



DECEMBER 5-9, 2023 | @SABCSSanAntonio

Phase III study of adjuvant ado-trastuzumab emtansine vs trastuzumab for residual invasive HER2-positive early breast cancer after neoadjuvant chemotherapy and HER2-targeted therapy: KATHERINE final IDFS and updated OS analysis

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IDFS, invasive disease-free survival; OS, overall survival

Disclosure information

Sibylle Loibl

I have the following relevant financial relationships to disclose:

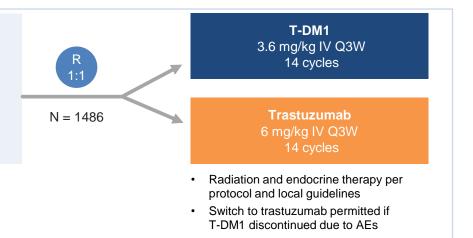
Grants and other support from Roche during the conduct of the study; grants and other support from AstraZeneca, AbbVie, Amgen, DSI, Gilead, Celgene/BMS, Novartis, and Pfizer; grants from Molecular Health; other support from Seagen, Sanofi, Relay, Olema, EirGenix, Merck KGaA, Lilly, GSK, Pierre Fabre, and Eisai outside the submitted work; a patent for VM Scope with royalties paid; a patent for EP14153692.0 pending; a patent for EP21152186.9 pending; and a patent for EP15702464.7 pending

Please refer to the abstract for all author conflicts of interest. All authors have received research support in the form of third-party writing assistance for this presentation from F. Hoffmann-La Roche Ltd.

The KATHERINE study is sponsored by F. Hoffmann-La Roche Ltd

KATHERINE study design

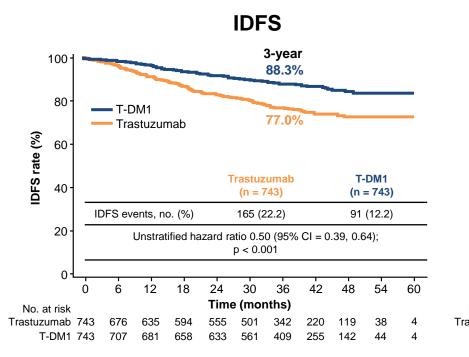
- Prior neoadjuvant therapy consisting of:
 - Minimum 6 cycles of chemotherapy
 - Minimum 9 weeks of trastuzumab
 - Second HER2-targeted agent allowed
- Residual invasive tumor in breast or axillary nodes
- Randomization within 12 weeks of surgery

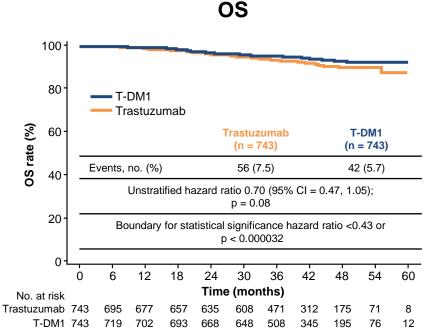


- Primary endpoint: IDFS
- Secondary endpoints: IDFS with second primary non-breast cancers included, DFS, OS, DRFI, safety, and QoL
- Stratification factors: Clinical stage at presentation (inoperable vs operable), HR status, preoperative HER2-directed therapy, pathologic nodal status after preoperative therapy

AE, adverse event; DFS, disease-free survival; DRFI, distant recurrence-free interval; HR, hormone receptor; IDFS, invasive disease-free survival; IV, intravenous; OS, overall survival; Q3W, every 3 weeks; QoL, quality of life; R, randomized; T-DM1, ado-trastuzumab emtansine. Adapted from N Engl J Med, von Minckwitz et al., Trastuzumab emtansine for residual invasive HER2-positive breast cancer, Vol. 380, Pages 617–628. Copyright[©] (2019) Massachusetts Medical Society.

