BERLIN 2025 ESMO congress

DESTINY Breast09

Trastuzumab deruxtecan (T-DXd) + pertuzumab vs taxane + trastuzumab + pertuzumab (THP) for patients with HER2+ advanced/metastatic breast cancer: additional analyses of DESTINY-Breast09 in key subgroups of interest

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On behalf of the DESTINY-Breast09 investigators

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Declaration of interests

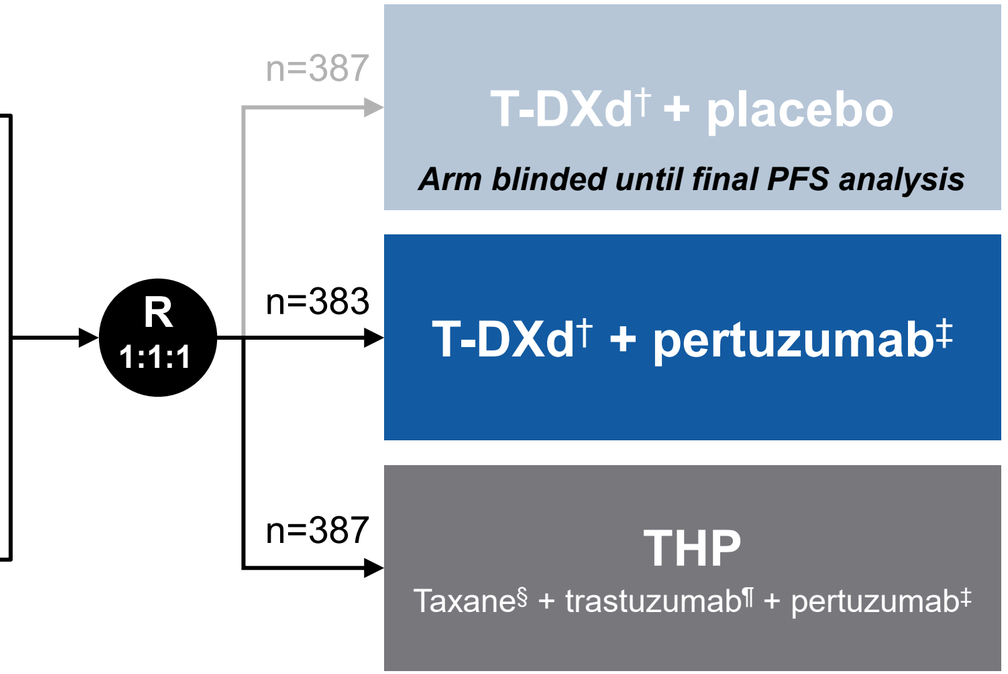
Commercial interests	Nature of relationship
AbbVie, AstraZeneca, Celgene, Daiichi Sankyo, Greenwich LifeSciences, Immunomedics/Gilead Sciences, Molecular Health, Novartis, Pfizer, and Roche	Receipt of research funding
Amgen, AstraZeneca, Bayer, BeiGene, Bicycle Therapeutics, Bristol Myers Squibb, Celgene, Daiichi Sankyo, Gilead Sciences, GSK, Jazz Pharmaceuticals, Lilly, Medscape, Merck, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi, Seagen, and Menarini-Stemline	Advisory board participation / receipt of consultation fees
GBG Forschungs GmbH	Employment
VMscope GmbH	Receipt of licensing fees

DESTINY-Breast09 study design

A randomized, multicenter, open-label,* Phase 3 study (NCT04784715)[1,2]

Patient population

- 1L HER2+ a/mBC
- DFI >6 mo from last (neo)adjuvant therapy
- One prior line of ET for a/mBC permitted
- Asymptomatic BMs allowed



Endpoints

Primary

- PFS (BICR)

Key secondary

- OS

Secondary

- PFS (INV)
- ORR (BICR/INV)
- DOR (BICR/INV)
- PFS2 (INV)
- Safety and tolerability

Stratification factors

- **De-novo (~52%) vs recurrent a/mBC**
- **HR+ (~54%) or HR−**
- ***PIK3CA*m detected (~31%) vs not detected**

- If T-DXd was discontinued owing to AEs (except Grade >2 ILD), patients could switch to trastuzumab‖
- Concurrent use of ET (aromatase inhibitor or tamoxifen) was allowed for those with HR+ disease after six cycles of T-DXd or discontinuation of taxane

*Open label for THP arm, double blinded for pertuzumab in experimental arms; †5.4 mg/kg Q3W; ‡840 mg loading dose, then 420 mg Q3W; §paclitaxel 80 mg/m^2 QW or 175 mg/m^2 Q3W, or docetaxel 75 mg/m^2 Q3W for a minimum of six cycles or until intolerable toxicity; ¶8 mg/kg loading dose, then 6 mg/kg Q3W; ‖without loading dose

1L, first-line; AE, adverse event; a/mBC, advanced/metastatic breast cancer; BICR, blinded independent central review; BM, brain metastasis; DFI, disease-free interval; DOR, duration of response; ET, endocrine therapy; HER2+, human epidermal growth factor receptor 2–positive; HR+/−, hormone receptor–positive/–negative; ILD, interstitial lung disease; INV, investigator; mo, months; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, second progression-free survival; *PIK3CA*m, *PIK3CA* mutation; Q3W, every 3 weeks; QW, once weekly; R, randomization; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

1. Tolaney SM, et al. Oral presentation at ASCO 2025 (Abstract LBA1008); 2. NCT04784715. Updated. August 1, 2025. Available from: https://clinicaltrials.gov/study/NCT04784715 (Accessed October 15, 2025)

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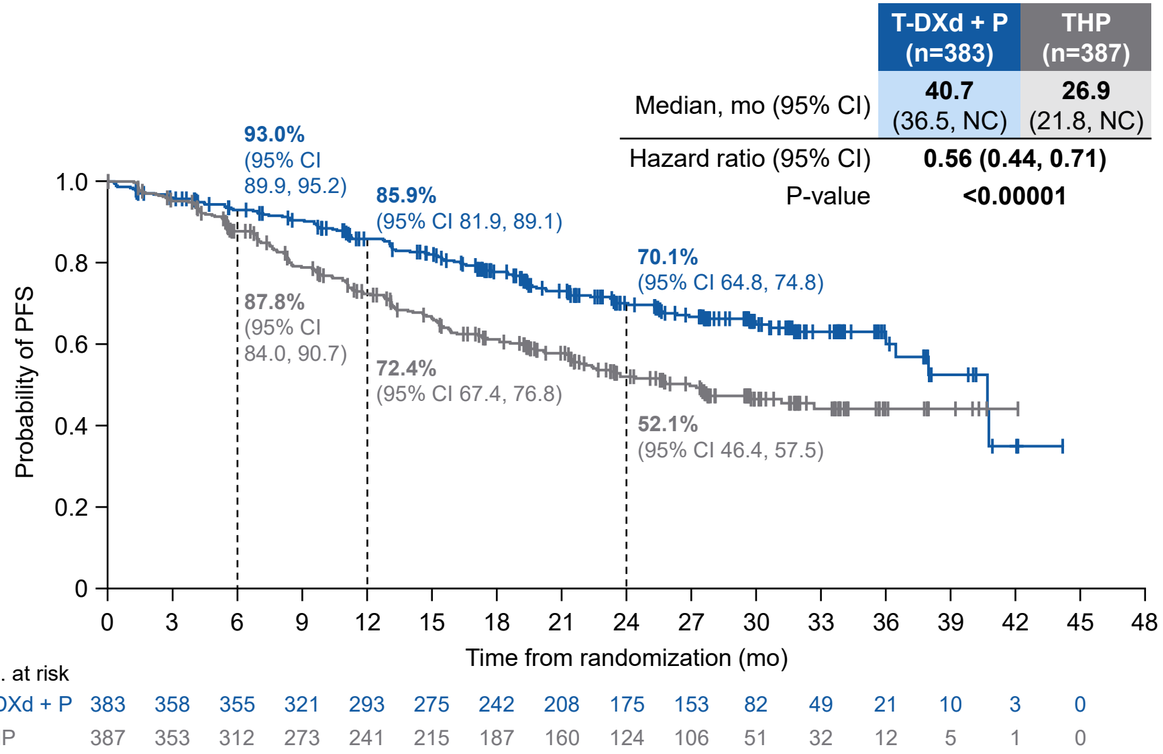
Background: DESTINY-Breast09 primary results

