Consensus or Controversy? Clinical Investigators Discuss and Debate Current Approaches to First- and Second-Line Therapy for HR-Positive Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, April 15, 2026

5:00 PM – 6:00 PM ET

Faculty

Sara A Hurvitz, MD, FACP

Virginia Kaklamani, MD, DSc

Moderator

Neil Love, MD

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Faculty

Sara A Hurvitz, MD, FACP
Professor of Medicine
Smith Family Endowed Chair in Women's Health
Senior Vice President, Clinical Research Division
Fred Hutchinson Cancer Center
Head, Division of Hematology/Oncology
Department of Medicine
UW Medicine
Seattle, Washington

Virginia Kaklamani, MD, DSc
Professor of Medicine
Ruth McLean Bowman Bowers Chair in Breast Cancer Research and Treatment
AB Alexander Distinguished Chair in Oncology
Leader, Breast Oncology Program
UT Health San Antonio MD Anderson Cancer Center
San Antonio, Texas

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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Contributing Clinical Investigators

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

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

Komal Jhaveri, MD, FACP, FASCO
Patricia and James Cayne Chair for Junior Faculty
Associate Attending Physician
Breast Medicine Service and Early Drug Development Service
Section Head, Endocrine Therapy Research Program
Clinical Director, Early Drug Development Service
Department of Medicine
Memorial Sloan Kettering Cancer Center
Associate Professor of Medicine
Weill Cornell College of Medicine
New York, New York

Maryam Lustberg, MD, MPH
Professor of Internal Medicine (Medical Oncology)
Director, Center for Breast Cancer
Yale School of Medicine
New Haven, Connecticut

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Commercial Support

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Dr Love — Disclosures

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Speakers Bureaus	AstraZeneca Pharmaceuticals LP, Gilead Sciences Inc

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Dr Burstein — Disclosures
Contributing Clinical Investigator

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Prof Curigliano — Disclosures
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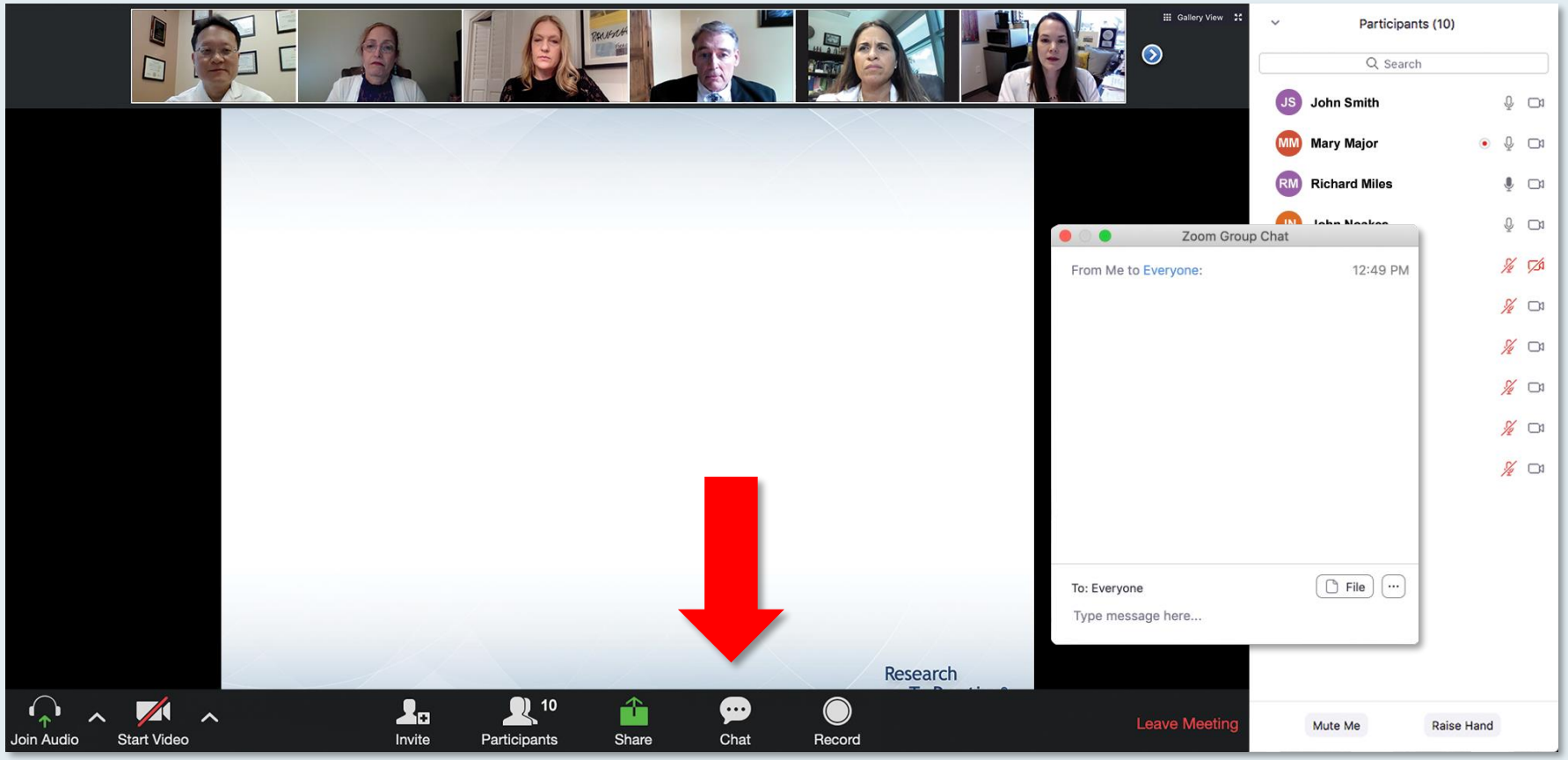

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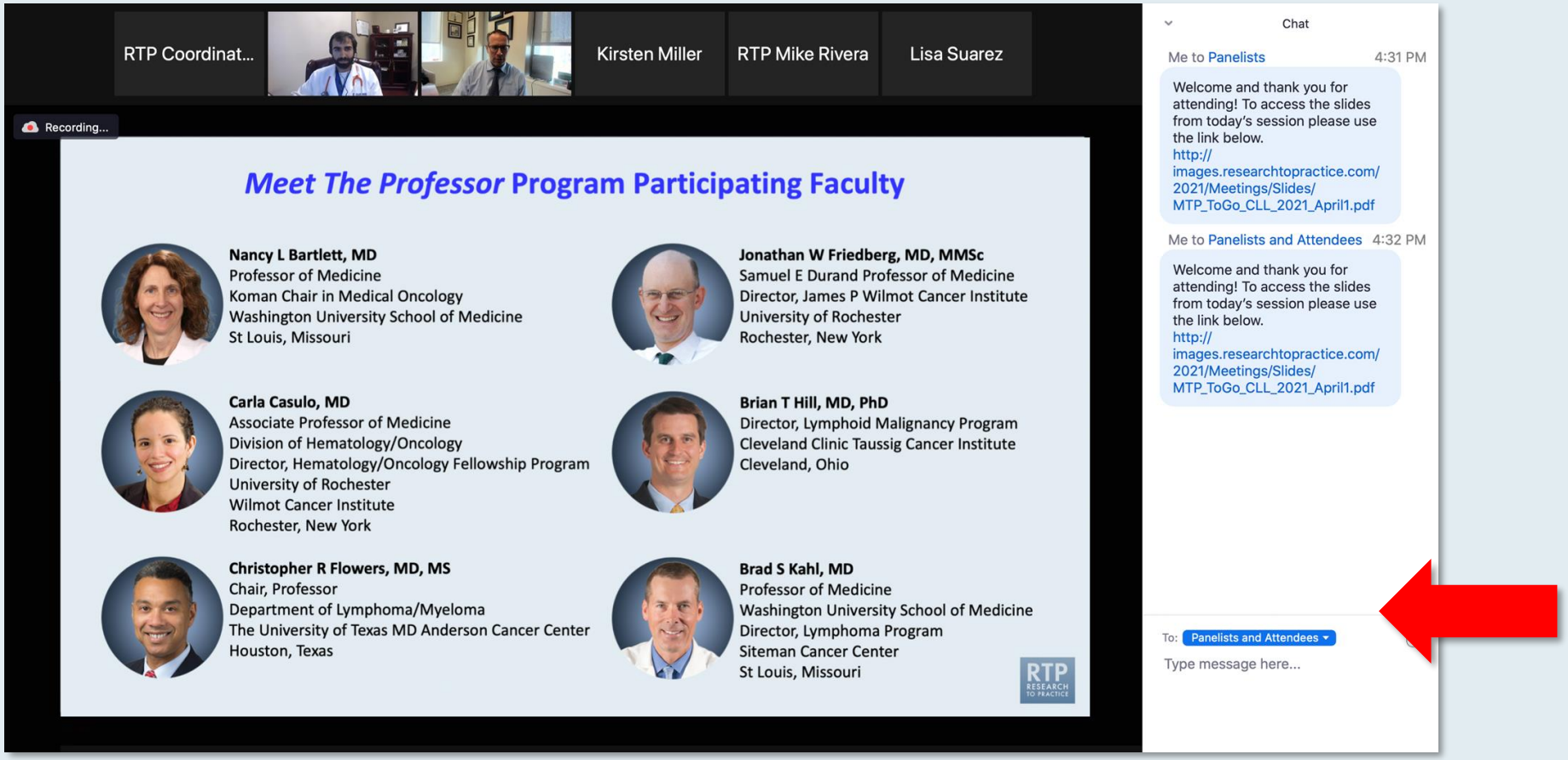

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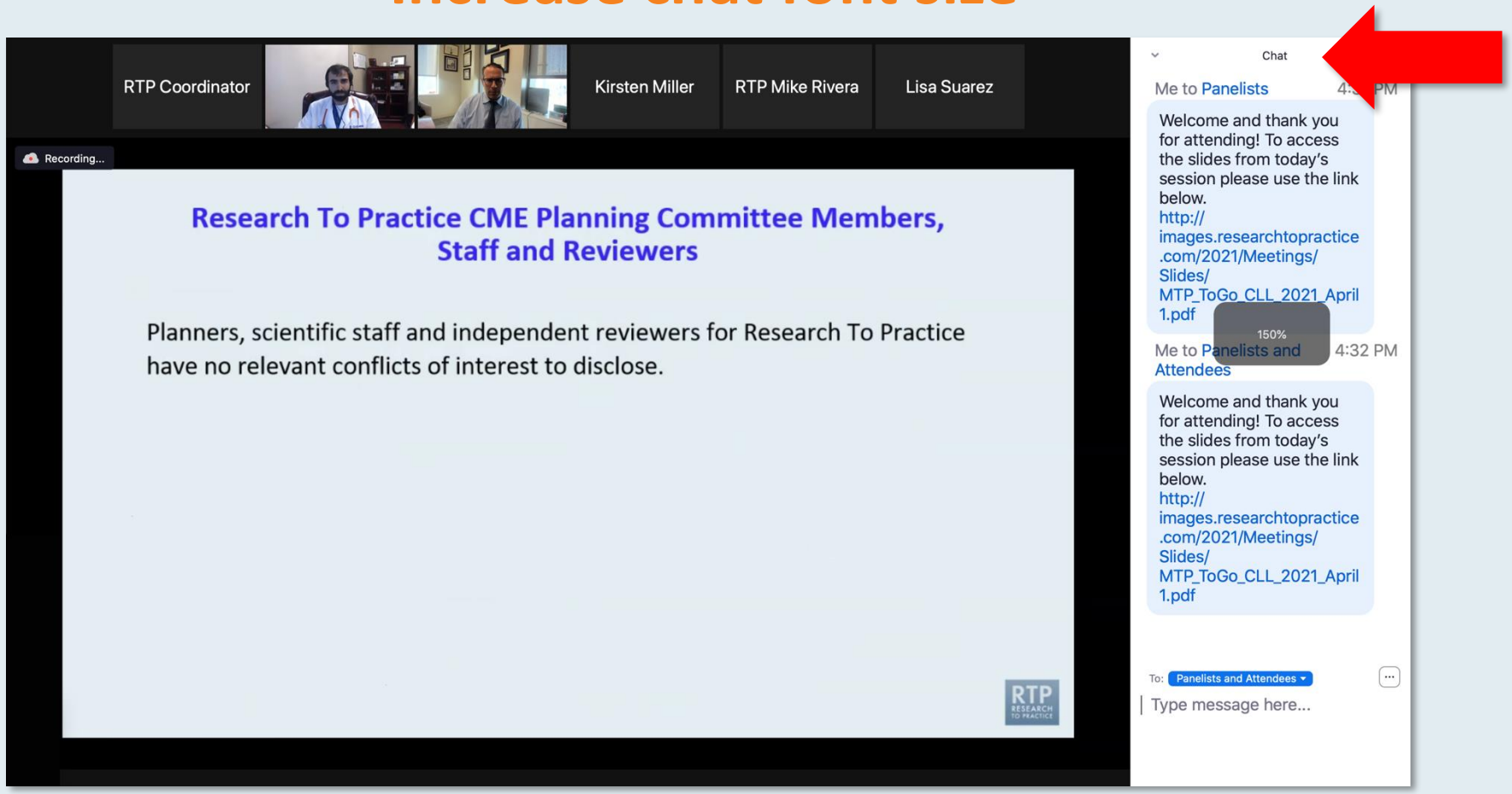

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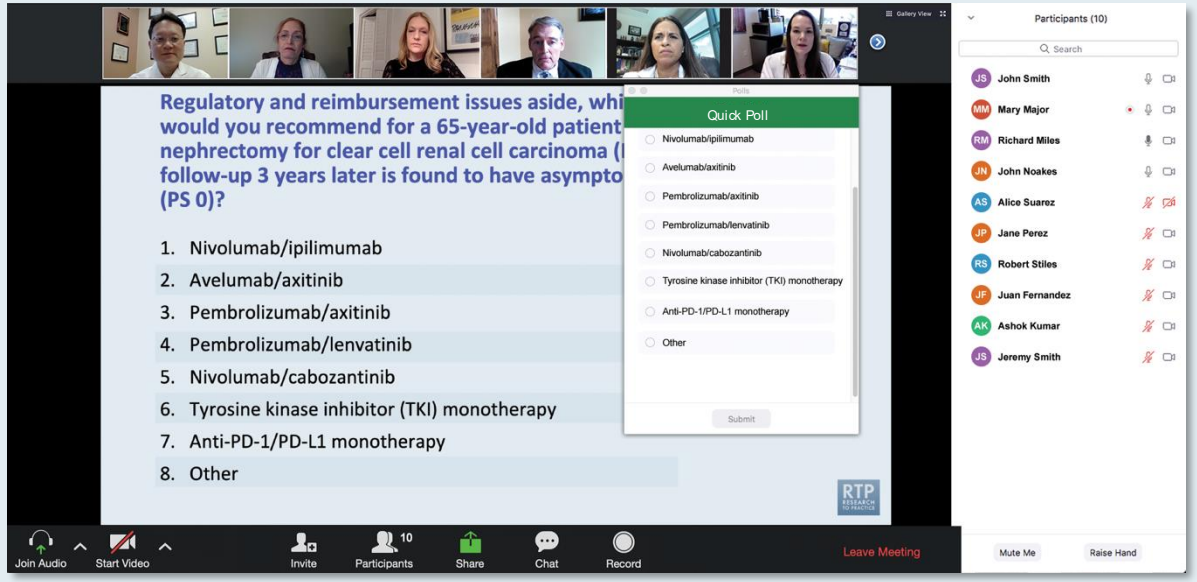

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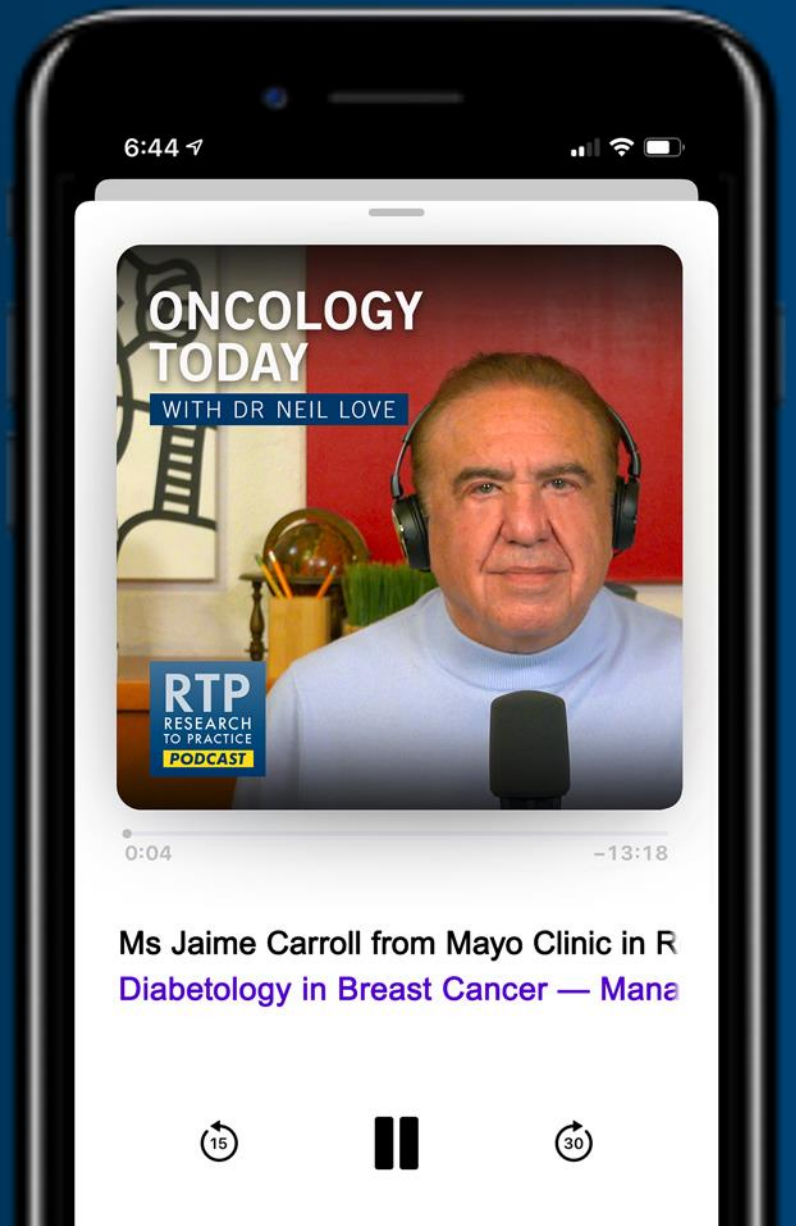

