Neoplasia Mammaria Stadi Precoci e Malattia Metastatica

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Disclosures

Scientific advisory board, meeting, congresses, consulence:

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Exact Science
Pierre Fabre
Epihonpharma

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Outline

- **Early breast cancer**
  - **Adjuvant HR+HER2-**
  - **Short-HER trial**

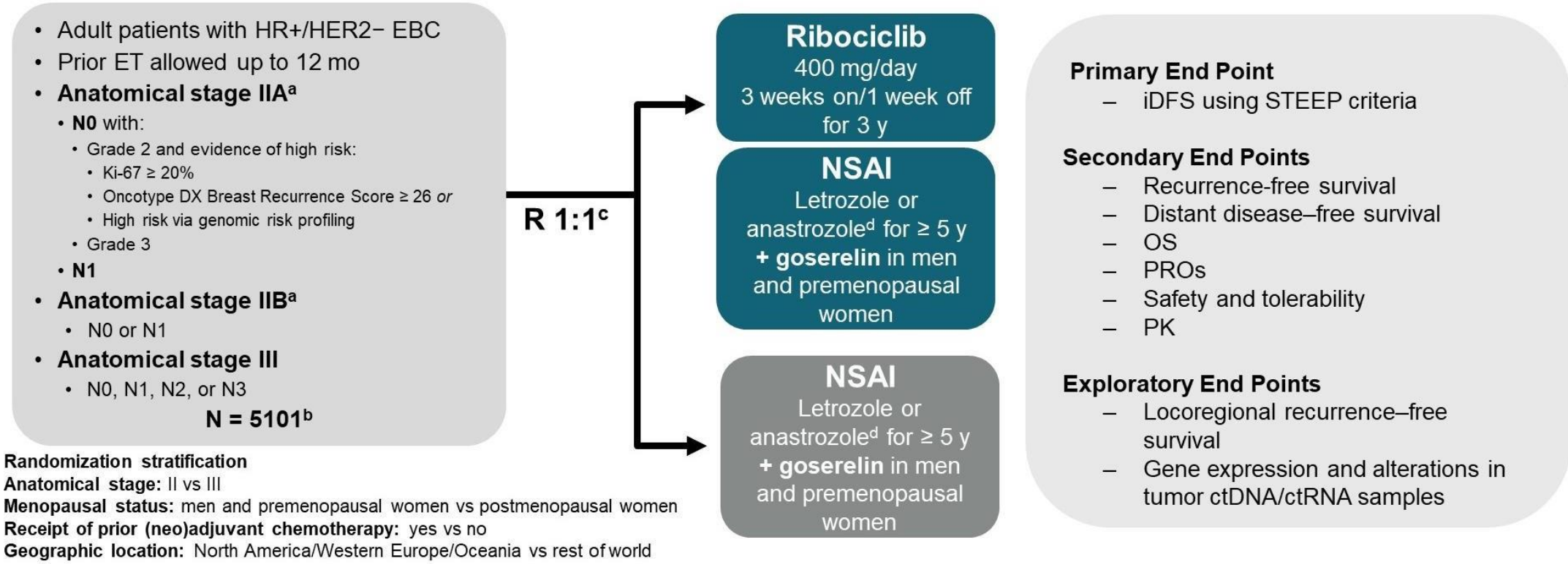
- **Metastatic breast cancer**
  - **Age-specific pooled analysis of T-DXd trials**
  - **Tropics**
  - **New associations**

Outline

- **Early breast cancer**
  - **Adjuvant HR+HER2-**
  - **Short-HER trial**

- **Metastatic breast cancer**
  - Age-specific pooled analysis of T-DXd trials
  - French retrospective study on treatment beyond T-DXd
  - Tropics
  - New associations

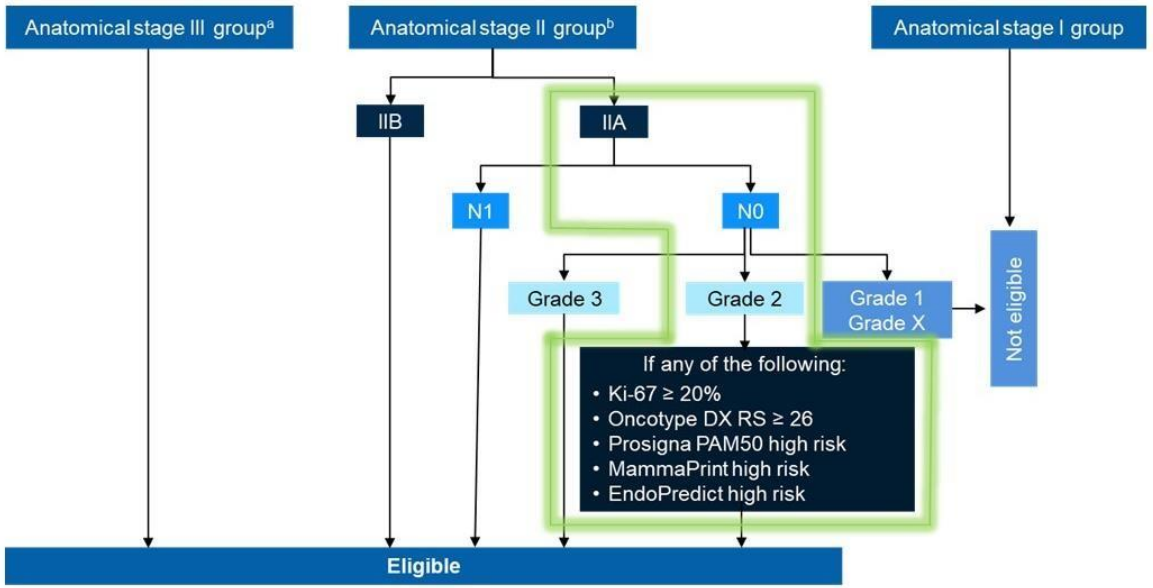
NATALEE: Study design



Randomization stratification
Anatomical stage: II vs III
Menopausal status: men and premenopausal women vs postmenopausal women
Receipt of prior (neo)adjuvant chemotherapy: yes vs no
Geographic location: North America/Western Europe/Oceania vs rest of world

Slamon D, et al. J Clin Oncol 2023;41(suppl 16):Abstract LBA500.

NATALEE: Eligible patients



AJCC anatomical staging[1]	TN (M0)	NATALEE[2,3]
Stage IA	T1N0	✗
Stage IB	T0N1mi	✗
	T1N1mi	✗
Stage IIA	T0N1	✓
	T1N1	✓
	T2N0	G3, or G2 with Ki-67 ≥ 20% or high genomic risk[c]
Stage IIB	T2N1	✓
	T3N0	✓
Stage IIIA	T0N2	✓
	T1N2	✓
	T2N2	✓
	T3N1	✓
	T3N2	✓
Stage IIIB	T4N0	✓
	T4N1	✓
	T4N2	✓
Stage IIIC	Any TN3	✓

AJCC, American Joint Committee on Cancer; G, grade; M, metastasis; N0, no nodal involvement;; N1mi, nodal micrometastases; N1, 1-3 axillary lymph nodes; N2, 4-9 axillary lymph nodes; N3, ≥ 10 axillary lymph nodes or collarbone lymph nodes; RS, Recurrence Score; T, tumor; T0, no evidence of primary tumor; T1, tumor is 2cm or less; T2, Tumor is more than 2cm bu less than 5cm; T3, tumor is more than 5cm; T4, tumor of any size growing into the chest wall or skin, includes inflammatory breast cancer.
[a] Including stage IIIA (N1/N2), IIIB (N0/N1/N2), or IIIC (N3). [b] Capped at 40% (≈ 2000 patients). Simplified inclusion criteria are used in the illustration. [c] High risk as determined by Oncotype DX, Prosigna PAM50, MammaPrint, or EndoPredict EPclin Risk Score.
References: 1. Amin MB, Edge SB, Greene FL, et al, eds. *AJCC Cancer Staging Manual*. 8th ed. New York, NY: Springer; 2017:587-636. 2. Slamon DJ, et al. *J Clin Oncol*. 2019;37(suppl 15) [abstract TPS597]. 3. Data on file. NATALEE CLEE011O12301C (TRIO033). Clinical study protocol. V4.0. Novartis Pharmaceuticals Corp; August 27, 2020.

Slamon D, et al. J Clin Oncol 2023;41(suppl 16):Abstract LBA500.

Baseline characteristics

Parameter	RIB + NSAI n = 2549	NSAI Alone n = 2552	All Patients N = 5101
Age, median (min-max), years	52 (24-90)	52 (24-89)	52 (24-90)
Menopausal status, n (%)			
Men[a] and premenopausal women	1126 (44)	1132 (44)	2258 (44)
Postmenopausal women	1423 (56)	1420 (56)	2843 (56)
Anatomical stage,[b,c] n (%)			
Stage IIA	479 (19)	521 (20)	1000 (20)
Stage IIB	532 (21)	513 (20)	1045 (20)
Stage III	1528 (60)	1512 (59)	3040 (60)
Nodal status at diagnosis, n (%)			
NX	272 (11)	264 (10)	536 (11)
N0	694 (27)	737 (29)	1431 (28)
N1	1050 (41)	1049 (41)	2099 (41)
N2/N3	483 (19)	467 (18)	950 (19)
Prior ET, n (%)[d]			
Yes	1824 (72)	1801 (71)	3625 (71)
Prior (neo)adjuvant CT, n (%)			
Yes	2249 (88)	2245 (88)	4494 (88)
ECOG PS, n (%)			
0	2106 (83)	2132 (84)	4238 (83)
1	440 (17)	418 (16)	858 (17)

CT, chemotherapy; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, endocrine therapy; N0, no nodal involvement; N1, 1-3 axillary lymph nodes; N2, 4-9 axillary lymph nodes; N3, ≥ 10 axillary lymph nodes or infra- or supraclavicular lymph nodes; NSAI, nonsteroidal aromatase inhibitor; NX, regional nodes were not assessed; OFS, ovarian function suppression; RIB, ribociclib.