KATHERINE primary analysis (2018): T-DM1 resulted in a 50% reduction in risk of recurrence of invasive disease or death versus trastuzumab





CCOD: July 25, 2018; median follow-up: 41.4 months (T-DM1) and 40.9 months (trastuzumab). CCOD, clinical cutoff date; CI, confidence interval; IDFS, invasive disease-free survival; OS, overall survival; T-DM1, ado-trastuzumab emtansine. Adapted from N Engl J Med, von Minckwitz et al., Trastuzumab emtansine for residual invasive HER2-positive breast cancer, Vol. 380, Pages 617–628. Copyright[©] (2019) Massachusetts Medical Society.

Analysis milestones



- FA of IDFS: Event-driven, after approximately 384 events have been recorded
 - There were 385 patients with an event (129 more than at the PA)
- 2nd OS IA: Pre-planned, occurred at the same time as the final IDFS analysis
 - Median follow-up time was 101 months, 60 months longer than at the PA
 - There were 215 OS events (117 more than at the PA)
- During the follow-up period, i.e. >30 days after the last dose of study drug, only deaths, serious AEs, or other AEs of concern that are believed to be related to prior treatment with study drug or study procedures were reported

AE, adverse event; CCOD, clinical cutoff date; FA, final analysis; FPI, first patient in; IA, interim analysis; IDFS, invasive disease-free survival; OS, overall survival; PA, primary analysis; T-DM1, ado-trastuzumab emtansine.

Patient disposition

	Trastuzumab	T-DM1
Randomized, ITT, n	743	743
Treated, n	720	740
Alive and on study, n (% of ITT)	461 (62.0)	521 (70.1)
Discontinued from study, n (%) With IDFS event reported Prior to IDFS event*	159 (21.4) 123 (16.6)	105 (14.1) 117 (15.7)

* Reasons include: Withdrawal by subject, 88 (11.8%) in the trastuzumab arm and 77 (10.4%) in the T-DM1 arm; lost to follow-up, 28 (3.8%) in the trastuzumab arm and 30 (4.0%) in the T-DM1 arm; other, 7 (0.9%) in the trastuzumab arm and 5 (0.7%) in the T-DM1 arm; physician decision, 0 in the trastuzumab arm and 5 (0.7%) in the T-DM1 arm. IDFS, invasive disease-free survival; ITT, intention-to-treat; T-DM1, ado-trastuzumab emtansine.

Baseline characteristics of the ITT population: Stratification factors

	Trastuzumab (n = 743)	T-DM1 (n = 743)
Clinical stage at presentation, n (%)		
Stages cT1–3N0–1M0 (operable)	553 (74.4)	558 (75.1)
Stage cT4NxM0 or cTxN2–3M0 (inoperable)	190 (25.6)	185 (24.9)
HR status, n (%)		
ER- and/or PgR-positive	540 (72.7)	534 (71.9)
ER-negative and PgR-negative/-unknown	203 (27.3)	209 (28.1)
Preoperative HER2-directed therapy, n (%)		
Trastuzumab alone	596 (80.2)	600 (80.8)
Trastuzumab plus additional HER2-directed agent(s)* – Trastuzumab plus pertuzumab ⁺	147 (19.8) 139 (18.7)	143 (19.2) 133 (17.9)
Pathologic nodal status after preoperative therapy, n (%)		
Node-positive	345 (46.4)	343 (46.2)
Node-negative/not done	398 (53.6)	400 (53.8)
Prior anthracycline, † n (%)	564 (75.9)	579 (77.9)

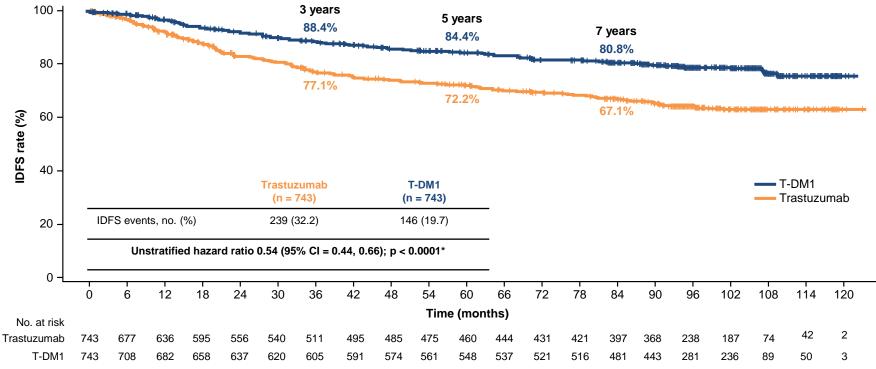
Data have been updated since the primary analysis.

