483	482	478	477	472	470	460	387	307	220	122	18	0	0
Pbo + Chemo/Pbo Responder	217	217	217	216	214	207	206	203	200	200	197	165	130	87	56	9	0	0
Pembro + Chemo/Pembro Non-Responder	290	287	275	262	245	236	224	215	209	201	192	164	126	83	43	10	0	0
Pbo + Chemo/Pbo Non-Responder	173	169	165	152	144	135	122	116	110	104	100	85	65	53	27	8	0	0

Data cutoff date: March 23, 2021.

Courtesy of Harold J Burstein, MD, PhD

KEYNOTE-522: 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%		

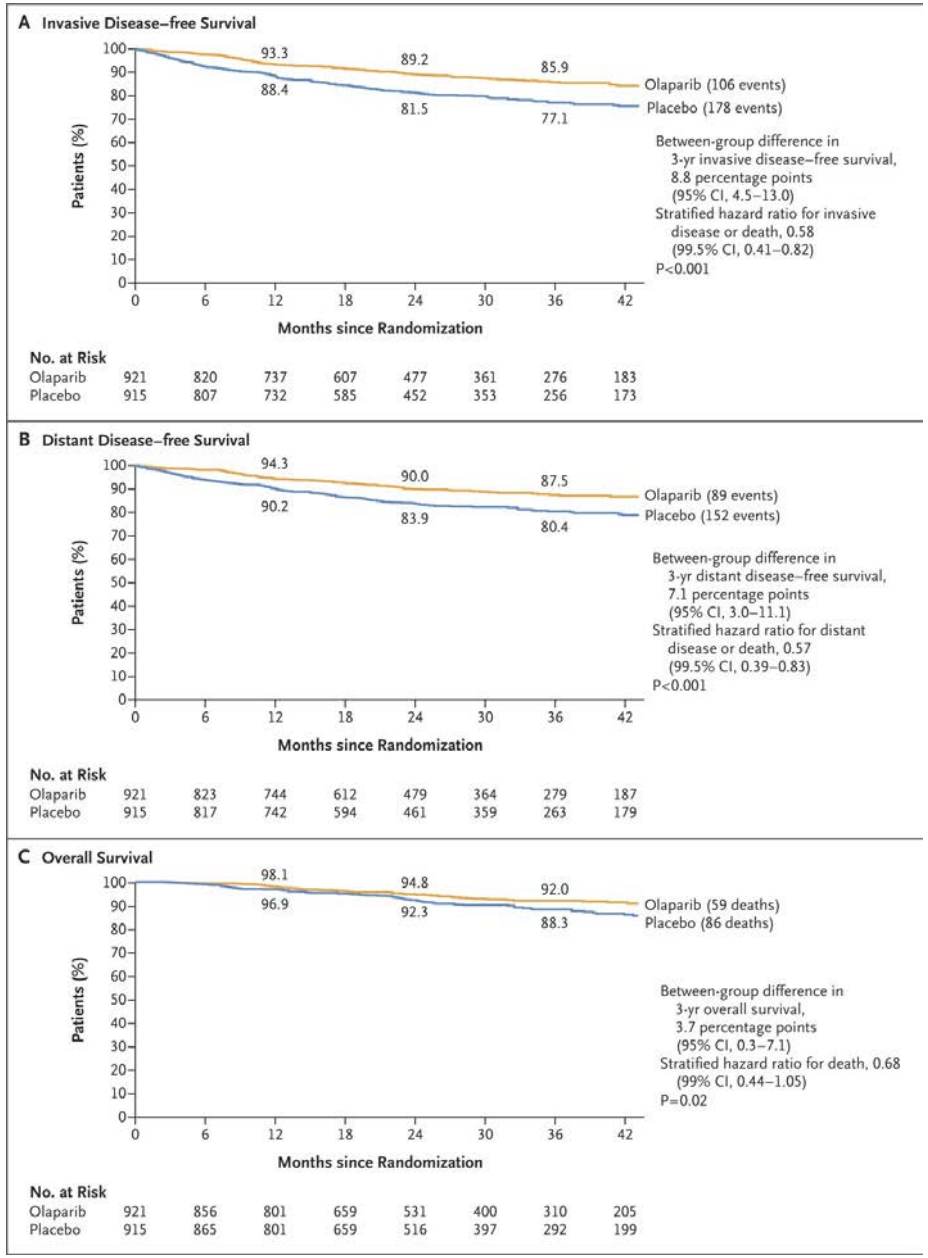
No. at Risk

Pembro + Chemo/Pembro	784	782	777	770	759	752	742	729	720	712	701	586	461	323	178	30	0	0
Pbo + Chemo/Pbo	390	390	389	386	385	380	366	360	354	350	343	286	223	157	89	17	0	0

[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [b]Prespecified *P*-value boundary of 0.00086 not reached at this analysis.
Data cutoff date: March 23, 2021.

Courtesy of Harold J Burstein, MD, PhD

OlympiA: adjuvant olaparib for BRCA1/2 breast cancer



Primary Endpoint: 3 year iDFS

- 85.9% vs 77.1% (8.8% difference)
- HR for disease or death 0.58 (99.5% CI 0.41 – 0.82) p<0.001

Secondary Endpoint: 3 year dDFS

- 87.5% vs 80.4% (7.1% difference)
- HR for distant disease or death 0.57 (99.5% CI 0.39 – 0.83) p<0.001