[a] In the RIB + NSAI arm, there were 11 men (0.4%); in the NSAI alone arm, there were 9 men (0.4%). [b] A total of 14 patients with stage I disease were included: 9 (0.4%) in the RIB + NSAI arm and 5 (0.2%) in the NSAI alone arm. [c] Stage is derived using TNM from surgery for patients having not received (neo)adjuvant treatment or as worst stage derived using TNM at diagnosis and TNM from surgery for patients having received (neo)adjuvant treatment. [d] Prior OFS was received by 670 patients (26.3%) in the RIB + NSAI arm and 620 (24.3%) in the NSAI alone arm.

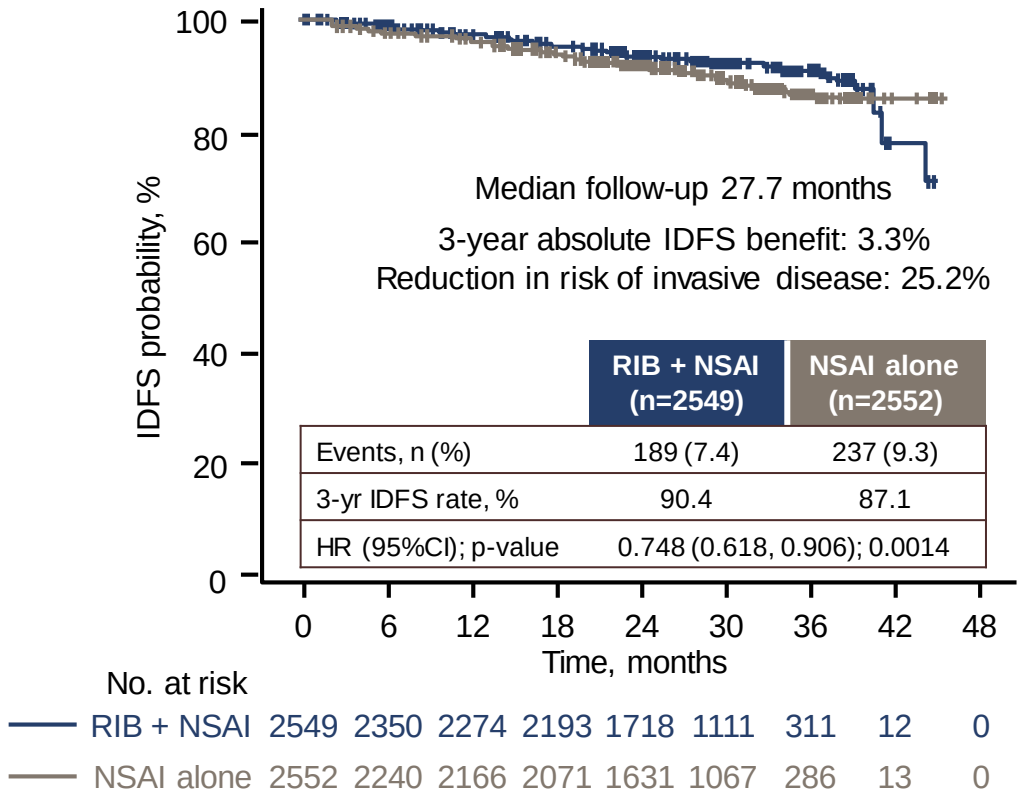
Patient disposition

Median follow-up of 34.0 months (minimum, 21 months)[a]

Parameter, n %	RIB + NSAI n = 2549	NSAI alone n = 2552
Patients treated	2526 (99)	2442 (96)
Patients with treatment ongoing[b]	1984 (78)	1826 (72)
Patients who discontinued NSAI	542 (21)	617 (24)
Primary reason for treatment discontinuation (NSAI)[c]		
Adverse Event	118 (5)	105 (4)
Patient/Physician decision	256 (10)	296 (12)
Disease relapse	142 (6)	186 (7)
Other[d]	13 (0.5)	15 (0.6)
Lost to follow-up	8 (0.3)	12 (0.5)
Death[e]	5 (0.2)	3 (0.1)
Patients who completed ribociclib treatment		
≥2 years (including ongoing)	1449 (57)	-
Completed 3 years RIB	515 (20)	-
Primary reason for early discontinuation of RIB[f]		-
Adverse Event	477 (19)	-

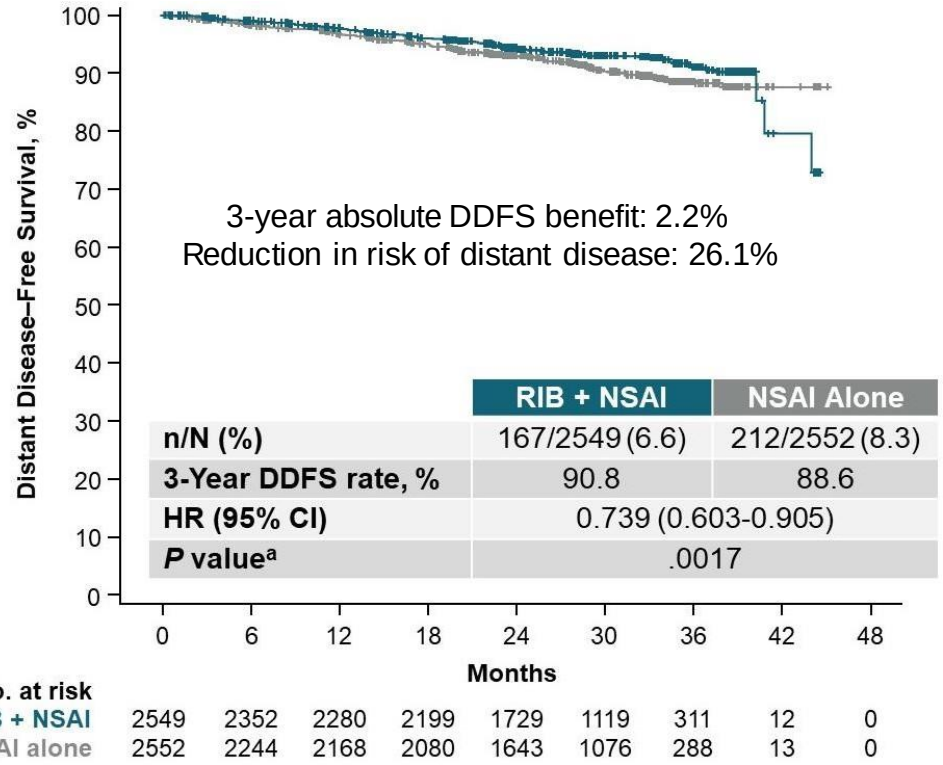
NSAI, nonsteroidal aromatase inhibitor; RIB, ribociclib.
[a] Randomization to data cutoff of January 11, 2023. [b] In the RIB + NSAI arm, the treatment is considered ongoing if the patient is continuing either study treatment. [c] All components of treatment are discontinued if NSAI is discontinued. [d] Includes protocol deviations. [e] Causes of death in the RIB + NSAI arm were COVID-19 pneumonia, pulmonary embolism, and traffic accident, and in patients who had previously discontinued RIB but remained on NSAI, the causes of death were cardiac arrest and brain edema; for patients in the NSAI alone arm, the causes of death were myocardial infraction, sepsis, and unknown. [f] RIB could be discontinued early due to AEs, all other reasons for discontinuations would require both components be discontinued and are captured above.

Primary endpoint: IDFS

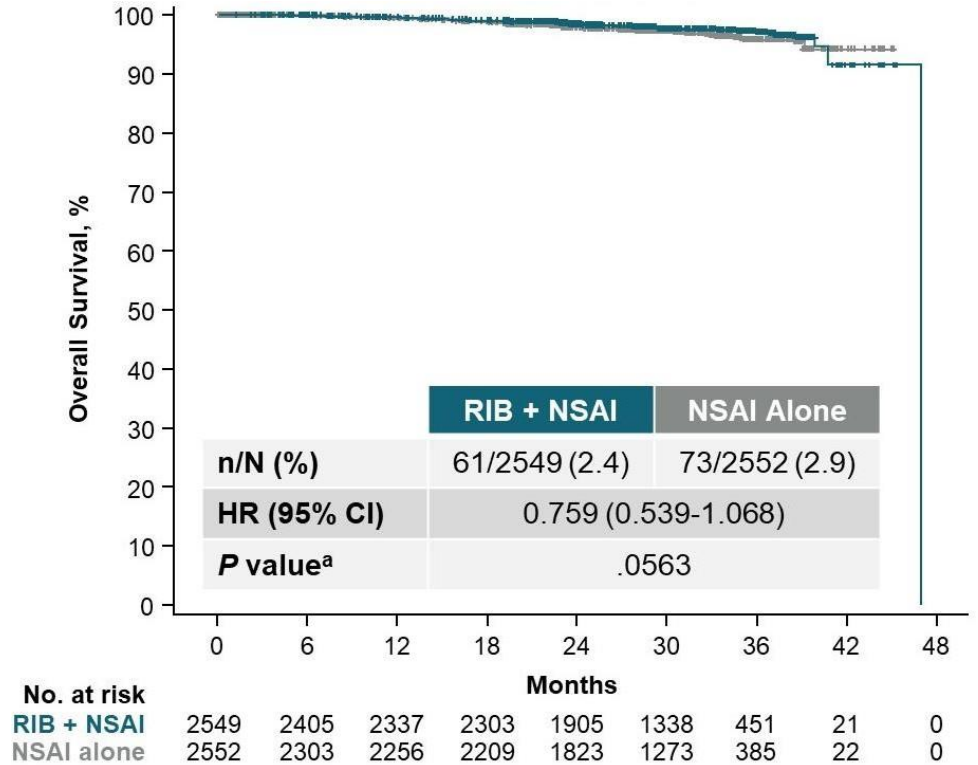


Secondary endpoints

DDFS



OS



monarchE: Efficacy of adjuvant abemaciclib + ET according to age

Key inclusion criteria

- HR+, HER2-, node-positive, high-risk EBC
- Pre-/postmenopausal women or men
- With or without prior (neo)adjuvant chemotherapy
- No metastatic disease
- Maximum of 16 mo from surgery to randomization and 3 mo of ET following the last non-ET

(n=5637; <65 yrs n=4787, ≥65 yrs n=850)

On-study treatment period
2 years

R
1:1

Abemaciclib 150 mg BID + **SoC ET†**
(n=2808; <65 yrs n=2371, ≥65 yrs n=437)

Stratification
- Prior chemotherapy
- Menopausal status
- Region

SoC ET†
(n=2829; <65 yrs n=2416, ≥65 yrs n=413)

Follow-up period
ET 3–8 years as clinically indicated

Primary endpoint
- IDFS

Secondary endpoints
- DRFS, OS, safety

*Patients ≥75 years accounted for 3% of the study population, precluding detailed outcome analysis in this subgroup; †AI or tamoxifen.