- T-DXd + P demonstrated a statistically significant and clinically meaningful **improvement in PFS by BICR vs THP**[1]
- Early OS data suggest a positive trend favoring T-DXd + P, with a **supportive hazard ratio of 0.60 for PFS2**[1]
- A consistent PFS benefit with T-DXd + P was also observed across **stratification factors**[1]
  - **Recurrent disease / prior treatment** (~50% of patients in this setting[2])
  - **HR-negative status** (~50% of patients[3])
  - ***PIK3CA* mutation** (~30% of patients[4,5])
- T-DXd + P safety data were consistent with known profiles of individual treatments[1]

DESTINY-Breast09 interim analysis (DCO February 26, 2025)
PFS by BICR: primary endpoint[1]



BICR, blinded independent central review; CI, confidence interval; DCO, data cutoff; HR, hormone receptor; mo, months; NC, not calculable; OS, overall survival; P, pertuzumab; PFS, progression-free survival; PFS2, second progression-free survival; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

1. Tolaney SM, et al. Oral presentation at ASCO 2025 (Abstract LBA1008); 2. Tripathy D, et al. *Oncologist.* 2020;25:e214–e222; 3. Baselga J, et al. *N Engl J Med.* 2012;366:109–119; 4. Baselga J, et al. *J Clin Oncol.* 2014;32:3753–3761; 5. Swain S, et al. *Cancer Res.* 2023;83(Suppl. 5):P2-11-07 (Abstract)

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Key baseline disease characteristics by subgroup

	Prior treatment status				HR status				*PIK3CA*m status			
	De novo		Recurrent		HR+		HR−		Detected		Not detected	
n (%)	T-DXd + P (n=200)	THP (n=200)	T-DXd + P (n=183)	THP (n=187)	T-DXd + P (n=207)	THP (n=209)	T-DXd + P (n=176)	THP (n=178)	T-DXd + P (n=116)	THP (n=121)	T-DXd + P (n=266)*	THP (n=266)
ECOG PS score												
0	136 (68.0)	121 (60.5)	120 (65.6)	125 (66.8)	141 (68.1)	129 (61.7)	115 (65.3)	117 (65.7)	71 (61.2)	76 (62.8)	185 (69.5)	170 (63.9)
1	64 (32.0)	79 (39.5)	63 (34.4)	62 (33.2)	66 (31.9)	80 (38.3)	61 (34.7)	61 (34.3)	45 (38.8)	45 (37.2)	81 (30.5)	96 (36.1)
Brain mets†	10 (5.0)	7 (3.5)	15 (8.2)	15 (8.0)	10 (4.8)	7 (3.3)	15 (8.5)	15 (8.4)	8 (6.9)	6 (5.0)	17 (6.4)	16 (6.0)
Visceral mets	146 (73.0)	137 (68.5)	135 (73.8)	131 (70.1)	147 (71.0)	141 (67.5)	134 (76.1)	127 (71.3)	75 (64.7)	77 (63.6)	205 (77.1)	191 (71.8)
Prior treatment status												
De novo					112 (54.1)	106 (50.7)	88 (50.0)	94 (52.8)	54 (46.6)	55 (45.5)	146 (54.9)	145 (54.5)
Recurrent					95 (45.9)	103 (49.3)	88 (50.0)	84 (47.2)	62 (53.4)	66 (54.5)	120 (45.1)	121 (45.5)
HR status												
Positive‡	112 (56.0)	106 (53.0)	95 (51.9)	103 (55.1)					61 (52.6)	64 (52.9)	146 (54.9)	145 (54.5)
Negative	88 (44.0)	94 (47.0)	88 (48.1)	84 (44.9)					55 (47.4)	57 (47.1)	120 (45.1)	121 (45.5)
***PIK3CA*m status**												
Detected	54 (27.0)	55 (27.5)	62 (33.9)	66 (35.3)	61 (29.5)	64 (30.6)	55 (31.3)	57 (32.0)				
Not detected	146 (73.0)	145 (72.5)	120 (65.6)*	121 (64.7)	146 (70.5)	145 (69.4)	120 (68.2)*	121 (68.0)				

Treatment arms were well balanced according to key disease characteristics

*One patient had missing *PIK3CA*m status; †participants were eligible if they had brain metastases that were clinically inactive or treated/asymptomatic; ‡defined as estrogen receptor–positive and/or progesterone receptor–positive (≥1%)
CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; HR(+/−), hormone receptor(–positive/–negative); mets, metastases; mo, months; NC, not calculable; P, pertuzumab; *PIK3CA*m, *PIK3CA* mutation; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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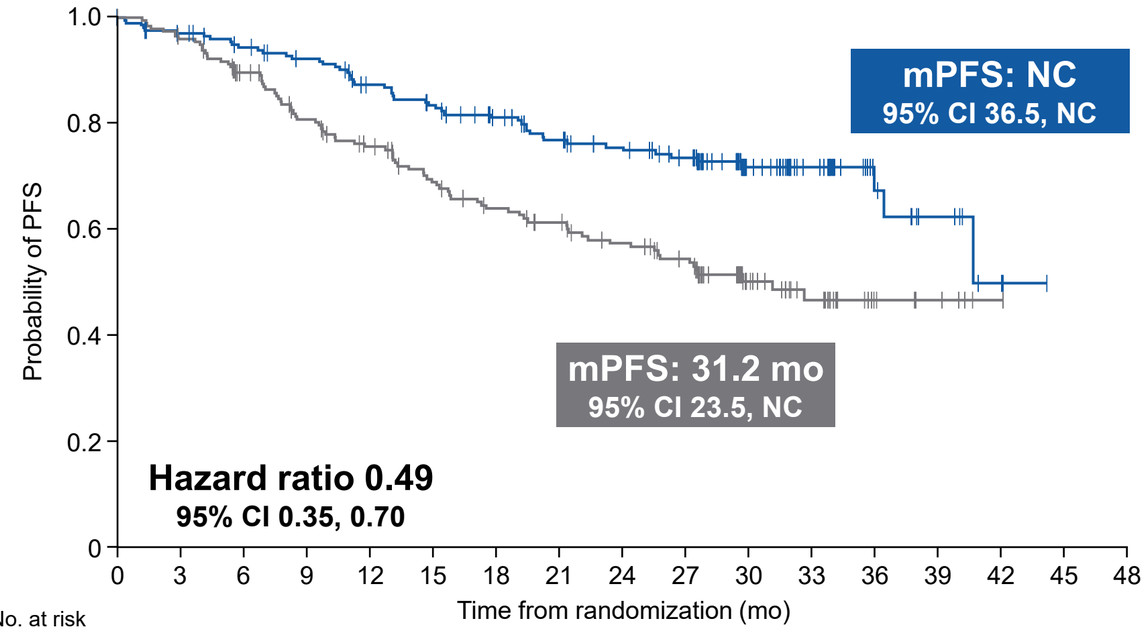
PFS by prior treatment status