Secondary endpoint: OS

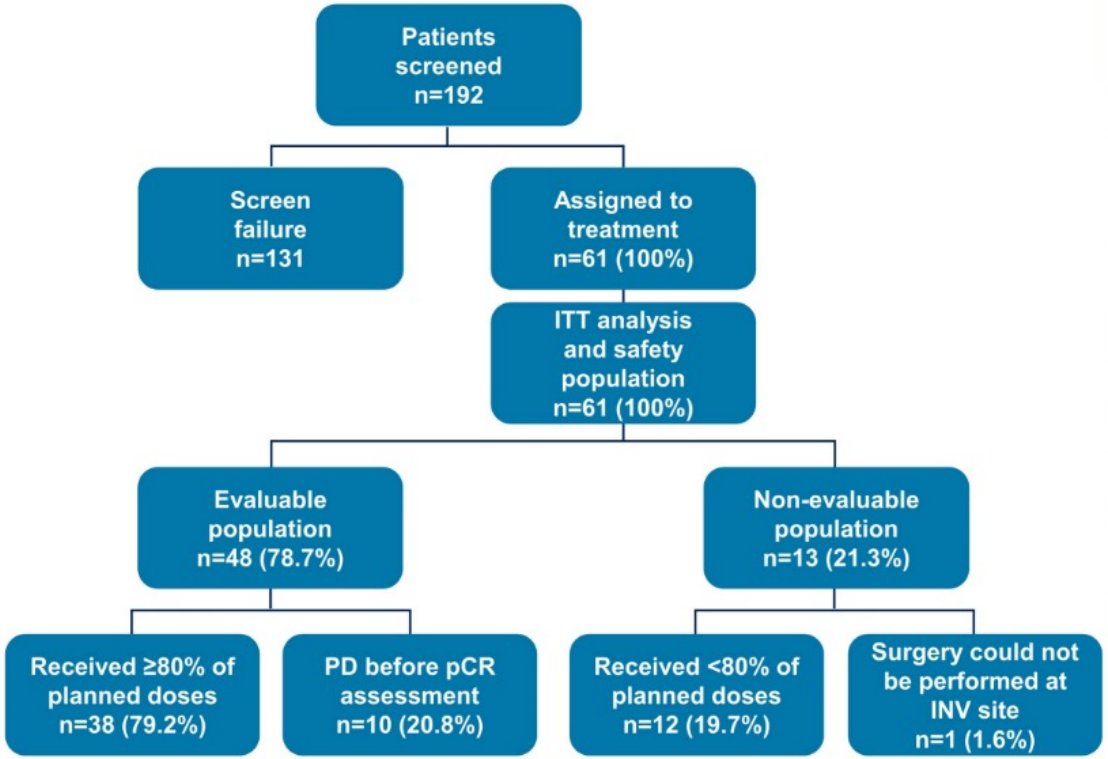
- Olaparib associated with fewer deaths (59 vs 86)
- HR for death 0.68 (99% CI 0.44 – 1.05) p=0.02

Tutt ANJ et al. N Engl J Med 2021;384:2394-2405

Courtesy of Harold J Burstein, MD, PhD

Neoadjuvant talazoparib in BRCA1/2 breast cancer

Patient Populations and Disposition



Patient disposition	Talazoparib (N=61)
Number (%) of patients	**n (%)**
Disposition phase: treatment	
Entered	61 (100.0)
Discontinued	16 (26.2)
Completed	45 (73.8)
Disposition phase: safety follow-up*	
Entered	49 (80.3)
Discontinued	0
Completed	49 (80.3)
Disposition phase: long-term follow-up	
Entered	58 (95.1)
Discontinued	58 (95.1)
Study closed by sponsor	55 (90.2)
Death	2 (3.3)
Withdrawal by subject	1 (1.6)

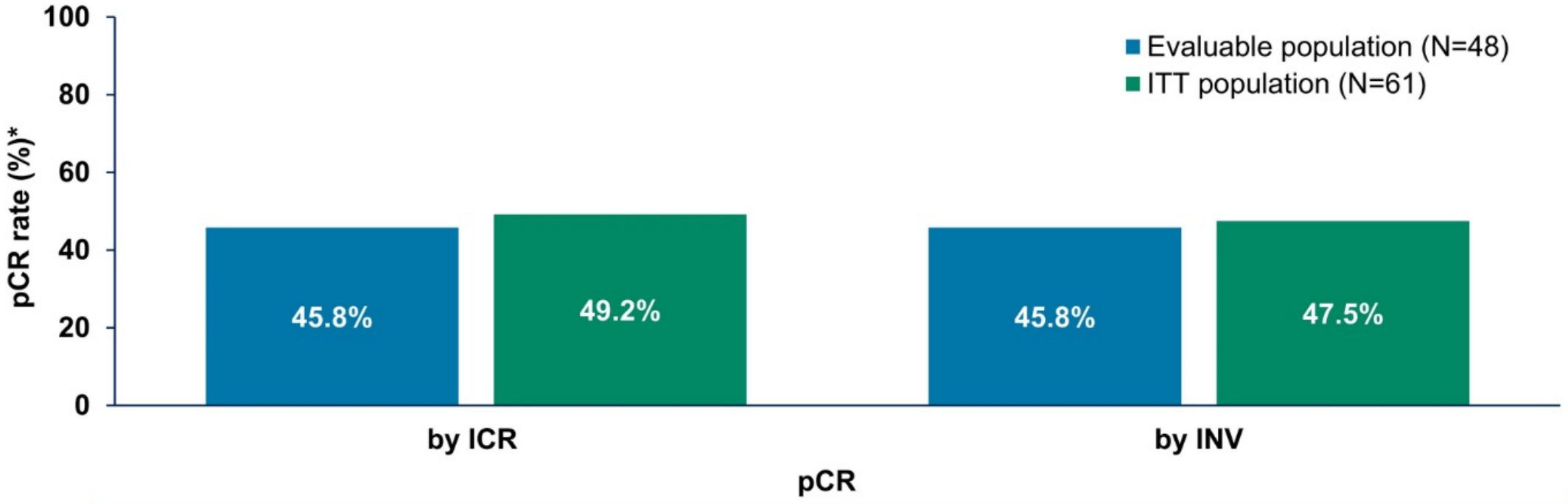
PD=progressive disease.
*Includes patients who completed surgical follow-up.