Hamilton EP, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 501.

Safety results

AEs, %		Abemaciclib + ET	
		<65 years (n=2361)	≥65 years (n=430)
Any	Any grade	98	99
	Grade ≥3	49	54
Clinically relevant			
Diarrhea	Grade 1	46	37
	Grade 2	31	30
	Grade 3	7	12
Fatigue	Grade 1	23	21
	Grade 2	14	20
	Grade 3	2	6
Neutropenia	Grade 1/2	27	22
	Grade ≥3	20	19
ALT increased	Grade 1/2	10	7
	Grade ≥3	3	3
VTE	Any grade	2	3
	Grade ≥3	1	1
ILD	Any grade	3	3
	Grade ≥3	<1	<1

Abemaciclib dose adjustments due to AEs, %	Abemaciclib + ET	
	<65 year (n=2361)	>65 years (n=430)
Interruptions	60	68
Reductions	41	55
Discontinuations	15	38
Without prior dose reductions	8	19

	Relative dose intensity, %		
	0–66 (n=928)	66–93 (n=928)	≥93% (n=927)
4-year IDFS rate, %	87.1	86.4	83.7

- Comparable AE rates across all age subgroups. Older patients tended to have higher rates of dose reductions and discontinuations, but this did not impact IDFS outcomes

Hamilton EP, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 501.

Efficacy results

- 4-year IDFS and DRFS benefits from abemaciclib were similar in older patients vs the ITT population

	IDFS			DRFS		
	ITT	<65 years	≥65 years	ITT	<65 years	≥65 years
Events/N						
Abemaciclib + ET	336/2808	270/2371	66/437	281/2808	230/2371	51/437
ET alone	499/2829	414/2416	85/413	421/2829	353/2416	68/413
HR (95% CI)	0.664 (0.578, 0.762)	0.646 (0.554, 0.753)	0.767 (0.556, 1.059)	0.659 (0.567, 0.767)	0.647 (0.584, 0.764)	0.748 (0.520, 1.077)
Interaction p-value	NA	0.35		NA	0.49	
4-year rate, %						
Abemaciclib + ET	85.8	86.5	82.0	88.4	88.8	86.1
ET alone	79.4	79.8	76.8	82.5	82.6	81.5
Absolute benefit	6.4	6.7	5.2	5.9	6.2	4.6

Hamilton EP, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 501.

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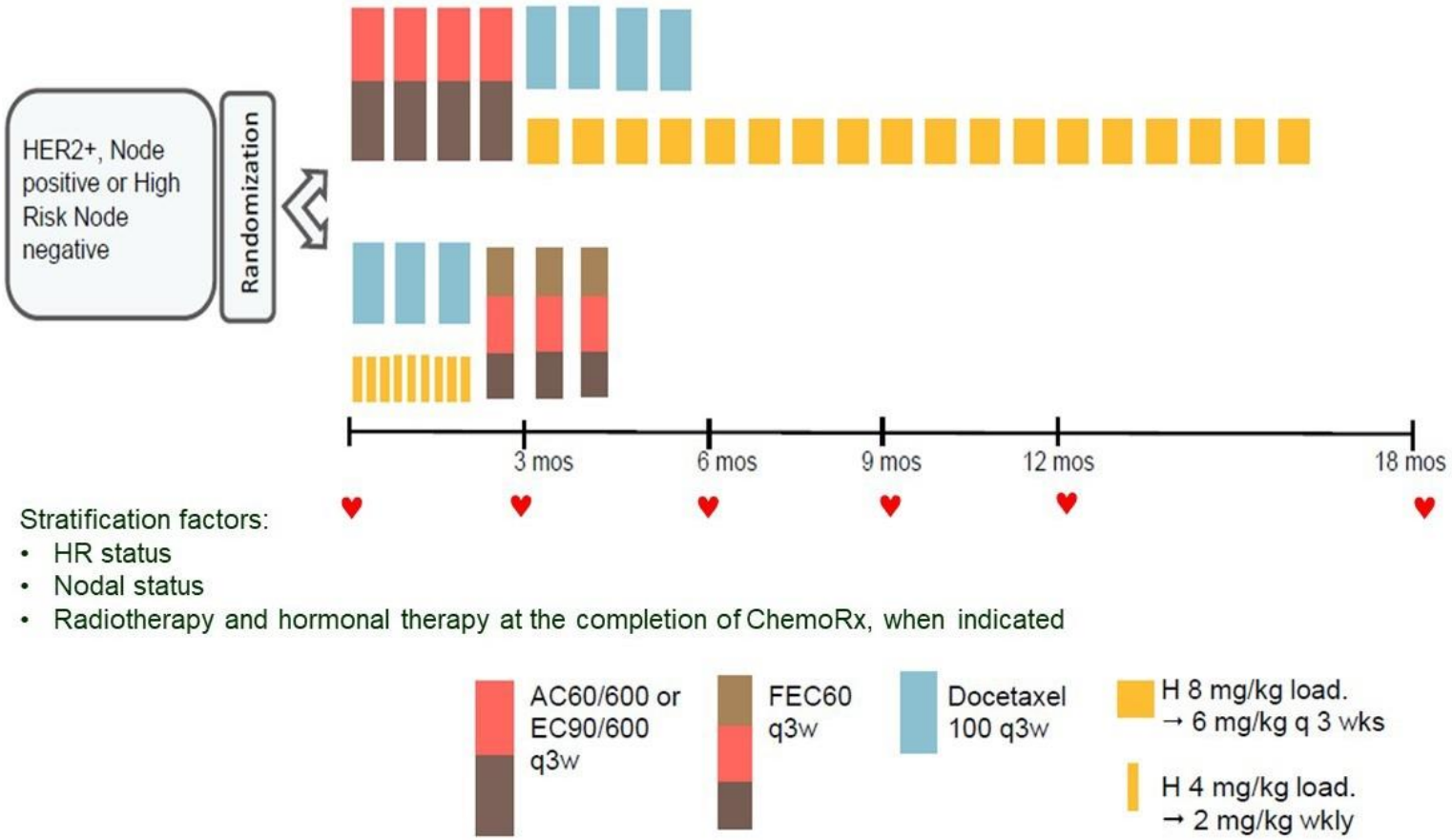
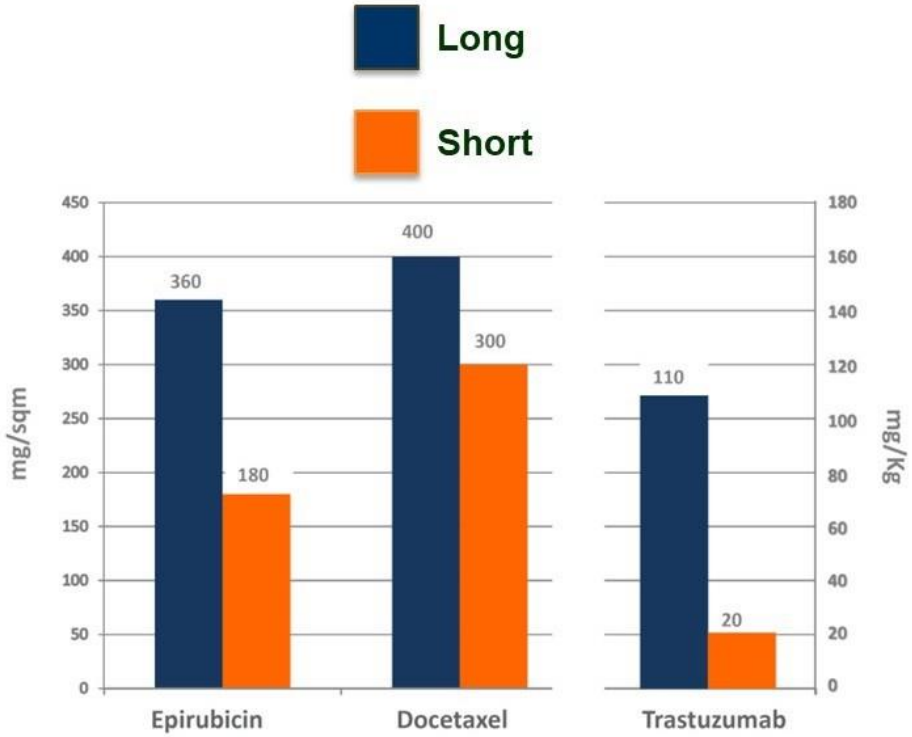
Reducing Trastuzumab Duration

