

KATHÉRINE final IDFS and updated OS analysis







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:

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Presenting author: Prof. Dr. Sibylle Loibl, M.D., Ph.D

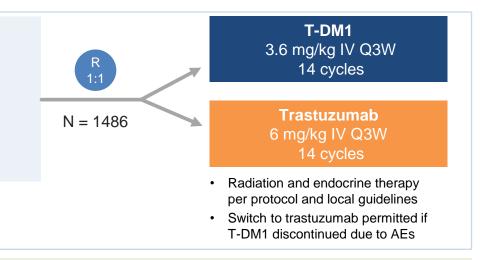
German Breast Group, Neu-Isenburg; Centre for Haematology and Oncology Bethanien, Goethe University, Frankfurt, Germany



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

#### 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



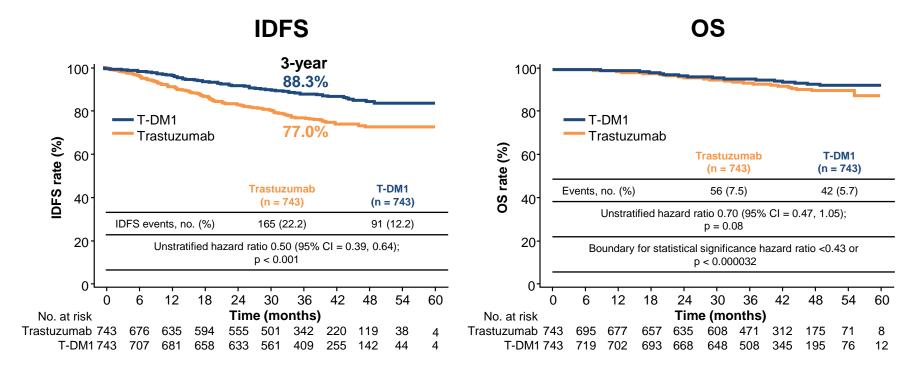
- Primary endpoint: IDFS
- Secondary endpoints: IDFS with second primary non-breast cancers included, DFS, OS, DRFI, safety, and QoL
- Stratification factors: Clinical stage at presentation (inoperable vs operable), HR status, preoperative HER2-directed therapy, pathologic nodal status after preoperative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

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#### **KATHERINE** primary analysis (2018)



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.

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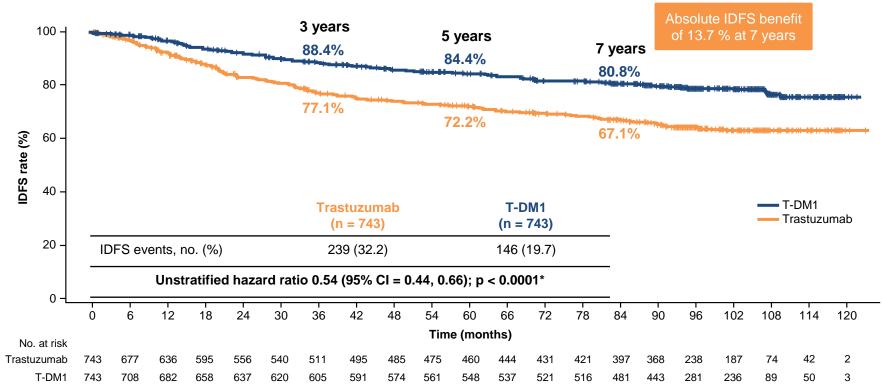
#### **Analysis milestones**



- 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.