Presented By: Jennifer K. Litton

2021 ASCO ANNUAL MEETING

Courtesy of Harold J Burstein, MD, PhD

Pathologic Complete Response



95% CI†	(32.0–60.6)	(36.7–61.6)	(32.0–60.6)	(35.0–60.1)
80% CI†	(36.4–55.2)	(41.0–57.4)		
Posterior probability that true pCR rate exceeds 45%	0.55	0.75		

*The denominator is N, the number of patients in the evaluable/ITT analysis set as per ICR/INV.
†The exact CI was calculated using the Blaker's method.

Courtesy of Harold J Burstein, MD, PhD

Agenda

Module 1: HER2-Positive Breast Cancer

- DESTINY-Breast03
- HER2CLIMB
- SUMMIT, ExteNET, CONTROL

Module 2: Triple-Negative Breast Cancer

- ASCENT, TROPION-PanTumor01
- KEYNOTE-522
- OlympiA, NEOTALA

Module 3: ER-Positive Breast Cancer

- RxPONDER
- monarchE
- SOLAR-1, BYLieve
- EMERALD

Self-Assessment Questions

The RxPONDER trial demonstrated that in the node-positive population, chemotherapy provided no treatment benefit in patients with a Recurrence Score® (RS) ≤25.

a. Agree
b. Disagree
c. I'm not sure

In the RxPONDER trial, the benefit from chemotherapy in premenopausal patients with node-positive tumors was about the same as was seen in previous randomized trials evaluating ovarian suppression versus tamoxifen.

a. Agree
b. Disagree
c. I'm not sure

Self-Assessment Questions

In the RxPONDER trial, what percent of premenopausal patients received adjuvant ovarian suppression/ablation?

What would you most likely recommend for a 46-year-old premenopausal woman with ER/PR-positive, HER2-negative IDC with 1 of 3 positive nodes and an RS of 8?

a. Chemotherapy/tamoxifen
b. Chemotherapy/ovarian suppression
c. Chemotherapy/ovarian suppression/aromatase inhibitor
d. Tamoxifen
e. Ovarian suppression
f. Ovarian suppression/aromatase inhibitor
g. Other

Self-Assessment Questions

In general, what is your approach to Ki-67 assays in localized breast cancer?

a. I didn't order them in the past, but now I do
b. I don't order them
c. I ordered them in the past and continue to do so

For an 89-year-old woman in good health with ER/PR-positive, HER2-negative IDC with 4 positive nodes, how would you approach the issue of adjuvant abemaciclib?

a. I would not recommend it
b. I would recommend it and order a Ki-67 assay
c. I would mention the monarchE trial results to the patient but recommend she not be treated
d. Other

Self-Assessment Questions

For a patient who is eligible to receive adjuvant abemaciclib and also has a BRCA germline mutation, would you recommend olaparib, abemaciclib or both?

a. Olaparib
b. Abemaciclib
c. Both olaparib and abemaciclib

How would you characterize the FDA indication for adjuvant abemaciclib?

a. Straightforward
b. Somewhat confusing
c. Very confusing

Self-Assessment Questions

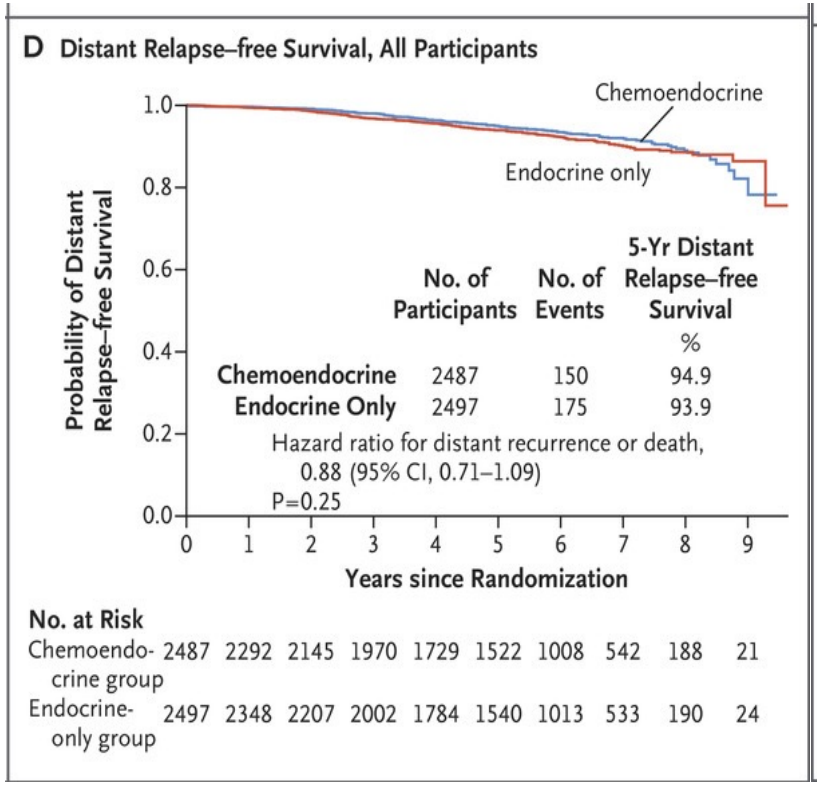
To date, no Phase III trial has demonstrated a survival benefit with the use of a CDK4/6 inhibitor in aromatase inhibitor-sensitive disease.