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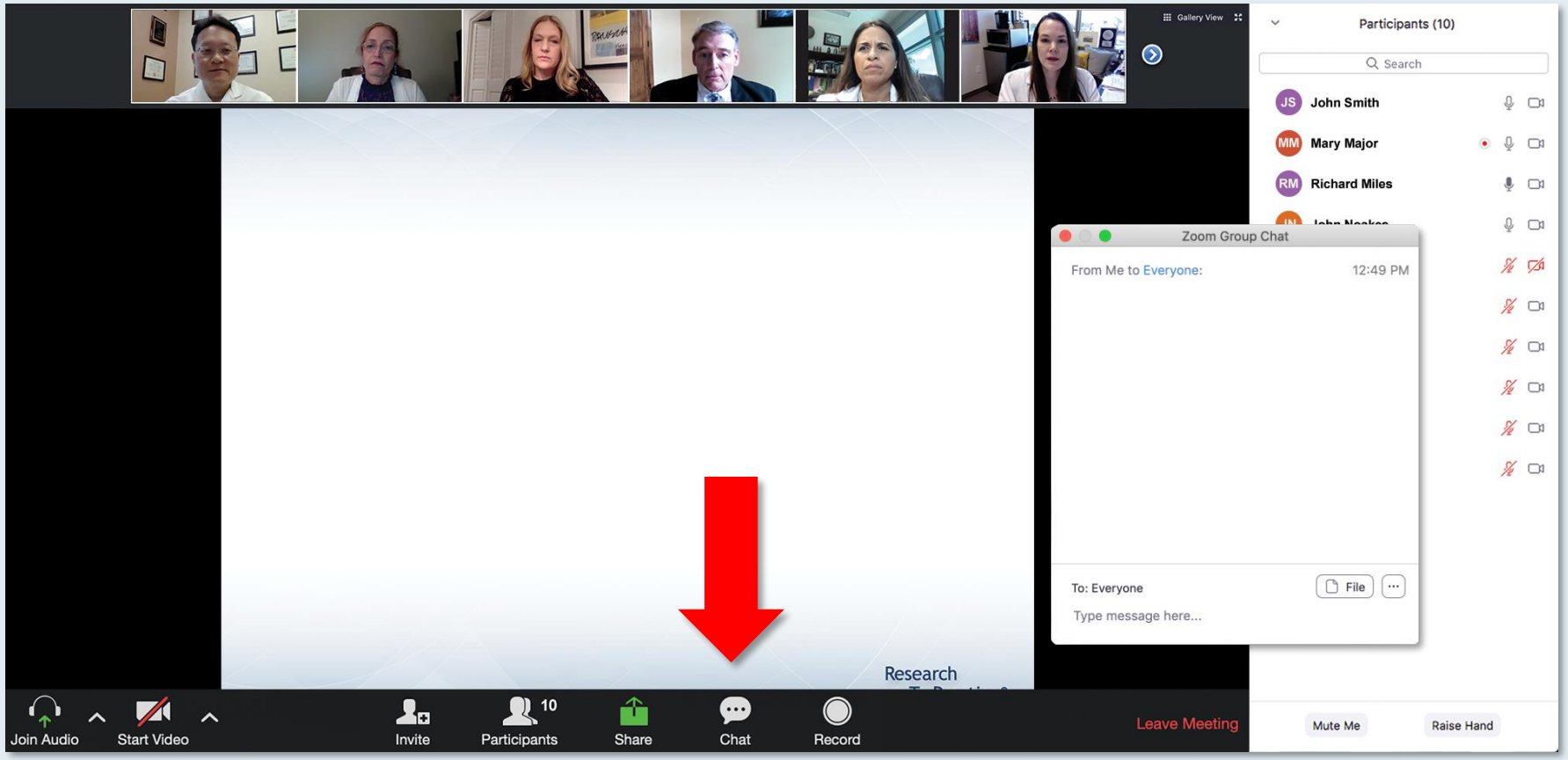

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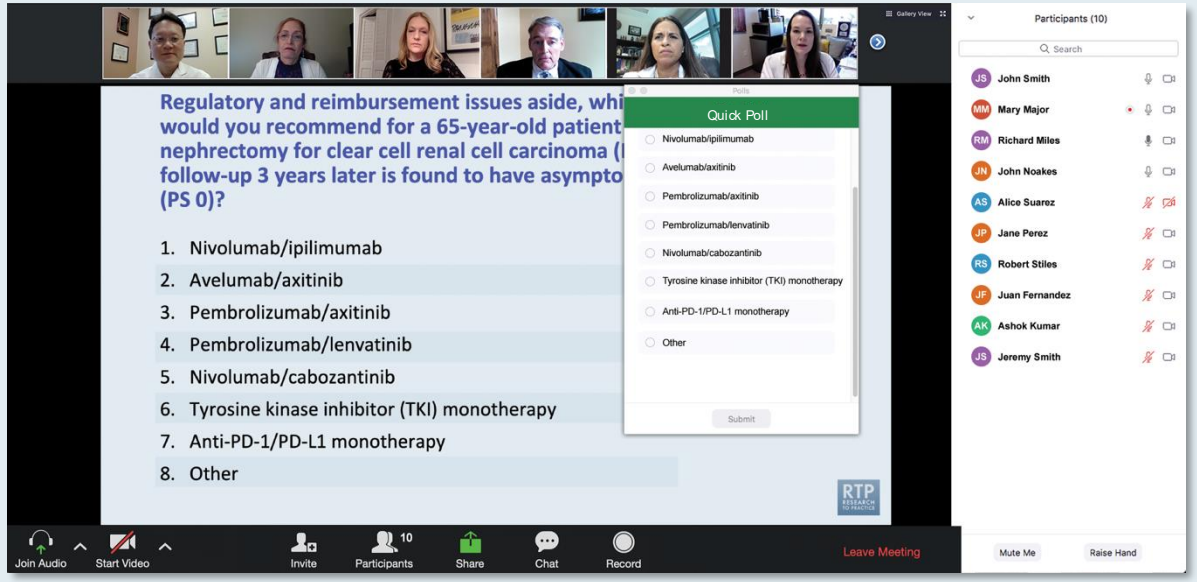

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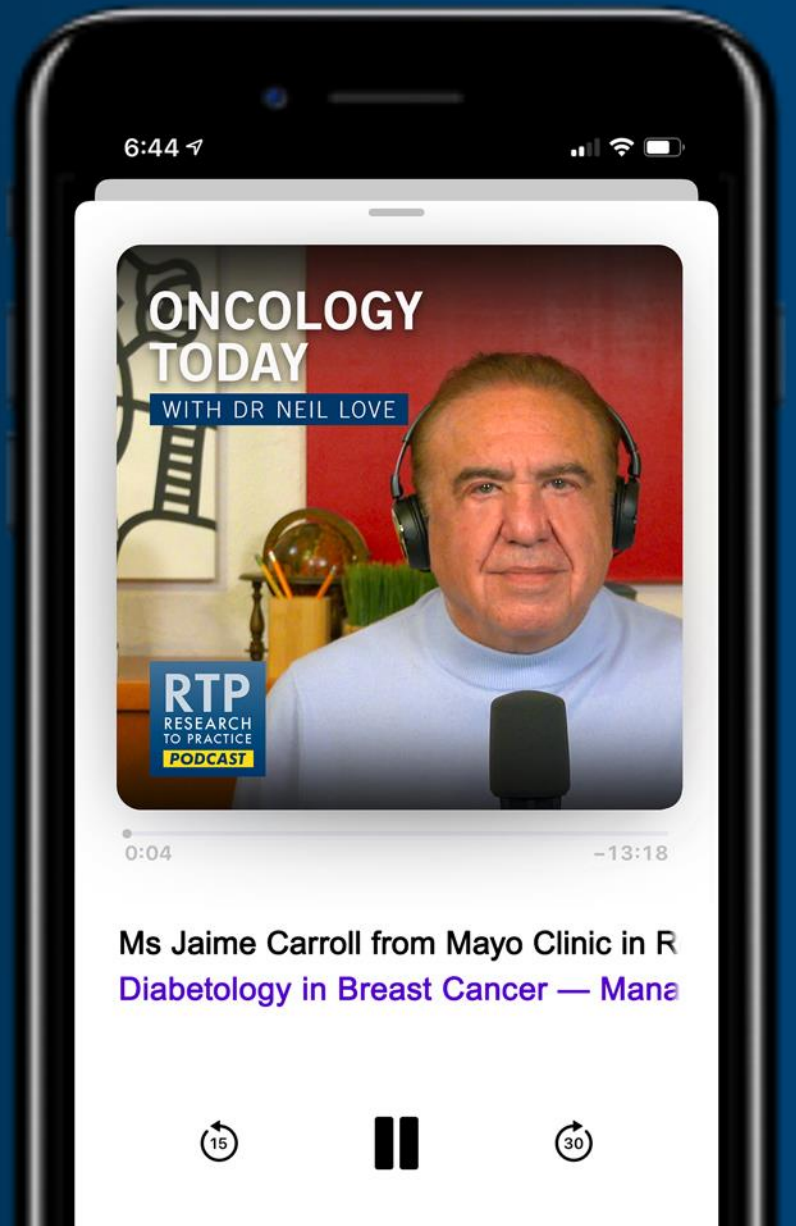

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Contributing Clinical Investigator

No relevant financial relationships to disclose.

Prof Curigliano — Disclosures
Contributing Clinical Investigator

Advisory Committees, Consulting Agreements and Speakers Bureaus	AstraZeneca Pharmaceuticals LP, Daiichi Sankyo Inc, Gilead Sciences Inc, Lilly, Menarini Group, Novartis, Pfizer Inc
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Dr Jhaveri — Disclosures
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Contracted Research	AstraZeneca Pharmaceuticals LP, Bicycle Therapeutics, Blueprint Medicines, BridgeBio Oncology Therapeutics, Eisai Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Pfizer Inc, Puma Biotechnology Inc, RayzeBio Inc, Scorpion Therapeutics, Zymeworks Inc

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Contracted Research	Astellas, AstraZeneca Pharmaceuticals LP

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Dr Love — Disclosures

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Agenda

Introduction: Which Biomarkers and When

Module 1: Optimizing First-Line Therapy for Patients with Hormone Receptor (HR)-Positive Metastatic Breast Cancer (mBC)

- Biomarker-based selection of first-line treatment
- Use of SERENA-6 strategy
- Use of inavolisib triplet

Module 2: Management of HR-Positive mBC Progressing on a CDK4/6 Inhibitor and Endocrine Therapy

- Biomarker-based selection of second-line treatment
- Use of selective estrogen receptor degrader (SERD) monotherapy
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AGREE
IN BETWEEN
DISAGREE

At what point do you typically first assess ESR1 mutation status in your patients with ER-positive, HER2-negative breast cancer?

 Dr Hurvitz	After disease progression on first-line therapy for metastatic disease
 Dr Kaklamani	After disease progression as long as pt is still candidate for hormone therapy
 Dr Burstein	At diagnosis of metastasis
 Prof Curigliano	After disease progression on first-line therapy for metastatic disease
 Dr Jhaveri	After disease progression on first-line therapy for metastatic disease
 Dr Lustberg	After disease progression on first-line therapy for metastatic disease

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Which ESR1 testing method do you use in your practice?

How would you compare the sensitivity of blood-based circulating tumor DNA (ctDNA) testing to that of tissue testing in assessing for the presence of ESR1 mutations?

	Testing method	Sensitivity
 Dr Hurvitz	ctDNA testing	ctDNA testing is more sensitive
 Dr Kaklamani	ctDNA testing	ctDNA testing is more sensitive
 Dr Burstein	Both	Tissue testing is more sensitive
 Prof Curigliano	ctDNA testing	ctDNA testing is more sensitive
 Dr Jhaveri	ctDNA testing	ctDNA testing is more sensitive
 Dr Lustberg	ctDNA testing	ctDNA testing is more sensitive

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Dr Kaklamani: Case Presentation 1

- 56 yo postmenopausal patient who was diagnosed with de novo metastatic disease to the liver and bones.
- Patient presented to her PCP with back pain. Xrays showed lesions in her T and L spine. Follow-up imaging showed a L breast mass and liver lesions. She had a biopsy of the breast mass and the liver lesion showing IDC ER 90%, PR 80% HER2 1+. NGS testing didn't show any actionable mutations and genetic testing was negative.
- She was started on ribociclib, letrozole and denosumab.
- After 1 mo of treatment her back pain subsided and staging scans showed partial response.
- She remained on therapy with ribociclib and letrozole for a total of 42 mo until she had disease progression in her bones with new bone lesions.
- Liquid biopsy negative. She was started on everolimus/fulvestrant.

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AGREE
IN BETWEEN
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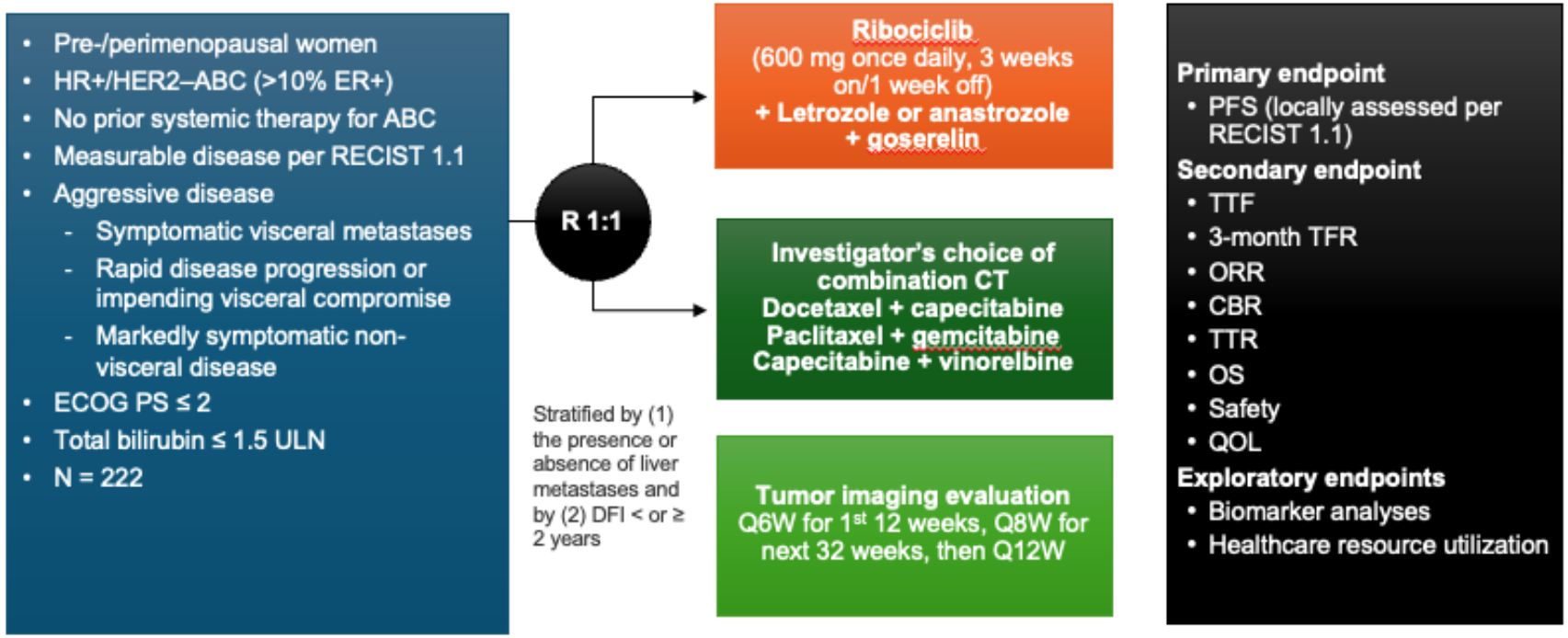
RIGHT Choice Phase II Study of First-Line ET/Ribociclib for Premenopausal Woman with mBC and Visceral Crisis or Symptomatic Disease



Demographics

Median age: 44

De novo MBC: 65%

Visceral mets: 78%

'Visceral' crisis (inv assessed): 52%

Symptomatic visceral mets: ~67%

ABC, advanced breast cancer; CBR, clinical benefit rate; CT, chemotherapy; ECOG, Eastern Cooperative Oncology Group; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PS, performance status; QoL, quality of life; TFR, treatment-free remission; TTF, time to treatment failure; TTR, time to recurrence.

Courtesy of Hope S Rugo, MD

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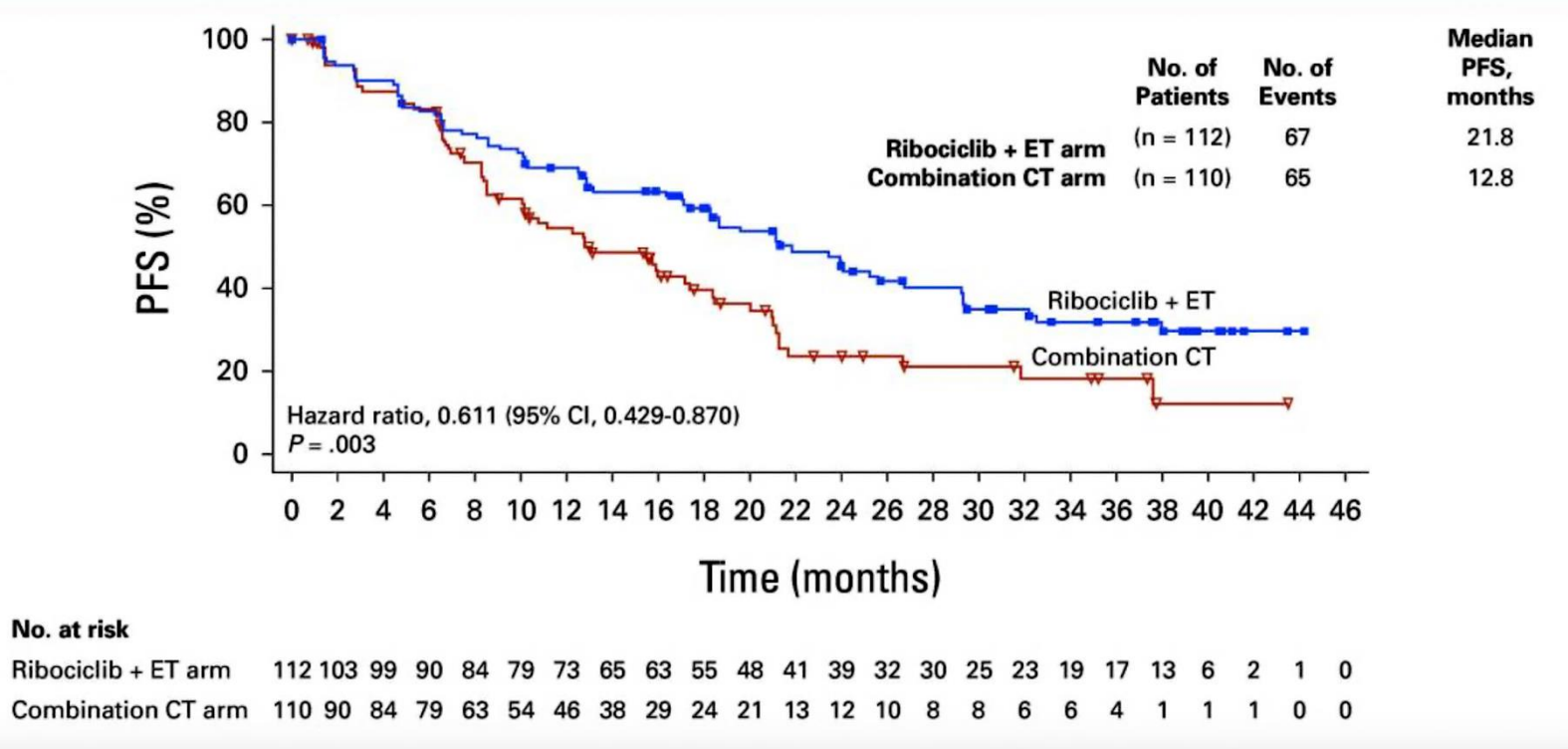
RIGHT Choice Final Results: Efficacy Outcomes



Overall response rate (ET/R vs CT):
66.1% vs 61.8%
CR: 6.3% vs 2.7%

Time to response (ET/R vs CT):
4.9 mo vs 3.2 mo
HR 0.76

PFS = progression-free survival; ET = endocrine therapy; R = ribociclib; CT = combination chemotherapy

Lu Y-S et al. *J Clin Oncol* 2024;42(23):2812-21.