Short-HER trial





36% premenopausal - Node positive 46% - HR-negative 32%

Conte PF et al, ASCO 2023

Reducing Trastuzumab Duration

Short-HER trial

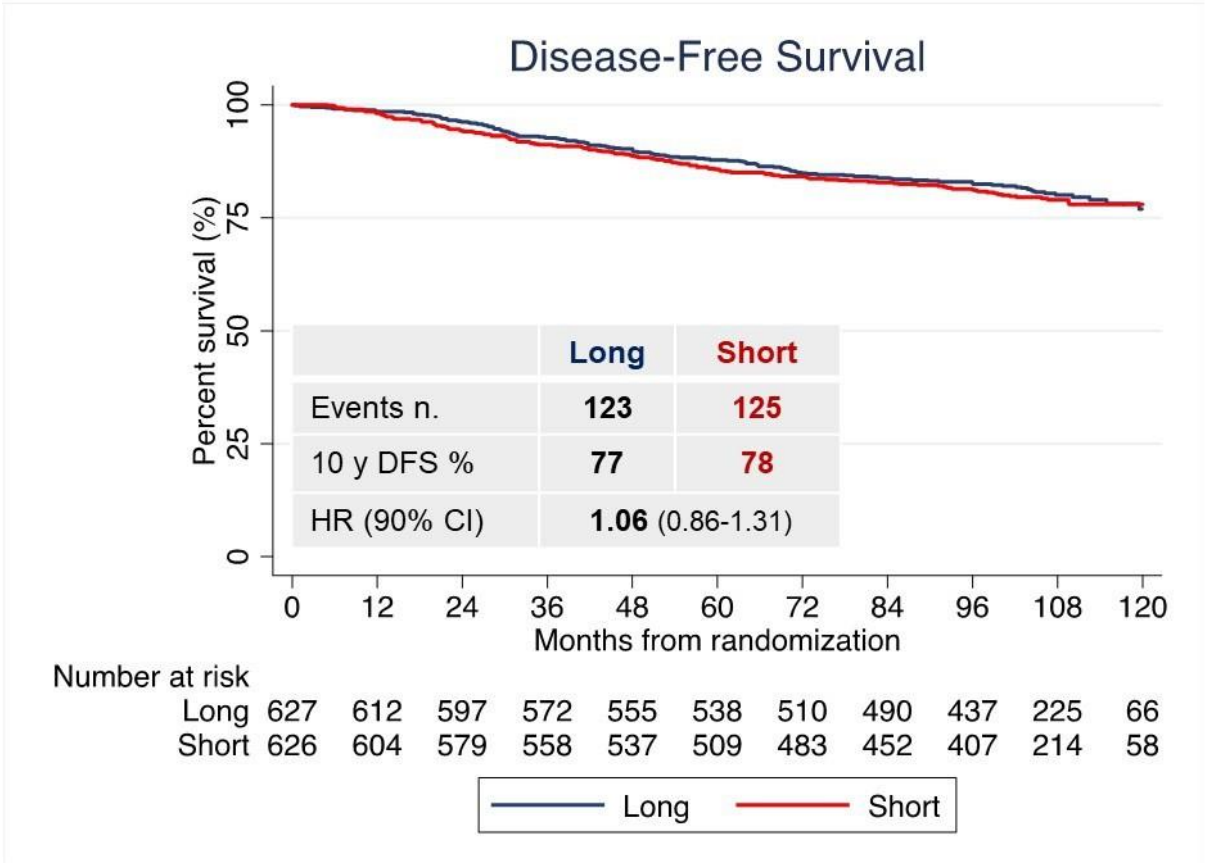
Study summary & Conclusions (ASCO 2017, Ann Oncol 2018)

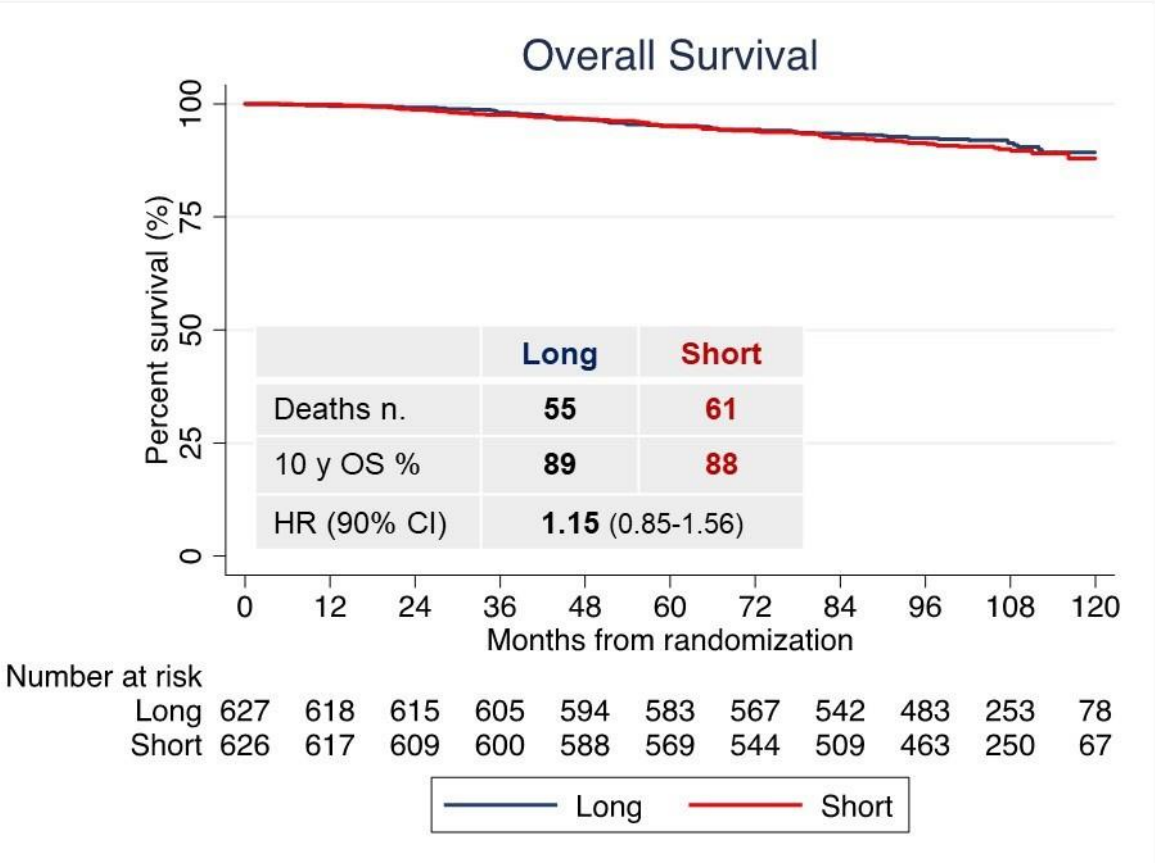
- After amendment, 1254 patients randomised
- At planned DFS event-driven analysis, median FUp was 5.2 years
- **5y DFS: Long Arm 87.5%, Short Arm 85.4%; HR= 1.15 (90% CI 0.91-1.46)**
- Non inferiority cannot be claimed on the basis of the frequentist approach
- According to the pre-planned Bayesian analysis, probability that the short treatment is not inferior was 0.78
- **Significant lower cardiac toxicity for the short treatment:**
  HR 0.32 (95% CI 0.21-0.50; p < 0.0001)