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



<sup>\*</sup> 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)

		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% CI	T-DM1 better	Trastuzumab better
All	1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)		
Clinical stage at presentation									(- , ,	T	
Inoperable	375	190	87	51.3	185	62	66.7	0.63	(0.45, 0.87)	ı <b>la</b>	
Operable	1111	553	152	72.3	558	84	85.4	0.48	(0.37, 0.63)	<u> </u>	
Hormone receptor status		000	.02	. 2.0	555	٠.		00	(0.07, 0.00)	Ţ	
Negative (ER-negative and PgR-negative/-unknown)	412	203	75	59.4	209	53	75.0	0.55	(0.39, 0.78)	H	
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										Ţ	
Trastuzumab alone	1196	596	198	66.4	600	128	79.5	0.56	(0.45, 0.70)	Ė	
Trastuzumab plus additional HER2-directed agent(s)	290	147	41	69.8	143	18	87.2	0.42	(0.24, 0.72)	<b>⊢</b> ■ <u>−</u> −	
Pathologic nodal status after preoperative therapy									, , ,	ŀ	
Node-positive	688	345	142	57.7	343	96	71.6	0.56	(0.43, 0.72)	<b>.</b>	
Node-negative/not done	798	398	97	74.8	400	50	88.8	0.47	(0.34, 0.66)	H <b>ar</b> i	
Central HER2 status by IHC								• • • • • • • • • • • • • • • • • • • •	(0.0.1, 0.00)	<u>-</u>	
0/1+	25	13	4	67.1	12	1	100.0	0.25	(0.03, 2.22)		<del>     </del>
2+	326	168	52	68.8	158	44	72.4	0.84	(0.56, 1.25)	)-II	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										į	
White	1081	530	158	69.3	551	110	80.7	0.59	(0.46, 0.75)		
Black or African American	40	19	11	51.3	21	2	88.9	0.13	(0.03, 0.59)	<b>⊢</b>	
Asian	129	64	22	62.9	65	16	75.3	0.65	(0.34, 1.23)	<b>⊢-¦=</b> -	+
American Indian or Alaska Native	86	50	25	50.2	36	8	75.8	0.40	(0.18, 0.88)	<del></del>	1
Other or multiple or unknown	150	80	23	71.0	70	10	86.8	0.45	(0.22, 0.95)	— <del>■</del> —	1

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

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

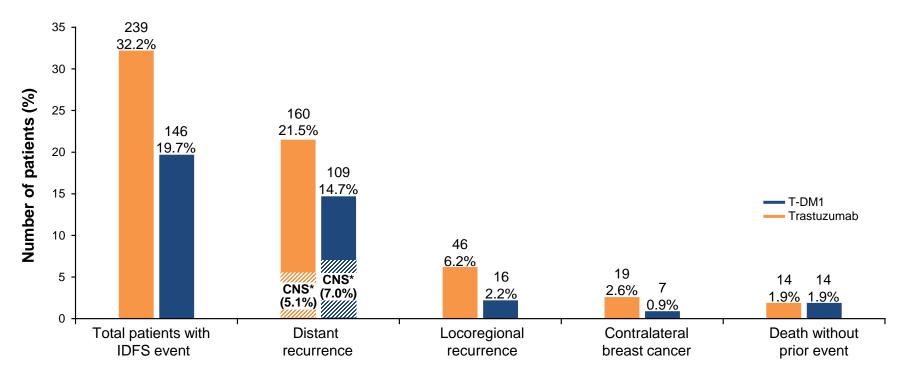
# Final IDFS analysis: Subgroups (2/2)