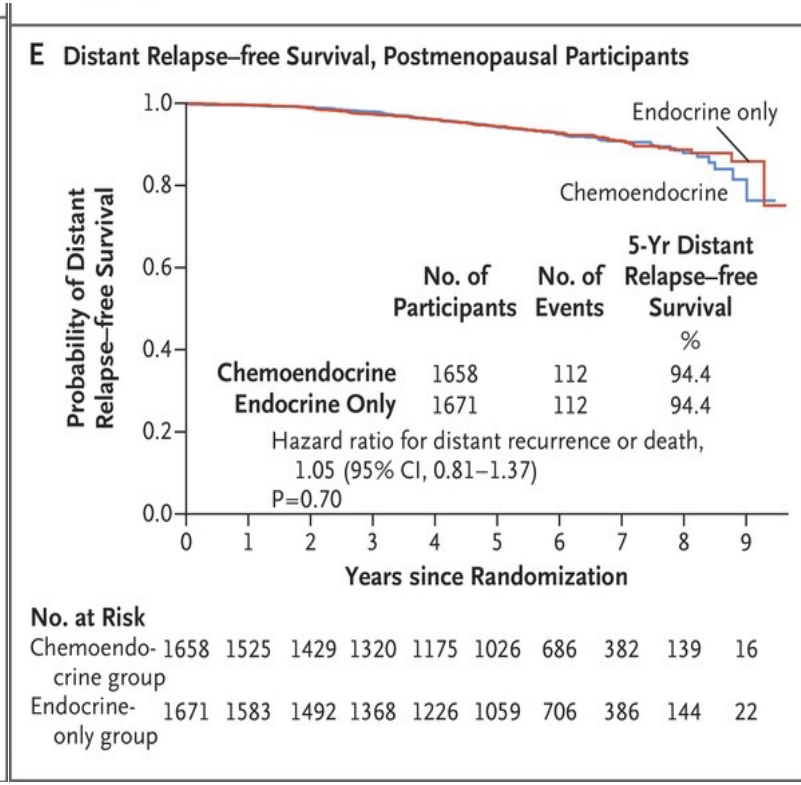
a. Agree
b. Disagree
c. I'm not sure

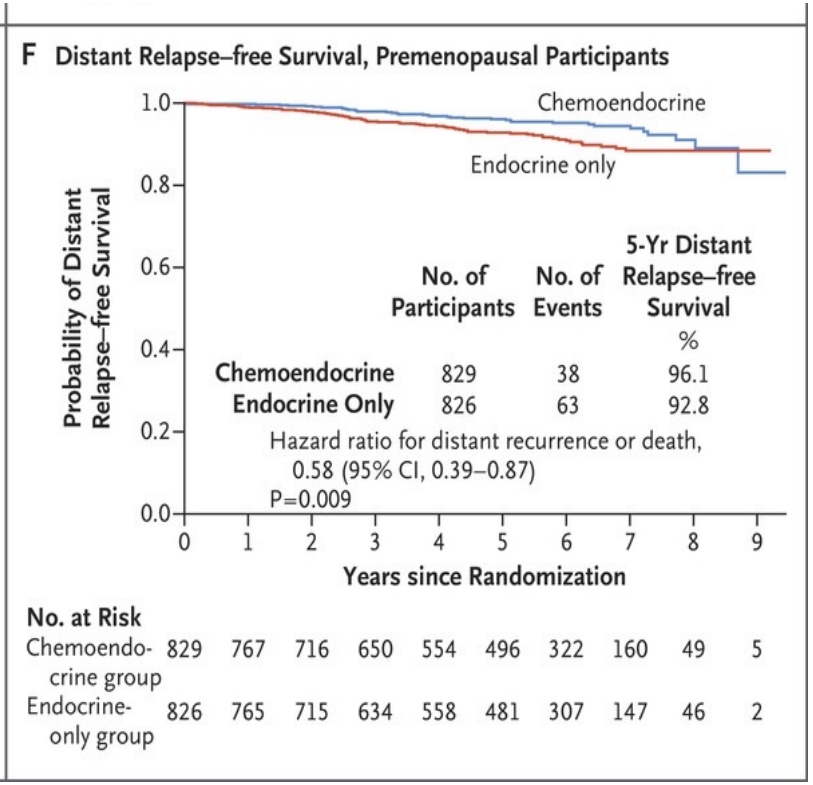
Oral SERDs appear to be at least as effective as fulvestrant and potentially more effective than aromatase inhibitors in patients with ER-positive breast cancer and an *ESR1* mutation.