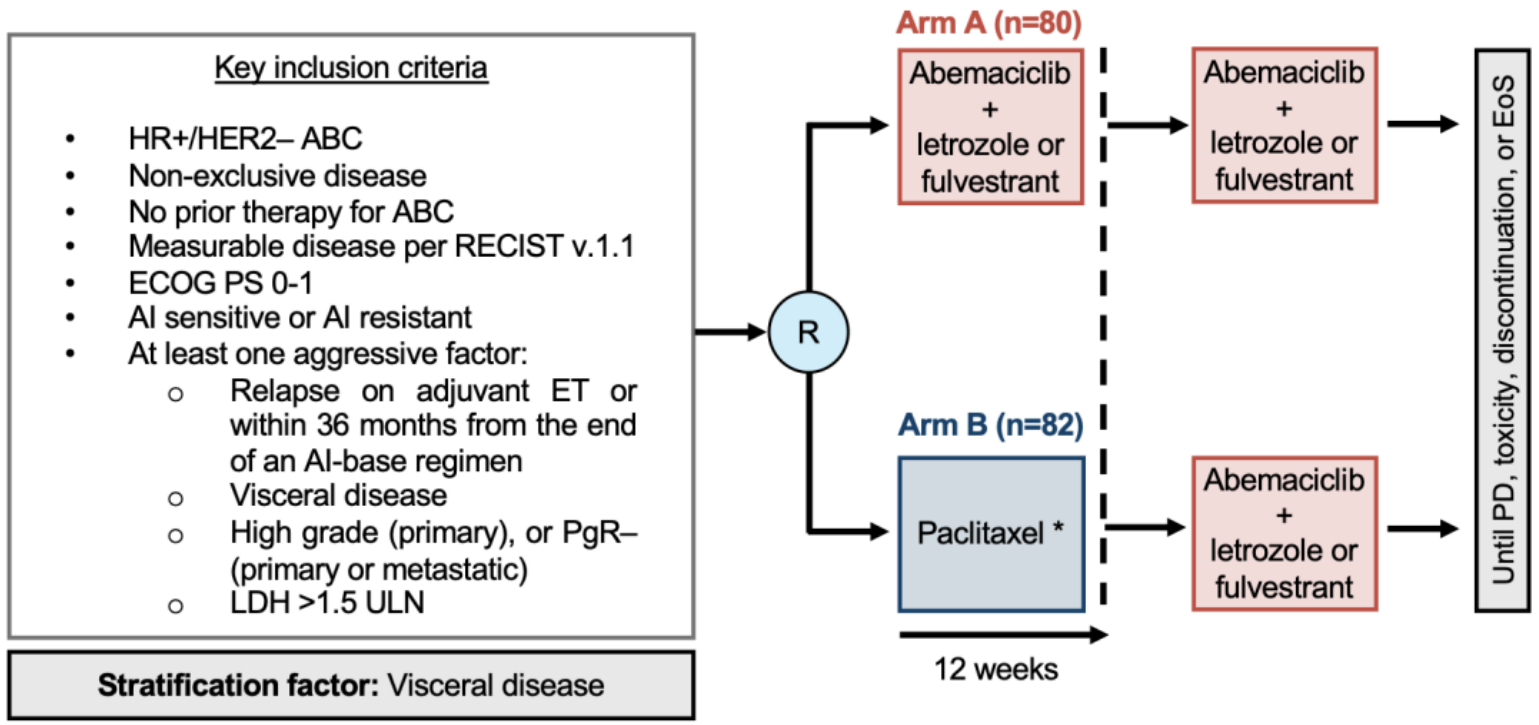
RIGHT CHOICE Final Results: Safety Summary

Events	Ribociclib + ET (n = 112), No. (%)			Combination CT (n = 100),[a] No. (%)		
	All Grades	Grade 3	Grade 4	All Grades	Grade 3	Grade 4
Any event[b]	112 (100.0)	71 (63.4)	18 (16.1)	100 (100.0)	62 (62.0)	11 (11.0)
Hematologic events						
Neutropenia	94 (83.9)	57 (50.9)	10 (8.9)	50 (50.0)	29 (29.0)	7 (7.0)
Leukopenia	55 (49.1)	28 (25.0)	0	26 (26.0)	7 (7.0)	1 (1.0)
Anemia	40 (35.7)	6 (5.4)	0	43 (43.0)	11 (11.0)	0
Nonhematologic events						
ALT increased	23 (20.5)	6 (5.4)	0	30 (30.0)	6 (6.0)	0
AST increased	23 (20.5)	8 (7.1)	0	29 (29.0)	5 (5.0)	0
Nausea	14 (12.5)	0	0	27 (27.0)	1 (1.0)	0
Alopecia	12 (10.7)	0	0	20 (20.0)	0	0
Vomiting	8 (7.1)	1 (0.9)	0	30 (30.0)	0	0
Diarrhea	3 (2.7)	0	0	26 (26.0)	1 (1.0)	0
Fatigue	9 (8.0)	0	0	25 (25.0)	2 (2.0)	0
Palmar-plantar erythrodysesthesia	3 (2.7)	0	0	32 (32.0)	5 (5.0)	0

RTP RESEARCH TO PRACTICE

Lu Y-S et al. *J Clin Oncol* 2024;42(23):2812-21.

ABIGAIL Phase II Study of Abemaciclib/ET with or without Paclitaxel Induction for Patients with mBC and Aggressive Disease Criteria



Primary objective:
Compare 12-week ORR per BICR in both groups.

Secondary endpoints:
PFS, OS, clinical benefit rate, time to response, duration of response, safety, maximum tumor shrinkage.

Newcombe hybrid score method was used. Based on 10% dropout rate, N ≥160 was necessary to attain 80% power at nominal level of two-sided α=0.05.

* According to response, clinicians can determine if patients extend paclitaxel to a maximum of 6 cycles after the first 12 weeks of treatment.

ABC, advanced breast cancer; AI, aromatase inhibitor; BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group Performance status; EoS, end of study; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; LDH, lactate dehydrogenase; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PgR, progesterone receptor; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; ULN, upper limit of normal.

de la Haba-Rodriguez J et al. ESMO 2024;Abstract LBA23.

ABIGAIL Primary Endpoint: 12-Week ORR by BICR

- The primary endpoint was met with a 12-week ORR per BICR of 58.8% in abemaciclib + ET, and 40.2% in paclitaxel (p = 0.0193).

	Abemaciclib + ET *N* = 80	Paclitaxel *N* = 82	Odd ratio (95% CI)	*p* value
12-week ORR in ITT population				
Complete response, partial response	47 (58.8%)	33 (40.2%)	**2.11 (1.13-3.96)**	**0.0193**
Stable disease, progressive disease , or discontinuation	33 (41.2%)	49 (59.8%)		
Response at 12 weeks since randomization				
Complete response	0 (0%)	0 (0%)	–	
Partial response	47 (58.8%)	33 (40.2%)		
Stable disease	24 (30.0%)	37 (45.2%)		
Progressive disease	1 (1.2%)	7 (8.5%)		
Not evaluable	8 (10.0%)	5 (6.1%)		
Death*	2 (2.5%)	2 (2.4%)		
Withdrawal of consent	2 (2.5%)	1 (1.3%)		
Toxicity	2 (2.5%)	0 (0%)		
Non-radiological progression	1 (1.25%)	0 (0%)		
Incorrect randomization	1 (1.25%)	2 (2.4%)		

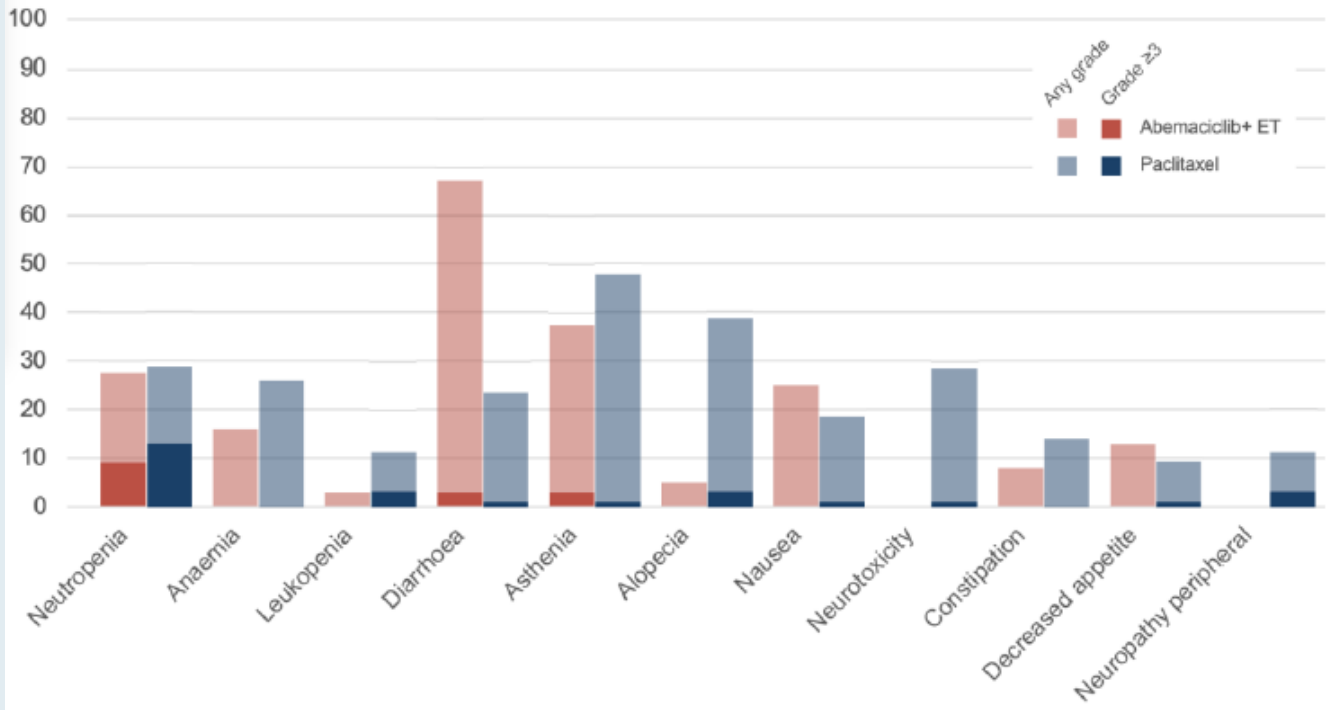
*Deaths were due to causes different from treatment-related toxicity.

ORR = overall response rate; BICR = blinded independent central review; ITT = intention to treat

de la Haba-Rodriguez J et al. ESMO 2024;Abstract LBA23.

ABIGAIL: Safety Results at 12 Weeks

Treatment-emergent adverse events (TEAEs) in ≥10% of patients



	Abemaciclib + ET		Paclitaxel	
12 week-TEAEs, %	Any grade	G≥3	Any grade	G≥3
Neutropenia	27	9	29	13
Anaemia	16	0	26	0
Leukopenia	3	0	11	3
Diarrhoea	68	3	23	1
Asthenia	37	3	48	1
Alopecia	5	0	39	3
Nausea	25	0	18	1
Neurotoxicity	0	0	28	1
Constipation	8	0	14	0
Decreased appetite	13	0	9	1
Neuropathy peripheral	0	0	11	3

de la Haba-Rodriguez J et al. ESMO 2024;Abstract LBA23.

Phase III Registration Studies of CDK4/6 Inhibitors

Agent	Trial	Line	PFS HR	*p*	CBR (%)	ORR (%) *[eval.]*	*OS HR*	*p*
Palbociclib	PLM-2	**SEN**	0.58	*< .0001*	85%	55% (Δ 10%)	**0.956**	***0.33***
	PLM-3	**RES**	0.46	*< .0001*	67%	25% (Δ 14%)	**0.81**	***0.022***
Ribociclib	MNL-2	**SEN**	0.57	*< .0001*	80%	53% (Δ 15%)	**0.76**	***0.004***
	MNL-3	**SEN/RES**	0.59	*< .0001*	70%	41% (Δ 12%)	**0.724**	***0.0045***
	MNL-7	**SEN/RES**	0.55	*< .0001*	79%	51% (Δ 15%)	**0.712**	***0.00973***
Abemaciclib	MRC-3	**SEN**	0.54	*< .0001*	78%	59% (Δ 15%)	**0.854**	***0.0664***
	MRC-2	**RES**	0.54	*< .0001*	NK	48% (Δ 27%)	**0.757**	***0.0137***

SEN, Sensitive to endocrine therapy by ABC-3; RES: Resistant criteria to prior endocrine therapy by ABC-3; CBR, clinical benefit rate; CDK, cyclin-dependent kinase; HR, hazard ratio; NK, not known; ORR, overall response rare; PFS, progression-free survival.

1. Palbociclib EU SmPC, 2019; 2. Ribociclib EU SmPC, 2019; 3. Abemaciclib EU SmPC 2019; Geotz SABCS 2023

Courtesy of Hope S Rugo, MD

Age 65, PS 0; de novo metastatic disease; symptomatic liver and bone metastases
HER2 IHC 1+, ESR1-negative, BRCA wild type

	PIK3CA-negative	PIK3CA-positive
 Dr Hurvitz	Ribociclib + AI	Ribociclib + AI
 Dr Kaklamani	Ribociclib + AI	Ribociclib + AI
 Dr Burstein	Abemaciclib + AI	Abemaciclib + AI
 Prof Curigliano	Ribociclib + AI	Ribociclib + AI
 Dr Jhaveri	Ribociclib + AI vs paclitaxel induction followed by switch*	Ribociclib + AI vs paclitaxel induction followed by switch*
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

*Depends on liver enzymes and bilirubin

AI = aromatase inhibitor

Age 65, PS 0; de novo metastatic disease; asymptomatic bone and/or soft tissue metastases

HER2 IHC 1+, ESR1-negative, BRCA wild type

	PIK3CA-negative	PIK3CA-positive
 Dr Hurvitz	Ribociclib + AI	Ribociclib + AI
 Dr Kaklamani	Ribociclib + AI	Ribociclib + AI
 Dr Burstein	CDK4/6i + AI	CDK4/6i + AI
 Prof Curigliano	Ribociclib + AI	Ribociclib + AI
 Dr Jhaveri	Ribociclib + AI	Ribociclib + AI
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

Age 65, PS 0; s/p 5 years of adjuvant anastrozole; 2 years later: Symptomatic liver and bone metastases

PIK3CA-negative, ESR1-negative, BRCA wild type

	HER2-low (IHC 1+)	HER2-negative (IHC 0)
 Dr Hurvitz	Ribociclib + AI	Ribociclib + AI
 Dr Kaklamani	Ribociclib + AI	Ribociclib + AI
 Dr Burstein	Abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Prof Curigliano	Ribociclib + AI	Ribociclib + AI
 Dr Jhaveri	Ribociclib + AI vs paclitaxel induction followed by switch*	Ribociclib + AI vs paclitaxel induction followed by switch*
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

* Depends on liver enzymes and bilirubin

Age 65, PS 0; s/p 5 years of adjuvant anastrozole; 2 years later: Asymptomatic bone and/or soft tissue metastases

PIK3CA-negative, ESR1-negative, BRCA wild type

	HER2-low (IHC 1+)	HER2-negative (IHC 0)
 Dr Hurvitz	Ribociclib + AI	Ribociclib + AI
 Dr Kaklamani	Ribociclib + AI	Ribociclib + AI
 Dr Burstein	Abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Prof Curigliano	Ribociclib + AI	Ribociclib + AI
 Dr Jhaveri	Ribociclib + AI	Ribociclib + AI
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

Age 65, PS 0; s/p 5 years of adjuvant anastrozole and 3 years of adjuvant ribociclib; 2 years later: Symptomatic liver and bone metastases

PIK3CA-negative, ESR1-negative, BRCA wild type

	HER2-low (IHC 1+)	HER2-negative (IHC 0)
 Dr Hurvitz	Abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Dr Kaklamani	T-DXd	Abemaciclib + AI
 Dr Burstein	T-DXd or capecitabine	T-DXd or capecitabine
 Prof Curigliano	Abemaciclib + AI	Abemaciclib + AI
 Dr Jhaveri	Abema/Ribo + AI vs Pacl induction followed by switch*	Abema/Ribo + AI vs Pacl induction followed by switch*
 Dr Lustberg	Abemaciclib + AI	Abemaciclib + AI

*Depends on liver enzymes and bilirubin

T-DXd = trastuzumab deruxtecan

Age 65, PS 0; s/p 5 years of adjuvant anastrozole and 3 years of adjuvant ribociclib;
2 years later: Asymptomatic bone and/or soft tissue metastases
PIK3CA-negative, ESR1-negative, BRCA wild type

	HER2-low (IHC 1+)	HER2-negative (IHC 0)
 Dr Hurvitz	Abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Dr Kaklamani	Abemaciclib + AI	Abemaciclib + AI
 Dr Burstein	Capecitabine	Capecitabine
 Prof Curigliano	Abemaciclib + AI	Abemaciclib + AI
 Dr Jhaveri	Abemaciclib or ribociclib + AI	Abemaciclib or ribociclib + AI
 Dr Lustberg	Abemaciclib + AI	Abemaciclib + AI

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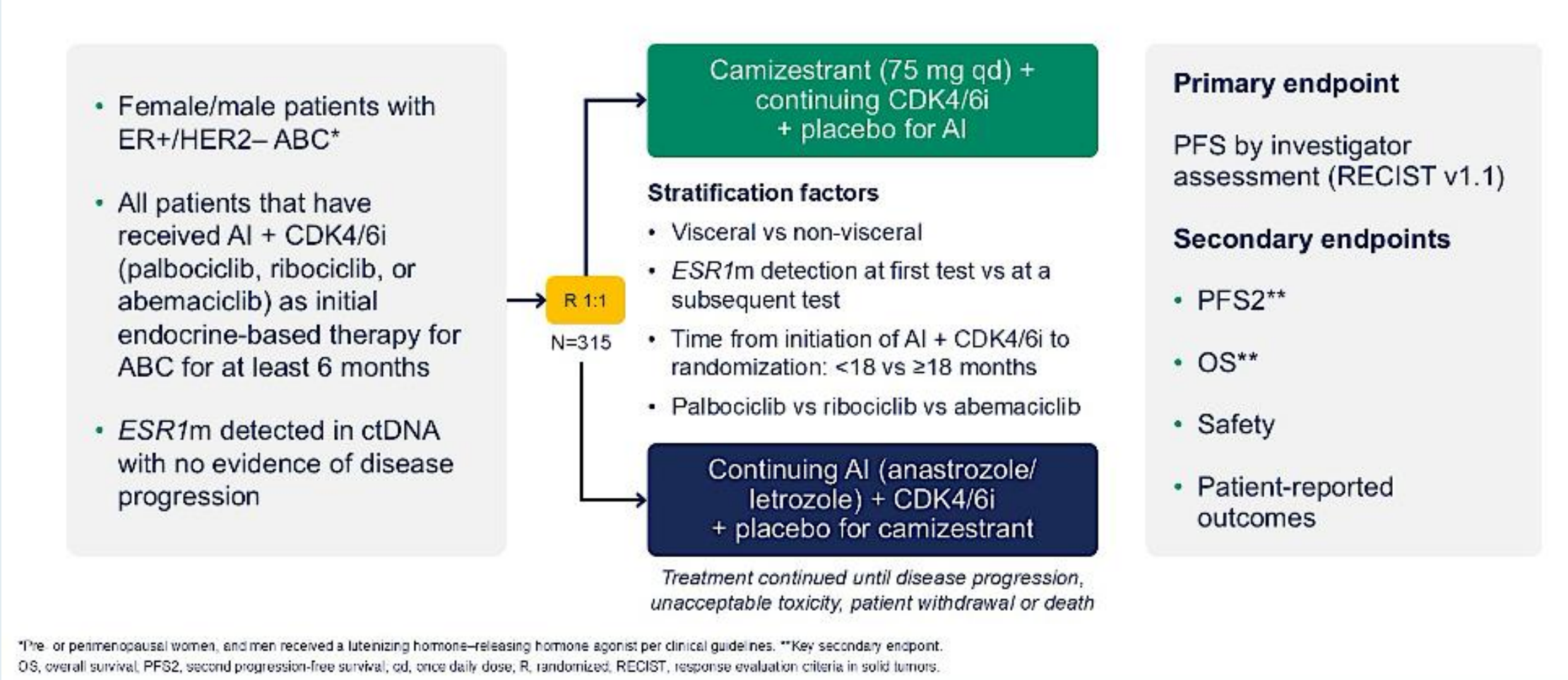
AGREE
IN BETWEEN
DISAGREE

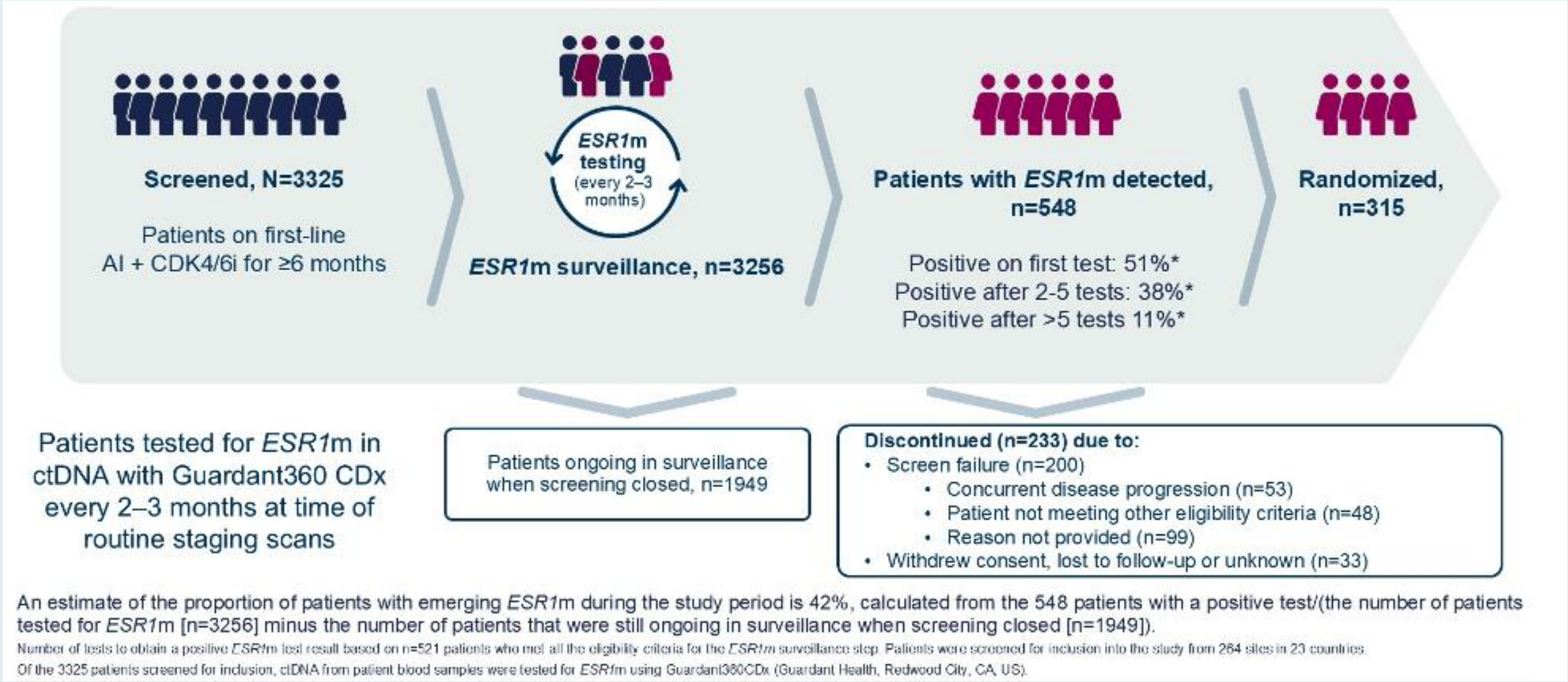
SERENA-6 Phase III Study of First-Line Camizestrant and CDK4/6 Inhibitor for Emerging ESR1-Mutated Breast Cancer



AI = aromatase inhibitor; CDK4/6i = CDK4/6 inhibitor; ABC = advanced breast cancer

Turner N et al. ASCO 2025;Abstract LBA4.