Total n	Patients per									
	group	n events	7-year IDFS	Patients per group	n events	7-year IDFS	Hazard ratio 95%	95% CI	T-DM1 better	Trastuzumab better
1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)	Ė	
									Ŧ	
637	306	78	74.6	331	59	82.0	0.65	(0.46, 0.90)	+	
359	184	60	66.8	175	22	87.4	0.35	(0.21, 0.56)	<b>⊢</b> ■-}	
359	185	67	62.9	174	41	78.4	0.55	(0.37, 0.80)	H <b>#</b> H	
108	57	28	46.4	51	19	62.0	0.59	(0.33, 1.06)	<u>- <del>-</del> -</u>	•
23	11	6	33.8	12	5	70.0	0.49	(0.15, 1.61)	<del></del> -	_
								,	<u> </u>	
673	332	83	74.0	341	48	87.1	0.53	(0.37, 0.75)	H <b>P</b> I	
432	212	76	63.6	220	47	78.0	0.50	(0.35, 0.72)	H	
189	103	47	52.4	86	28	69.5	0.56	(0.35, 0.89)	⊢ <del>∳</del> ⊣	
67	30	19	32.1	37	21	38.6	0.67	(0.36, 1.24)	<u>-                                    </u>	4
125	66	14	79.1	59	2	98.2	0.13	(0.03, 0.59)	<del> }</del>	
									1	
328	160	36	76.7	168	25	85.7	0.62	(0.37, 1.03)	<b>⊢</b>	
								•	i	
296	153	46	67.2	143	28	81.2	0.56	(0.35, 0.90)	<b>⊢</b>	
1064	522	170	66.7	542	104	80.9	0.52	(0.41, 0.66)	•	
126	68	23	69.4	58	14	78.6	0.67	(0.34, 1.30)	i	
	637 359 359 108 23 673 432 189 67 125 328	637 306 359 184 359 185 108 57 23 11 673 332 432 212 189 103 67 30 125 66 328 160 296 153 1064 522	637 306 78 359 184 60 359 185 67 108 57 28 23 11 6 673 332 83 432 212 76 189 103 47 67 30 19 125 66 14  328 160 36  296 153 46 1064 522 170	637 306 78 74.6 359 184 60 66.8 359 185 67 62.9 108 57 28 46.4 23 11 6 33.8 673 332 83 74.0 432 212 76 63.6 189 103 47 52.4 67 30 19 32.1 125 66 14 79.1 328 160 36 76.7 296 153 46 67.2 1064 522 170 66.7	637         306         78         74.6         331           359         184         60         66.8         175           359         185         67         62.9         174           108         57         28         46.4         51           23         11         6         33.8         12           673         332         83         74.0         341           432         212         76         63.6         220           189         103         47         52.4         86           67         30         19         32.1         37           125         66         14         79.1         59           328         160         36         76.7         168           296         153         46         67.2         143           1064         522         170         66.7         542	637         306         78         74.6         331         59           359         184         60         66.8         175         22           359         185         67         62.9         174         41           108         57         28         46.4         51         19           23         11         6         33.8         12         5           673         332         83         74.0         341         48           432         212         76         63.6         220         47           189         103         47         52.4         86         28           67         30         19         32.1         37         21           125         66         14         79.1         59         2           328         160         36         76.7         168         25           296         153         46         67.2         143         28           1064         522         170         66.7         542         104	637         306         78         74.6         331         59         82.0           359         184         60         66.8         175         22         87.4           359         185         67         62.9         174         41         78.4           108         57         28         46.4         51         19         62.0           23         11         6         33.8         12         5         70.0           673         332         83         74.0         341         48         87.1           432         212         76         63.6         220         47         78.0           189         103         47         52.4         86         28         69.5           67         30         19         32.1         37         21         38.6           125         66         14         79.1         59         2         98.2           328         160         36         76.7         168         25         85.7           296         153         46         67.2         143         28         81.2           1064         522         17	637         306         78         74.6         331         59         82.0         0.65           359         184         60         66.8         175         22         87.4         0.35           359         185         67         62.9         174         41         78.4         0.55           108         57         28         46.4         51         19         62.0         0.59           23         11         6         33.8         12         5         70.0         0.49           673         332         83         74.0         341         48         87.1         0.53           432         212         76         63.6         220         47         78.0         0.50           189         103         47         52.4         86         28         69.5         0.56           67         30         19         32.1         37         21         38.6         0.67           125         66         14         79.1         59         2         98.2         0.13           328         160         36         76.7         168         25         85.7         0.62	637         306         78         74.6         331         59         82.0         0.65         (0.46, 0.90)           359         184         60         66.8         175         22         87.4         0.35         (0.21, 0.56)           359         185         67         62.9         174         41         78.4         0.55         (0.37, 0.80)           108         57         28         46.4         51         19         62.0         0.59         (0.33, 1.06)           23         11         6         33.8         12         5         70.0         0.49         (0.15, 1.61)           673         332         83         74.0         341         48         87.1         0.53         (0.37,0.75)           432         212         76         63.6         220         47         78.0         0.50         (0.35, 0.72)           189         103         47         52.4         86         28         69.5         0.56         (0.35, 0.89)           67         30         19         32.1         37         21         38.6         0.67         (0.36, 1.24)           125         66         14         79.1	637 306 78 74.6 331 59 82.0 0.65 (0.46, 0.90) 359 184 60 66.8 175 22 87.4 0.35 (0.21, 0.56) 359 185 67 62.9 174 41 78.4 0.55 (0.37, 0.80) 108 57 28 46.4 51 19 62.0 0.59 (0.33, 1.06) 23 11 6 33.8 12 5 70.0 0.49 (0.15, 1.61) 673 332 83 74.0 341 48 87.1 0.53 (0.37,0.75) 432 212 76 63.6 220 47 78.0 0.50 (0.35, 0.72) 189 103 47 52.4 86 28 69.5 0.56 (0.35, 0.89) 67 30 19 32.1 37 21 38.6 0.67 (0.36, 1.24) 125 66 14 79.1 59 2 98.2 0.13 (0.03, 0.59) 328 160 36 76.7 168 25 85.7 0.62 (0.37, 1.03)