a. Agree
b. Disagree
c. I'm not sure

RxPONDER: Clinical Outcomes among Patients with a Recurrence Score ≤25





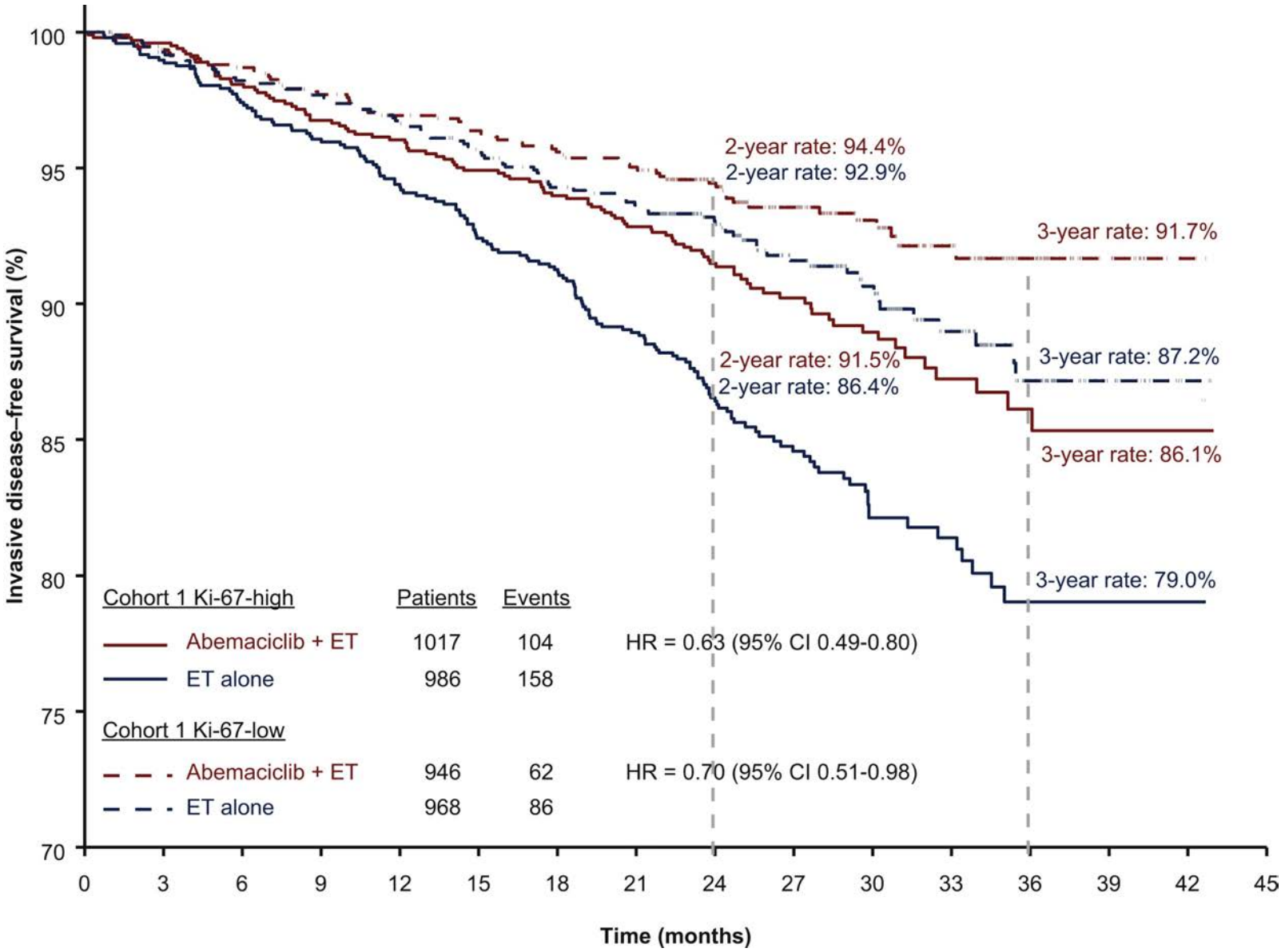


K Kalinsky et al.
N Engl J Med 2021. DOI: 10.1056/NEJMoa2108873

Courtesy of Harold J Burstein, MD, PhD

monarchE
2021 Update

Outcomes
By Ki67 hi/low

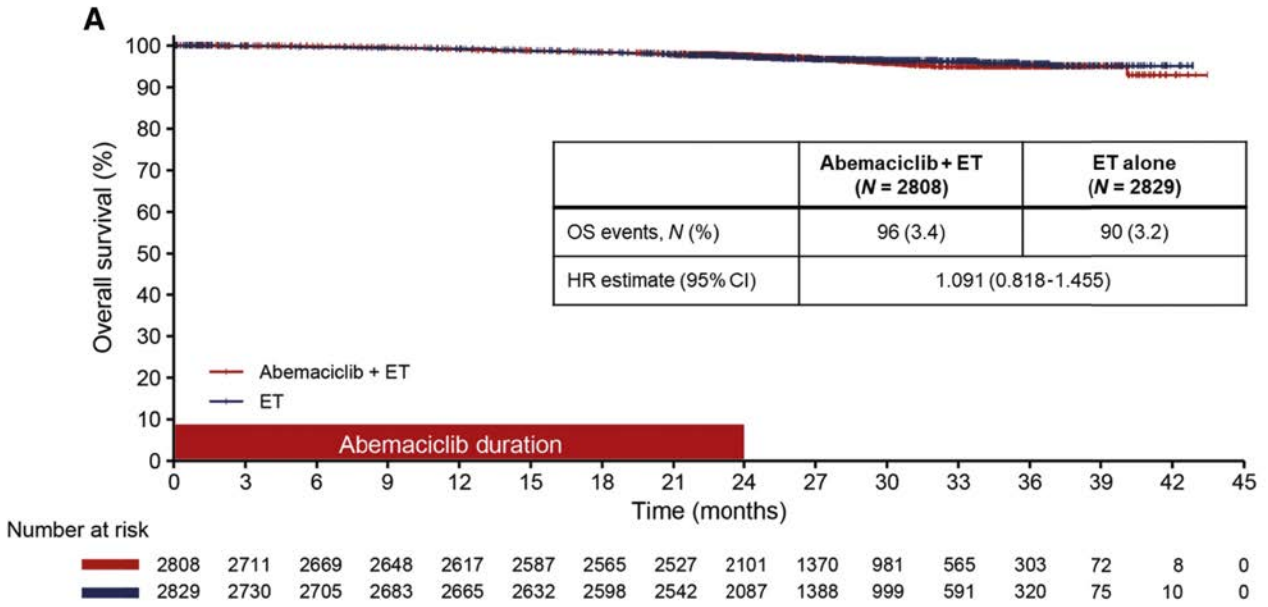


Annals of Oncology 2021 321571-1581DOI: (10.1016/j.annonc.2021.09.015)