* Non-pertuzumab HER2-directed agents included neratinib, afatinib, and lapatinib.

[†] Not a stratification factor, included for informational purposes.

ER, estrogen receptor; HR, hormone receptor; ITT, intention-to-treat; PgR, progesterone receptor; T-DM1, ado-trastuzumab emtansine.

KATHERINE IDFS final analysis; median follow-up 8.4 years (101 months)



* p-value for IDFS is now exploratory given the statistical significance was established at the primary analysis. CI, confidence interval; IDFS, invasive disease-free survival; T-DM1, ado-trastuzumab emtansine.

Final IDFS analysis: Subgroups (1/2)

		Trastuzu	mab (n = 74	43)	T-DM1 (n = 743)						
Baseline risk factors	Total n	Patients per group	n events	7-year IDFS	Patients per group	n events	7-year IDFS	Hazard ratio	95% CI	T-DM1 better	Trastuzumab better
AII	1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)		
Clinical stage at presentation	1100	1.10	200	0	1.10		0010	0.01	(0111, 0100)		
Inoperable	375	190	87	51.3	185	62	66.7	0.63	(0.45, 0.87)	H a H	
Operable	1111	553	152	72.3	558	84	85.4	0.48	(0.37, 0.63)	<u> </u>	
Hormone receptor status		000		. 2.0	000	0.	0011	0110	(0.07, 0.00)		
Negative (ER-negative and PgR-negative/-unknown)	412	203	75	59.4	209	53	75.0	0.55	(0.39, 0.78)	H a ri	
Positive (ER- and/or PgR-positive)	1074	540	164	69.8	534	93	83.1	0.52	(0.40, 0.67)	.	
Preoperative HER2-directed therapy											
Trastuzumab alone	1196	596	198	66.4	600	128	79.5	0.56	(0.45, 0.70)	i i i i i i i i i i i i i i i i i i i	
Trastuzumab plus additional HER2-directed agent(s)	290	147	41	69.8	143	18	87.2	0.42	(0.24, 0.72)	, international de la construcción de la construcc	
Pathologic nodal status after preoperative therapy									,		
Node-positive	688	345	142	57.7	343	96	71.6	0.56	(0.43, 0.72)		
Node-negative/not done	798	398	97	74.8	400	50	88.8	0.47	(0.34, 0.66)	H	
Central HER2 status by IHC									, , ,	1	
0/1+	25	13	4	67.1	12	1	100.0	0.25	(0.03, 2.22)	· · · · · ·	}_
2+	326	168	52	68.8	158	44	72.4	0.84	(0.56, 1.25)) H	h
3+	1132	559	183	66.5	573	101	82.8	0.47	(0.37, 0.60)		
Unknown	3	3	0	100.0				NE	(NE, NE)	1	
Race										1	
White	1081	530	158	69.3	551	110	80.7	0.59	(0.46, 0.75)	i i i i i i i i i i i i i i i i i i i	
Black or African American	40	19	11	51.3	21	2	88.9	0.13	(0.03, 0.59)	⊢ _	
Asian	129	64	22	62.9	65	16	75.3	0.65	(0.34, 1.23)	⊢	ł
American Indian or Alaska Native	86	50	25	50.2	36	8	75.8	0.40	(0.18, 0.88)	┝╌╼┸╌┥	
Other or multiple or unknown	150	80	23	71.0	70	10	86.8	0.45	(0.22, 0.95)		

CI, confidence interval; ER, estrogen receptor; IDFS, invasive disease-free survival;

IHC, immunohistochemistry; NE, not evaluable; PgR, progesterone receptor; T-DM1, ado-trastuzumab emtansine.