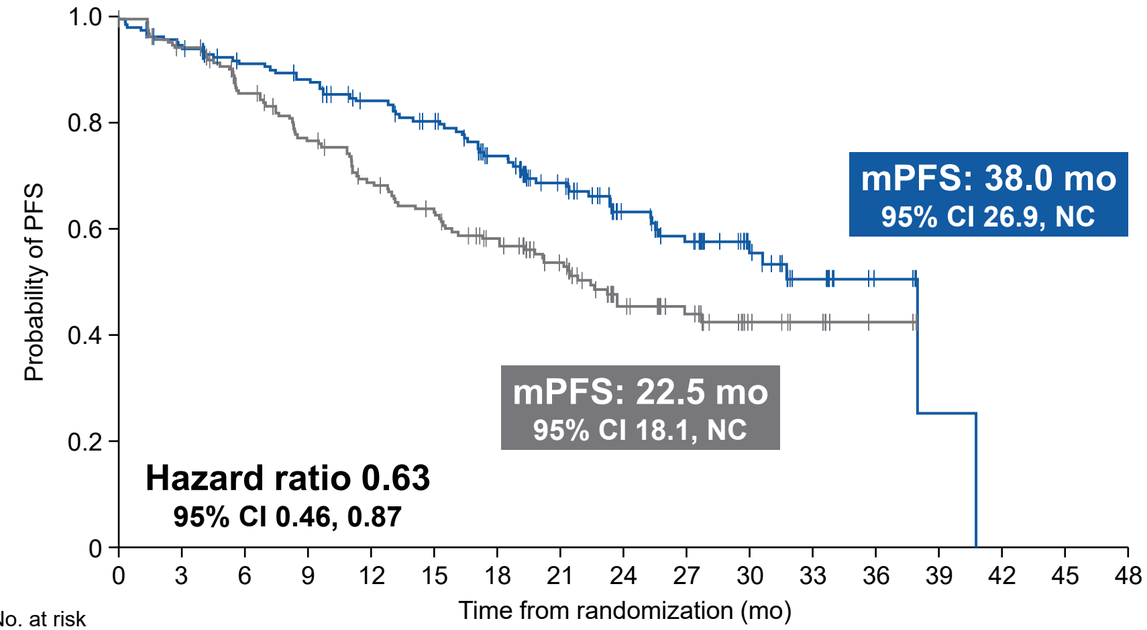
PFS:* *de novo*



No. at risk

T-DXd + P	200	189	179	171	157	148	136	124	117	106	55	35	16	9	3	0
THP	200	185	165	144	129	113	101	94	84	74	36	23	8	5	1	0

PFS:* recurrent



No. at risk

T-DXd + P	183	169	156	150	136	127	106	84	58	47	27	14	5	1	0	
THP	187	168	147	129	112	102	86	66	40	32	15	9	4	0	0	

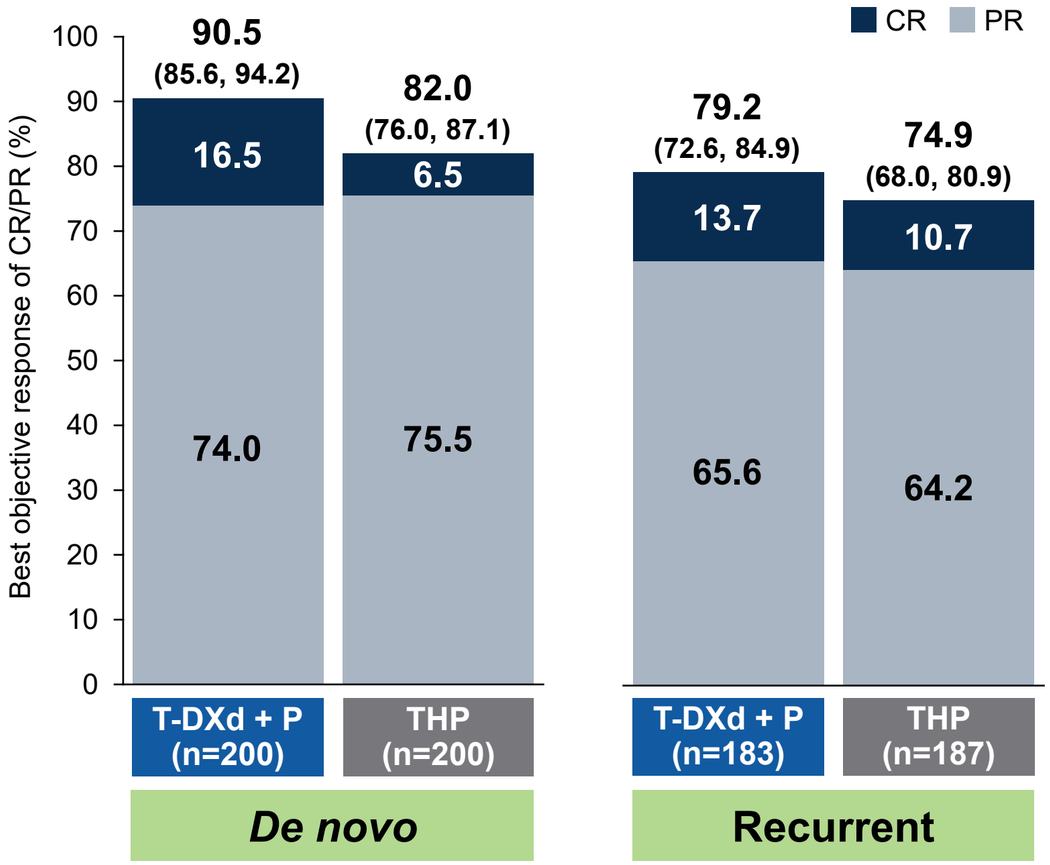
T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of de-novo or recurrent status

*By blinded independent central review

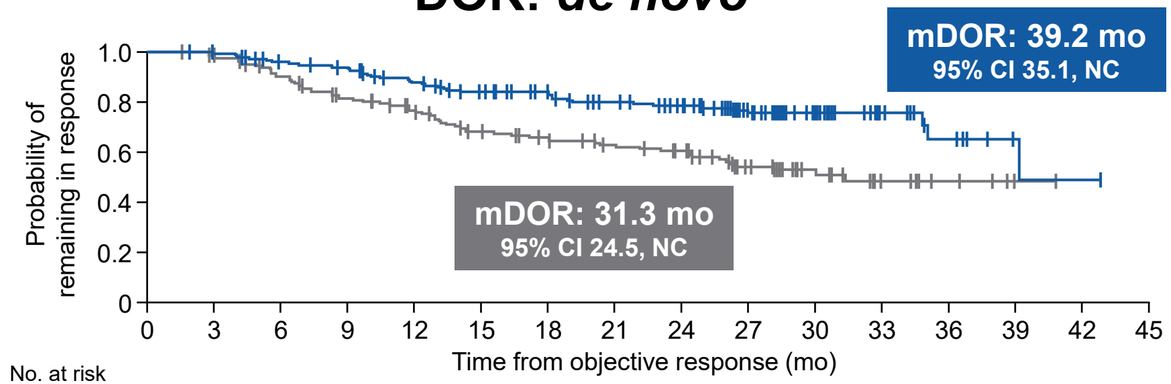
CI, confidence interval; mPFS, median progression-free survival; mo, months; NC, not calculable; P, pertuzumab; PFS, progression-free survival; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