Courtesy of Harold J Burstein, MD, PhD

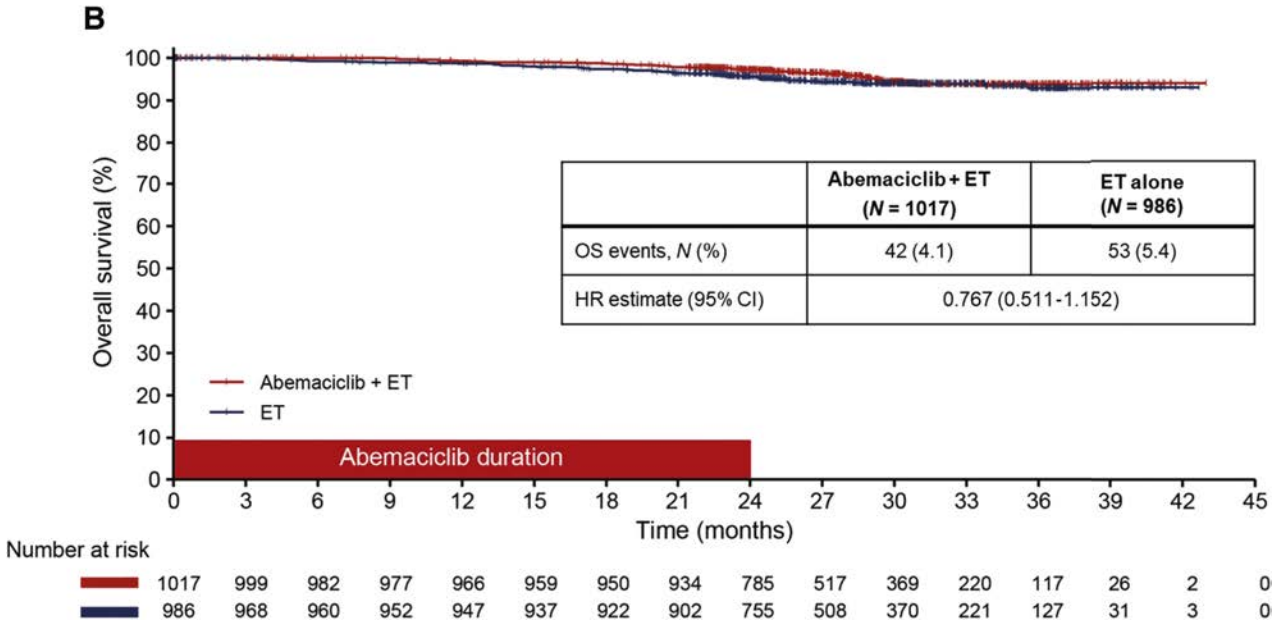
monarchE
2021 Update

Overall
Survival



	Abemaciclib + ET (*N* = 2808)	ET alone (*N* = 2829)
OS events, *N* (%)	96 (3.4)	90 (3.2)
HR estimate (95% CI)	1.091 (0.818-1.455)	

Overall study



	Abemaciclib + ET (*N* = 1017)	ET alone (*N* = 986)
OS events, *N* (%)	42 (4.1)	53 (5.4)
HR estimate (95% CI)	0.767 (0.511-1.152)	

FDA cohort of Ki67 > 20%

Annals of Oncology DOI: (10.1016/j.annonc.2021.10.015)

Courtesy of Harold J Burstein, MD, PhD

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]

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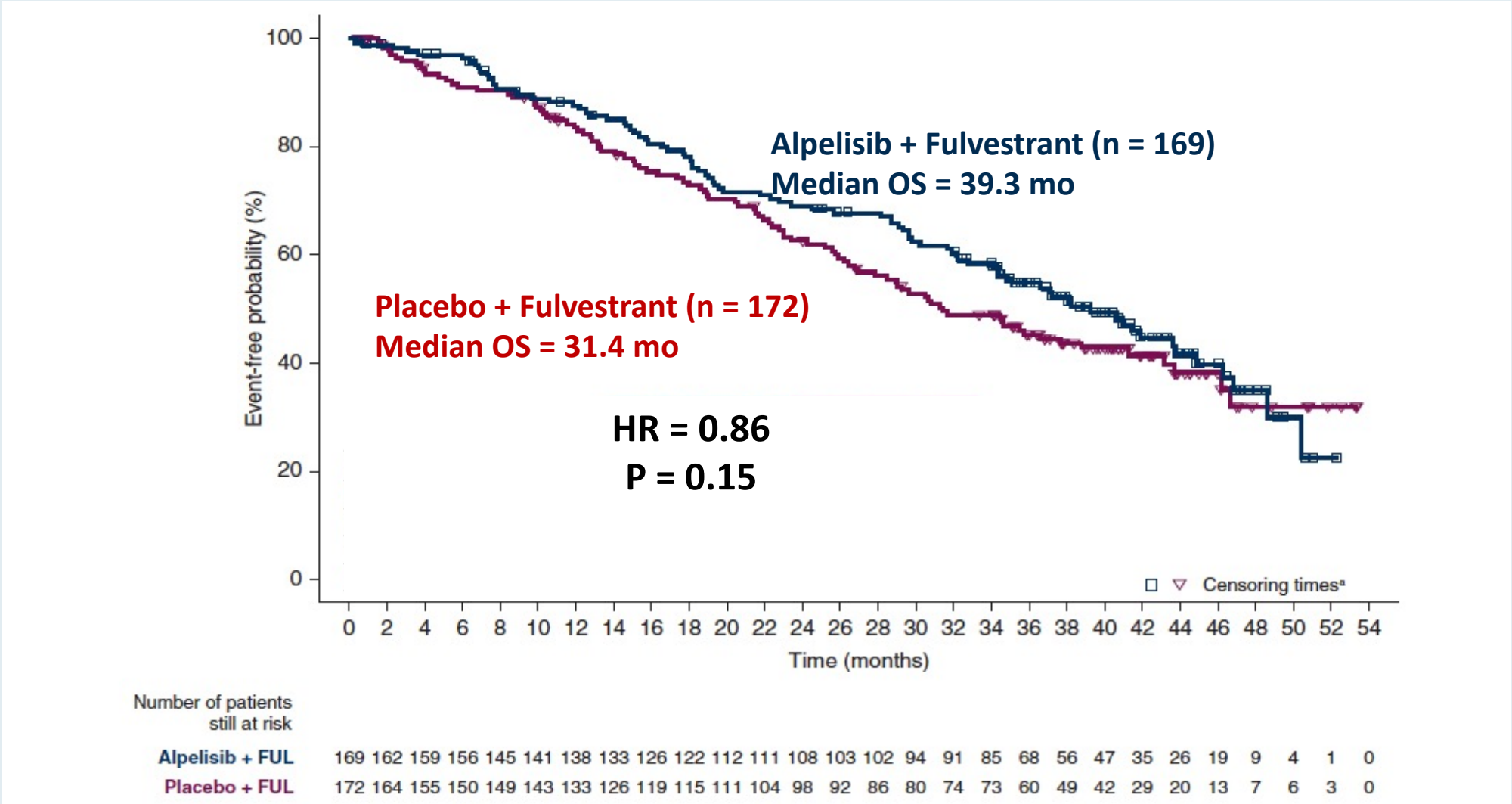
Available online 25 November 2020