SERENA-6: ESR1m Surveillance



An estimate of the proportion of patients with emerging *ESR1*m during the study period is 42%, calculated from the 548 patients with a positive test/(the number of patients tested for *ESR1*m [n=3256] minus the number of patients that were still ongoing in surveillance when screening closed [n=1949]).

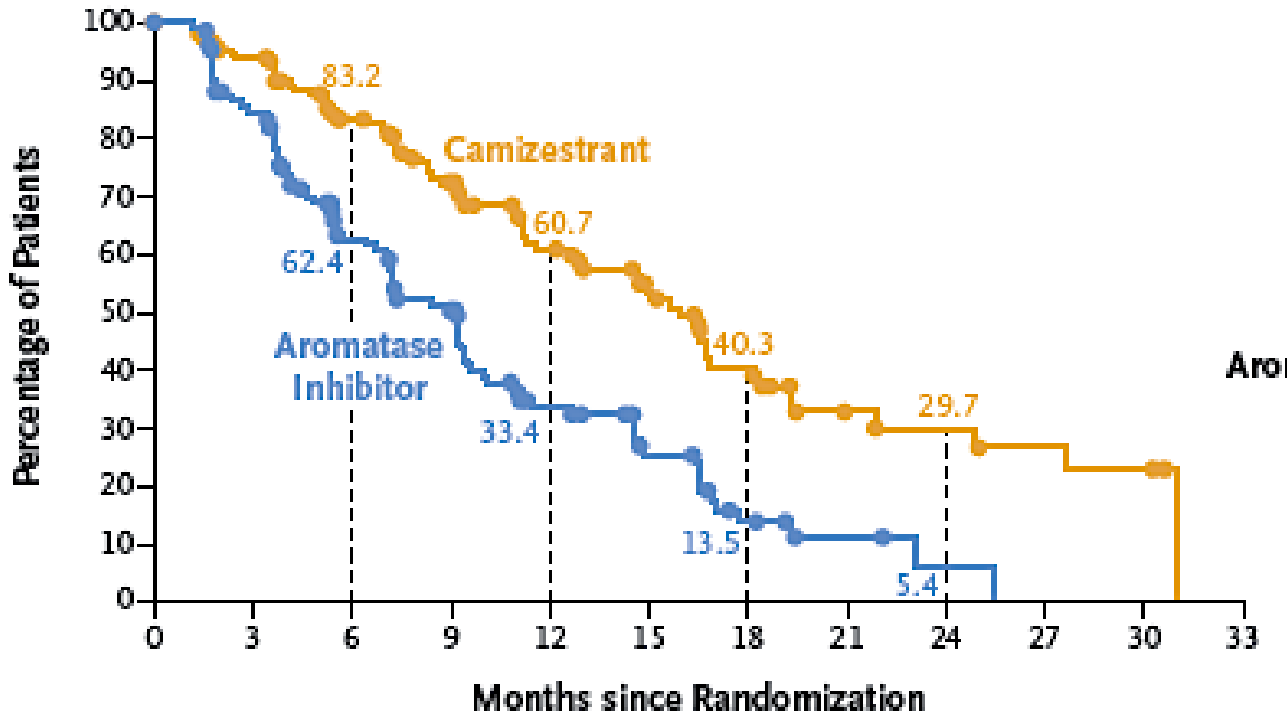
Number of tests to obtain a positive *ESR1*m test result based on n=521 patients who met all the eligibility criteria for the *ESR1*m surveillance step. Patients were screened for inclusion into the study from 264 sites in 23 countries.

Of the 3325 patients screened for inclusion, ctDNA from patient blood samples were tested for *ESR1*m using Guardant360CDx (Guardant Health, Redwood City, CA, US).

ESR1m = ESR1 mutation

Turner N et al. ASCO 2025;Abstract LBA4; Bidard F-C et al. *N Engl J Med* 2025;393:569-80.

SERENA-6: PFS



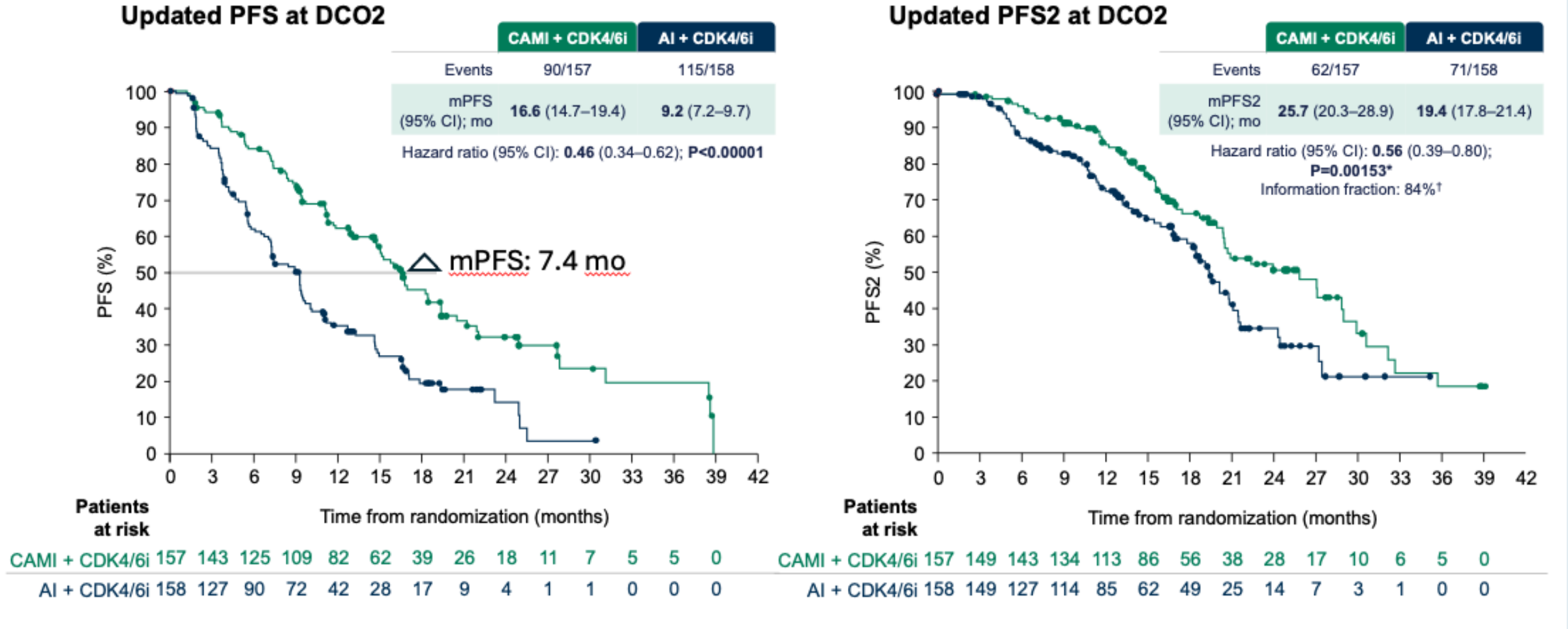
No. at Risk												
Camizestrant	157	138	105	82	55	41	26	11	9	7	6	0
Aromatase inhibitor	158	124	73	55	29	17	7	3	1	0	0	0

	No. of Patients with Event (%)	Median Progression-free Survival (95% CI)
		mo
Camizestrant (N=157)	71 (45.2)	16.0 (12.7–18.2)
Aromatase Inhibitor (N=158)	100 (63.3)	9.2 (7.2–9.5)

Adjusted hazard ratio for disease progression or death, 0.44 (95% CI, 0.31–0.60)
P<0.0001

Turner N et al. ASCO 2025;Abstract LBA4; Bidard F-C et al. *N Engl J Med* 2025;393:569-80.

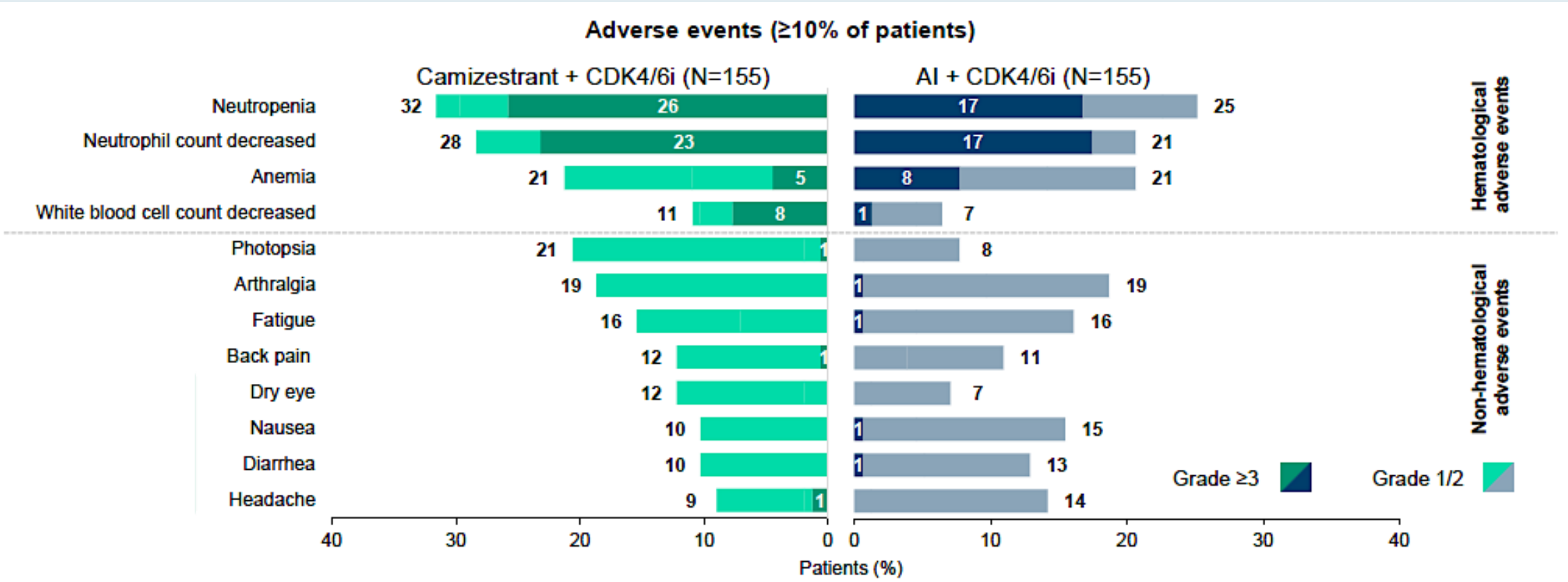
SERENA-6: Updated PFS and PFS2 at Data Cutoff 2



DCO = data cutoff

Bidard F-C et al. SABCS 2025;Abstract RF7-03.

SERENA-6: Updated Safety at Data Cutoff 2



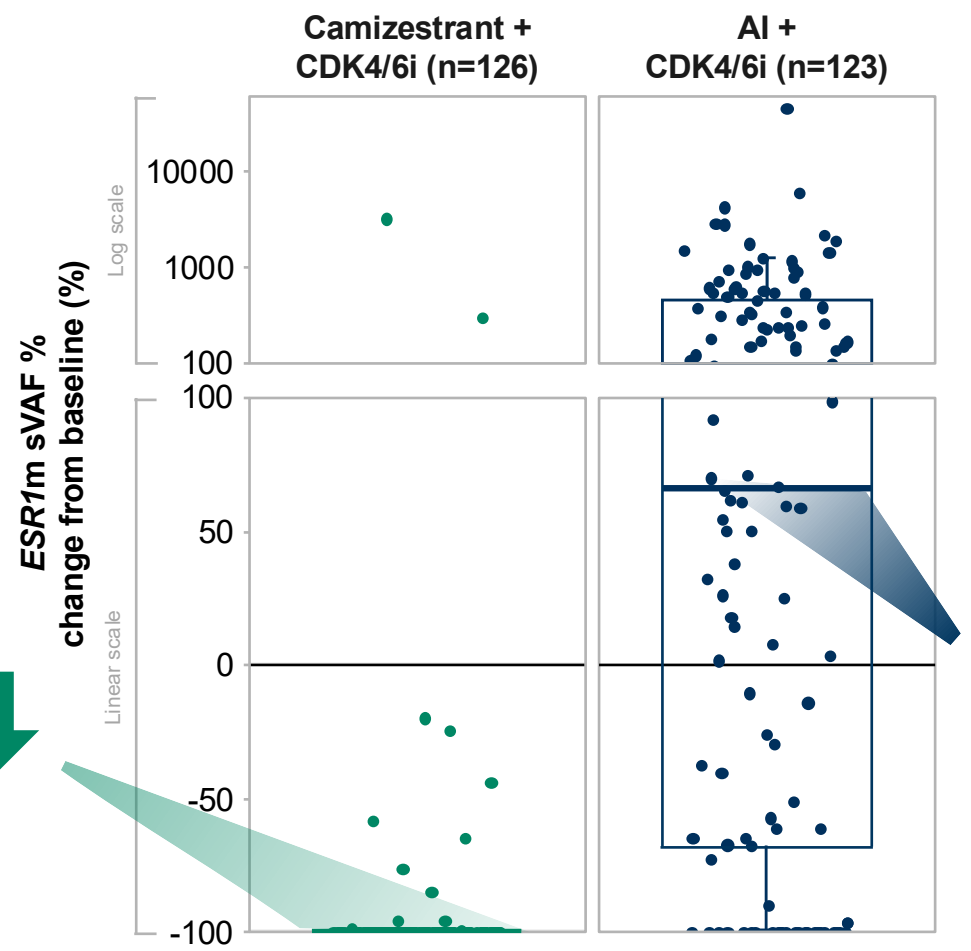
- Exposure time-adjusted incidence rates were similar between treatment arms for hematological adverse events
- At DCO2, there were no additional adverse events leading to treatment discontinuation of camizestrant (n=2, 1%). One additional patient discontinued AI due to adverse events (n=4, 3%)

Second pre-specified data cut DCO2: June 30, 2025.

Bidard F-C et al. SABCS 2025;Abstract RF7-03.

Camizestrant + CDK4/6i profoundly reduces *ESR1*m ctDNA vs AI + CDK4/6i

*ESR1*m allele frequency was **profoundly reduced** in the camizestrant + CDK4/6i arm vs the AI + CDK4/6i arm (Wilcoxon nominal P<0.00001)



In the AI + CDK4/6i arm, *ESR1*m allele frequency increased >500% from baseline in **24.4%** of patients vs **0.8%** of patients in the camizestrant + CDK4/6i arm

Median change from baseline at C3D1 (8 weeks):

−100% (IQR: −100 to −100)

Median change from baseline at C3D1 (8 weeks):

+66.7% (IQR: −67.9 to +465.0)

Baseline VAF were balanced across arms.
IQR, interquartile range; (s)VAF, (summed) variant allele fraction.
Second pre-specified data cut **DCO2: June 30, 2025.**

Bidard F-C et al. SABCS 2025; Abstract RF7-03

A 65-year-old woman presents with de novo ER-positive, HER2-negative (IHC 0/null) mBC with multiple minimally symptomatic bone metastases. Biomarker evaluation is negative for ESR1 mutations and PIK3CA/AKT1/PTEN alterations. She is started on ribociclib with anastrozole and followed with serial ctDNA testing for ESR1 mutations. Regulatory and reimbursement issues aside, what would you most likely recommend if she is found to have an ESR1 mutation without radiographic evidence of disease progression after 1 year? After 3 years?

	ESR1 mutation 1 year later	ESR1 mutation 3 years later
 Dr Hurvitz	Continue ribociclib/anastrozole until radiographic evidence of PD	Continue ribociclib/anastrozole until radiographic evidence of PD
 Dr Kaklamani	Continue ribociclib/anastrozole until radiographic evidence of PD	Continue ribociclib/anastrozole until radiographic evidence of PD
 Dr Burstein	Continue ribociclib/anastrozole until radiographic evidence of PD	Continue ribociclib/anastrozole until radiographic evidence of PD
 Prof Curigliano	Switch to ribociclib + camizestrant	Switch to ribociclib + camizestrant
 Dr Jhaveri	SERENA-6 vs imlunestrant + abema/giredestrant + everolimus	SERENA-6 vs imlunestrant + abema/giredestrant + everolimus
 Dr Lustberg	Continue ribociclib/anastrozole until radiographic evidence of PD	Continue ribociclib/anastrozole until radiographic evidence of PD

PD = progressive disease

Regulatory and reimbursement issues aside, do you believe that the results from the SERENA-6 study justify the routine use of serial ctDNA monitoring for early detection of ESR1 mutations in patients with ER-positive, HER2-negative mBC receiving first-line therapy? If yes, how often would you conduct ctDNA analysis?

	Routine use of ESR1 serial ctDNA monitoring?	How often
 Dr Hurvitz	No	N/A
 Dr Kaklamani	No	N/A
 Dr Burstein	No	N/A
 Prof Curigliano	Yes	Every 3 months after 18 months of first-line therapy
 Dr Jhaveri	No	N/A
 Dr Lustberg	No	N/A

Agenda

Introduction: Which Biomarkers and When

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- Use of SERENA-6 strategy
- Use of inavolisib triplet

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- Use of selective estrogen receptor degrader (SERD) monotherapy
- Use of AKT inhibitors

Dr Hurvitz: Case Presentation 1

- 54 yo woman with pT1N1 grade 2 ER+ PR- HER2 1+ breast cancer with Onco*type* DX® RS® of 20 was treated with lumpectomy/SLNB followed by RT and 2 years of letrozole.
- Was in a low impact motor vehicle accident and was seen in ER for severe mid-back pain. Imaging revealed a T5 burst fracture and several suspicious bone lesions.
- Biopsy confirmed ER+ HER2- MBC. ctDNA sent revealing PIK3CA mutation. Two months prior patient had started GLP1 rec agonist for obesity and metformin for hyperglycemia (HbA1c 6.9). Glucose testing now: HbA1c 6.0, FPG 125.