cORR and DOR by prior treatment status

cORR, % (95% CI)*



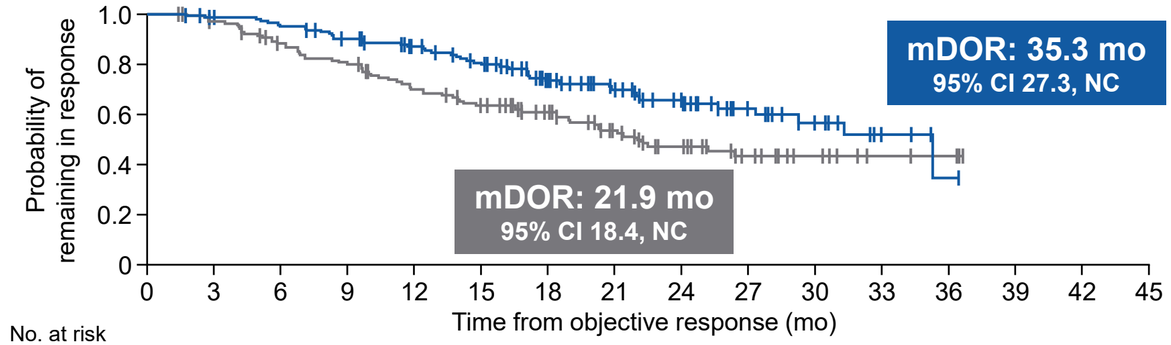
DOR: *de novo*



No. at risk

T-DXd + P	181	178	166	160	145	132	124	112	103	75	44	22	12	4	1	0
THP	164	158	141	122	110	94	86	79	73	48	27	11	6	1	0	0

DOR: recurrent



No. at risk

T-DXd + P	145	139	133	122	111	98	75	56	43	25	15	5	2	0
THP	140	133	117	107	90	78	63	46	32	18	9	4	3	0

CR rates and DOR favored T-DXd + P vs THP regardless of prior treatment status

*By blinded independent central review

CI, confidence interval; cORR, confirmed objective response rate; CR, complete response; DOR, duration of response; mDOR, median duration of response; mo, months; NC, not calculable; P, pertuzumab; PR, partial response; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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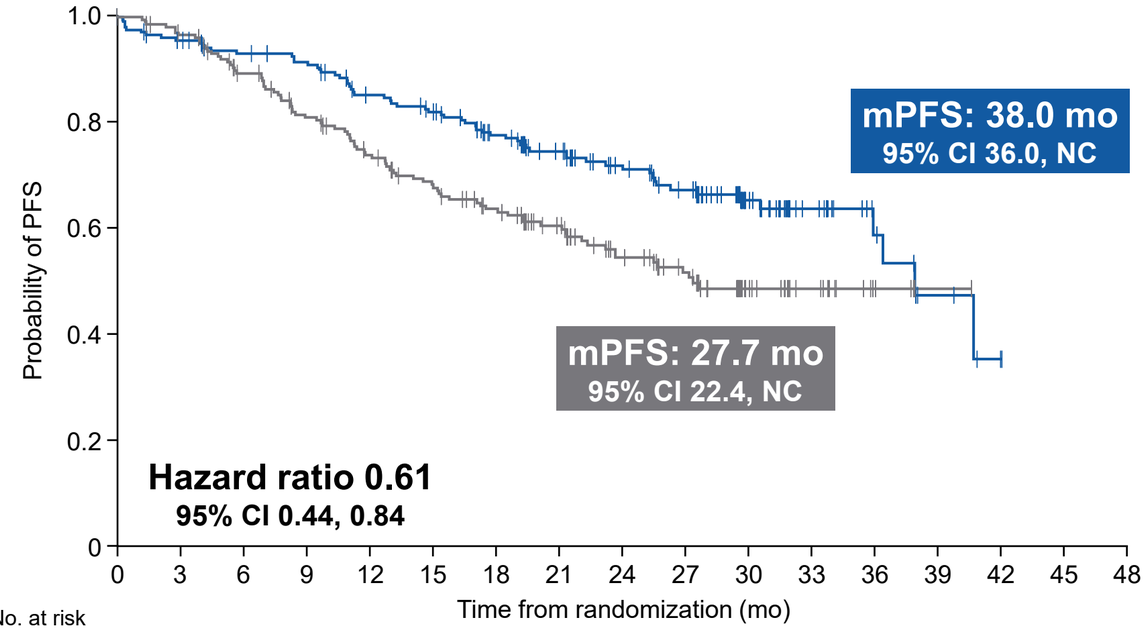
PFS by HR status

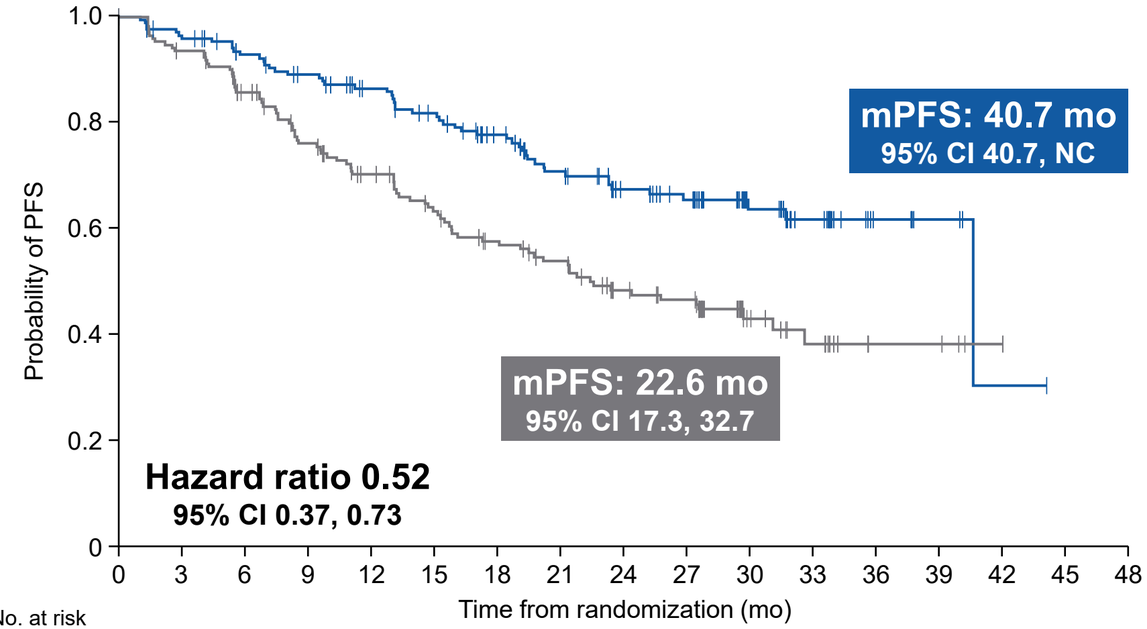
PFS:* HR+



No. at risk

T-DXd + P	207	194	184	179	162	154	136	117	99	85	46	24	13	6	2	0
THP	209	194	173	153	136	123	107	88	67	54	28	18	8	1	0	0

PFS:* HR−



No. at risk

T-DXd + P	176	164	151	142	131	121	106	91	76	68	36	25	8	4	1	0
THP	178	159	139	120	105	92	80	72	57	52	23	14	4	4	1	0

Patients with HR+ disease could receive concurrent ET after six cycles of T-DXd or discontinuation of taxane, which occurred in **13.5% (T-DXd + P)** versus **38.3% (THP)** of patients