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

<sup>\*</sup> Includes all ypT4 and one patient with ypTX.

#### Site of first occurrence of an IDFS event

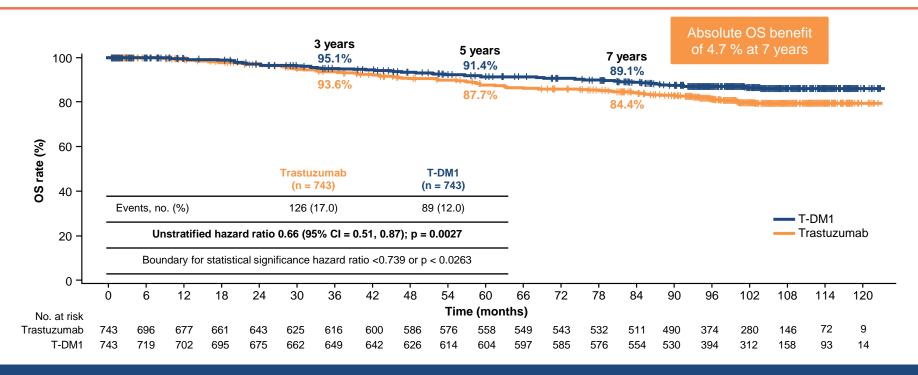


<sup>\*</sup> CNS metastases as component of distant recurrence (isolated or with other sites).

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.

# 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 <sup>†</sup>	18 (2.5)	18 (2.4)

<sup>\*</sup> 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.