Dr Hurvitz: Case Presentation 1 (Continued)

- Decided to start fulvestrant, palbociclib, inavolisib. Glucose monitoring first two weeks, only grade 1 hyperglycemia.
- However, she presented on day 15 of cycle 1 for lab work and ANC was 900, K was 2.9 and she was having grade 3 diarrhea (8 BM per day over baseline) for 3 days. She was able to keep up with oral hydration; given IV fluids and potassium in clinic.
- Fulvestrant was given, Palbo (held for diarrhea, not ANC) and inavolisib were held and she was started on antidiarrheal regimen.

Dr Hurvitz: Case Presentation 1 (Continued)

- Ultimately over the course of the next week, diarrhea resolved; resumed inavolisib (6 mg) and palbociclib (125 mg). ANC on day 1 of cycle 2 was 600.
- Held palbociclib - ultimately had to dose reduce to 100 mg. Fatigue prominent. Pt concerned about long term tolerability of this regimen.


AGREE
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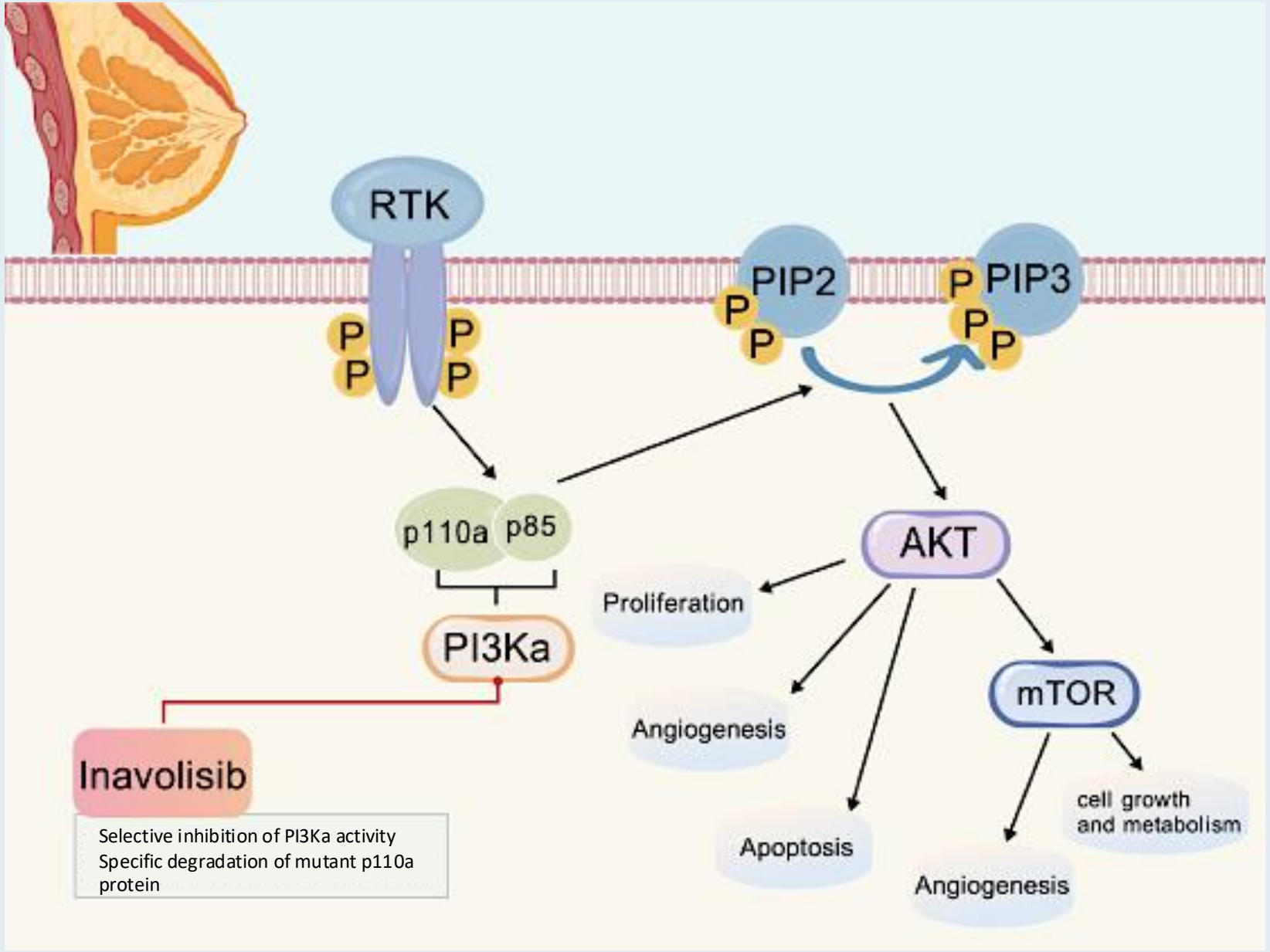
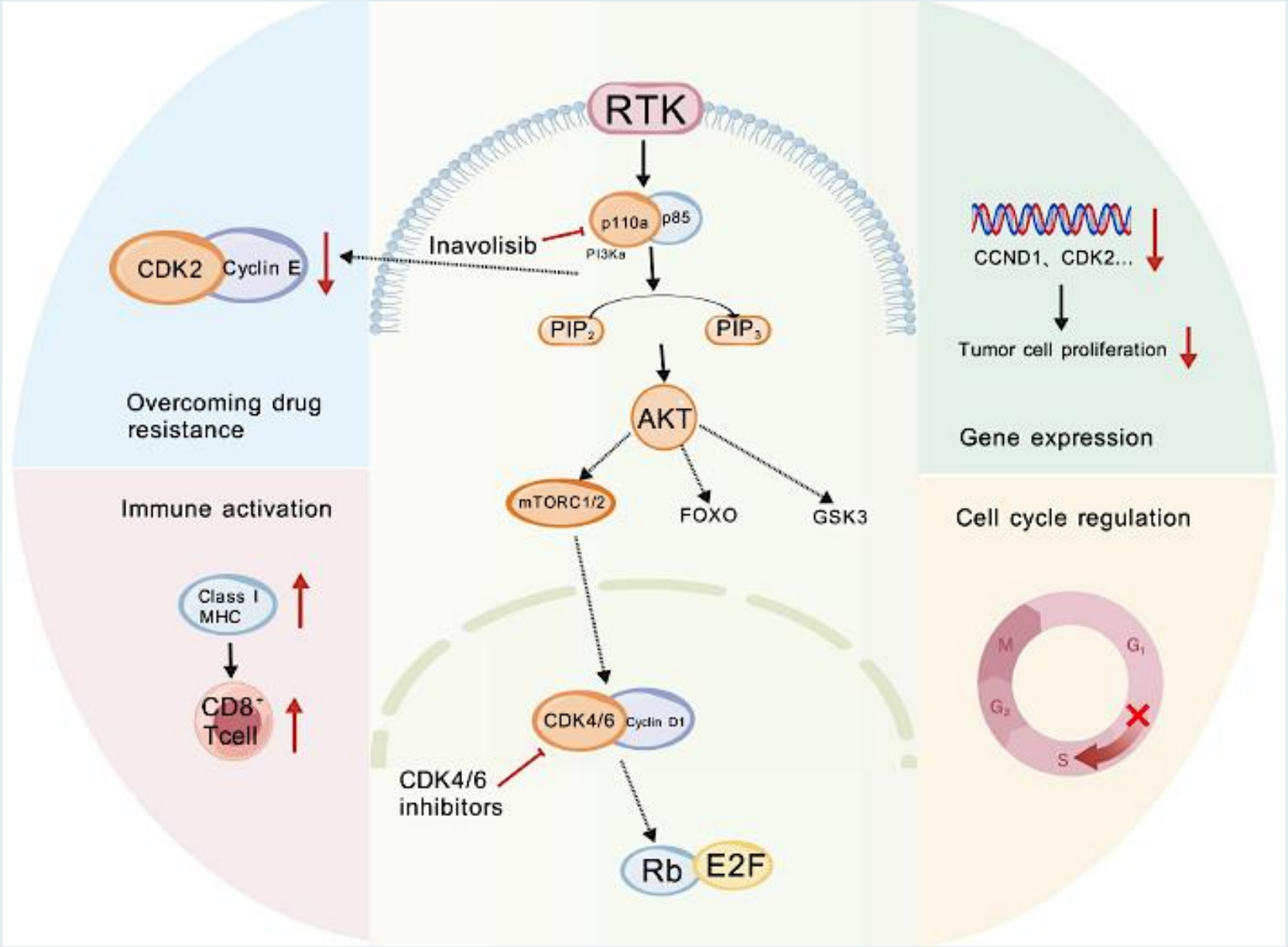
DISAGREE

Inavolisib Mechanism of Action



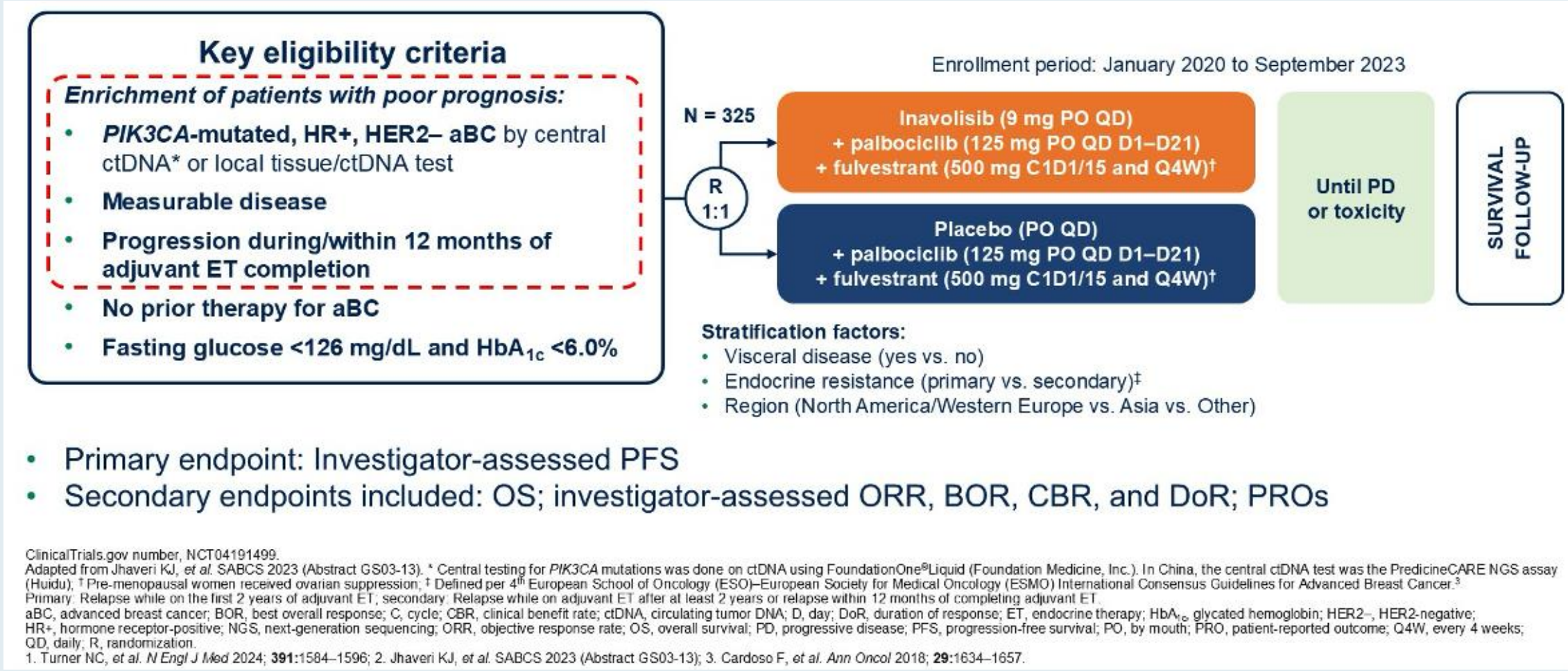
Zhu R et al. *Front Immunol* 2025;16:1693927.

Synergistic Mechanism of Inavolisib with CDK4/6 Inhibitors



Zhu R et al. *Front Immunol* 2025;16:1693927.

INAVO120 Phase III Trial of First-Line Inavolisib with Palbociclib/Fulvestrant for Patients with PIK3CA-Mutant Localized Relapsing HR-Positive, HER2–Negative mBC

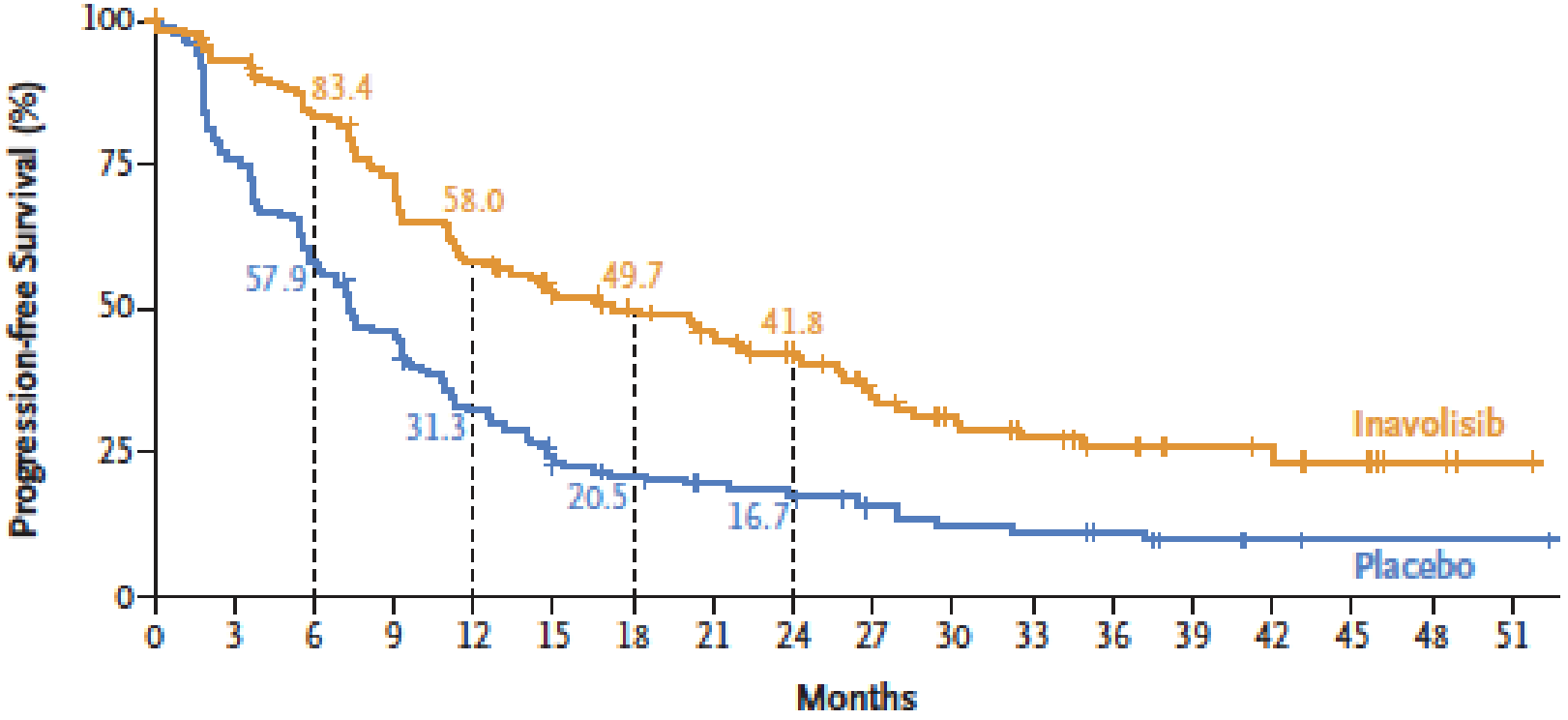


- Primary endpoint: Investigator-assessed PFS
- Secondary endpoints included: OS; investigator-assessed ORR, BOR, CBR, and DoR; PROs

ClinicalTrials.gov number, NCT04191499.
Adapted from Jhaveri KJ, *et al.* SABCS 2023 (Abstract GS03-13). * Central testing for *PIK3CA* mutations was done on ctDNA using FoundationOne®Liquid (Foundation Medicine, Inc.). In China, the central ctDNA test was the PredicineCARE NGS assay (Huidu). † Pre-menopausal women received ovarian suppression. ‡ Defined per 4th European School of Oncology (ESO)–European Society for Medical Oncology (ESMO) International Consensus Guidelines for Advanced Breast Cancer.[3] Primary: Relapse while on the first 2 years of adjuvant ET; secondary: Relapse while on adjuvant ET after at least 2 years or relapse within 12 months of completing adjuvant ET.
aBC, advanced breast cancer; BOR, best overall response; C, cycle; CBR, clinical benefit rate; ctDNA, circulating tumor DNA; D, day; DoR, duration of response; ET, endocrine therapy; HbA_{1c}, glycated hemoglobin; HER2–, HER2-negative; HR+, hormone receptor-positive; NGS, next-generation sequencing; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PO, by mouth; PRO, patient-reported outcome; Q4W, every 4 weeks; QD, daily; R, randomization.
1. Turner NC, *et al. N Engl J Med* 2024; **391**:1584–1596; 2. Jhaveri KJ, *et al.* SABCS 2023 (Abstract GS03-13); 3. Cardoso F, *et al. Ann Oncol* 2018; **29**:1634–1657.

Turner N et al. ASCO 2025;Abstract 1003.

INAVO120: Updated PFS



No. at Risk

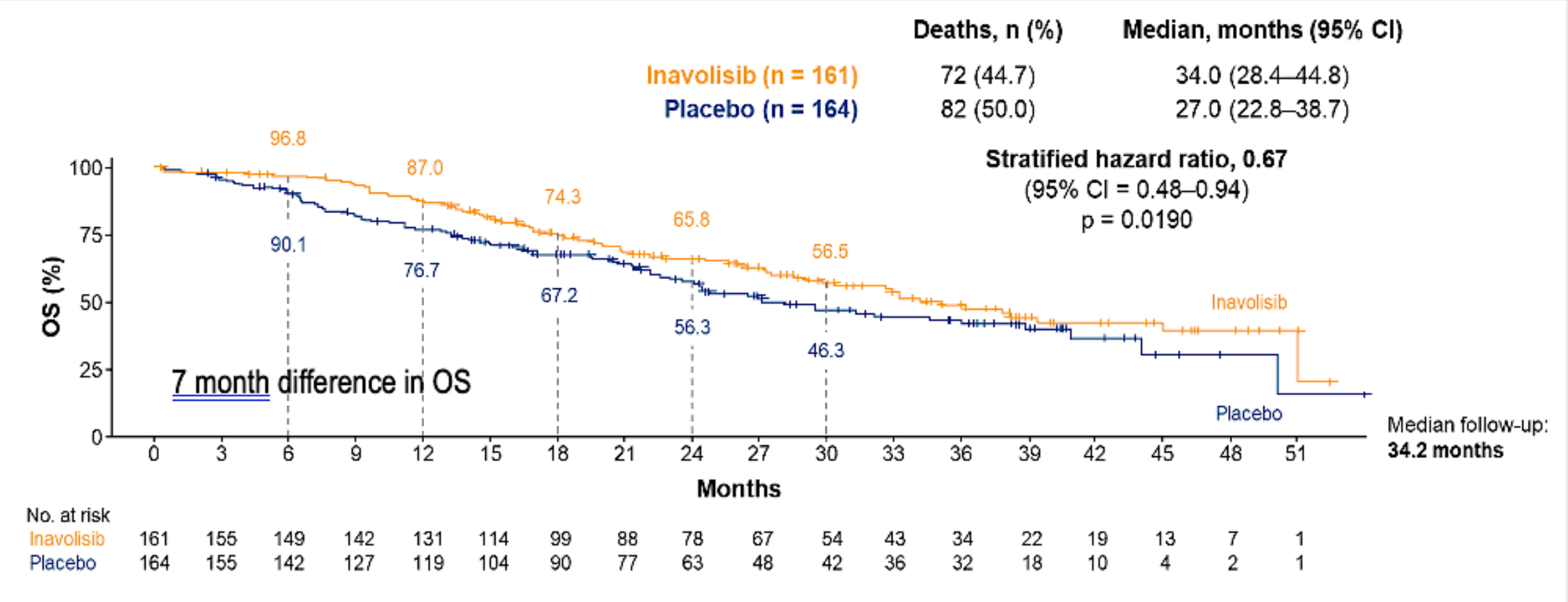
Inavolisib	161	146	129	112	89	73	65	57	46	32	25	19	15	11	10	7	3	1
Placebo	164	125	95	74	50	34	30	24	21	14	11	10	8	4	2	1	1	1

	No. of Patients with Event (%)	Median Progression-free Survival (95% CI)
		mo
Inavolisib (N=161)	103 (64.0)	17.2 (11.6–22.2)
Placebo (N=164)	141 (86.0)	7.3 (5.9–9.2)

Stratified hazard ratio for disease progression or death, 0.42 (95% CI, 0.32–0.55)

Turner N et al. ASCO 2025;Abstract 1003; Jhaveri K et al. *N Engl J Med* 2025;393:151-61.