T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of HR status

*By blinded independent central review

CI, confidence interval; ET, endocrine therapy; HR(+/−), hormone receptor(–positive/–negative); mPFS, median progression-free survival; mo, months; NC, not calculable; P, pertuzumab; PFS, progression-free survival; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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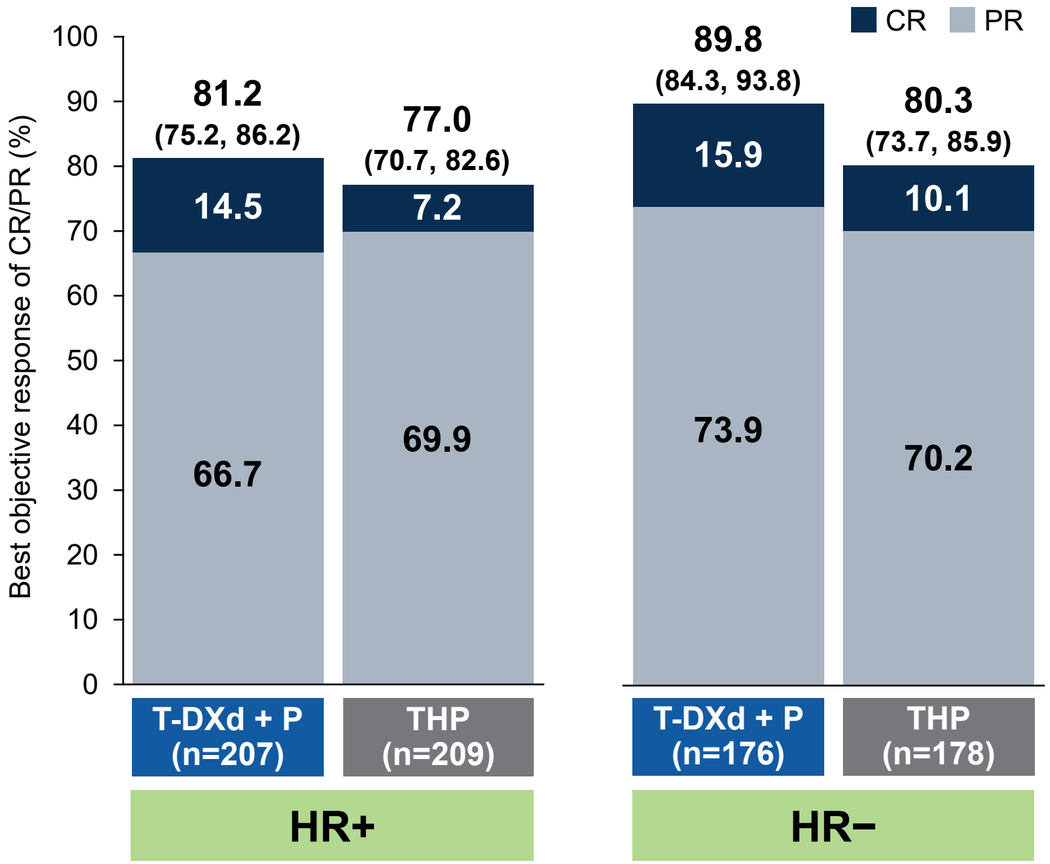
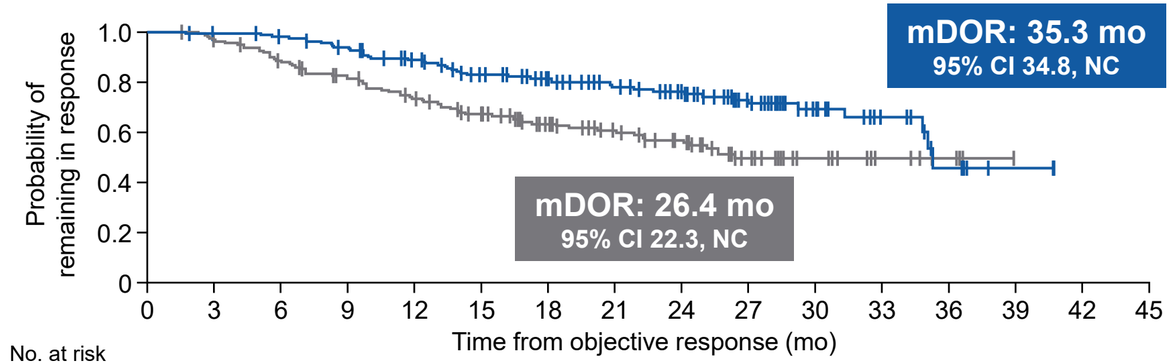
cORR and DOR by HR status

cORR, % (95% CI)*



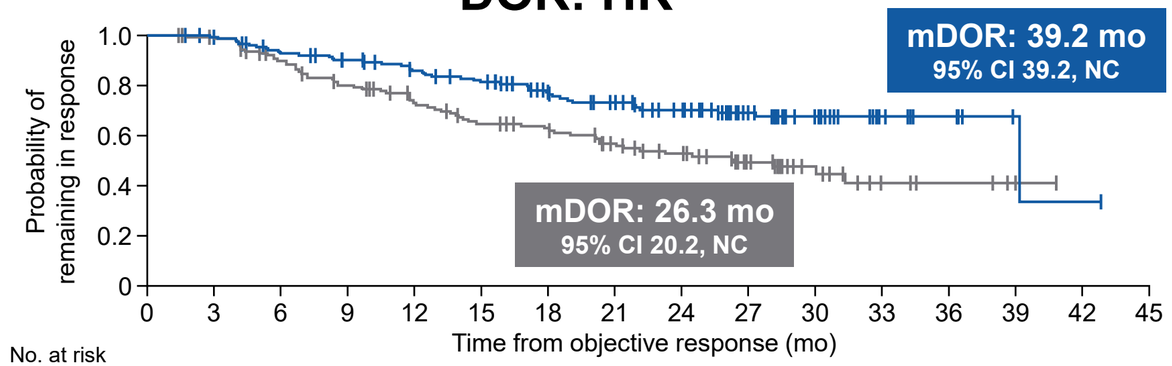
DOR: HR+



No. at risk

T-DXd + P	168	165	161	152	137	120	106	86	76	53	29	13	6	2	0
THP	161	153	138	124	109	94	77	65	54	34	19	9	5	0	0

DOR: HR−



No. at risk

T-DXd + P	158	152	138	130	119	110	93	82	70	47	30	14	8	2	1	0
THP	143	138	120	105	91	78	72	60	51	32	17	6	4	1	0	0

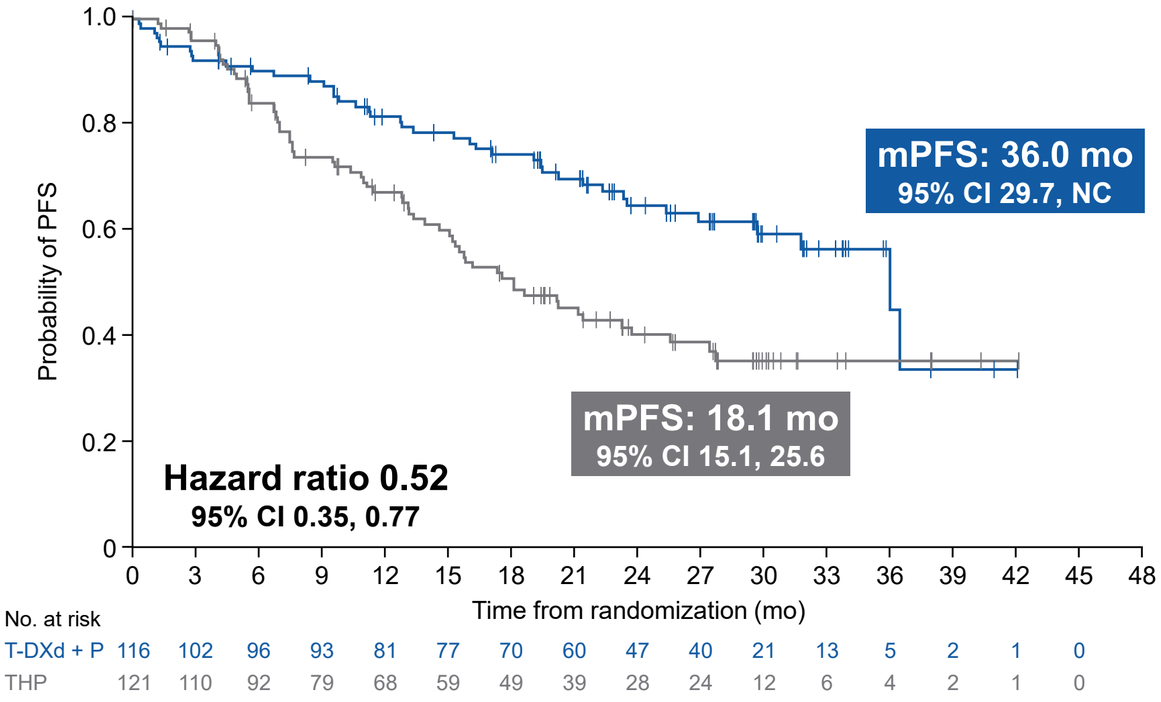
CR rates and DOR favored T-DXd + P vs THP regardless of HR status

*By blinded independent central review

CI, confidence interval; cORR, confirmed objective response rate; CR, complete response; DOR, duration of response; HR(+/−), hormone receptor(–positive/–negative); mDOR, median duration of response; mo, months; NC, not calculable; P, pertuzumab; PR, partial response; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