Conte PF et al, Ann Oncol 2018;29(18):2328-33

Reducing Trastuzumab Duration

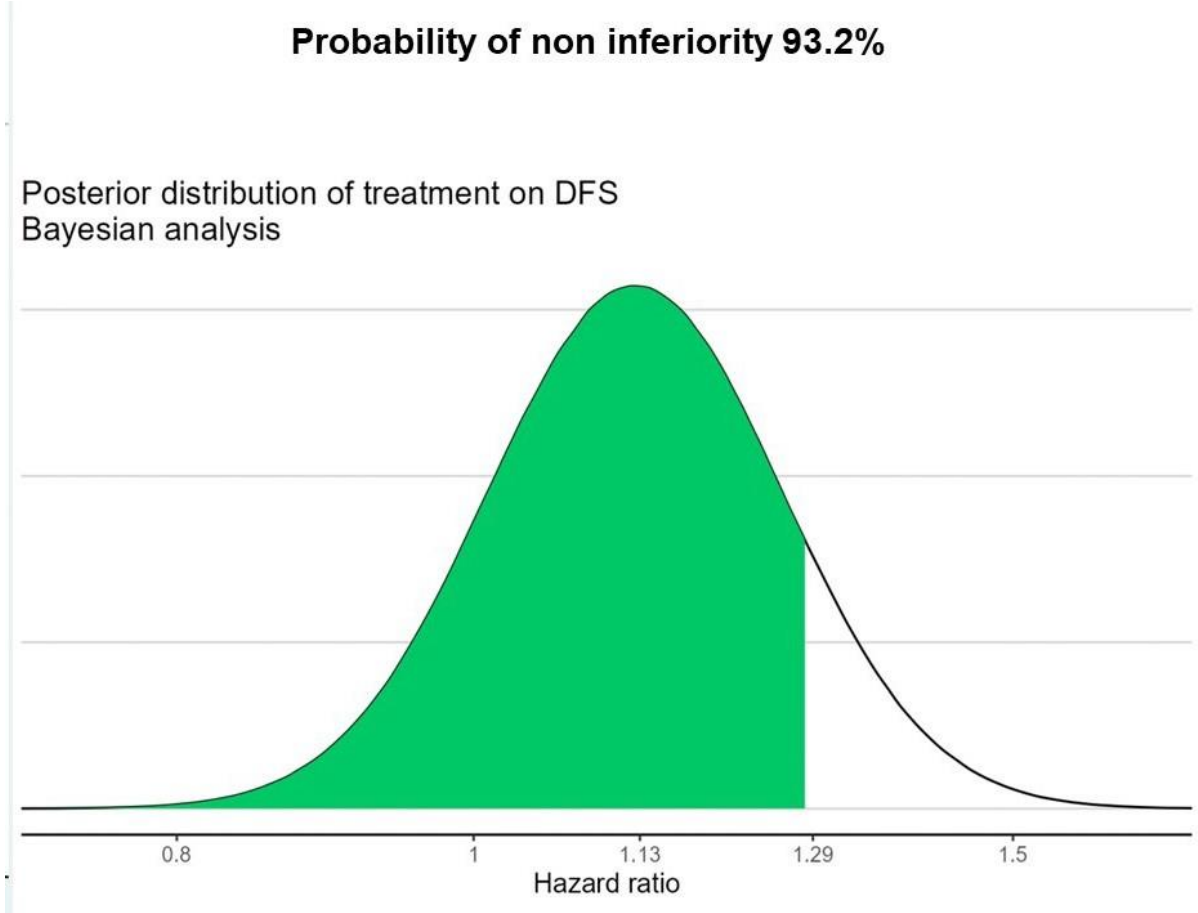
Median follow-up: 9 years



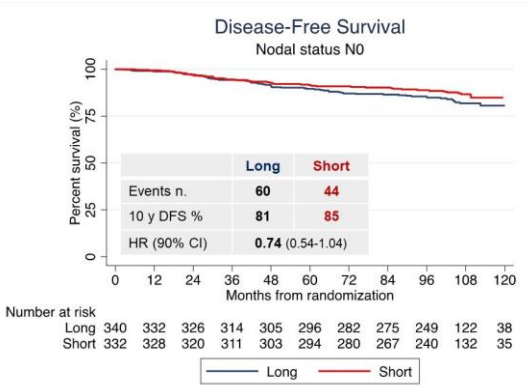


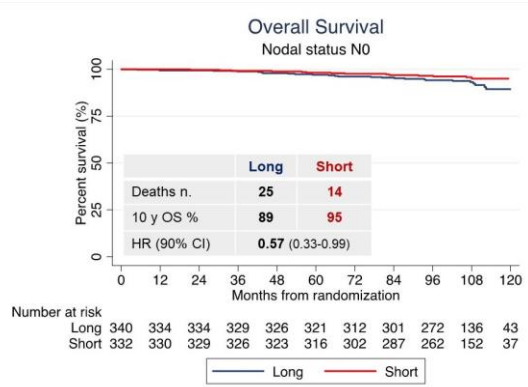
Conte PF et al, ASCO 2023

Reducing Trastuzumab Duration

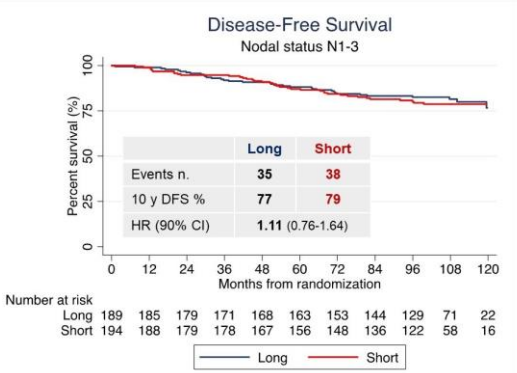


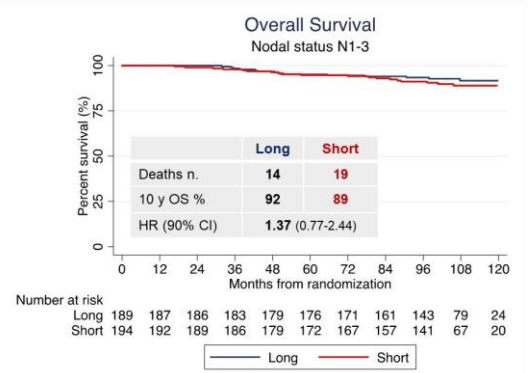
N0



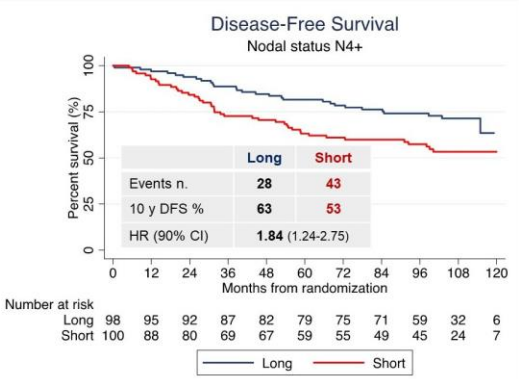


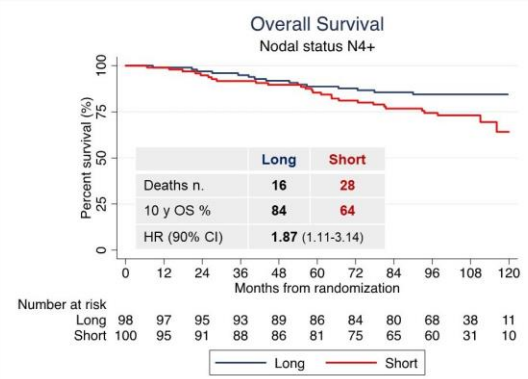
N1-3





N4+





Conte PF et al, ASCO 2023

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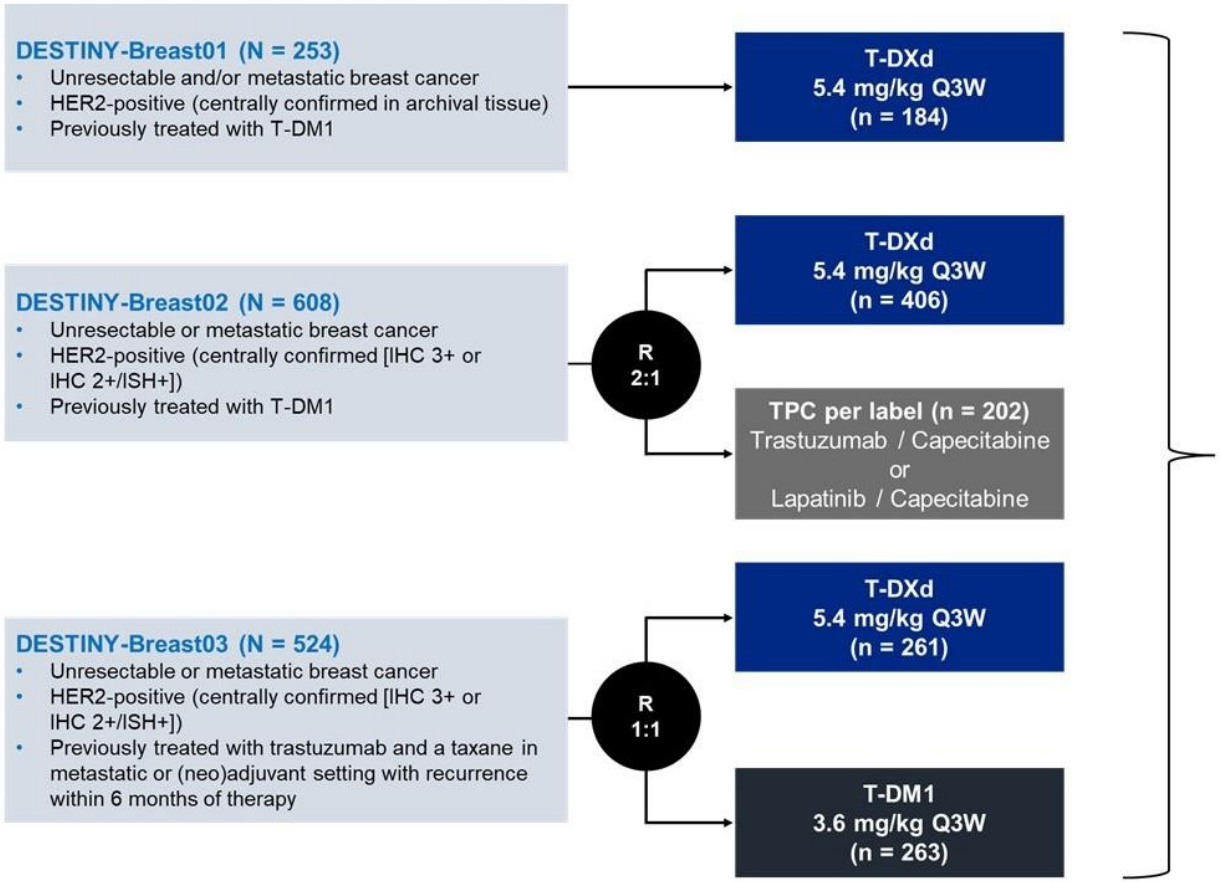
Trastuzumab Deruxtecan in HER2+ MBC



	T-DXd Pool		
	<65 (n = 673)	≥65 (n = 178)	≥75 (n = 34)
Age, median (range), years	51.5 (22.4-65.0)	69.9 (65.0-96.0)	79.0 (75.0-96.0)
Female, n (%)	670 (99.6)	177 (99.4)	34 (100.0)
Region, n (%)			
Asia	253 (37.6)	71 (39.9)	8 (23.5)
North America	82 (12.2)	29 (16.3)	8 (23.5)
Europe	220 (32.7)	54 (30.3)	14 (41.2)
Rest of world	118 (17.5)	24 (13.5)	4 (11.8)
Disease history, n (%)			
De novo mBC	183 (27.2)	49 (27.5)	9 (26.5)
Recurrent BC	348 (51.7)	84 (47.2)	15 (44.1)
Missing[b]	142 (21.1)	45 (25.3)	10 (29.4)
Time from the initial diagnosis of BC to randomization, median (range), mo	48.8 (1.5-318.1)	65.2 (6.0-431.4)	64.6 (6.2-431.4)
ECOG PS			
0	399 (59.3)	85 (47.8)	14 (41.2)
1	271 (40.3)	93 (52.2)	20 (58.8)

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Trastuzumab Deruxtecan in HER2+ MBC

Medical History and Comorbidities[a]