INAVO120: Updated Overall Survival



Turner N et al. ASCO 2025;Abstract 1003; Jhaveri K et al. *N Engl J Med* 2025;393:151-61.

INAVO120: Selected Adverse Events

	Inavolisib (n = 161)		Placebo (n = 163)	
Patients, n (%)	**Any grade**	**Grade 3 or 4**	**Any grade**	**Grade 3 or 4**
Neutropenia	147 (91.3)	133 (82.6)	148 (90.8)	131 (80.4)
Thrombocytopenia	80 (49.7)	22 (13.7)	75 (46.0)	8 (4.9)
Stomatitis or mucosal inflammation	89 (55.3)	9 (5.6)	47 (28.8)	0
Anemia	64 (39.8)	11 (6.8)	62 (38.0)	3 (1.8)
Hyperglycemia	102 (63.4)	11 (6.8)	22 (13.5)	0
Diarrhea†	84 (52.2)	6 (3.7)	26 (16.0)	0
Nausea	47 (29.2)	0	32 (19.6)	0
Rash	43 (26.7)	0	32 (19.6)	1 (0.6)
Ocular toxicities‡	47 (29.2)	1 (0.6)	26 (16.0)	0
Aspartate transaminase/ alanine transaminase increase	34 (21.1)	7 (4.3)	37 (22.7)	4 (2.5)
Vomiting	26 (16.1)	2 (1.2)	10 (6.1)	2 (1.2)
Lymphopenia	6 (3.7)	1 (0.6)	15 (9.2)	3 (1.8)
Pneumonitis§	5 (3.1)	1 (0.6)	2 (1.2)	0

Turner N et al. ASCO 2025;Abstract 1003; Jhaveri K et al. *N Engl J Med* 2025;393:151-61.

Age 65, PS 0; metastatic disease after 2 years of planned 5 years of adjuvant AI; symptomatic liver and bone metastases

HER2 IHC 1+, ESR1-negative, BRCA wild type

	PIK3CA-negative	PIK3CA-positive
 Dr Hurvitz	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Kaklamani	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Burstein	Abemaciclib + fulvestrant OR capecitabine	Inavolisib + palbociclib + fulvestrant OR fulvestrant + capivasertib OR capecitabine
 Prof Curigliano	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Jhaveri	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

Age 65, PS 0; metastatic disease after 2 years of planned 5 years of adjuvant AI; asymptomatic bone and/or soft tissue metastases

HER2 IHC 1+, ESR1-negative, BRCA wild type

	PIK3CA-negative	PIK3CA-positive
 Dr Hurvitz	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Kaklamani	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Burstein	Fulvestrant + CDK4/6i	Inavolisib + palbociclib + fulvestrant
 Prof Curigliano	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Jhaveri	Ribociclib + fulvestrant	Inavolisib + palbociclib + fulvestrant
 Dr Lustberg	Ribociclib + AI	Ribociclib + AI

CDK4/6i = CDK4/6 inhibitor

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Dr Kaklamani: Case Presentation 2

- 48 yo premenopausal woman
- She had been diagnosed with a T2N1 R IDC ER 90% PR 80% HER2 0 6 y prior and had received adjuvant chemotherapy with TC and was put on goserelin and anastrozole for 5 y.
- 14 mo after discontinuing anastrozole she presented with fatigue and workup showed lung and bone lesions. A lung biopsy showed ER 80% PR 80% HER2 1+. NGS testing didn't show any actionable mutation. Genetic testing was negative.
- She was put on denosumab, ribociclib, goserelin and letrozole and after an initial partial response she was found to have disease progression in her bones 35 mo after initiation of 1st line therapy.
- She had ctDNA showing an ESR1 mutation and was started on elacestrant.
- She is currently on elacestrant for 22 mo having PR on treatment.

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AGREE
IN BETWEEN
DISAGREE

FDA Approves Elacestrant for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer

Press Release: January 27, 2023

"On January 27, 2023, the Food and Drug Administration (FDA) approved elacestrant for postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

FDA also approved the Guardant360 CDx assay as a companion diagnostic device to identify patients with breast cancer for treatment with elacestrant.

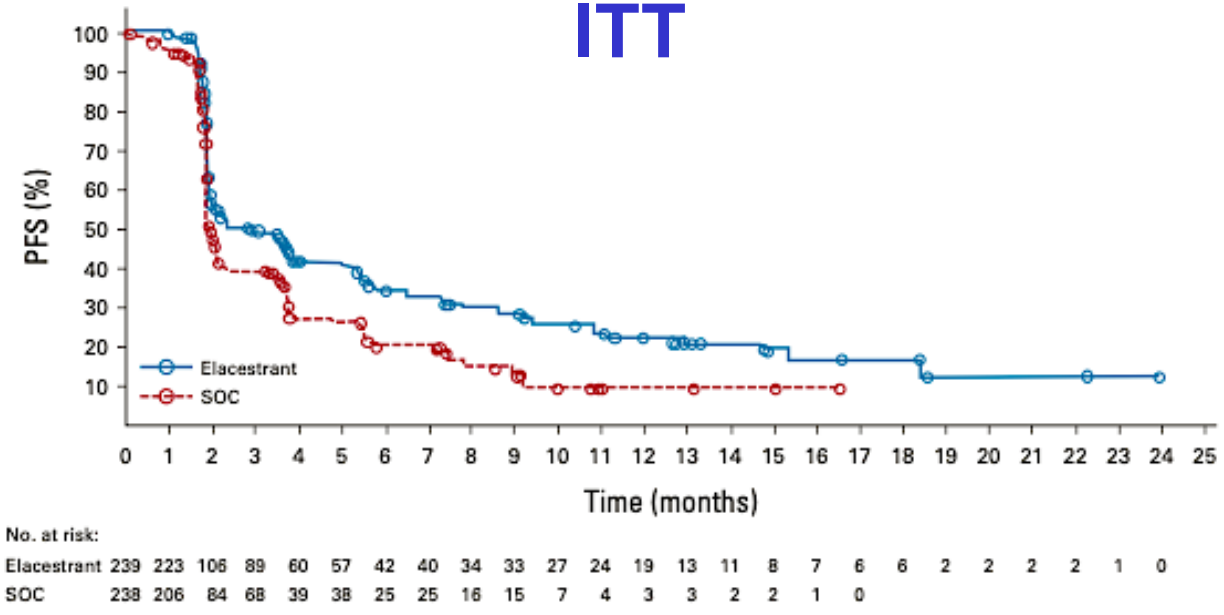
Efficacy was evaluated in EMERALD (NCT03778931), a randomized, open-label, active-controlled, multicenter trial that enrolled 478 postmenopausal women and men with ER-positive, HER2-negative advanced or metastatic breast cancer of which 228 patients had ESR1 mutations."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-elacestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast-cancer

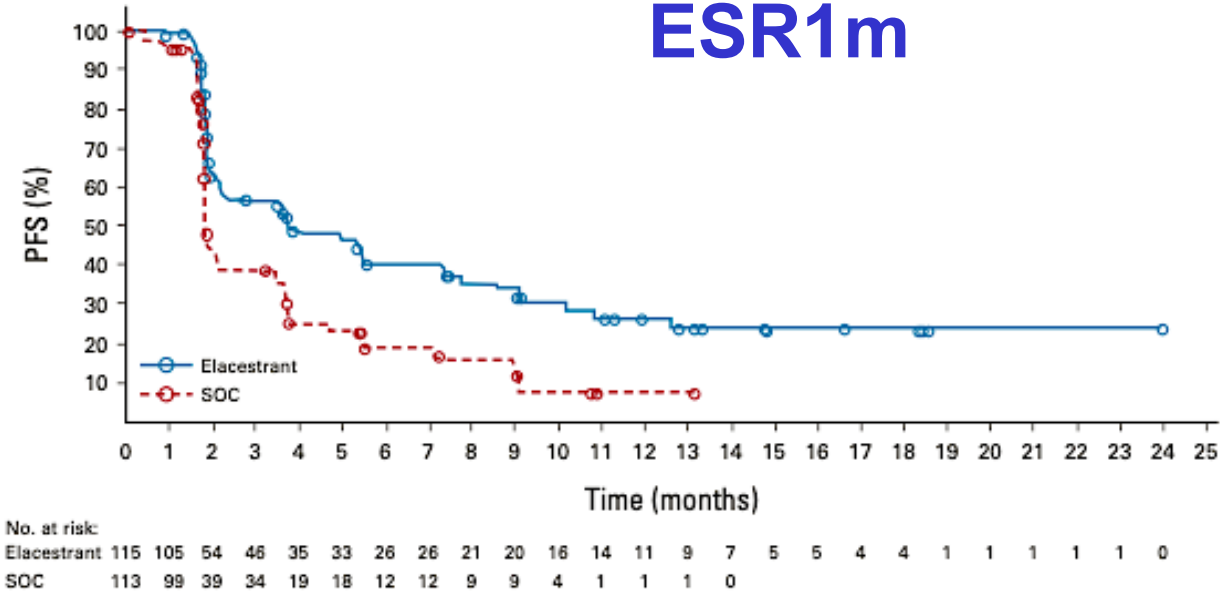
RTP RESEARCH TO PRACTICE

EMERALD: Phase III Trial of Elacestrant versus Standard Endocrine Therapy for ER-Positive, HER2-Negative Advanced Breast Cancer

ITT



ESR1m



	Elacestrant (n = 239)	SOC (n = 238)
Events, No. (%)	144 (60.3)	156 (65.5)
HR (95% CI)	0.70 (0.55 to 0.88)	
P	.0018	
6-month PFS, % (95% CI)	34.3 (27.2 to 41.5)	20.4 (14.1 to 26.7)
12-month PFS, % (95% CI)	22.3 (15.2 to 29.4)	9.4 (4.0 to 14.8)

	Elacestrant (n = 115)	SOC (n = 113)
Events, No. (%)	62 (53.9)	78 (69.0)
HR (95% CI)	0.55 (0.39 to 0.77)	
P	.0005	
6-month PFS, % (95% CI)	40.8 (30.1 to 51.4)	19.1 (10.5 to 27.8)
12-month PFS, % (95% CI)	26.8 (16.2 to 37.4)	8.2 (1.3 to 15.1)

SOC = standard of care

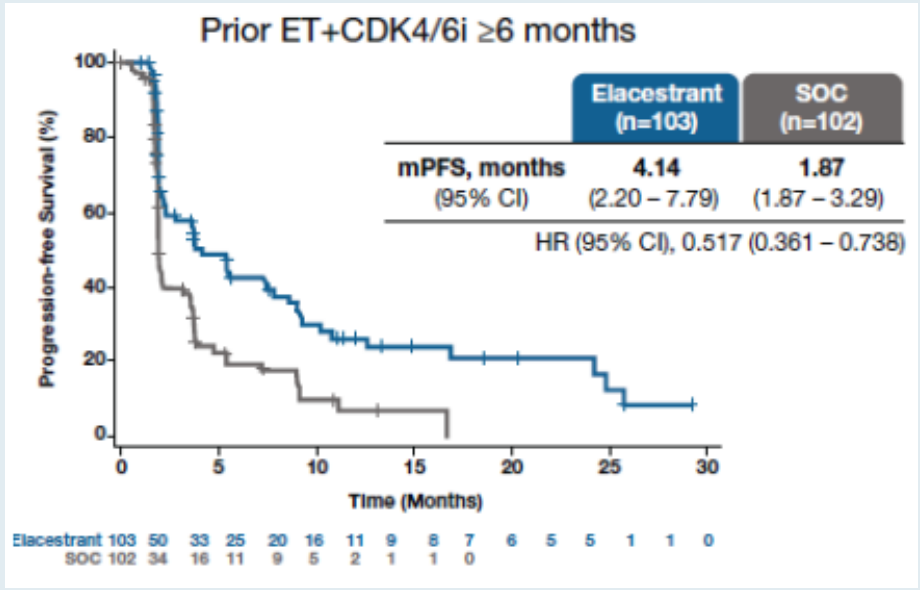
Bidard F-C et al. *J Clin Oncol* 2022;40(28):3246-56.

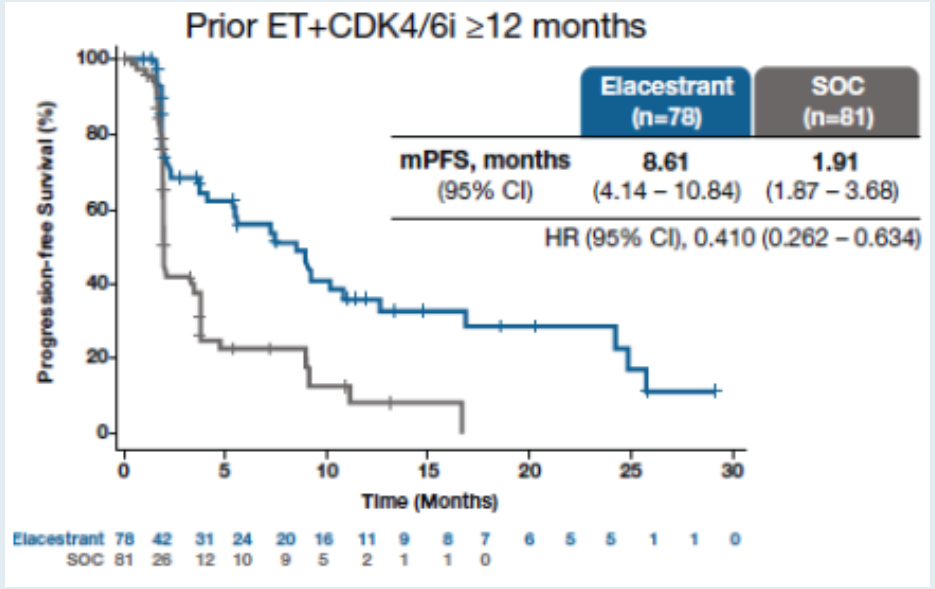
EMERALD: Adverse Events

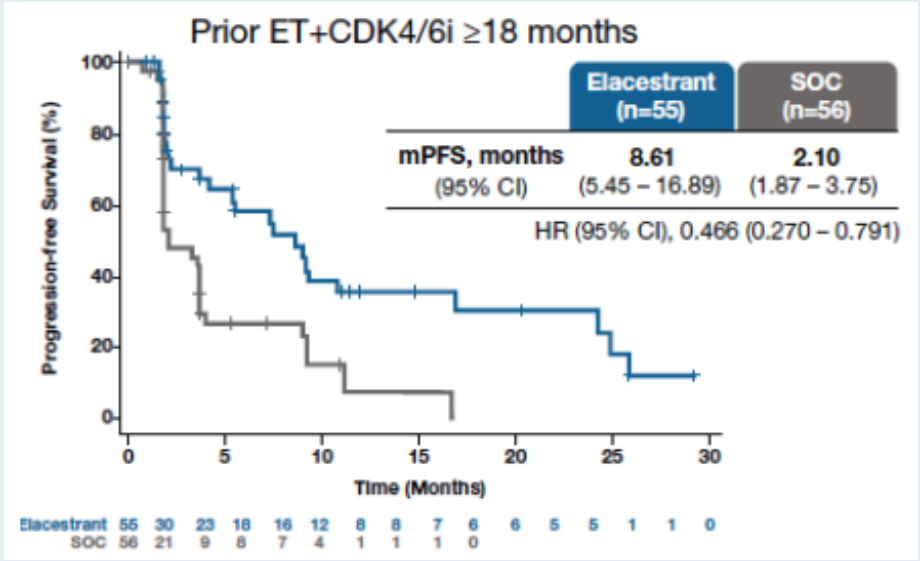
AEs[c] Occurring in ≥ 10% of Patients in Any Arm	Elacestrant		Total		Fulvestrant		AI	
	All Grades	Grade 3/4	All Grades	Grade 3/4	All Grades	Grade 3/4	All Grades	Grade 3/4
Nausea	83 (35.0)[d]	6 (2.5)	43 (18.8)	2 (0.9)	26 (16.1)	0	17 (25.0)	2 (2.9)
Fatigue	45 (19.0)	2 (0.8)	43 (18.8)	2 (0.9)	35 (21.7)	1 (0.6)	8 (11.8)	1 (1.5)
Vomiting	45 (19.0)[e]	2 (0.8)	19 (8.3)	0	12 (7.5)	0	7 (10.3)	0
Decreased appetite	35 (14.8)	2 (0.8)	21 (9.2)	1 (0.4)	12 (7.5)	0	9 (13.2)	1 (1.5)
Arthralgia	34 (14.3)	2 (0.8)	37 (16.2)	0	28 (17.4)	0	9 (13.2)	0
Diarrhea	33 (13.9)	0	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)	0
AST increased	31 (13.1)	4 (1.7)	28 (12.2)	2 (0.9)	20 (12.4)	2 (1.2)	8 (11.8)	0
Headache	29 (12.2)	4 (1.7)	26 (11.4)	0	18 (11.2)	0	8 (11.8)	0
Constipation	29 (12.2)	0	15 (6.6)	0	10 (6.2)	0	5 (7.4)	0
Hot flush	27 (11.4)	0	19 (8.3)	0	15 (9.3)	0	4 (5.9)	0
Dyspepsia	24 (10.1)	0	6 (2.6)	0	4 (2.5)	0	2 (2.9)	0
ALT increased	22 (9.3)	5 (2.1)	23 (10.0)	1 (0.4)	17 (10.6)	0	6 (8.8)	1 (1.5)

Bidard F-C et al. *J Clin Oncol* 2022;40(28):3246-56.

EMERALD: Subgroup Efficacy by Duration of CDK4/6 Inhibitor (ESR1m)

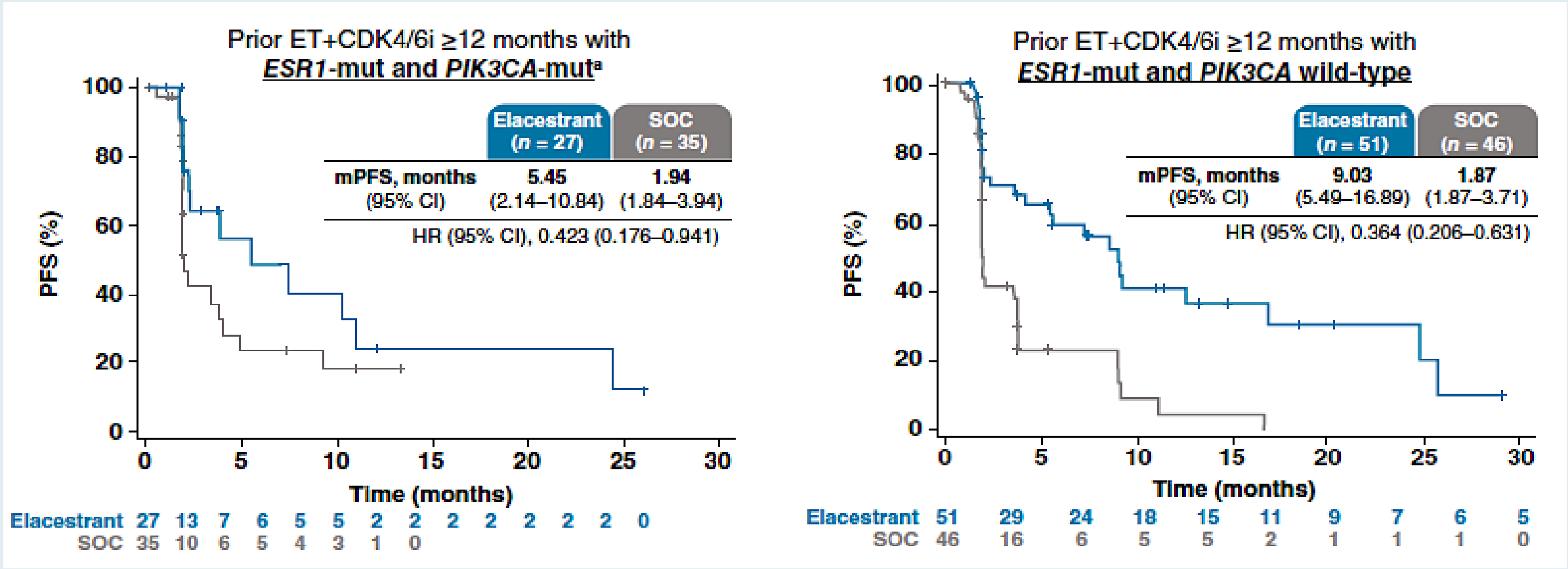






Bardia A et al. *Clin Cancer Res* 2024;30(19):4299-309.