PFS by *PIK3CA*m status

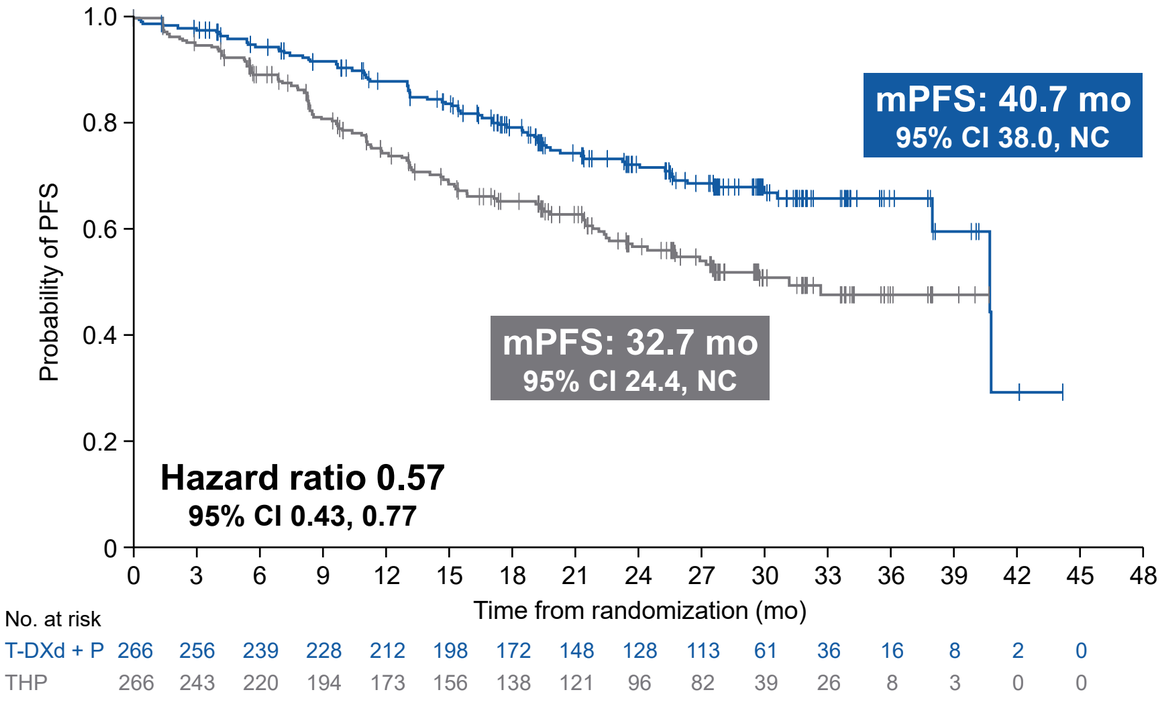
PFS:* *PIK3CA*m detected



No. at risk

T-DXd + P	116	102	96	93	81	77	70	60	47	40	21	13	5	2	1	0
THP	121	110	92	79	68	59	49	39	28	24	12	6	4	2	1	0

PFS:* *PIK3CA*m not detected†



No. at risk

T-DXd + P	266	256	239	228	212	198	172	148	128	113	61	36	16	8	2	0
THP	266	243	220	194	173	156	138	121	96	82	39	26	8	3	0	0

T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of *PIK3CA*m status

*By blinded independent central review; †one patient in the T-DXd + P arm had missing *PIK3CA*m status
CI, confidence interval; mo, months; mPFS, median progression-free survival; NC, not calculable; P, pertuzumab; PFS, progression-free survival; *PIK3CA*m, *PIK3CA* mutation; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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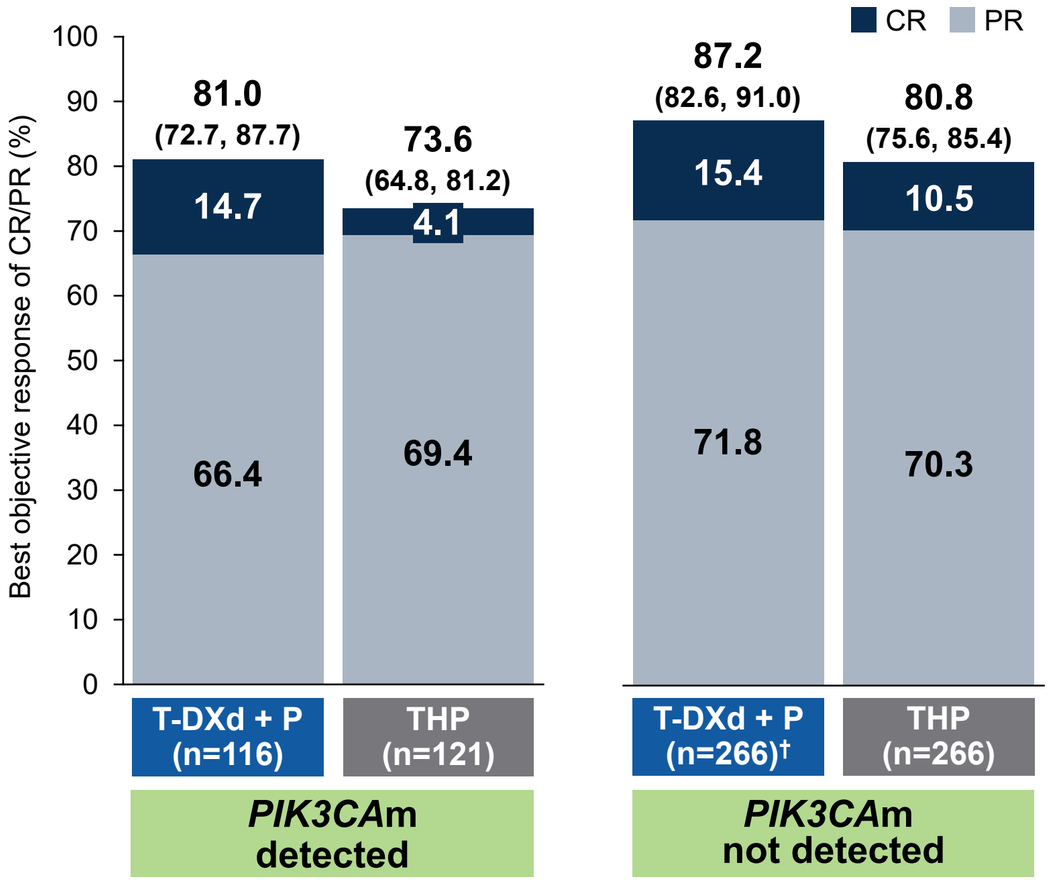
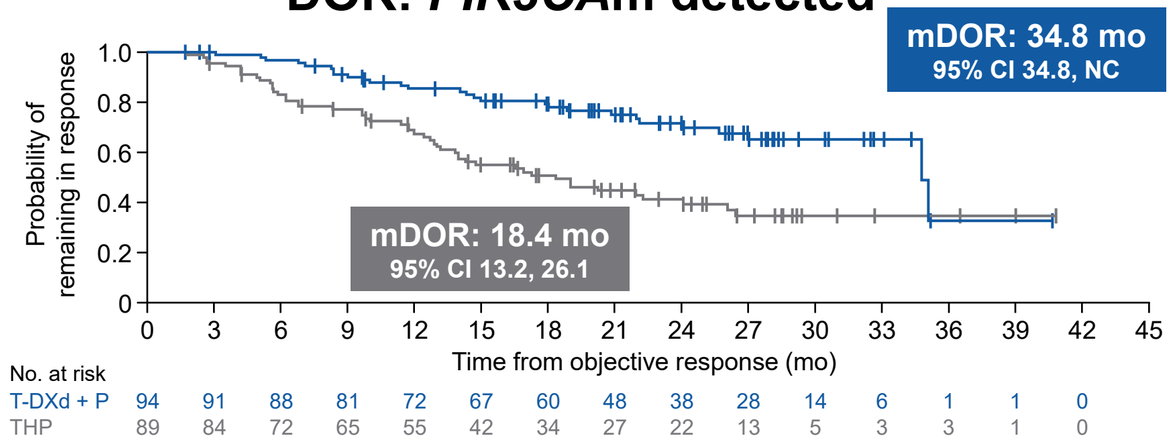
cORR and DOR by *PIK3CA*m status

