

## Supplemental Online Content

Martin M, Hegg R, Kim S-B, et al. Treatment with adjuvant abemaciclib plus endocrine therapy in patients with high-risk early breast cancer who received neoadjuvant chemotherapy: a prespecified analysis of the monarchE randomized clinical trial. *JAMA Oncol*. Published online June 2, 2022. doi:10.1001/jamaoncol.2022.1488

**eFigure 1.** CONSORT Diagram in the ITT population

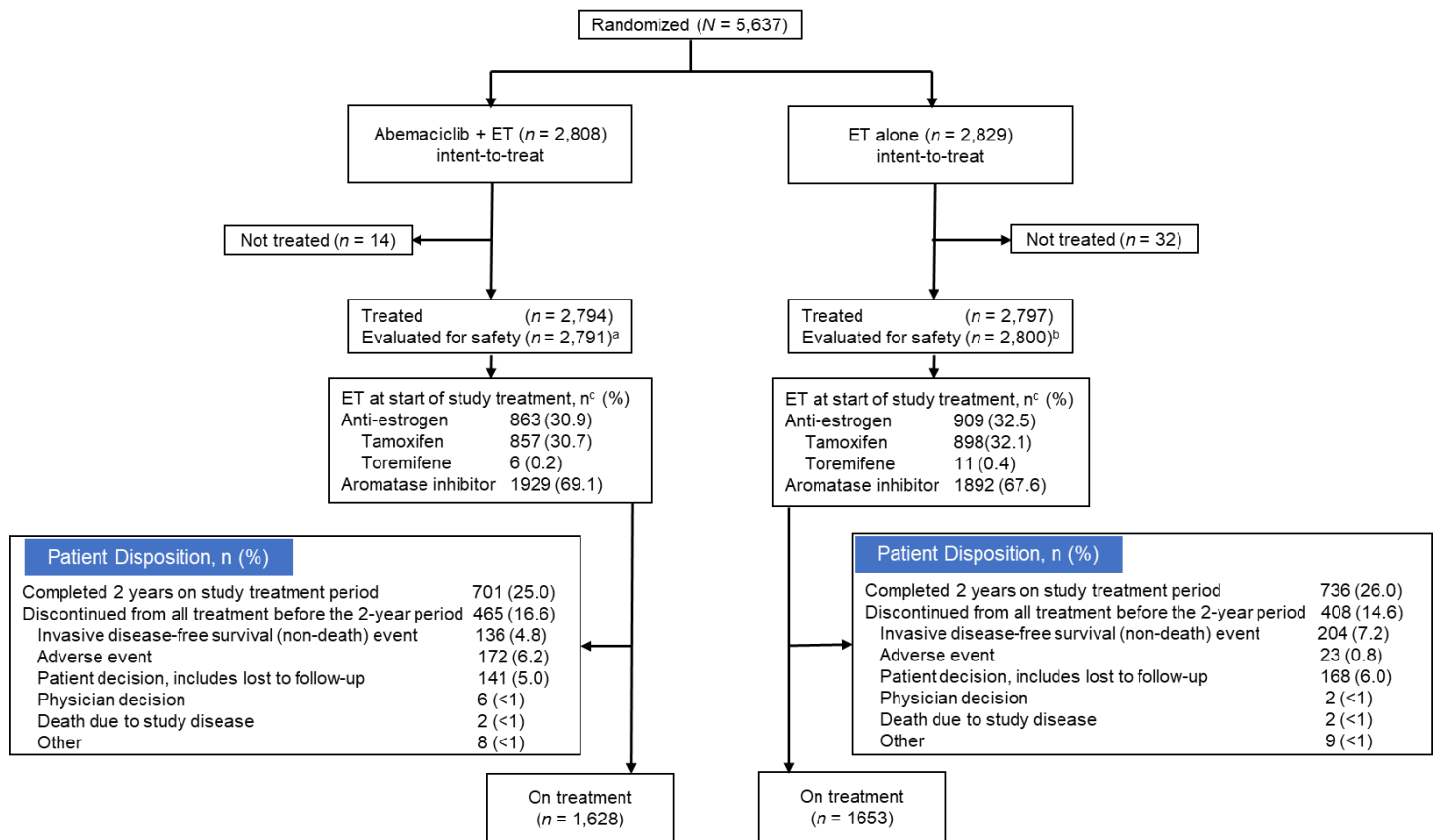
**eTable 1.** Patient Demographics and Disease Characteristics