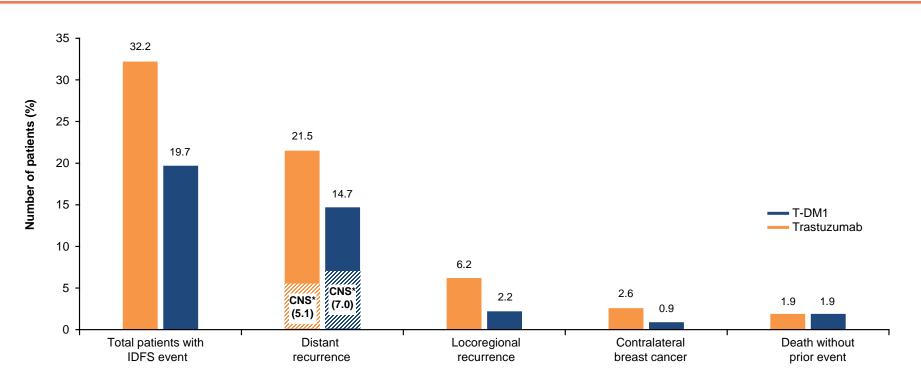
Final IDFS analysis: Subgroups (2/2)

		Trastuzumab (n = 743)			T-DM1 (n = 743)						
Baseline risk factors	Total n	Patients per group	n events	7-year IDFS	Patients per group	n events	7-year IDFS	Hazard ratio	95% Cl	T-DM1 better	Trastuzumab better
All	1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)		
Primary tumor stage (at definitive surgery)									· · ·	ī	
ypT0, ypT1a, ypT1b, ypT1mic, ypTis	637	306	78	74.6	331	59	82.0	0.65	(0.46, 0.90)	L H	
ypT1, ypT1c	359	184	60	66.8	175	22	87.4		(0.21, 0.56)	⊢∎→	
ypT2	359	185	67	62.9	174	41	78.4		(0.37, 0.80)	- inite	
ypT3	108	57	28	46.4	51	19	62.0		(0.33, 1.06)		
ypT4*	23	11	6	33.8	12	5	70.0		(0.15, 1.61)	۱ ۱	
Regional lymph node stage (at definitive surgery)									()		
ypN0	673	332	83	74.0	341	48	87.1	0.53	(0.37,0.75)	H a nger	
ypN1	432	212	76	63.6	220	47	78.0	0.50	(0.35, 0.72)	H a iri	
ypN2	189	103	47	52.4	86	28	69.5	0.56	(0.35, 0.89)	⊢ ģ ⊣	
ypN3	67	30	19	32.1	37	21	38.6	0.67	(0.36, 1.24)	┝╌╁╾	÷.
ypNX	125	66	14	79.1	59	2	98.2	0.13	(0.03, 0.59)	⊢ }	
Residual disease ≤1 cm with negative axillary lymph nodes											
ypT1a, ypT1b or ypT1mic and ypN0	328	160	36	76.7	168	25	85.7	0.62	(0.37, 1.03)	, international data in the second	4
Age group (years)									,	ł	
<40	296	153	46	67.2	143	28	81.2	0.56	(0.35, 0.90)	⊢ a ⊣	
40–64	1064	522	170	66.7	542	104	80.9	0.52	(0.41, 0.66)		
≥65	126	68	23	69.4	58	14	78.6	0.67	(0.34, 1.30)	⊢-¦æ-	4
Region									,		
North America	334	164	44	70.5	170	23	85.1	0.42	(0.25, 0.70)	, ⊢≣¦i	
Rest of the world	346	176	79	55.1	170	47	74.7		(0.36, 0.73)	H R -1'	
Western Europe	806	403	116	71.2	403	76	81.7		(0.45, 0.80)		

* Includes all ypT4 and one patient with ypTX.