cORR, % (95% CI)*



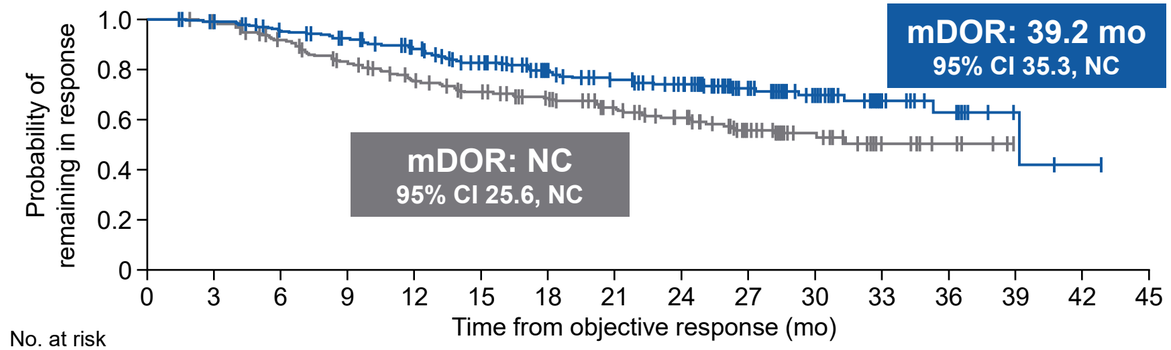
DOR: *PIK3CA*m detected



No. at risk

T-DXd + P	94	91	88	81	72	67	60	48	38	28	14	6	1	1	0
THP	89	84	72	65	55	42	34	27	22	13	5	3	3	1	0

DOR: *PIK3CA*m not detected†



No. at risk

T-DXd + P	232	226	211	201	184	163	139	120	108	72	45	21	13	3	1	0
THP	215	207	186	164	145	130	115	98	83	53	31	12	6	0	0	0

CR rates and DOR favored T-DXd + P vs THP regardless of *PIK3CA*m status

*By blinded independent central review; †one patient in the T-DXd + P arm had missing *PIK3CA*m status
CI, confidence interval; cORR, confirmed objective response rate; CR, complete response; DOR, duration of response; mDOR, median duration of response; mo, months; NC, not calculable; P, pertuzumab; *PIK3CA*m, *PIK3CA* mutation; PR, partial response; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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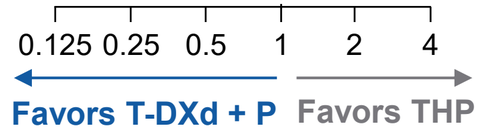
PFS2 by subgroup

	No. of events / no. of patients		mPFS2, mo (95% CI)		Hazard ratio (95% CI)
	T-DXd + P	THP	T-DXd + P	THP	
Prior treatment status					
De novo	38/200	59/200	NC	37.4 (36.1, NC)	0.55 (0.36, 0.83)
Recurrent	41/183	56/187	NC	36.5 (30.2, NC)	0.66 (0.44, 0.99)
HR status					
Positive	38/207	62/209	NC	NC (33.2, NC)	0.54 (0.36, 0.81)
Negative	41/176	53/178	NC (39.6, NC)	36.5 (33.1, NC)	0.67 (0.44, 1.01)
***PIK3CA*m status**					
Detected	29/116	44/121	NC	33.2 (24.2, NC)	0.57 (0.35, 0.91)
Not detected	49/266*	71/266	NC (39.6, NC)	37.4 (36.1, NC)	0.61 (0.42, 0.87)



Clinically meaningful improvement in PFS2 with T-DXd + P vs THP across subgroups

*One patient in the T-DXd + P arm had missing *PIK3CA*m status. Size of circle is proportional to the number of events. PFS2 was defined by investigators according to local standard clinical practice as the time from randomization to second progression (earliest progression event following first subsequent therapy) or death
CI, confidence interval; HR, hormone receptor; mo, months; mPFS2, median second progression-free survival; NC, not calculable; P, pertuzumab; PFS2, second progression-free survival; *PIK3CA*m, *PIK3CA* mutation; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

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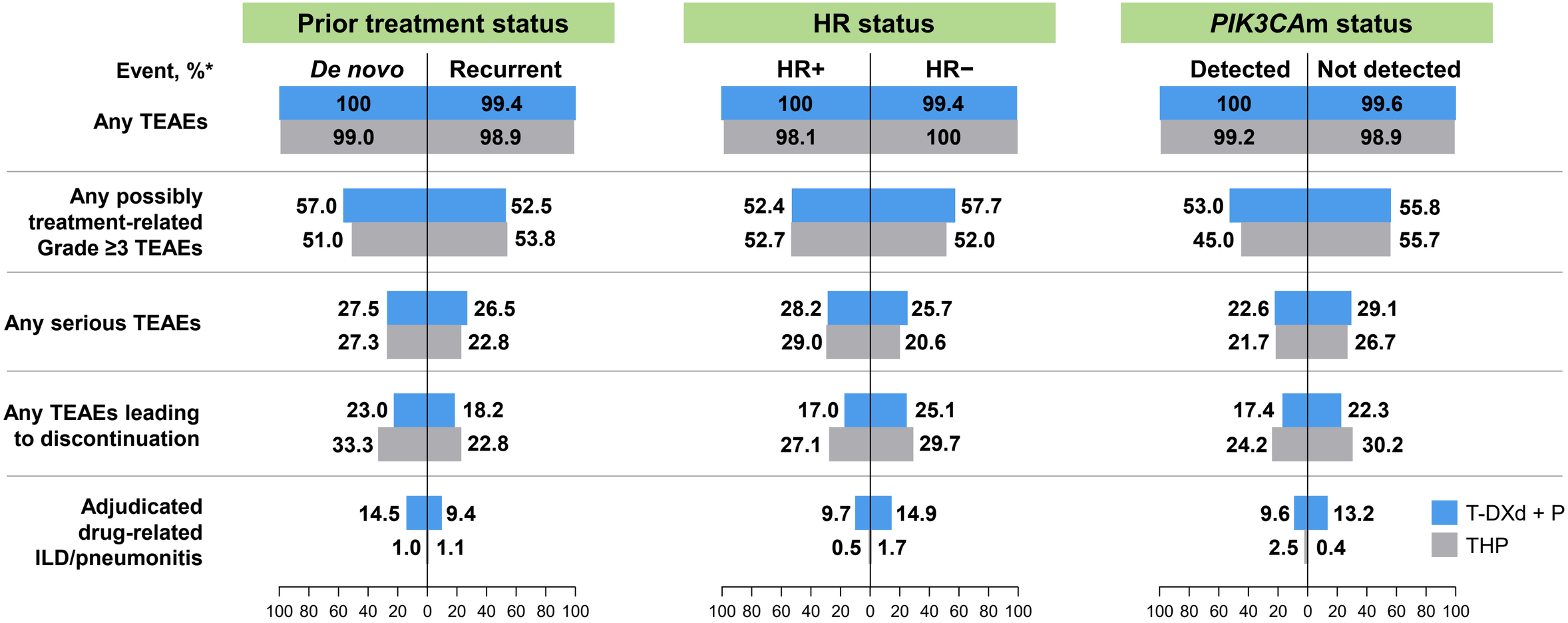
Safety summary by subgroup



Safety profiles in subgroups were in line with the overall safety population

*Includes TEAEs with an onset date on or after the date of first dose and up to and including 47 days following the date of last dose of study medication or before the initiation of the first subsequent cancer therapy (whichever occurs first). Safety analyses included all patients who received at least one dose of study medication (at least one study drug). HR(+/−), hormone receptor(–positive/–negative); ILD, interstitial lung disease; P, pertuzumab; *PIK3CA*m, *PIK3CA* mutation; T-DXd, trastuzumab deruxtecan; TEAE, treatment-emergent adverse event; THP, taxane + trastuzumab + pertuzumab