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

RTP Year in Review 2022

SOLAR-1: OS for Patients with Advanced Breast Cancer with a PIK3CA Mutation



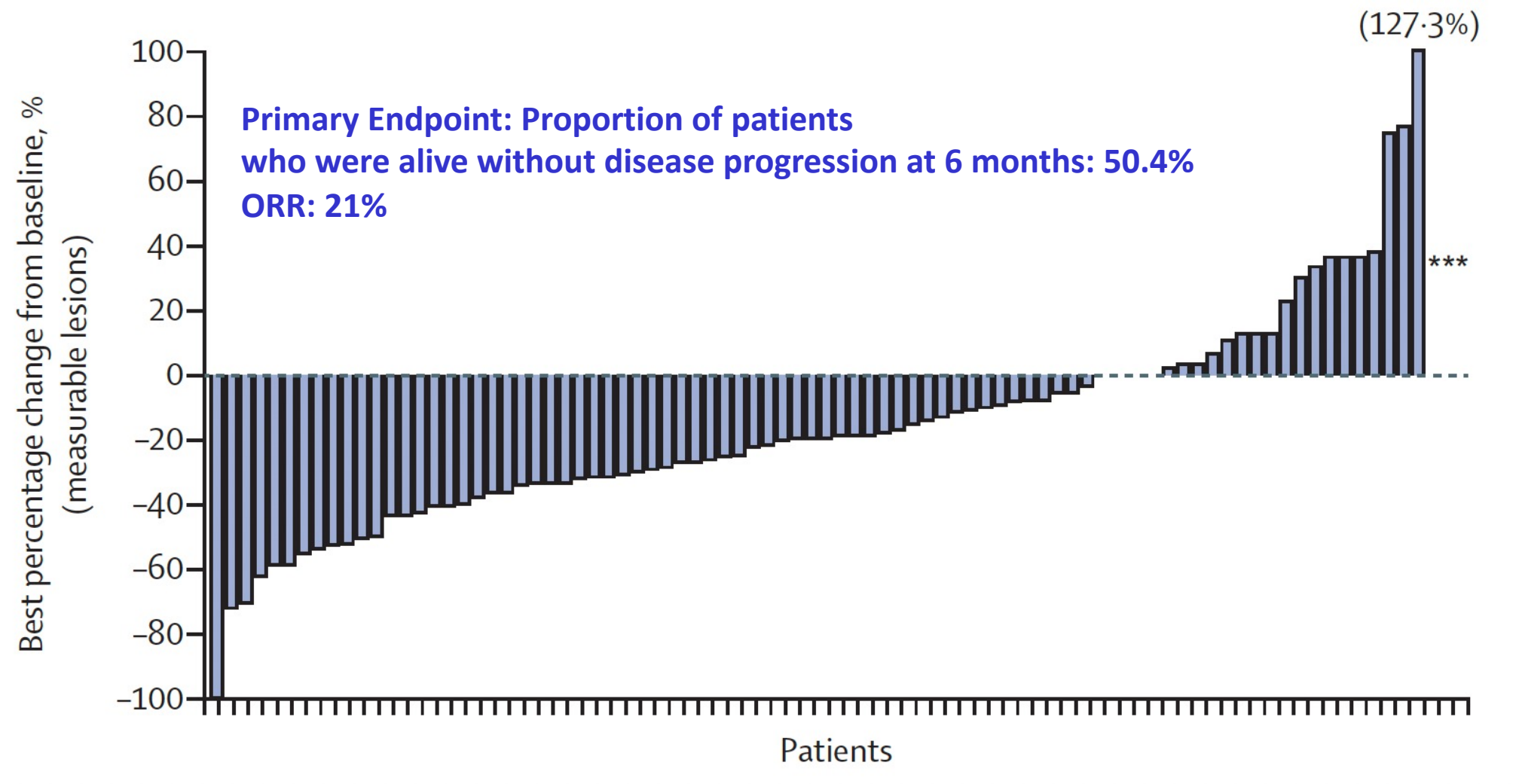
André F et al. *Ann Oncol* 2021;32(2):208-17.

Lancet Oncol 2021;22:489-98.