**eTable 2.** Tumor characteristics and demographics by treatment arm in patients that received NAC

**eTable 3.** TEAEs in patients who received NAC

This supplemental material has been provided by the authors to give readers additional information about their work.

eFigure 1 – CONSORT Diagram in the ITT population



Other: non-compliance (0.3, 0), protocol deviation (0, 0.2), and study terminated (0, 0.1) in the abemaciclib+ET and ET alone arm, respectively  
 At the time of data cut-off 2020-07-08

ET, endocrine therapy; N, number of patients in the safety population; n, number of patients within category.

<sup>a</sup> Four patients randomly assigned to the abemaciclib arm only received ET and were evaluated for safety in the control arm;

<sup>b</sup> One patient randomly assigned to the control arm received abemaciclib and was evaluated for safety in the abemaciclib arm;

<sup>c</sup> A total of 1 patient in each arm double counted as having received both tamoxifen and aromatase inhibitor as first ET due to data entry error

For ovarian suppression detail, please see Table 1 in Johnson et al.<sup>8</sup>

		Neoadjuvant Chemotherapy		
		Yes	No <sup>a</sup>	
		Patients treated with NAC	Patients treated with Adjuvant CT	Patients with no chemo
		N=2056	N=3264	N=317
Age, years	Median (range)	49 (22-84)	52 (23-88)	64 (24-89)
Menopausal status	Premenopausal	1028 (50.1%)	1363 (41.8%)	63 (19.9%)
	Postmenopausal	1025 (49.9%)	1901 (58.2%)	254 (80.1%)
Radiologic tumor size at diagnosis	<2 cm	337 (16.4%)	1120 (34.3%)	108 (34.4%)
	2-5 cm	1044 (50.8%)	1663 (50.9%)	161 (50.8%)
	≥5 cm	599 (29.1%)	343 (10.5%)	39 (12.3%)
Histological grade*	Grade 1	127 (6.2%)	252 (7.7%)	46 (14.5%)
	Grade 2	1015 (49.4%)	1591 (48.7%)	166 (52.4%)
	Grade 3	754 (36.7%)	1306 (40.0%)	90 (28.4%)
Pretreatment Central Ki-67	<20%	490 (23.8%)	1314 (40.3%)	123 (38.8%)
	≥20%	902 (43.9%)	1459 (44.7%)	137 (43.2%)
	Unavailable	658 (32.0%)	491 (15.0%)	57 (18.0%)
Chemotherapy <sup>b</sup>	Anthracycline/taxane	1917 (93.2%)	2855 (87.5%)	N/A
	Anthracycline (without taxane)	71 (3.5%)	144 (4.4%)	
	Taxane (without anthracycline)	64 (3.1%)	243 (7.4%)	
	Other <sup>c</sup>	4 (0.2%)	22 (0.7%)	
Type of surgery	BCS <sup>d</sup>	497 (24.2%)	1046 (32.0%)	90 (28.4%)
	Mastectomy	1557 (75.7%)	2217 (67.9%)	226 (71.3%)
Pathologic tumor size at surgery	<2 cm	739 (35.9%)	734 (22.5%)	75 (23.7%)
	2-5 cm	804 (39.1%)	1830 (56.1%)	157 (49.5%)
	≥5 cm	455 (22.1%)	681 (20.9%)	81 (25.6%)
	0 <sup>e</sup>	9 (0.4%)	4 (0.1%)	1 (0.3%)
	1 to 3	913 (44.4%)	1170 (35.8%)	177 (55.8%)

Number of positive lymph nodes that qualified the patient for enrolment (diagnosis or surgery)	≥4 or more	1134 (55.2%)	2090 (64.0%)	138 (43.5%)
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eTable 1. Patient Demographics and Disease Characteristics