Conclusions

- In this subgroup analysis of DESTINY-Breast09, 1L treatment with T-DXd + P demonstrated a clinically meaningful PFS benefit vs THP regardless of prior treatment, HR, or *PIK3CA*m status, reflecting results in the overall population
- DOR consistently favored T-DXd + P (**median of ~3 years**), and CR rates were higher with T-DXd + P (**13.7–16.5%**) than THP (**4.1–10.7%**) in all subgroups
- No new safety signals were identified for T-DXd + P; safety outcomes for each arm were broadly similar across subgroups and in line with the overall population

T-DXd + P represents an effective 1L treatment for patients with HER2+ a/mBC, regardless of prior treatment, HR, or *PIK3CA*m status

1L, first-line; a/mBC, advanced/metastatic breast cancer; CR, complete response; DOR, duration of response; HER2+, human epidermal growth factor receptor 2–positive; HR, hormone receptor; P, pertuzumab; PFS, progression-free survival; *PIK3CA*m, *PIK3CA* mutation; T-DXd, trastuzumab deruxtecan; THP, taxane + trastuzumab + pertuzumab

Sibylle Loibl, MD, PhD

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DESTINY-Breast09 primary manuscript available at NEJM.org on 29 October 2025

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trastuzumab Deruxtecan plus Pertuzumab for HER2-Positive Metastatic Breast Cancer

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DESTINY-Breast09

BERLIN 2025 ESMO congress

What is the purpose of the DESTINY-Breast09 key subgroups analysis?

In **DESTINY-Breast09, trastuzumab deruxtecan (T-DXd) + pertuzumab** was compared with standard therapy – known as **THP (taxane + trastuzumab + pertuzumab)** – for people with **advanced/metastatic breast cancers** that have a higher-than-normal level of a protein called HER2 (known as '**HER2-positive**'). This was the first treatment (**first line**) these people received for advanced/metastatic breast cancer, although people were permitted to have had one hormone therapy.

In an interim analysis of DESTINY-Breast09 (reported in June 2025), people in the **T-DXd + pertuzumab** arm lived longer without their disease growing, spreading, or getting worse than people in the **THP** arm

People in the study could have cancers that were **newly diagnosed or recurrent**, **hormone receptor–positive (HR+) or –negative (HR−)**, **or that did or did not have a detectable *PIK3CA* mutation**. These characteristics can affect how a cancer progresses and how it responds to treatment. The aim of this analysis was to find out how well each treatment performed according to these characteristics.

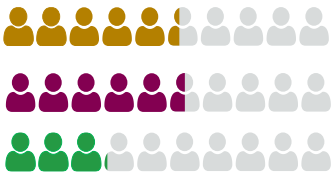
What did this subgroup analysis show?

People in the T-DXd + pertuzumab arm lived longer without cancer progression than those in the THP arm, regardless of whether they had newly diagnosed or recurrent cancer, HR+ or HR− cancer, or cancer with or without a detectable *PIK3CA* mutation. These characteristics did not affect the safety of each treatment

How was the DESTINY-Breast09 key subgroups analysis carried out?

Start of study

Before the study, people and their cancers were assessed to find out which of the **newly diagnosed / recurrent**, **HR**, and ***PIK3CA* mutation** categories they belonged to:



~5 in 10 (52%) people had **newly diagnosed** advanced/metastatic breast cancer

~5 in 10 (54%) people had cancers that were **HR+**

~3 in 10 (31%) people had cancers with a **detected *PIK3CA* mutation**

People were randomly assigned to receive either **T-DXd + pertuzumab (n=383)** or **THP (n=387)***

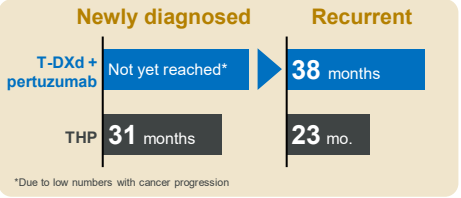
*There was another group of people who received T-DXd without pertuzumab, which will be evaluated versus THP in a future analysis

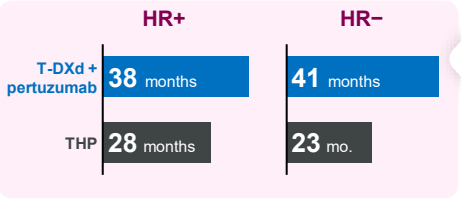
Overall balance of subgroups

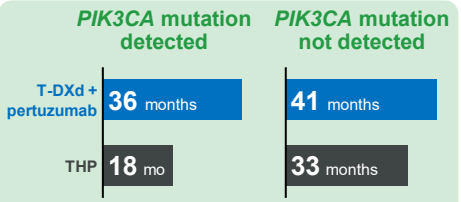
The **newly diagnosed vs recurrent, HR+ vs HR−**, and ***PIK3CA* mutation detected vs not detected** groups all had different numbers of people but, within each pair that were compared, a similar number received T-DXd + pertuzumab or THP

Time without progression

The timepoint after randomization at which half of the people were expected to be alive without cancer progression (known as **median progression-free survival**) was:

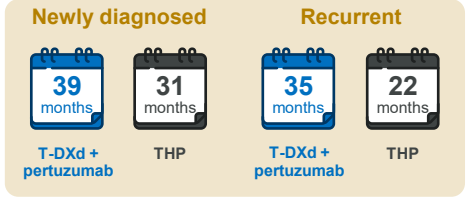


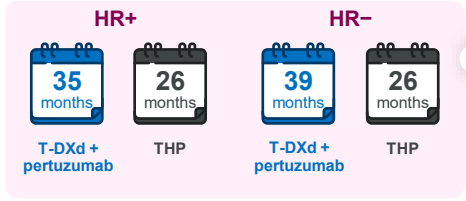


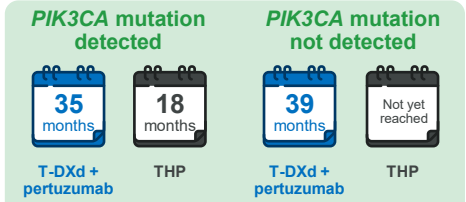


Duration of response

The expected length of time for which at least half the people who responded to treatment continued to respond (known as **median duration of response**) was:

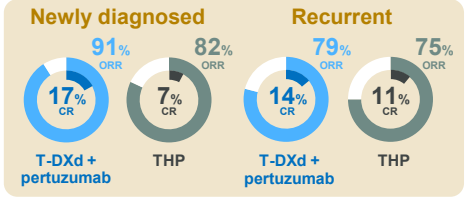


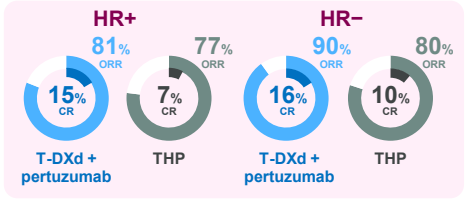


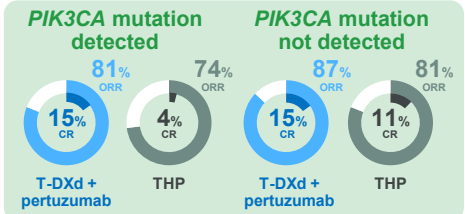


Response to treatment

The proportions of people with at least a **30% decrease in tumor size** (**objective response rate [ORR]**) and who had **no signs of cancer** after treatment (**complete response [CR]**) were:







Safety

No new safety signals were identified; safety outcomes for each treatment arm were broadly similar across subgroups and in line with the overall population

What's next?

The study will continue to explore T-DXd with and without pertuzumab compared with THP at longer follow up, and will also look at efficacy and safety in more subgroups

How do the results of this analysis help to improve the treatment of cancer?

Data showed that T-DXd + pertuzumab was beneficial for a broad range of people with HER2-positive advanced/metastatic breast cancer, supporting use of this combination as a new first-line treatment option

Where can I access more information?

DESTINY-Breast09 ClinicalTrials.gov identifier NCT04784715

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