# 2<sup>nd</sup> 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		Trastuzumab better
All	1486	743	126	84.4	743	89	89.1	0.66	(0.51, 0.87)		
Clinical stage at presentation									(,,	Th	
Inoperable	375	190	57	69.0	185	44	77.5	0.71	(0.48, 1.05)	+++	
Operable	1111	553	69	89.4	558	45	92.7	0.62	(0.42, 0.90)		
Hormone receptor status									(==, ===,	· · · · · · · · · · · · · · · · · · ·	
Negative (ER-negative and PgR-negative/-unknown)	412	203	44	79.9	209	38	83.4	0.73	(0.48, 1.13)	<u></u>	
Positive (ER- and/or PgR-positive)	1074	540	82	85.9	534	51	91.3	0.60	(0.42, 0.85)	- <b>-</b>	
Preoperative HER2-directed therapy										Ţl	
Trastuzumab alone	1196	596	105	84.1	600	77	88.6	0.68	(0.51, 0.91)		
Trastuzumab plus additional HER2-directed agent(s)	290	147	21	85.7	143	12	91.0	0.57	(0.28, 1.16)	<b>⊢</b>	
Pathologic nodal status after preoperative therapy									, , ,		
Node-positive	688	345	90	75.6	343	62	83.4	0.61	(0.44, 0.84)	Hamile I	
Node-negative/not done	798	398	36	91.4	400	27	94.0	0.74	(0.45, 1.21)	H	
Central HER2 status by IHC									(,		
0/1+	25	13	4	75.0	12	0	100.0	<0.01	(0.00, NE)	<del></del>	
2+	326	168	28	83.4	158	28	83.3	1.03	(0.61, 1.73)	<del>( p -</del>	ı
3+	1132	559	94	84.8	573	61	90.4	0.59	(0.43, 0.82)	H <b>al</b> l	
Unknown	3	3	0	100.0				NE	(NE, NE)	:	
Race										!	
White	1081	530	80	86.3	551	64	89.0	0.72	(0.52, 1.01)	•	
Black or African American	40	19	8	73.3	21	1	94.1	0.10	(0.01, 0.80)	<u></u>	
Asian	129	64	15	78.0	65	9	90.0	0.53	(0.23, 1.21)	<del>⊢₌¦∤</del>	
American Indian or Alaska Native	86	50	14	68.9	36	8	78.8	0.75	(0.31, 1.78)	<b>├──<del> </del> </b>	
Other or multiple or unknown	150	80	9	89.3	70	7	92.3	0.87	(0.32, 2.32)	— <del> ■</del> !— ———————————————————————————————————	<del></del>