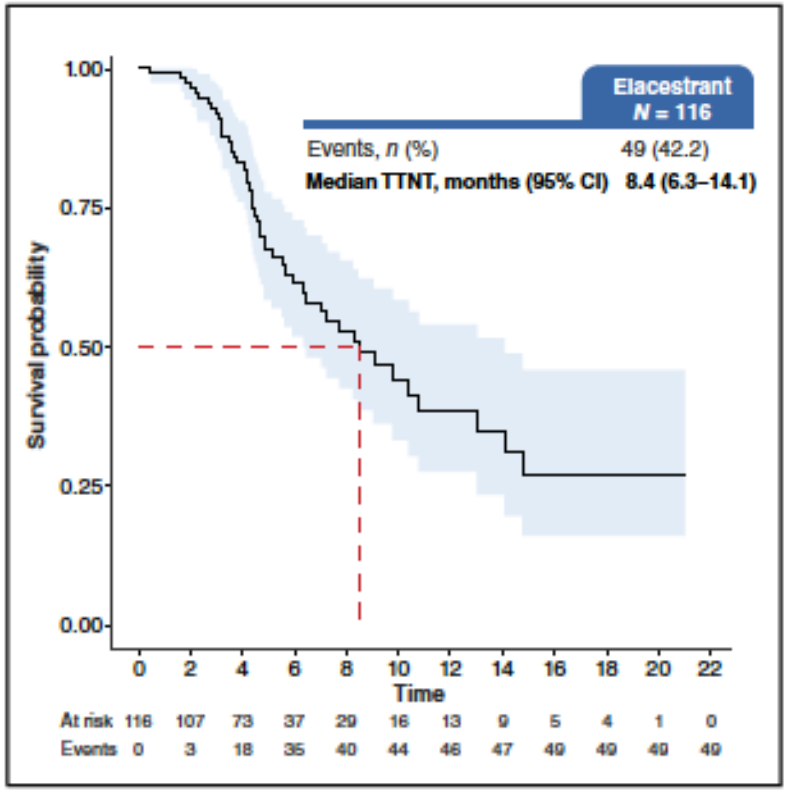
EMERALD: Subgroup Efficacy in Patients with ESR1m and Prior ET and CDK4/6 Inhibitor ≥12 months



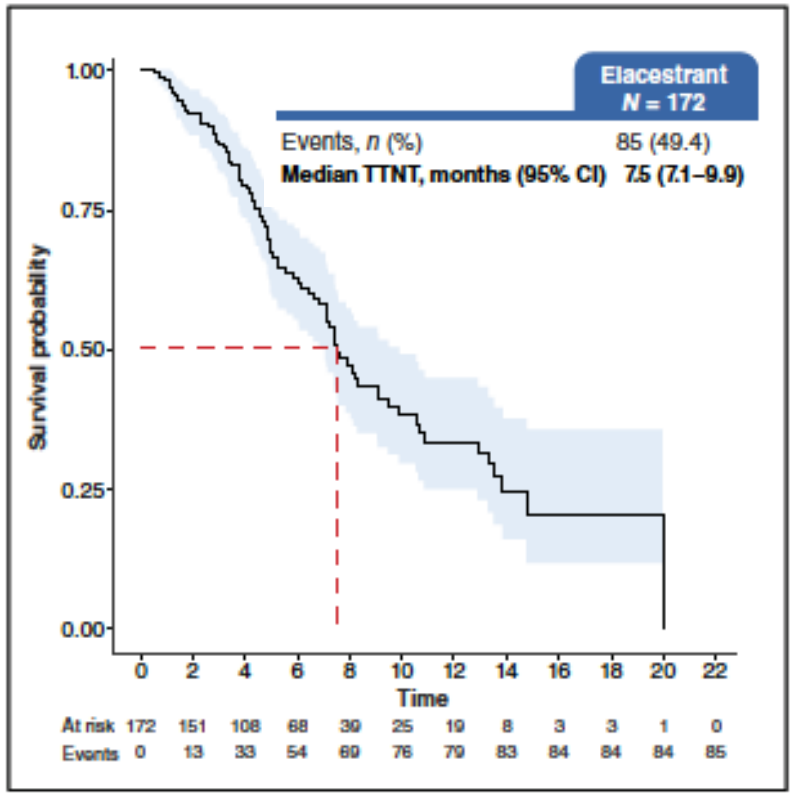
Bardia A et al. *Clin Cancer Res* 2024;30(19):4299-309.

EMERALD: Real-World Data

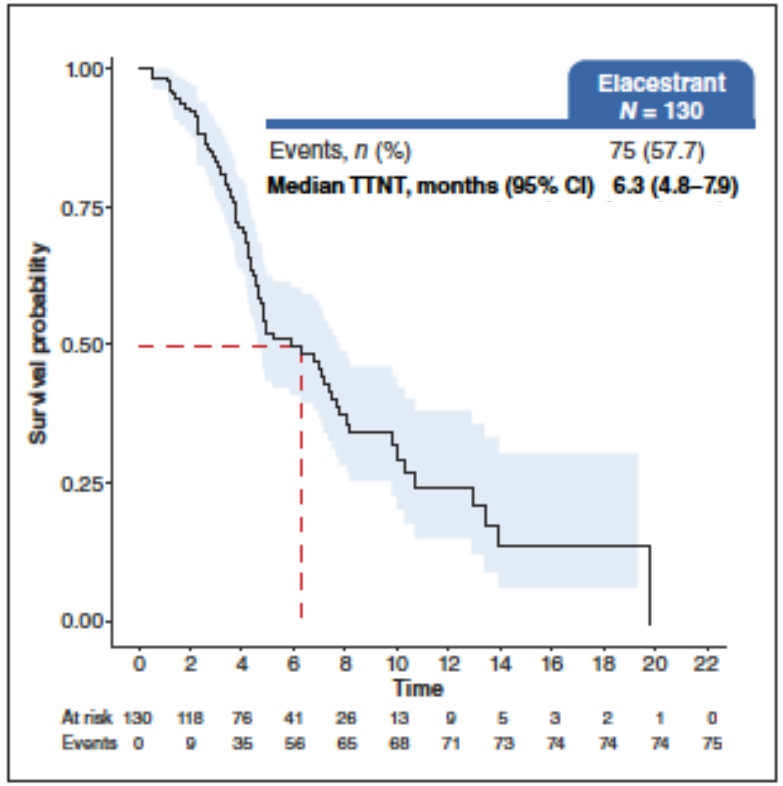
1–2 Prior lines of ET ± CDK4/6i ≥12 months



≥3 Prior lines of ET ± CDK4/6i

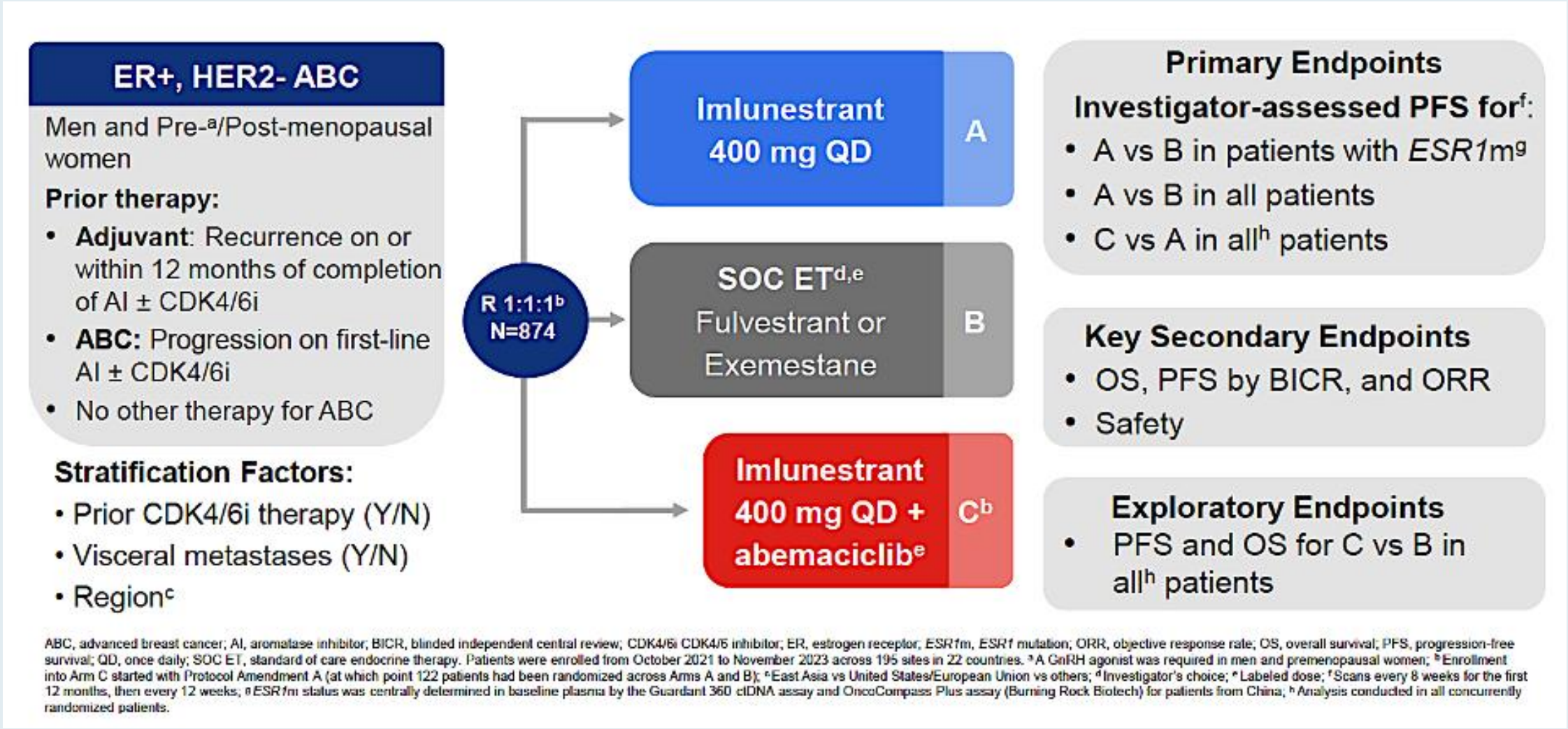


Coexisting *ESR1* and *PI3K* pathway mutations



Rugo HS et al. *Clin Cancer Res* 2026;32:179-87.

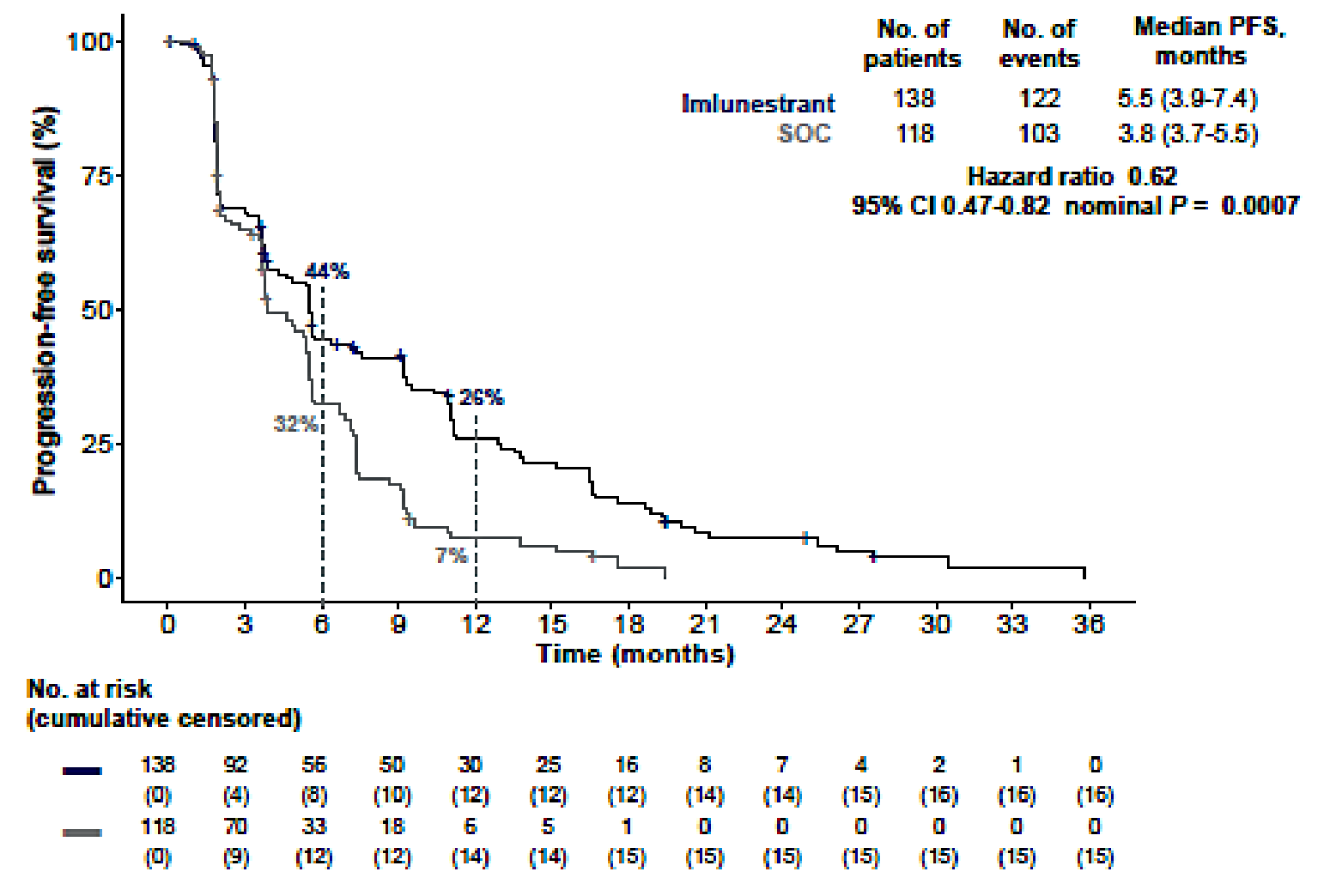
EMBER-3: Phase III Trial of Imlunestrant with or without Abemaciclib for Advanced Breast Cancer



ABC, advanced breast cancer; AI, aromatase inhibitor; BICR, blinded independent central review; CDK4/6i CDK4/6 inhibitor; ER, estrogen receptor; *ESR1*m, *ESR1* mutation; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QD, once daily; SOC ET, standard of care endocrine therapy. Patients were enrolled from October 2021 to November 2023 across 195 sites in 22 countries. [a]A GnRH agonist was required in men and premenopausal women; [b]Enrollment into Arm C started with Protocol Amendment A (at which point 122 patients had been randomized across Arms A and B); [c]East Asia vs United States/European Union vs others; [d]Investigator's choice; [e]Labeled dose; [f]Scans every 8 weeks for the first 12 months, then every 12 weeks; [g]*ESR1*m status was centrally determined in baseline plasma by the Guardant 360 cfDNA assay and OncoCompass Plus assay (Burning Rock Biotech) for patients from China; [h]Analysis conducted in all concurrently randomized patients.

Jhaveri KL et al. SABCS 2024;Abstract GS1-01.

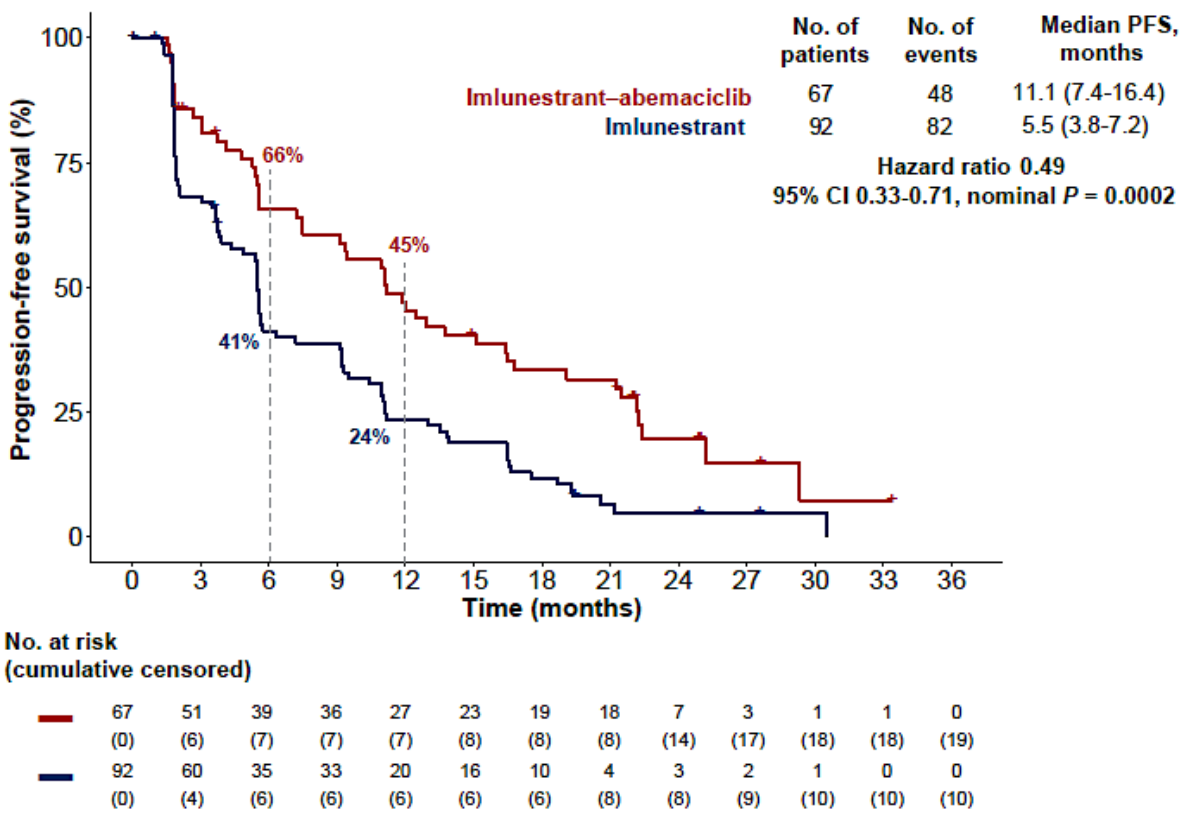
EMBER-3 Updated PFS: Efficacy of Imlunestrant Monotherapy Compared to ET for Patients with ESR1m



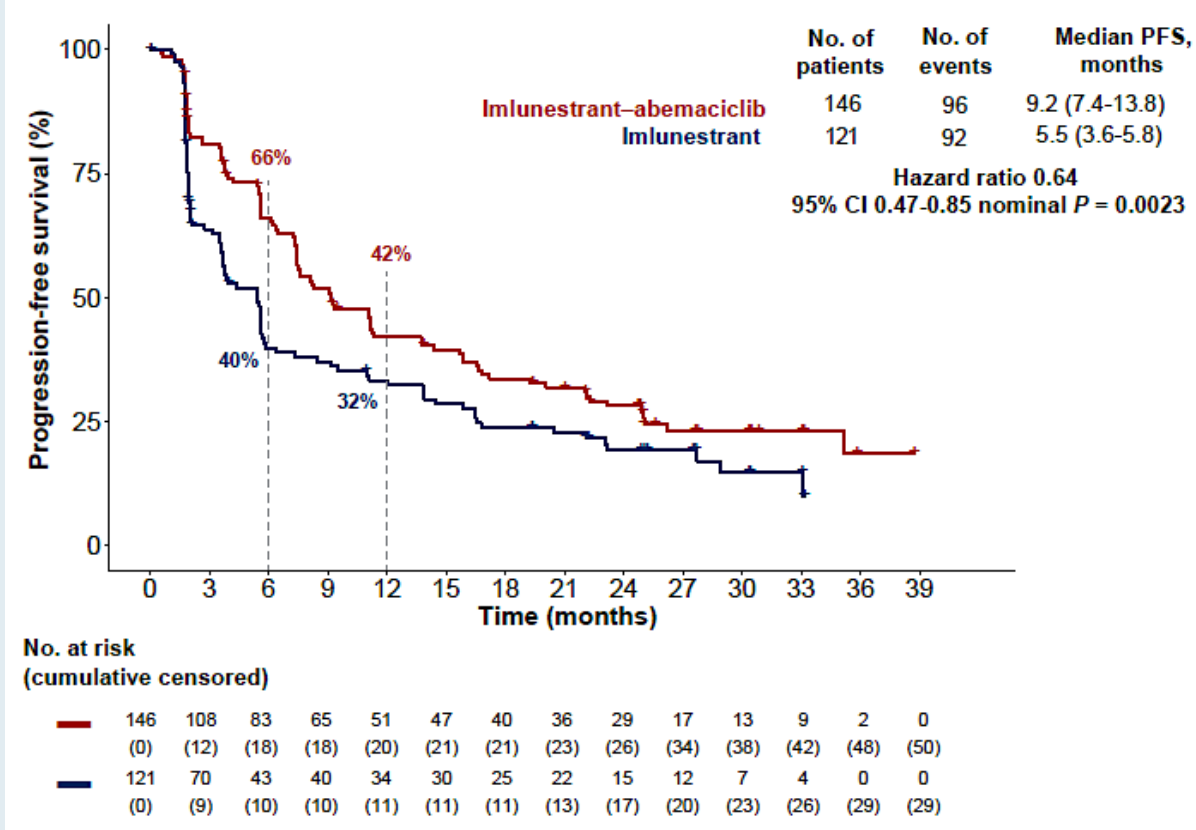
Jhaveri KL et al. *Ann Oncol* 2025;37(4):532-43.