	T-DXd Pool			TPC (DB-02)			T-DM1 (DB-03)		
	<65 (n = 673)	≥65 (n = 178)	≥75 (n = 34)	<65 (n = 164)	≥65 (n = 38)	≥75 (n = 8)	<65 (n = 206)	≥65 (n = 57)	≥75 (n = 8)
Disorders									
Blood and lymphatic system disorders (SOC)	73 (10.8)	26 (14.6)	5 (14.7)	12 (7.3)	6 (15.8)	1 (12.5)	14 (6.8)	6 (10.5)	1 (12.5)
Anemia	41 (6.1)	18 (10.1)	3 (8.8)	9 (5.5)	4 (10.5)	1 (12.5)	6 (2.9)	2 (3.5)	1 (12.5)
Cardiac disorders (SOC)	57 (8.5)	21 (11.8)	4 (11.8)	7 (4.3)	3 (7.9)	0	8 (3.9)	5 (8.8)	0
Diabetes mellitus	29 (4.3)	17 (9.6)	4 (11.8)	7 (4.3)	3 (7.9)	2 (25.0)	6 (2.9)	8 (14.0)	1 (12.5)
Renal and urinary disorders (SOC)	23 (3.4)	16 (9.0)	6 (17.6)	3 (1.8)	4 (10.5)	1 (12.5)	3 (1.5)	11 (19.3)	0
Vascular disorders (SOC)	174 (25.9)	109 (61.2)	28 (82.4)	43 (26.2)	24 (63.2)	5 (62.5)	52 (25.2)	31 (54.4)	6 (75.0)
Hypertension	123 (18.3)	93 (52.2)	26 (76.5)	30 (18.3)	24 (63.2)	5 (62.5)	35 (17.0)	28 (49.1)	5 (62.5)
Baseline renal function[b]									
Normal function	432 (64.2)	34 (19.1)	0	104 (63.4)	8 (21.1)	0	124 (60.2)	8 (14.0)	0
Mild renal impairment	205 (30.5)	91 (51.1)	14 (41.2)	54 (32.9)	22 (57.9)	3 (37.5)	77 (37.4)	28 (49.1)	3 (37.5)
Moderate renal impairment	35 (5.2)	53 (29.8)	20 (58.8)	6 (3.7)	8 (21.1)	5 (62.5)	4 (1.9)	21 (36.8)	5 (62.5)
Baseline hepatic function[c]									
Normal function	406 (60.3)	101 (56.7)	20 (58.8)	78 (47.6)	21 (55.3)	2 (25.0)	162 (78.6)	50 (87.7)	8 (100.0)
Mild hepatic impairment	260 (38.6)	75 (42.1)	14 (41.2)	86 (52.4)	17 (44.7)	6 (75.0)	43 (20.9)	7 (12.3)	0
Moderate hepatic impairment	2 (0.3)	2 (1.1)	0	0	0	0	0	0	0

- Comorbidities were generally low in the overall population due to selection criteria

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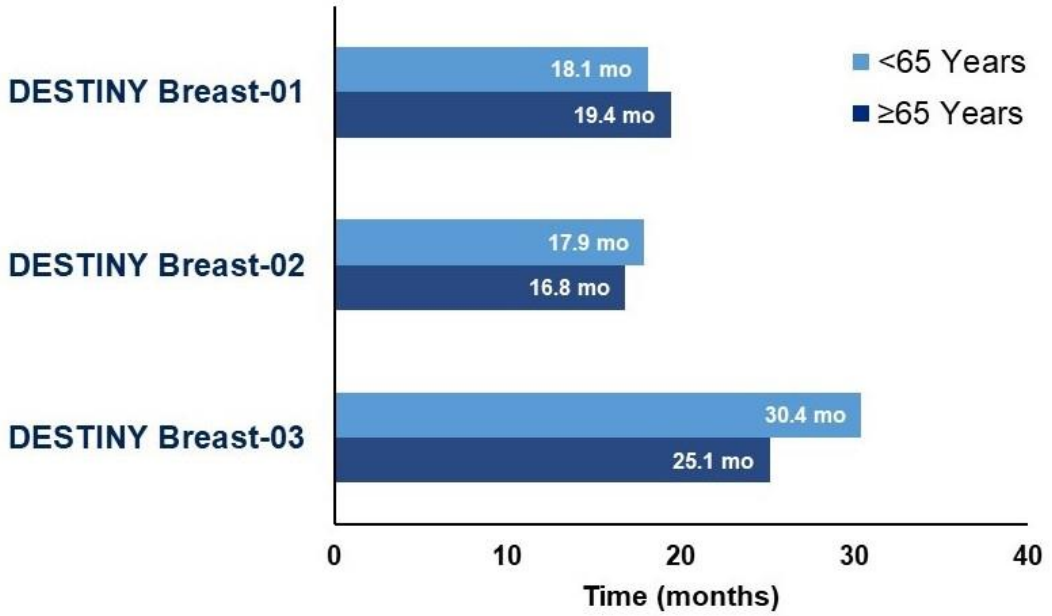
Trastuzumab Deruxtecan in HER2+ MBC

Descriptive Efficacy According to Age for T-DXd[a]

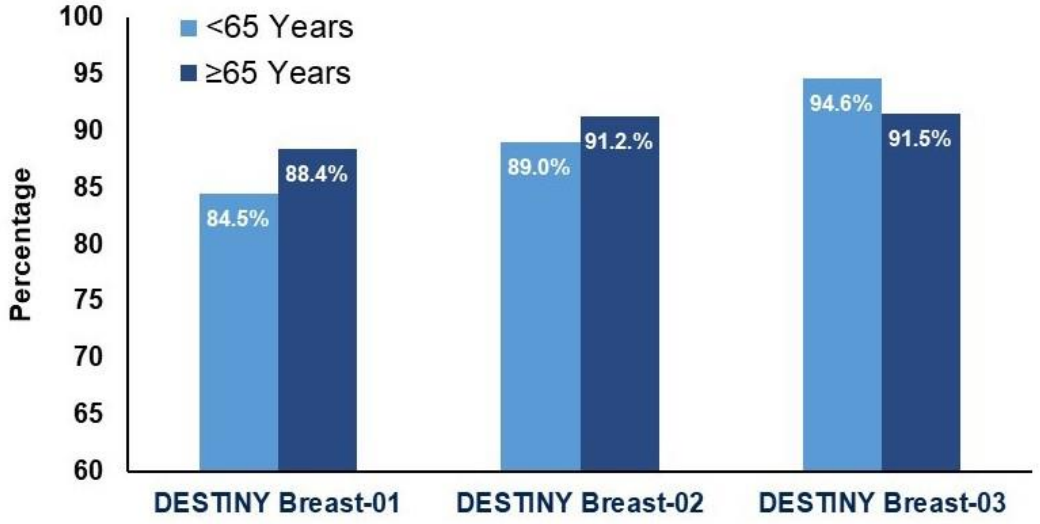
Median Progression Free Survival



Median Overall Survival

	DESTINY-Breast01		DESTINY-Breast02		DESTINY-Breast03	
	<65 (n = 140)	≥65 (n = 44)	<65 (n = 321)	≥65 (n = 85)	<65 (n = 212)	≥65 (n = 49)
mOS, months (95% CI)	28.1 (23.3-36.1)	30.9 (21.9-NE)	NR (35.5-NE)	30.2 (22.3-39.2)	NR (40.5-NE)	NR (26.3-NE)

12-month Landmark Overall Survival



- Efficacy in patients aged <65 and ≥65 years treated with T-DXd was generally similar; however no formal comparison was made

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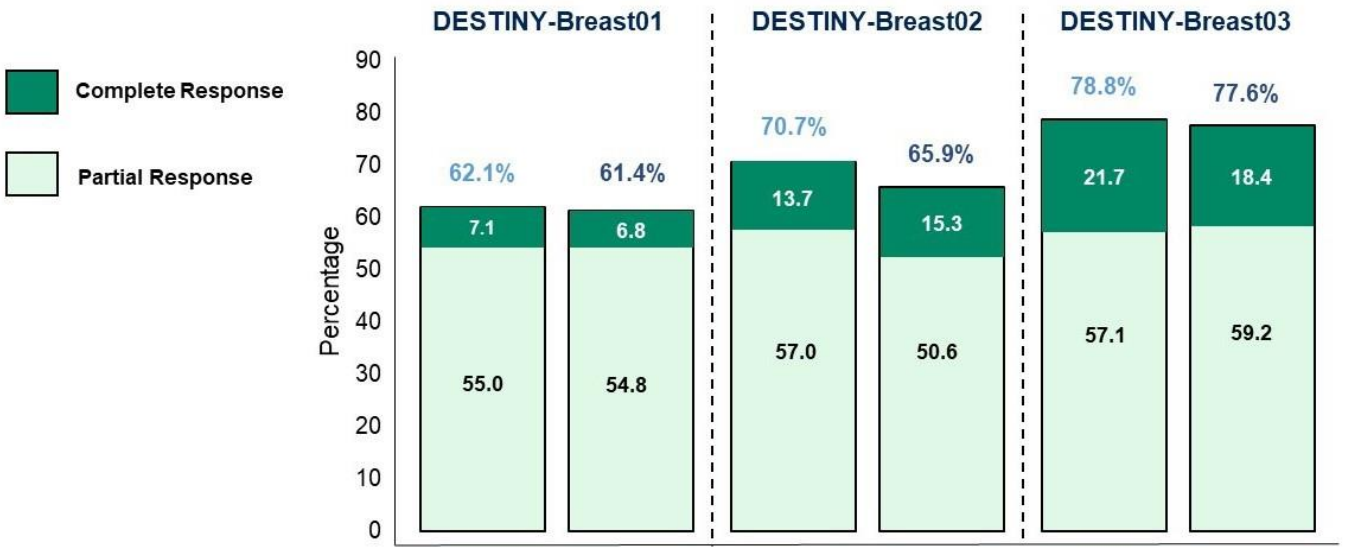
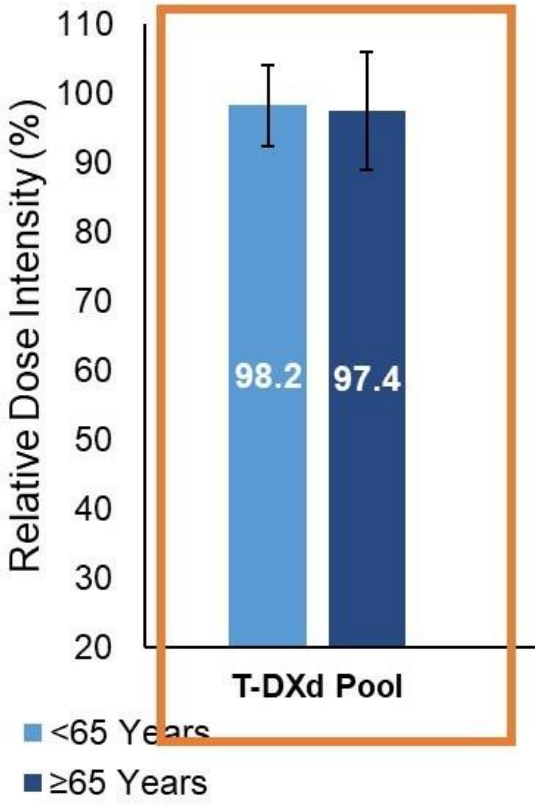
Trastuzumab Deruxtecan in HER2+ MBC