CI, confidence interval; IDFS, invasive disease-free survival; T-DM1, ado-trastuzumab emtansine.

Site of first occurrence of an IDFS event



* CNS metastases as component of distant recurrence (isolated or with other sites). *M* Trastuzumab *M* T-DM1 CNS recurrence after first IDFS event: 19 patients (2.6%) in the trastuzumab arm and four patients (0.5%) in the T-DM1 arm. CNS, central nervous system; IDFS, invasive disease-free survival; T-DM1, ado-trastuzumab emtansine.

Follow-up medications after IDFS events (ITT)

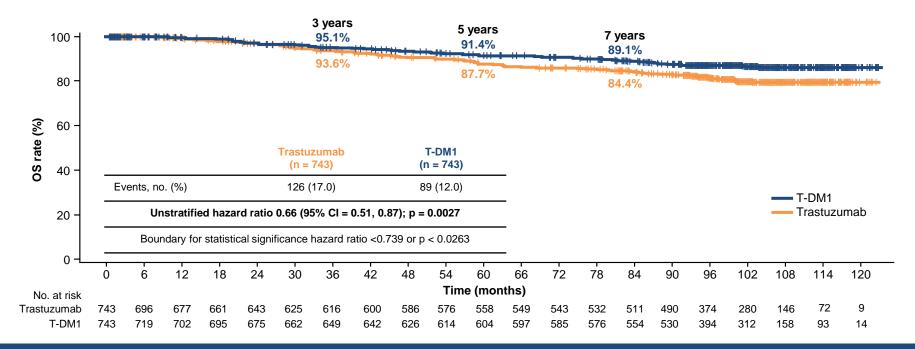
	Trastuzumab (n = 743)	T-DM1 (n = 743)
Total number of patients with an IDFS event, n	239	146
Total number of patients with documentation of ≥1 treatment following an IDFS event, n (%)	169 (70.7)	94 (64.4)
Class, n (%)*		
HER2-directed therapies Pertuzumab Trastuzumab T-DM1 T-DXd Tyrosine kinase inhibitors (lapatinib, neratinib, pyrotinib, pazopanib)	132 (78.1) 73 (43.2) 114 (67.5) 53 (31.4) 3 (1.8) 31 (18.3)	61 (64.9) 30 (31.9) 52 (55.3) 12 (12.8) 6 (6.4) 26 (27.7)
Platinum compounds	17 (10.1)	10 (10.6)
Taxanes	102 (60.4)	40 (42.6)
Capecitabine	51 (30.2)	44 (46.8)

* Percentages based on number of patients who received ≥1 follow-up medication.

IDFS, invasive disease-free survival; ITT, intention-to-treat; T-DM1, ado-trastuzumab emtansine;

T-DXd, trastuzumab deruxtecan.

KATHERINE 2nd OS interim analysis; median follow-up 8.4 years (101 months)



Significant reduction in risk of death by 34% with T-DM1

CI, confidence interval; OS, overall survival; T-DM1, ado-trastuzumab emtansine.

Summary of deaths

	Trastuzumab (n = 720)	T-DM1 (n = 740)
Total number of deaths, n (%)	126 (17.5)	89 (12.0)
Cause of death		
Breast cancer	108 (15.0)	70 (9.5)
Adverse event	0	1 (0.1)*
Other [†]	18 (2.5)	18 (2.4)

* Fatal adverse event was intracranial hemorrhage diagnosed after a fall with platelet count of 55,000. † Other causes of death: Respiratory disorders, cardiac disorders, infections, cerebrovascular disorders,

secondary malignancies, surgical procedures, and unknown. T-DM1, ado-trastuzumab emtansine.