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

# 2<sup>nd</sup> OS interim analysis: Subgroups (2/2)

otal n 486	Patients per group	n events	7-year OS	Patients per group	n events	7-year	Hazard		T-DM1	Trastuzumab
	743	400			ii cveiita	os	Hazard ratio	95% CI		better
		126	84.4	743	89	89.1	0.66	(0.51, 0.87)	i I	
								, , ,	T	
637	306	41	89.4	331	38	89.5	0.86	(0.55, 1.34)	H	Н
359	184	27	84.6	175	15	91.1	0.55	(0.29, 1.03)	<b>⊢</b>	•
359	185	38	79.9	174	23	89.8	0.57	(0.34, 0.95)	<b>⊢</b>	
108	57	17	74.1	51	10	78.2	0.59	(0.27, 1.29)	⊢ <del>i</del>	4
23	11	3	63.5	12	3	80.0	0.72	(0.14, 3.58)	<del></del>	<del></del>
									<u>!</u>	
673	332	32	90.7	341	27	92.8	0.82	(0.49,1.37)	H	H
432	212	46	80.9	220	30	86.6	0.57	(0.36, 0.90)	H	
189	103	33	70.0	86	16	87.1	0.48	(0.26, 0.87)	<b>—</b> —	
67	30	11	53.8	37	16	54.2	0.93	(0.43, 2.00)	<u> </u>	H
125	66	4	94.8	59	-0	100.0	<0.01	(0.00, NE) <		
									I I	
328	160	13	93.1	168	16	92.3	1.18	(0.57, 2.45)	۳	
									i	
296	153	16	89.2	143	15	88.4	0.93	(0.46, 1.88)		H
1064	522	92	83.9	542	66	89.3	0.65	(0.47, 0.89)	4	
126	68	18	77.6	58	8	88.8	0.50	(0.22, 1.14)	<del></del>	H
								1 1	1	1.1.1111111 1.11
	23 673 432 189 67 125 328 296 064	23 11  673 332  432 212  189 103  67 30  125 66  328 160  296 153  064 522	23     11     3       673     332     32       432     212     46       189     103     33       67     30     11       125     66     4       328     160     13       296     153     16       064     522     92	23     11     3     63.5       673     332     32     90.7       432     212     46     80.9       189     103     33     70.0       67     30     11     53.8       125     66     4     94.8       328     160     13     93.1       296     153     16     89.2       064     522     92     83.9	23     11     3     63.5     12       673     332     32     90.7     341       432     212     46     80.9     220       189     103     33     70.0     86       67     30     11     53.8     37       125     66     4     94.8     59       328     160     13     93.1     168       296     153     16     89.2     143       064     522     92     83.9     542	23     11     3     63.5     12     3       673     332     32     90.7     341     27       432     212     46     80.9     220     30       189     103     33     70.0     86     16       67     30     11     53.8     37     16       125     66     4     94.8     59     0       328     160     13     93.1     168     16       296     153     16     89.2     143     15       064     522     92     83.9     542     66	23     11     3     63.5     12     3     80.0       673     332     32     90.7     341     27     92.8       432     212     46     80.9     220     30     86.6       189     103     33     70.0     86     16     87.1       67     30     11     53.8     37     16     54.2       125     66     4     94.8     59     0     100.0       328     160     13     93.1     168     16     92.3       296     153     16     89.2     143     15     88.4       064     522     92     83.9     542     66     89.3	23     11     3     63.5     12     3     80.0     0.72       673     332     32     90.7     341     27     92.8     0.82       432     212     46     80.9     220     30     86.6     0.57       189     103     33     70.0     86     16     87.1     0.48       67     30     11     53.8     37     16     54.2     0.93       125     66     4     94.8     59     0     100.0     <0.01	23     11     3     63.5     12     3     80.0     0.72     (0.14, 3.58)       673     332     32     90.7     341     27     92.8     0.82     (0.49,1.37)       432     212     46     80.9     220     30     86.6     0.57     (0.36, 0.90)       189     103     33     70.0     86     16     87.1     0.48     (0.26, 0.87)       67     30     11     53.8     37     16     54.2     0.93     (0.43, 2.00)       125     66     4     94.8     59     0     100.0     <0.01	23 11 3 63.5 12 3 80.0 0.72 (0.14, 3.58)  673 332 32 90.7 341 27 92.8 0.82 (0.49,1.37)  432 212 46 80.9 220 30 86.6 0.57 (0.36, 0.90)  189 103 33 70.0 86 16 87.1 0.48 (0.26, 0.87)  67 30 11 53.8 37 16 54.2 0.93 (0.43, 2.00)  125 66 4 94.8 59 0 100.0 <0.01 (0.00, NE)  328 160 13 93.1 168 16 92.3 1.18 (0.57, 2.45)  1996 153 16 89.2 143 15 88.4 0.93 (0.46, 1.88)  1996 153 16 89.2 143 15 88.4 0.93 (0.46, 1.88)

<sup>\*</sup> Includes all ypT4 and one patient with ypTX. CI, confidence interval; NE, not evaluable; OS, overall 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)

<sup>\*</sup> 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.

## 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) Investigations Cardiac disorders Nervous system disorders Hepatobiliary disorders Metabolism and nutrition disorders Skin and subcutaneous tissue disorders	12 (1.7) 5 (0.7) 5 (0.7) 0 0 0	24 (3.2) 9 (1.2) 5 (0.7) 4 (0.5) 2 (0.3) 2 (0.3) 2 (0.3)
Serious AE Cardiac disorders Hepatobiliary disorders Vascular disorders	4 (0.6) 3 (0.4) 0 1 (0.1)	2 (0.3) 0 2 (0.3) 0
Grade ≥3 AE Cardiac disorders Hepatobiliary disorders	3 (0.4) 3 (0.4) 0	3 (0.4) 1 (0.1) 2 (0.3)

<sup>\*</sup> 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%
- 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.

BACK UP

#### **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