EMBER-3 Updated PFS: Efficacy of Imlunestrant with Abemaciclib Compared to Imlunestant

ESR1m



No ESR1m



In all patients, regardless of ESR1m, the median PFS of imlunestrant with abemaciclib versus imlunestrant was 10.9 versus 5.5 months (HR 0.59, 95% CI 0.47-0.74, nominal $p < 0.0001$).

Jhaveri KL et al. *Ann Oncol* 2025;37(4):532-43.

Age 65, PS 0; HER2 IHC 1+, BRCA wild-type mBC
Metastatic PD after ribociclib/letrozole for 2 years
ESR1-negative, PIK3CA/AKT1/PTEN-negative

	Symptomatic liver and bone metastases	Asymptomatic bone metastases
 Dr Hurvitz	Everolimus + fulvestrant	Everolimus + fulvestrant
 Dr Kaklamani	Everolimus + fulvestrant	Everolimus + fulvestrant
 Dr Burstein	Abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Prof Curigliano	T-DXd	Capecitabine
 Dr Jhaveri	Everolimus + fulvestrant or abemaciclib + fulvestrant	Abemaciclib + fulvestrant
 Dr Lustberg	Everolimus + fulvestrant	Everolimus + fulvestrant

Age 65, PS 0; HER2 IHC 1+, BRCA wild-type mBC
Metastatic PD after ribociclib/letrozole for 10 months
ESR1-negative, PIK3CA/AKT1/PTEN-negative

	Symptomatic liver and bone metastases	Asymptomatic bone metastases
 Dr Hurvitz	Capecitabine	Everolimus + fulvestrant
 Dr Kaklamani	T-DXd	Everolimus + fulvestrant
 Dr Burstein	Capecitabine	Abemaciclib + fulvestrant
 Prof Curigliano	T-DXd	Capecitabine
 Dr Jhaveri	T-DXd	Capecitabine
 Dr Lustberg	T-DXd	Capecitabine

Which second-line treatment would you recommend for a 65-year-old woman (PS 0) with ER/PR-positive, HER2-low (IHC 1+) breast cancer with the biomarker testing results below who develops symptomatic liver and bone metastases after ribociclib/letrozole for 2 years? After ribociclib/letrozole for 10 months?
ESR1-positive, PIK3CA/AKT1/PTEN-negative

	PD after ribociclib/letrozole 2 years	PD after ribociclib/letrozole 10 months
 Dr Hurvitz	Elacestrant or imlunestant*	T-DXd
 Dr Kaklamani	Elacestrant	T-DXd
 Dr Burstein	Imlunestrant + abemaciclib	Capecitabine
 Prof Curigliano	Elacestrant	Capecitabine
 Dr Jhaveri	Imlunestrant + abemaciclib	Imlunestrant + abemaciclib or T-DXd
 Dr Lustberg	Elacestrant	T-DXd

* Or imlunestrant/abemaciclib if covered

Agenda

Introduction: Which Biomarkers and When

Module 1: Optimizing First-Line Therapy for Patients with Hormone Receptor (HR)-Positive Metastatic Breast Cancer (mBC)

- Biomarker-based selection of first-line treatment
- Use of SERENA-6 strategy
- Use of inavolisib triplet

Module 2: Management of HR-Positive mBC Progressing on a CDK4/6 Inhibitor and Endocrine Therapy

- Biomarker-based selection of second-line treatment
- Use of selective estrogen receptor degrader (SERD) monotherapy
- Use of AKT inhibitors

Dr Hurvitz: Case Presentation 2

- 38 yo woman treated for de novo MBC to bones, lungs, LNs treated with first line ribociclib/AI/ovarian suppression (then BSO) with disease control for 3 years. At PD in lungs, ctDNA revealed ESR1mut, switched to elacestrant. Has 5-year-old twins and works as a paralegal.
- Prominent nausea with vomiting two to three times a week and fatigue noted at first follow up visit. Had not been taking antiemetic. Teaching re use of ondansetron. At next f/u visit pt notes resolution of vomiting but still with nausea in the morning til past lunch and has lost 8 lbs (6% body weight). Initiated olanzapine 5 mg in the evenings. Next visit, substantially better. Weight stabilized.


AGREE
IN BETWEEN
DISAGREE

If vepdegestrant becomes available for patients with HR-positive, HER2-negative mBC and an ESR1 mutation, will you use it or oral SERD monotherapy first?

 Dr Hurvitz	Oral SERD monotherapy
 Dr Kaklamani	Oral SERD monotherapy
 Dr Burstein	Oral SERD monotherapy
 Prof Curigliano	Oral SERD monotherapy
 Dr Jhaveri	Oral SERD monotherapy
 Dr Lustberg	Oral SERD monotherapy

RTP RESEARCH TO PRACTICE

Based on published research data and your own clinical experience, how would you indirectly compare the global efficacy and tolerability/toxicity of elacestrant, imlunestrant, camizestrant and giredestrant when administered as monotherapy for endocrine therapy-pretreated ER-positive, HER2-negative mBC with an ESR1 mutation?

	Efficacy	Tolerability
 Dr Hurvitz	Not enough data to tell	About the same
 Dr Kaklamani	About the same	About the same
 Dr Burstein	About the same	Imlunestrant is most tolerable; Elacestrant is least tolerable
 Prof Curigliano	About the same	About the same
 Dr Jhaveri	About the same	Slightly distinct, but all have only low-grade toxicities
 Dr Lustberg	About the same	Elacestrant is most tolerable

Agenda

Introduction: Which Biomarkers and When

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- Use of AKT inhibitors

Dr Kaklamani: Case Presentation 3

- 65 yo postmenopausal found to have 2.4 cm R IDC, LN- ER 60% PR 50% HER2 0. Her 21 gene Recurrence Score was 21 and she was given adjuvant endocrine therapy with anastrozole.
- She discontinued anastrozole due to MS complaints after 1 y and presented 3 y later with back pain.
- Imaging showed spinal mets and NGS testing showed a PIK3CA mutation.
- She was started on denozumab, palbociclib and exemestane and remained on therapy for 18 mo with stable disease but then was found to have a new liver metastasis.
- ctDNA showed the PIK3CA mutation but no other actionable alteration.
- She was started on capivasertib and fulvestrant and has been on this treatment for the past 14 mo with partial response to the bones.


AGREE
IN BETWEEN
DISAGREE

Capivasertib + Fulvestrant in AI-Resistant HR+/HER2- BC *CAPItello-291 Phase 3*

Study Design

Patients with HR+/HER2– ABC

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

R1:1 (N=708)

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

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

Dual primary endpoints

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

Key secondary endpoints

Overall survival
- Overall
- AKT pathway-altered tumors

Objective response rate
- Overall
- AKT pathway-altered tumors

Dana-Farber Cancer Institute

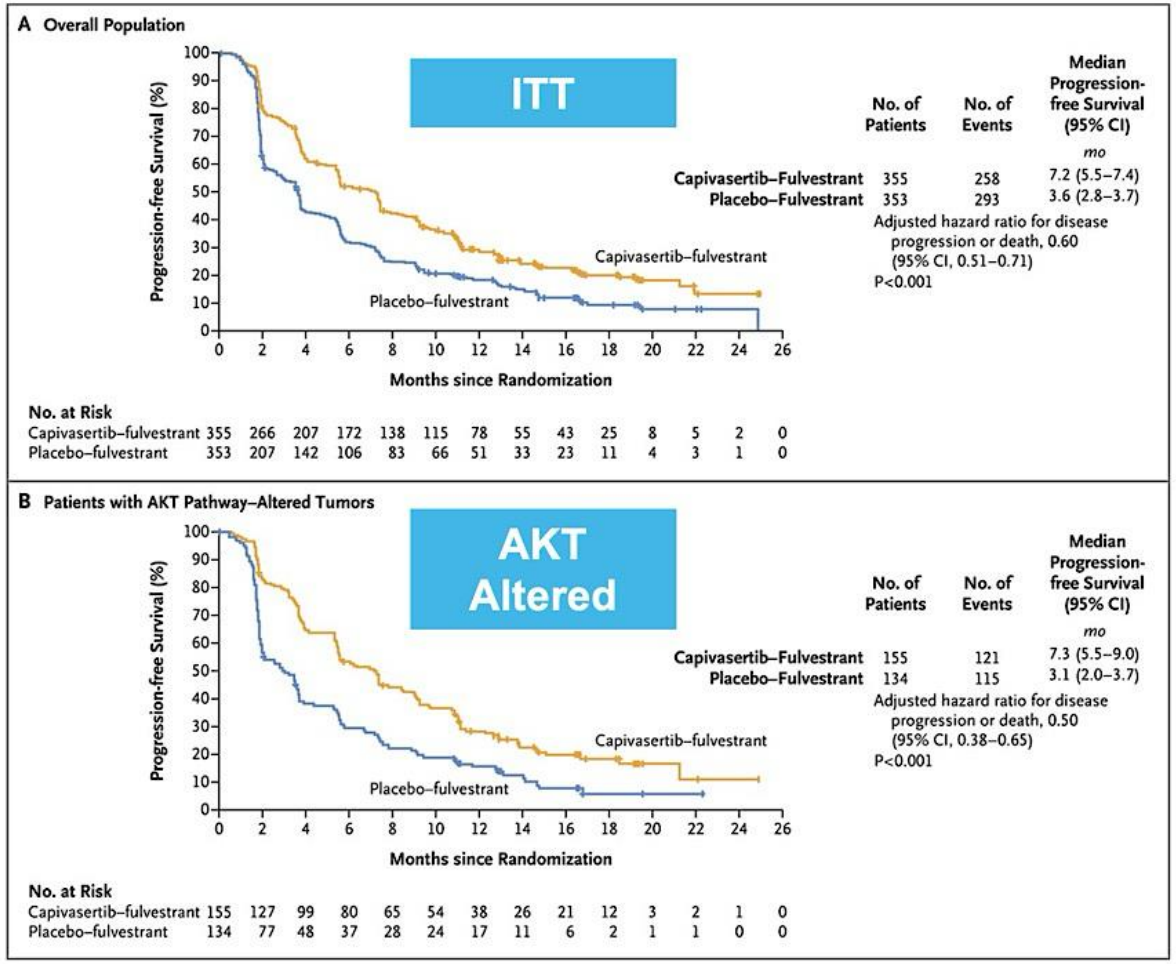
Turner NC, et al. SABCS 2022. Oral Presentation GS3-04. Turner NC, et al. N Engl J Med. 2023;388(22):2058-2070.

Erica L. Mayer MD, MPH | 2025

Courtesy of Erica Mayer, MD, MPH

CAPItello-291: Investigator-Assessed PFS in Overall Population and AKT-Pathway Altered

- Study met dual primary endpoints, showing significantly prolonged PFS with capivasertib + FULV vs placebo + FULV in overall and AKT pathway–altered populations (41% AKT altered)
- 69% prior CDK4/6i
- Exploratory analysis observed improved PFS in nonaltered subpopulation (HR: 0.70; 95% CI: 0.56-0.88)
  - 16% unknown mutation status



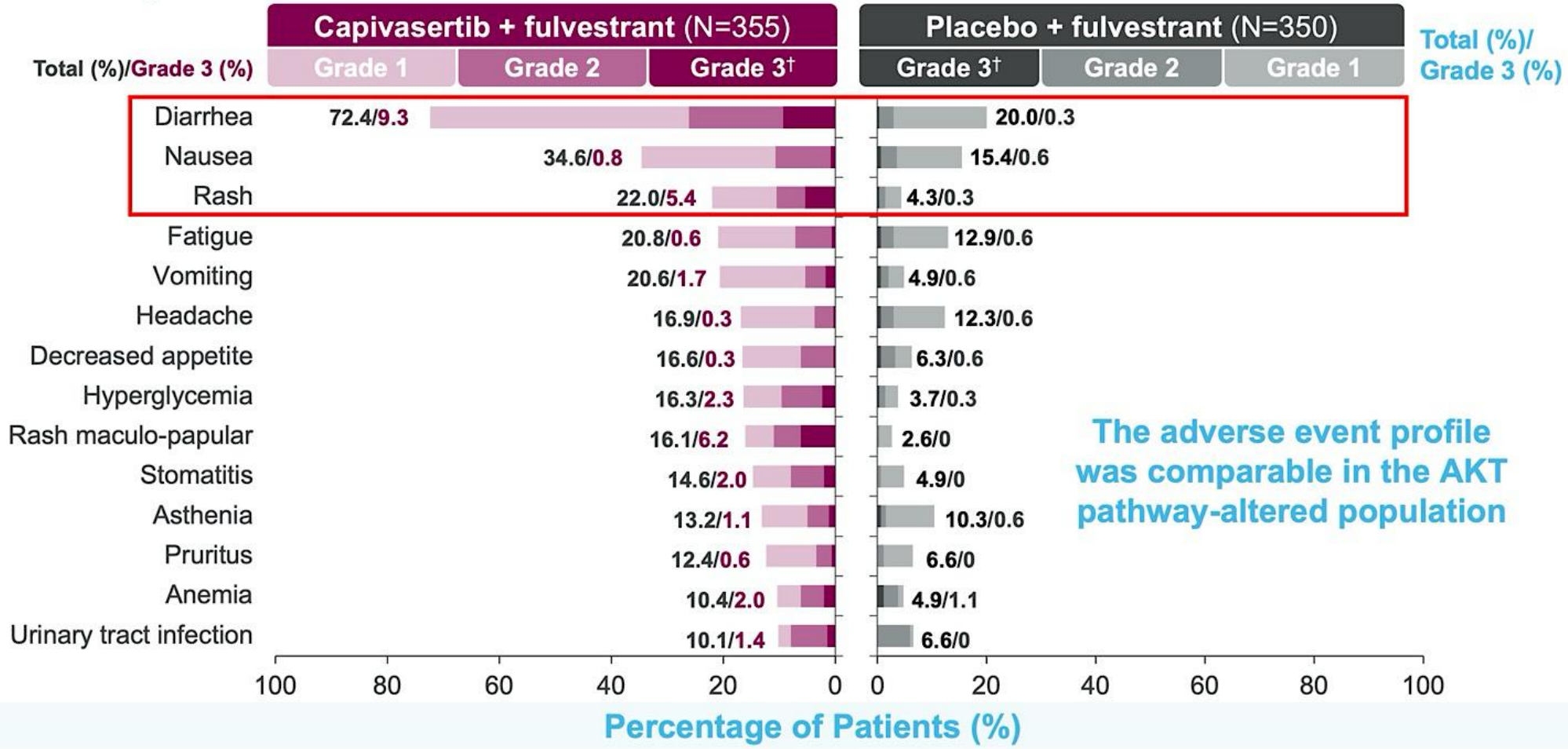
Turner NC, et al. N Engl J Med. 2023;388(22):2058-2070.

Dana-Farber Cancer Institute

Courtesy of Erica Mayer, MD, MPH

RTP RESEARCH TO PRACTICE

Adverse Events (>10% of patients) – Overall Population



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

•Adverse events of any grade related to rash (group term including rash, rash macular, maculo-papular rash, rash papular and rash pruritic) were reported in 38.0% of the patients in the capivasertib + fulvestrant arm (grade ≥3 in 12.1%) and in 7.1% of those in the placebo + fulvestrant group (grade ≥3 in 0.3%). †All events shown were Grade 3 except one case of Grade 4 hyperglycemia in the capivasertib + fulvestrant arm. *This presentation is the intellectual property of the author/presenter. Contact them at nick.turner@icr.ac.uk for permission to reprint and/or distribute.

Dana-Farber Cancer Institute

Erica L. Mayer MD, MPH | 2025

Courtesy of Erica Mayer, MD, MPH

Age 65, PS 0; HER2 IHC 1+, BRCA wild-type mBC
S/p ribociclib/letrozole for 2 years
ESR1-positive, PIK3CA/AKT1/PTEN-positive

	Symptomatic liver and bone metastases	Asymptomatic bone metastases
 Dr Hurvitz	Capivasertib + fulvestrant*	Capivasertib + fulvestrant
 Dr Kaklamani	Elacestrant	Elacestrant
 Dr Burstein	Capivasertib + fulvestrant or capecitabine	Capivasertib + fulvestrant
 Prof Curigliano	Capivasertib + fulvestrant	Elacestrant
 Dr Jhaveri	Imlunestrant + abemaciclib or capivasertib + fulvestrant	Imlunestrant + abemaciclib
 Dr Lustberg	Elacestrant	Elacestrant

* If impending liver failure, would use T-DXd

Age 65, PS 0; HER2 IHC 1+, BRCA wild-type mBC
S/p ribociclib/letrozole for 10 months
ESR1-positive, PIK3CA/AKT1/PTEN-positive

	Symptomatic liver and bone metastases	Asymptomatic bone metastases
 Dr Hurvitz	Capivasertib + fulvestrant*	Capivasertib + fulvestrant
 Dr Kaklamani	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Dr Burstein	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Prof Curigliano	Capivasertib + fulvestrant	Elacestrant
 Dr Jhaveri	T-DXd	Capecitabine vs imlunestrant + abemaciclib vs capivasertib
 Dr Lustberg	T-DXd	Capivasertib + fulvestrant

* If impending liver failure, would use T-DXd

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 Dr Jhaveri	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Dr Lustberg	Capivasertib + fulvestrant	Capivasertib + fulvestrant

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 Dr Kaklamani	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Dr Burstein	T-DXd or capecitabine	Capivasertib + fulvestrant
 Prof Curigliano	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Dr Jhaveri	Capivasertib + fulvestrant	Capivasertib + fulvestrant
 Dr Lustberg	T-DXd	Capivasertib + fulvestrant

* If impending liver failure, would use T-DXd

Dr Hurvitz: Case Presentation 3

- 67 yo woman with ER+ HER2 1+ MBC with an ESR1 mutation, PIK3CA wild type, previously treated with ribociclib/fulvestrant for 1 year, now with progression in the liver and symptomatic bone metastases.
- The patient has a follow-up appointment next week.

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

Colorectal Cancer

A CME/MOC-Accredited Live Webinar

Thursday, April 16, 2026
5:00 PM – 6:00 PM ET

Faculty

Arvind Dasari, MD, MS
Anwaar Saeed, MD

Moderator

Neil Love, MD

RTP Year in Review 2026

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