Alpelisib plus fulvestrant in *PIK3CA*-mutated, hormone receptor-positive advanced breast cancer after a CDK4/6 inhibitor (BYLieve): one cohort of a phase 2, multicentre, open-label, non-comparative study

Hope S Rugo, Florence Lerebours, Eva Ciruelos, Pamela Drullinsky, Manuel Ruiz-Borrego, Patrick Neven, Yeon Hee Park, Aleix Prat, Thomas Bachelot, Dejan Juric, Nicholas Turner, Nickolas Sophos, Juan Pablo Zarate, Christina Arce, Yu-Ming Shen, Stuart Turner, Hemanth Kanakamedala, Wei-Chun Hsu, Stephen Chia

BYLieve Efficacy Outcomes



Primary Endpoint: Proportion of patients who were alive without disease progression at 6 months: 50.4%
ORR: 21%

Rugo HS et al. *Lancet Oncol* 2021;22:489-98.

New therapies to target ER: Oral SERDs & SERCAs

Class	Name of Drug	Clinical Development phase
Oral SERD	GDC-9545/Giredestrant	Phase 3
	AZD9833/Camizestrant	Phase 3
	RAD-1901/Elacestrant	Phase 3
	SAR-439859/Amcenestrant	Phase 3
	G1T48/Rintodestrant	Phase 3
	G1T48/Rintodestrant	Phase 2
	ZB-716/Borestrant	Phase 1/2
	D-0502	Phase 1
	SHR9549	Phase 1
SERCA	H3B-6545	Phase 1
CERAN	OP-1250	Phase 1
PROTAC	ARV-471	Phase 1

SERD – Selective ER Degraders

SERCA - Selective ER Covalent Antagonist

CERAN - Complete ER Antagonist

PROTAC - Proteolysis Targeting Chimera

Novel endocrine agents (oral SERDs, PROTAC, SERCA, CERAN) are active after fulvestrant and/or CDK4/6 inhibitors and work against both *ESR1 wt* and *ESR1* mutant tumours

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

Oral SERD in 2/3L MBC: Elacestrant Phase 3 Trial (EMERALD)

Emerald Trial

- ER+, HER2- MBC
- 1-2L of prior ET
- PD on CDK4/6i
- Max. 1L of chemo

R 1:1

n = 239 → **Elacestrant** 400mg OD

n = 238 → **AI or Fulvestrant** (Investigator choice)

Median PFS

	Elacestrant	AI or Fulvestrant	
ITT	2.79	1.91	HR=0.697 [95% CI: 0.552, 0.88]; *P*=0.0018
ESR1-Mt	3.78	1.82	HR=0.546 [95% CI: 0.387, 0.768]; *P*=0.0005

Stratification factors:

- mESR1 status (central lab)
- Prior Fulvestrant use (yes vs no)
- Visceral disease(yes vs no)

Study Population:

- 2L, 46% vs 41%
- 100% prior CDK4/6

Primary endpoints:

- PFS (BICR) in ITT
- PFS (BICR) in mESR1

Key Secondary endpoint: OS

Side effects:

- leading to discontinuation: Elacestrant 6.3%, SOC 4.4%
- Grade ≥3: Elacestrant 7.2%, SOC 3.1% (nausea 2.1% vs 0.9%).

Courtesy of Professor Peter Schmid, FRCP, MD, PhD

EMERALD: Treatment-Emergent Adverse Events

	Elacestrant N = 237, n (%)		SOC					
			Total N = 229, n (%)		Fulvestrant N = 161, n (%)		AI N = 68, n (%)	
Preferred Term	All Grades	Grade 3/4	All Grades	Grade 3/4	All Grades	Grade 3/4	All Grades	Grade 3/4
Nausea	83 (35.0)	6 (2.5)	43 (18.8)	2 (0.9)	26 (16.1)	-	17 (25.0)	2 (2.9)
Fatigue	45 (19.0)	2 (0.8)	43 (18.8)	2 (0.9)	35 (21.7)	1 (0.6)	8 (11.8)	1 (1.5)
Vomiting	45 (19.0)	2 (0.8)	19 (8.3)	-	12 (7.5)	-	7 (10.3)	-
Decreased appetite	35 (14.8)	2 (0.8)	21 (9.2)	1 (0.4)	12 (7.5)	-	9 (13.2)	1 (1.5)
Arthralgia	34 (14.3)	2 (0.8)	37 (16.2)	-	28 (17.4)	-	9 (13.2)	-
Diarrhea	33 (13.9)	-	23 (10.0)	2 (0.9)	14 (8.7)	1 (0.6)	9 (13.2)	1 (1.5)
Back pain	33 (13.9)	6 (2.5)	22 (9.6)	1 (0.4)	16 (9.9)	1 (0.6)	6 (8.8)	-
Aspartate aminotransferase increased	31 (13.1)	4 (1.7)	28 (12.2)	2 (0.9)	20 (12.4)	2 (1.2)	8 (11.8)	-
Headache	29 (12.2)	4 (1.7)	26 (11.4)	-	18 (11.2)	-	8 (11.8)	-
Constipation	29 (12.2)	-	15 (6.6)	-	10 (6.2)	-	5 (7.4)	-
Hot flush	27 (11.4)	-	19 (8.3)	-	15 (9.3)	-	4 (5.9)	-
Dyspepsia	24 (10.1)	-	6 (2.6)	-	4 (2.5)	-	2 (2.9)	-
Alanine aminotransferase increased	22 (9.3)	5 (2.1)	23 (10.0)	1 (0.4)	17 (10.6)	-	6 (8.8)	1 (1.5)

Bardia A et al. SABCS 2021;Abstract GS2-02.

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

Targeted Therapy for Non-Small Cell Lung Cancer

Tuesday, January 11, 2022
5:00 PM – 6:00 PM ET

Faculty

John V Heymach, MD, PhD
Zofia Piotrowska, MD, MHS

Moderator

Neil Love, MD

RTP Year in Review 2022

Thank you for joining us!

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

RTP Year in Review 2022