

Supplementary Appendix

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

Supplement to: von Minckwitz G, Procter M, de Azambuja E, et al. Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer. *N Engl J Med* 2017;377:122-31. DOI: 10.1056/NEJMoa1703643

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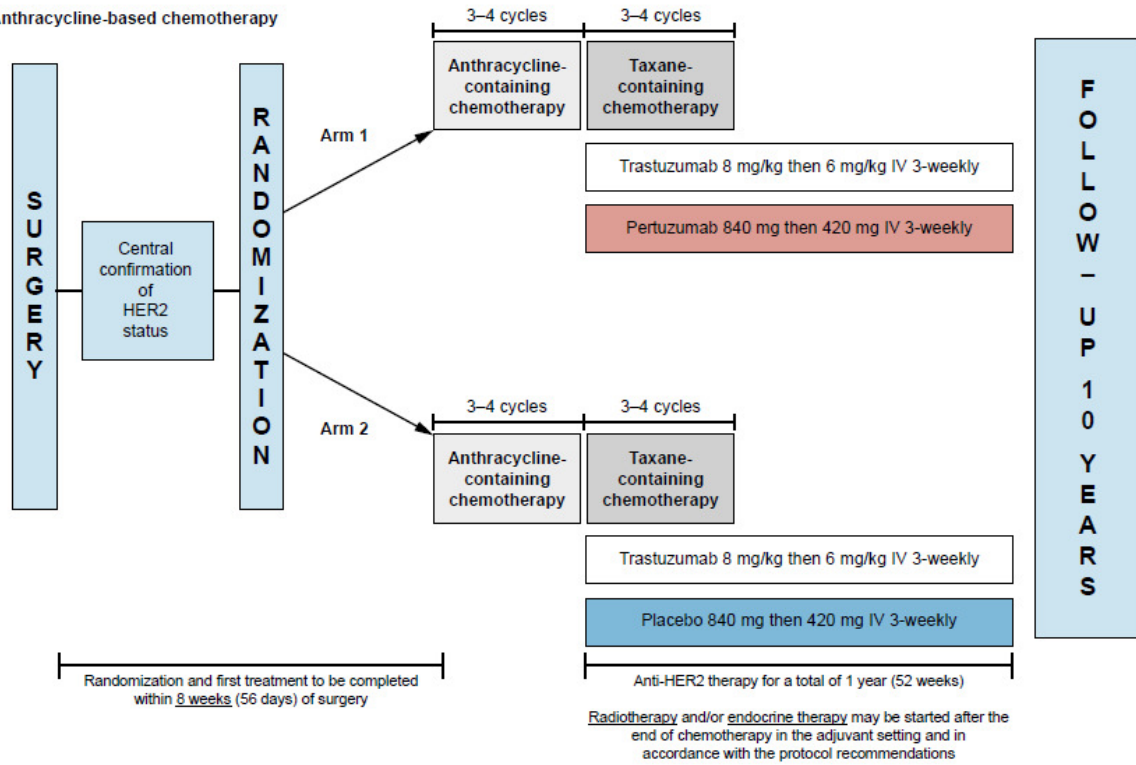
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Texas Oncology-El Paso Cancer Treatment Center Grandview	United States	RIVERA Ragene
Texas Oncology - Houston (Gessner)	United States	HOLMES Frankie.
Northwest Cancer Specialists - Portland (NE Hoyt St)	United States	SMITH John
Texas Oncology-Fort Worth 12th Ave	United States	OOMMEN Sanjay
Texas Oncology-Baylor Sammons Cancer Center	United States	OSBORNE Cynthia
Cancer Centers of the Carolina; Eastside Medical Center	United States	EDENFIELD William.
Nebraska Cancer Research Center	United States	SOORI Gamini

Figure S1. Schema for the APHINITY Trial.

IV denotes intravenous.