2nd OS interim analysis: Subgroups (1/2)

	Trastuzumab (n = 743) T-DM1 (n = 743)										
Baseline risk factors	Total n	Patients per group	n events	7-year OS	Patients per group	n events	7-year OS	Hazard ratio	95% CI	T-DM1 better	Trastuzumab better
All	1486	743	126	84.4	743	89	89.1	0.66	(0.51, 0.87)		
Clinical stage at presentation	1400	740	120	04.4	140	00	00.1	0.00	(0.01, 0.07)		
Inoperable	375	190	57	69.0	185	44	77.5	0.71	(0.48, 1.05)	·#-	4
Operable	1111	553	69	89.4	558	45	92.7	0.62	(0.42, 0.90)	, 📥	
Hormone receptor status		000		0011	000	.0	02	0.02	(01.12, 0.00)		
Negative (ER-negative and PgR-negative/-unknown)	412	203	44	79.9	209	38	83.4	0.73	(0.48, 1.13)	, F	4
Positive (ER- and/or PgR-positive)	1074	540	82	85.9	534	51	91.3	0.60	(0.42, 0.85)	· 💼	
Preoperative HER2-directed therapy											
Trastuzumab alone	1196	596	105	84.1	600	77	88.6	0.68	(0.51, 0.91)	ė.	
Trastuzumab plus additional HER2-directed agent(s)	290	147	21	85.7	143	12	91.0	0.57	(0.28, 1.16)		4
Pathologic nodal status after preoperative therapy									,	1	
Node-positive	688	345	90	75.6	343	62	83.4	0.61	(0.44, 0.84)	H a h	
Node-negative/not done	798	398	36	91.4	400	27	94.0	0.74	(0.45, 1.21)	H	4
Central HER2 status by IHC									,	1	
0/1+	25	13	4	75.0	12	0	100.0	<0.01	(0.00, NE)	← →	
2+	326	168	28	83.4	158	28	83.3	1.03	(0.61, 1.73)	ί.	
3+	1132	559	94	84.8	573	61	90.4	0.59	(0.43, 0.82)	-	
Unknown	3	3	0	100.0				NE	(NE, NE)	1	
Race											
White	1081	530	80	86.3	551	64	89.0	0.72	(0.52, 1.01)	, H a	
Black or African American	40	19	8	73.3	21	1	94.1	0.10	(0.01, 0.80)	·	
Asian	129	64	15	78.0	65	9	90.0	0.53	(0.23, 1.21)	⊢∎¦	h
American Indian or Alaska Native	86	50	14	68.9	36	8	78.8	0.75	(0.31, 1.78)	⊢ ≱	⊢ i
Other or multiple or unknown	150	80	9	89.3	70	7	92.3	0.87	(0.32, 2.32)		⊢ ⊣

CI, confidence interval; ER, estrogen receptor; IHC, immunohistochemistry; NE, not evaluable; OS, overall survival; PgR, progesterone receptor; T-DM1, ado-trastuzumab emtansine.

2nd OS interim analysis: Subgroups (2/2)

		Trastuzur	nab (n = 74	13)	T-DM1 (n = 743)						
Baseline risk factors	Total n	Patients per group	n events	7-year OS	Patients per group	n events	7-year OS	Hazard ratio	95% CI	T-DM1 better	Trastuzumab better
All	1486	743	126	84.4	743	89	89.1	0.66	(0.51, 0.87)		
Primary tumor stage (at definitive surgery)									(
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ypT1, ypT1c	359	184	27	84.6	175	15	91.1	0.55	(0.29, 1.03)	⊢ ∎	
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ypT4*	23	11	3	63.5	12	3	80.0	0.72	(0.14, 3.58)	⊢÷	
Regional lymph node stage (at definitive surgery)									,	1	
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ypN1	432	212	46	80.9	220	30	86.6	0.57	(0.36, 0.90)	HEH	
ypN2	189	103	33	70.0	86	16	87.1	0.48	(0.26, 0.87)	⊢∎÷i	
ypN3	67	30	11	53.8	37	16	54.2	0.93	(0.43, 2.00)	н т и	— 1
урNХ	125	66	4	94.8	59	0	100.0	<0.01	(0.00, NE) 🗲		\longrightarrow
Residual disease ≤1 cm with negative axillary lymph nodes										1	
ypT1a, ypT1b or ypT1mic and ypN0	328	160	13	93.1	168	16	92.3	1.18	(0.57, 2.45)	<u>ب</u> ب	■→
Age group (years)										İ	
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40–64	1064	522	92	83.9	542	66	89.3	0.65	(0.47, 0.89)	· •	
≥65	126	68	18	77.6	58	8	88.8	0.50	(0.22, 1.14)	⊦ ∎ ¦	н
Region											
North America	334	164	26	83.5	170	12	93.3	0.39	(0.20, 0.77)	⊢ ∎ -i	
Rest of the world	346	176	46	74.7	170	31	85.0	0.62	(0.39, 0.98)	⊢ ∰	
Western Europe	806	403	54	88.9	403	46	89.1	0.84	(0.57, 1.25)	H	h
									1/100	1/10	1 10 100