Confirmed ORR by BICR[a] with T-DXd



	DESTINY-Breast01 <65 (n = 140)	DESTINY-Breast01 ≥65 (n = 44)	DESTINY-Breast02 <65 (n = 321)	DESTINY-Breast02 ≥65 (n = 85)	DESTINY-Breast03 <65 (n = 212)	DESTINY-Breast03 ≥65 (n = 49)
Stable disease	49 (35.0)	16 (36.4)	69 (21.5)	26 (30.6)	38 (17.9)	9 (18.4)
Progressive disease	3 (2.1)	0	17 (5.3)	2 (2.4)	3 (1.4)	0
Not evaluable	1 (0.7)	1 (2.3)	8 (2.5)	1 (1.2)	4 (1.9)	2 (4.1)
Duration of response, months (95% CI)	20.8 (14.8-NE)	15.5 (9.7-NE)	19.6 (15.6-NE)	19.4 (12.2-NE)	36.6 (26.3-NE)	20.3 (12.5-NE)
Disease control rate, n (%)	136 (97.1)	43 (97.7)	296 (92.2)	82 (96.5)	205 (96.7)	47 (95.9)

Relative Dose Intensity



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Most common drug-related TEAEs in ≥20% of patients

	T-DXd Pool		
	<65 (n = 668)	≥65 (n = 177)	≥75 (n = 33)
Any grade[a] drug-related TEAEs, n (%)	**653 (97.8)**	**176 (99.4)**	**33 (100.0)**
Nausea	497 (74.4)	112 (63.3)	21 (63.6)
Fatigue[b]	344 (51.5)	98 (55.4)	21 (63.6)
Vomiting	268 (40.1)	59 (33.3)	10 (30.3)
Alopecia	265 (39.7)	63 (35.6)	10 (30.3)
Neutropenia[c]	240 (35.9)	72 (40.7)	9 (27.3)
Decreased appetite	181 (27.1)	53 (29.9)	9 (27.3)
Anemia[d]	180 (26.9)	61 (34.5)	12 (36.4)
Leukopenia[e]	156 (23.4)	49 (27.7)	6 (18.2)
Thrombocytopenia[f]	149 (22.3)	50 (28.2)	3 (9.1)
Constipation	148 (22.2)	36 (20.3)	4 (12.1)
Transaminases increased[g]	146 (21.9)	34 (19.2)	1 (3.0)
Diarrhea	142 (21.3)	48 (27.1)	6 (18.2)
Stomatitis[h]	82 (12.3)	35 (19.8)	2 (6.1)

Any grade drug-related TEAEs were similar across age groups

Most common grade ≥3 drug-related TEAEs in ≥5% of patients

	T-DXd Pool		
	<65 (n = 668)	≥65 (n = 177)	≥75 (n = 33)
Grade ≥3[a] drug-related TEAEs, n (%)	**291 (43.6)**	**96 (54.2)**	**13 (39.4)**
Neutropenia[b]	117 (17.5)	41 (23.2)	4 (12.1)
Fatigue[c]	52 (7.8)	20 (11.3)	5 (15.2)
Nausea	43 (6.4)	15 (8.5)	4 (12.1)
Anemia[d]	42 (6.3)	20 (11.3)	3 (9.1)
Leukopenia[e]	42 (6.3)	15 (8.5)	2 (6.1)
Lymphopenia[f]	28 (4.2)	11 (6.2)	1 (3.0)
Thrombocytopenia[g]	28 (4.2)	9 (5.1)	0
Transaminases increased[h]	18 (2.7)	1 (0.6)	0
Diarrhea	9 (1.3)	4 (2.3)	0

Most Common Grade ≥3 Drug-r

Patients ≥65 years of age experienced more grade ≥3 TEAEs across all trials

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Adjudicated Drug-related ILD/Pneumonitis[a]

	T-DXd Pool			TPC (DB-02)			T-DM1 (DB-03)		
	<65 (n = 668)	≥65 (n = 177)	≥75 (n = 33)	<65 (n = 157)	≥65 (n = 38)	≥75 (n = 8)	<65 (n = 204)	≥65 (n = 57)	≥75 (n = 8)
Any grade, n (%)	**79 (11.8)**	**31 (17.5)**	**5 (15.2)**	**0**	**1 (2.6)**	**0**	**6 (2.9)**	**2 (3.5)**	**1 (12.5)**
1	21 (3.1)	7 (4.0)	0	0	0	0	3 (1.5)	1 (1.8)	0
2	48 (7.2)	20 (11.3)	5 (15.2)	0	0	0	2 (1.0)	1 (1.8)	1 (12.5)
3	4 (0.6)	3 (1.7)	0	0	1 (2.6)	0	1 (0.5)	0	0
4	0	0	0	0	0	0	0	0	0
5	6 (0.9)	1 (0.6)	0	0	0	0	0	0	0

- Rates of adjudicated ILD/pneumonitis were generally higher in patients ≥65 years of age across all trials compared to patients <65 years of age
- Most drug-related ILD/pneumonitis cases were of low grade

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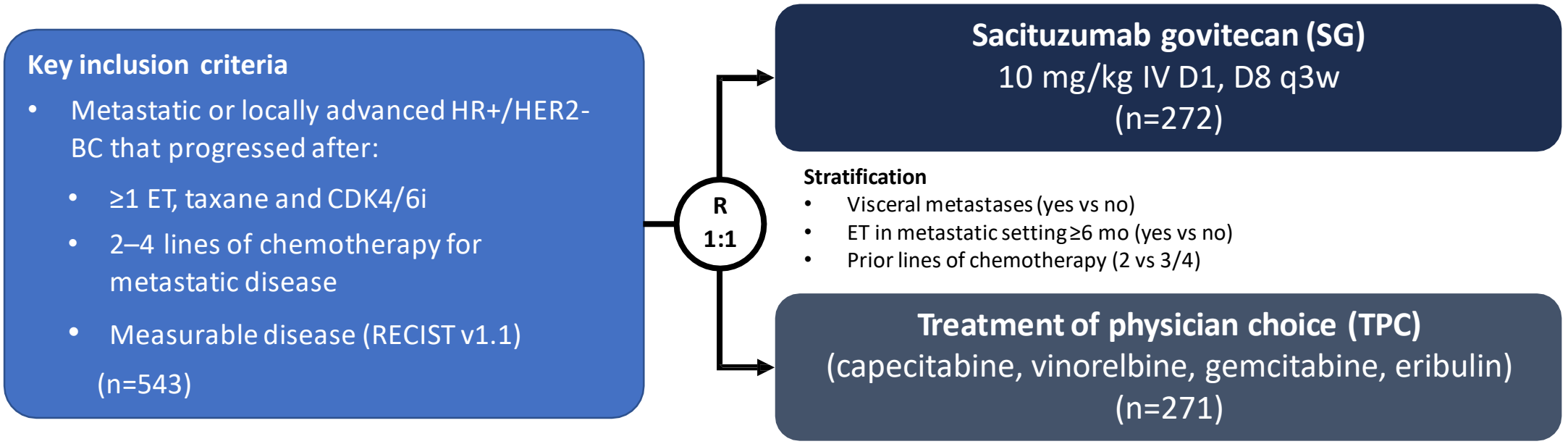
TROPiCS-02: Final OS for sacituzumab govitecan in HR+ HER2- MBC



Primary endpoint

- PFS (BICR)

Secondary endpoints

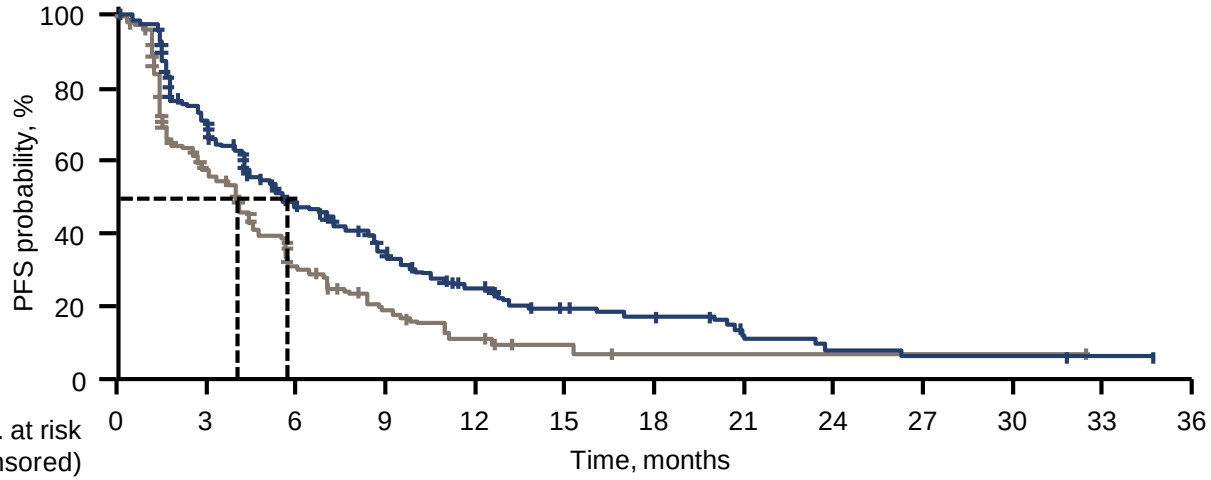
- OS, ORR, DoR, CBR, PRO, safety

Tolaney SM, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 1003.