<sup>a</sup>Some patients did not receive chemotherapy; <sup>b</sup>Includes neoadjuvant and adjuvant chemotherapy; <sup>c</sup>Other includes single agent cyclophosphamide as well as other chemotherapy agents; <sup>d</sup>BCS: breast conserving surgery; <sup>e</sup>Patients with 0 positive lymph nodes were inadvertently enrolled  
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eTable 2 - Tumor characteristics and demographics by treatment arm in patients that received NAC

		Patients Treated With NAC	
		Abemaciclib + ET	ET Alone
		N=1025	N=1031
Age (median, range)	Median (range)	49 (25-84)	49 (22-78)
Menopausal status	Premenopausal	512 (50.1)	516 (50.0)
	Postmenopausal	510 (49.9)	515 (50.0)
Radiologic tumor size at diagnosis	<2 cm	164 (16.0)	173 (16.8)
	2-5 cm	519 (50.6)	525 (50.9)
	≥5 cm	306 (29.9)	293 (28.4)
Number of positive lymph nodes that qualified the patient for enrolment (at diagnosis or at surgery)*	0 <sup>a</sup>	3 (0.3)	6 (0.6)
	1 to 3	450 (43.9)	463 (44.9)
	≥4 or more	572 (55.8)	562 (54.5)
Histological grade*	Grade 1	62 (6.0)	65 (6.3)
	Grade 2	489 (47.7)	526 (51.0)
	Grade 3	398 (38.8)	356 (34.5)
Central Ki-67 prior to NAC	<20%	242 (23.6)	248 (24.1)
	≥20%	450 (43.9)	452 (43.8)
	Unavailable	333 (32.5)	331 (32.1)
Type of surgery	BCS	234 (22.8)	263 (25.5)
	Mastectomy	789 (77.0)	768 (74.5)
Residual pathological tumor size at surgery	<2 cm <sup>a</sup>	370 (36.1)	369 (35.8)
	2-5 cm	394 (38.4)	410 (39.8)
	≥5 cm	228 (22.2)	227 (22.0)

<sup>a</sup>Patients with 0 lymph node were inadvertently enrolled

eTable 3. TEAEs in patients who received NAC

	Abemaciclib + ET			ET alone		
	N = 1018, n (%)			N = 1019, n (%)		
	Any Grade	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4
Any TEAE	996 (97.8)	488 (47.9)	23 (2.3)	907 (89.0)	132 (13.0)	10 (1.0)
≥20% in either arm						
Diarrhea	840 (82.5)	83 (8.2)	0 <sup>c</sup>	83 (8.1)	2 (0.2)	0
Infection <sup>a</sup>	488 (47.9)	50 (4.9)	2 (0.2)	357 (35.0)	22 (2.2)	0 <sup>d</sup>
Neutropenia	461 (45.3)	223 (21.9)	7 (0.7)	69 (6.8)	9 (0.9)	2 (0.2)
Fatigue <sup>b</sup>	400 (39.3)	29 (2.8)	N/A	176 (17.3)	1 (0.1)	N/A
Abdominal Pain <sup>b</sup>	377 (37.0)	13 (1.3)	N/A	95 (9.3)	4 (0.4)	N/A
Leukopenia	371 (36.4)	139 (13.7)	2 (0.2)	72 (7.1)	4 (0.4)	0
Nausea <sup>b</sup>	293 (28.8)	5 (0.5)	N/A	85 (8.3)	0	N/A
Arthralgia <sup>b</sup>	240 (23.6)	4 (0.4)	N/A	325 (31.9)	5 (0.5)	N/A
Anemia	227 (22.3)	14 (1.4)	0	32 (3.1)	3 (0.3)	0
Hot Flush <sup>b</sup>	156 (15.3)	2 (0.2)	N/A	231 (22.7)	6 (0.6)	N/A

<sup>a</sup>Infection is a composite term that includes all reported preferred terms that are part of the infections and infestations system organ class; <sup>b</sup>Preferred term has a maximum CTCAE Grade of 3; <sup>c</sup>1 Grade 5 event occurred; <sup>d</sup>2 Grade 5 events occurred