Further follow-up is needed for smaller subgroups, or for subgroups with a general lower risk

* Includes all ypT4 and one patient with ypTX. CI, confidence interval; NE, not evaluable; OS, overall survival; T-DM1, ado-trastuzumab emtansine.

Related AEs during the post-treatment period*

Patients, n (%) with ≥1:	Trastuzumab (n = 720)	T-DM1 (n = 740)
AE (any grade, >1 patient in either arm)	12 (1.7)	24 (3.2)
Investigations	5 (0.7)	9 (1.2)
Cardiac disorders	5 (0.7)	5 (0.7)
Nervous system disorders	0	4 (0.5)
Hepatobiliary disorders	0	2 (0.3)
Metabolism and nutrition disorders	0	2 (0.3)
Skin and subcutaneous tissue disorders	0	2 (0.3)
Serious AE	4 (0.6)	2 (0.3)
Cardiac disorders	3 (0.4)	0
Hepatobiliary disorders	0	2 (0.3)
Vascular disorders	1 (0.1)	0
Grade ≥3 AE	3 (0.4)	3 (0.4)
Cardiac disorders	3 (0.4)	1 (0.1)
Hepatobiliary disorders	0	2 (0.3)

* Related to study treatment or to study procedures. Includes AEs with date of onset >30 days after last dose of study treatment. During the follow-up period, only deaths, serious AEs, or other AEs of concern that are believed to be related to prior treatment with study drug or study procedures were reported. AE, adverse event; T-DM1, ado-trastuzumab emtansine.

KATHERINE summary and conclusions

- After 8.4 years (101 months) median follow-up, T-DM1 significantly improved OS in patients with HER2-positive early breast cancer with residual invasive disease after neoadjuvant therapy
 - Hazard ratio 0.66 (95% CI 0.51, 0.87), p = 0.0027
 - 7-year OS rates: 89.1% (T-DM1) vs 84.4% (trastuzumab), a difference of 4.7%
 - OS benefit was seen across key subgroups, including clinical stage at presentation, HR status, pathologic nodal status, and prior HER2-directed therapy
- IDFS benefit of T-DM1 was sustained in the ITT population with longer follow-up with a hazard ratio of 0.54 (95% CI 0.44, 0.66) as well as in key subgroups
 - 7-year IDFS rates: 80.8% (T-DM1) vs 67.1% (trastuzumab), a difference of 13.7%
- No new safety issues emerged with longer follow-up
 - Cardiac toxicity was rare in both arms
- T-DM1 is the first therapy to show improved survival post-surgery in patients with HER2-positive early breast cancer with residual invasive disease after neoadjuvant therapy
- Follow-up is ongoing for the final OS analysis

CI, confidence interval; HR, hormone receptor; IDFS, invasive disease-free survival; ITT, intention-to-treat; OS, overall survival; T-DM1, ado-trastuzumab emtansine.

Thank you

To all the patients who participated in KATHERINE along with their families, with special acknowledgment to those on the control arm

To the KATHERINE investigators and their research staff at the 273 sites in 28 countries

Research support in the form of third-party writing assistance for this presentation, furnished by Alison McGonagle, PhD, of Nucleus Global, an Inizio Company, was provided by F. Hoffmann-La Roche Ltd



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