SG continued to demonstrate survival improvements compared to TPC

PFS

	SG (n=272)	TPC (n=271)
mPFS, mo (95%CI)	5.5 (4.2, 6.9)	4.0 (3.0, 4.4)
HR (95% CI); p-value*	0.65 (0.53, 0.81); 0.0001	

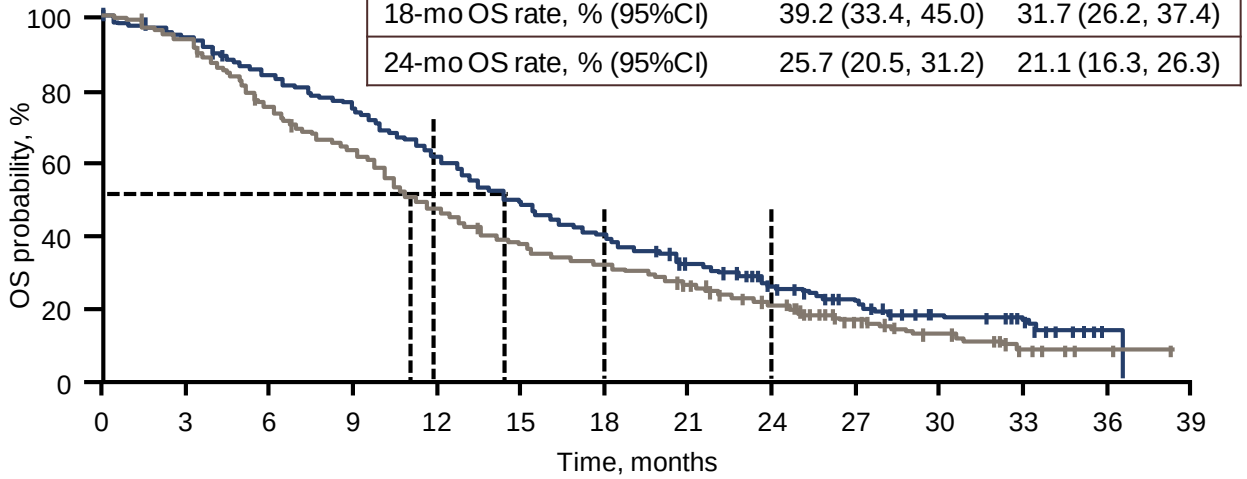


No. at risk (censored)

SG	272 (0)	148 (86)	82 (127)	48 (149)	27 (164)	17 (170)	13 (172)	6 (176)	3 (179)	2 (180)	2 (180)	1 (180)	0 (180)
TPC	271 (0)	109 (96)	42 (144)	18 (160)	7 (168)	3 (169)	1 (170)	1 (170)	1 (170)	1 (170)	1 (170)	1 (170)	

OS

	SG (n=272)	TPC (n=271)
mOS, mo (95%CI)	14.5 (13.0, 16.0)	11.2 (10.2, 12.6)
HR (95% CI); p-value*	0.79 (0.65, 0.95); 0.0133	
12-mo OS rate, % (95%CI)	60.9 (54.8, 66.4)	47.1 (41.0, 53.0)
18-mo OS rate, % (95%CI)	39.2 (33.4, 45.0)	31.7 (26.2, 37.4)
24-mo OS rate, % (95%CI)	25.7 (20.5, 31.2)	21.1 (16.3, 26.3)



SG	272 (0)	253 (17)	223 (45)	200 (68)	163 (105)	130 (138)	105 (163)	71 (184)	52 (196)	33 (204)	19 (209)	13 (211)	1 (213)	0 (214)
TPC	271 (0)	251 (16)	199 (66)	167 (97)	124 (140)	96 (166)	82 (180)	66 (193)	46 (206)	27 (214)	15 (220)	7 (224)	1 (224)	0 (224)

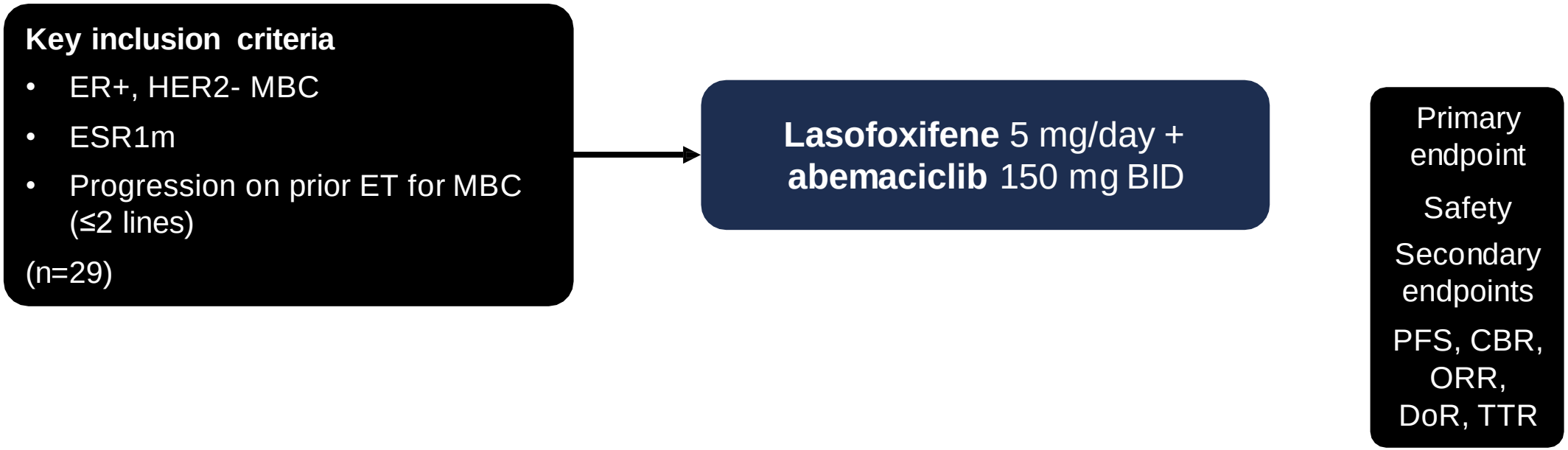
*Nominal p-value.

Tolaney SM, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 1003.

ELAINE 2: Lasofoxifene + abemaciclib in ESR1m ER+/HER2- MBC

Objective

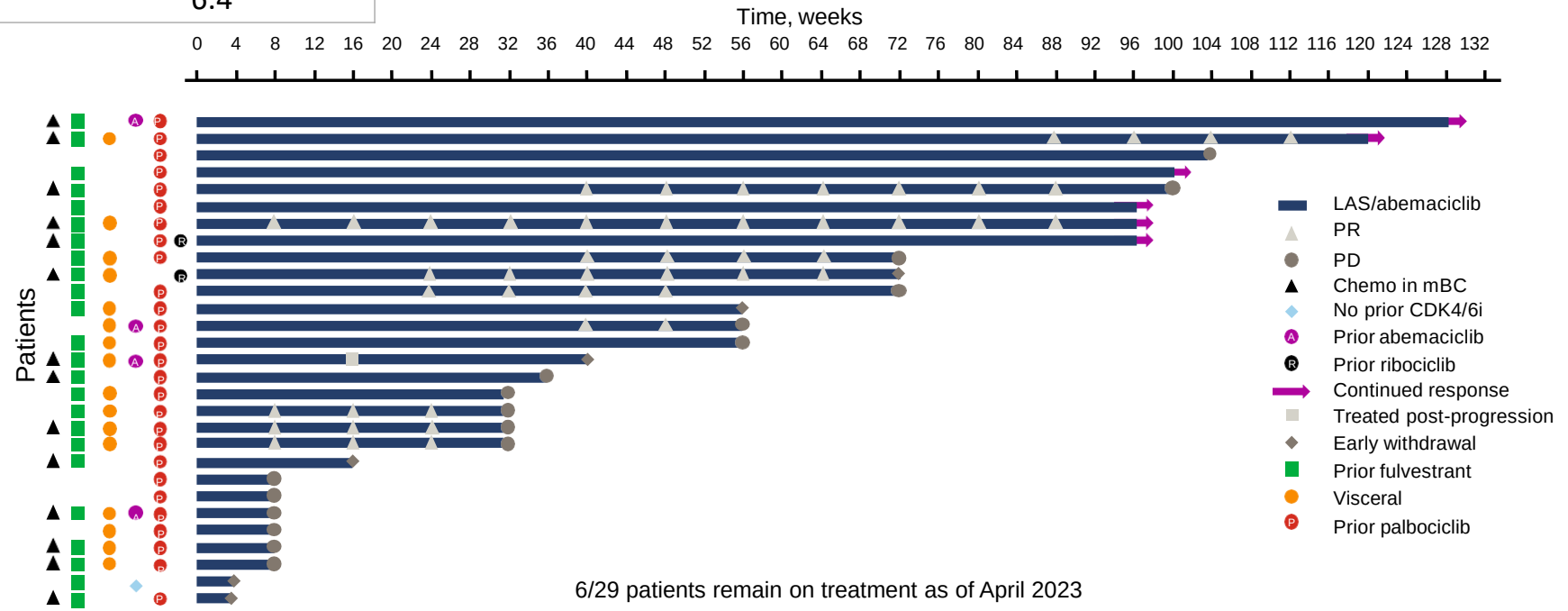
- To evaluate the updated safety and efficacy of lasofoxifene + abemaciclib in patients with ESR1m HR+, HER2- MBC in the post-CDK4/6i setting



Damodaran S, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 1057.

ELAINE 2: Lasofoxifene + abemaciclib in ESR1m ER+, HER2- MBC

	n=29
mPFS, weeks (95%CI)	56.0 (31.9, NE)
PFS rate, % (95%CI)	
6-month	76.1 (54.4, 88.5)
12-month	56.1 (34.9, 72.8)
18-month	38.8 (20.0, 57.3)
ORR, % (95%CI)	55.6 (33.7, 75.4)
CBR, % (95%CI)	65.5 (47.3, 80.1)
mTTR, mo	5.7
mDoR, mo	6.4



6/29 patients remain on treatment as of April 2023

Damodaran S, et al. *J Clin Oncol* 2023;41(suppl 16):Abstract 1057.

Thank you for your attention