A Anthracycline-based chemotherapy



B Non-anthracycline-based chemotherapy

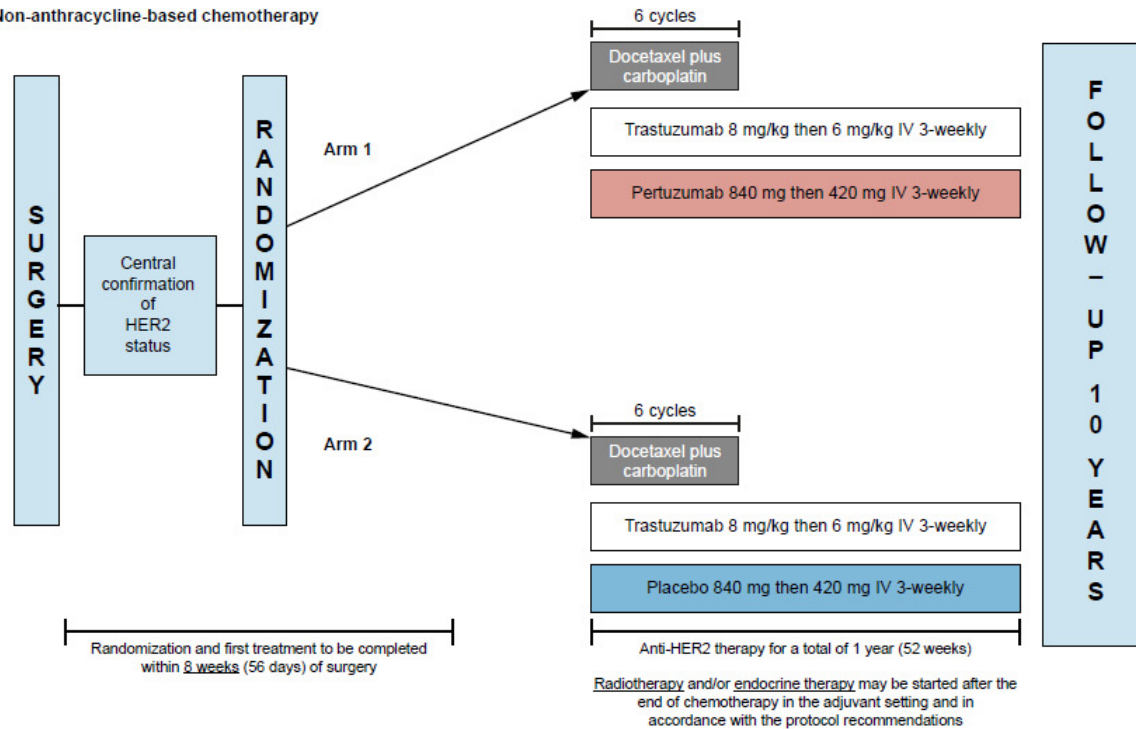
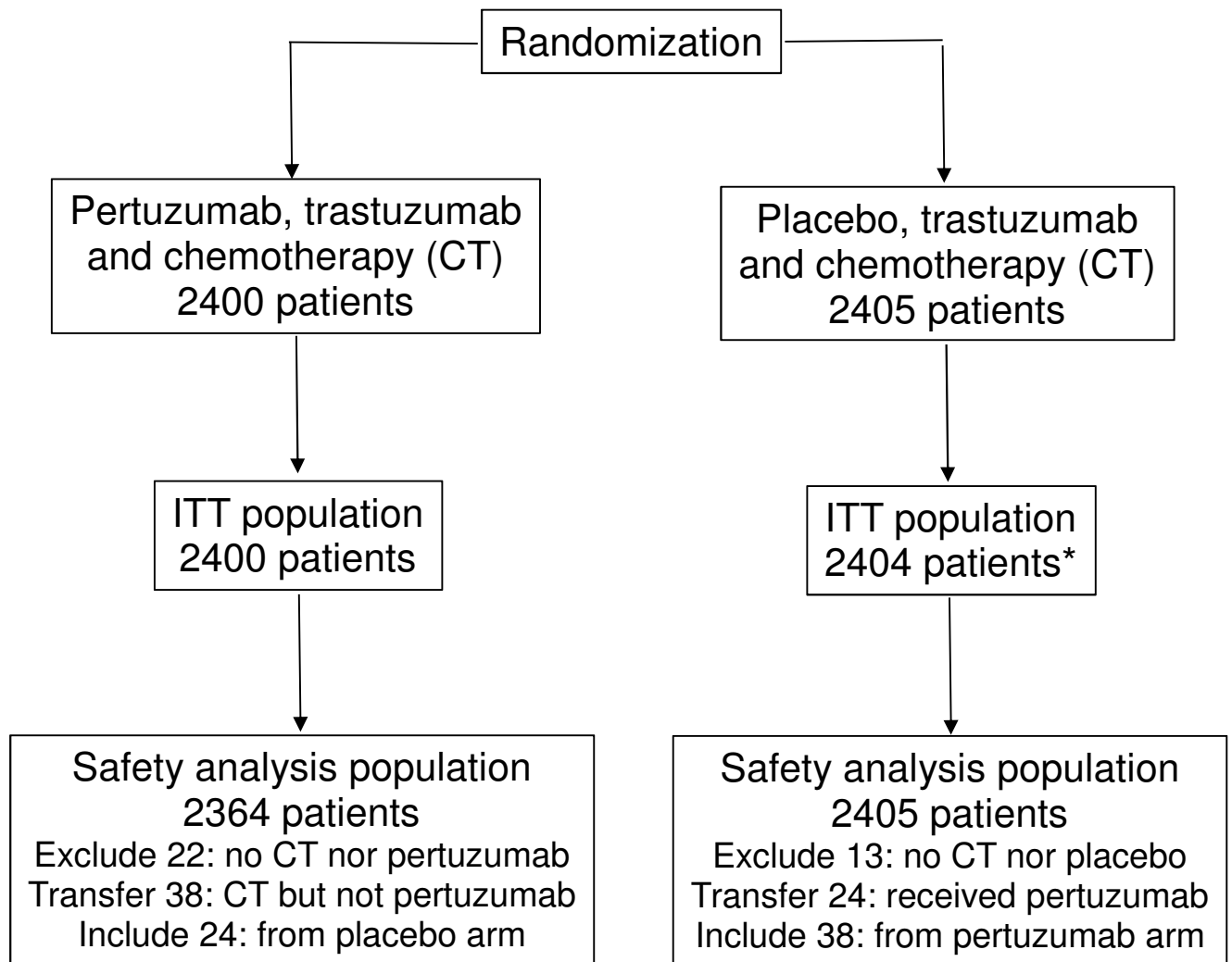


Figure S2. CONSORT Diagram for the APHINITY Trial.



* One patient excluded from the ITT population due to her falsification of personal information

ITT denotes intent-to-treat.

Figure S3. Kaplan–Meier Plots of Invasive Disease-Free Survival by Hormone Receptor Status.

Panel A shows plots for hormone receptor-negative disease. Panel B shows plots for hormone receptor-positive disease. CI denotes confidence interval.

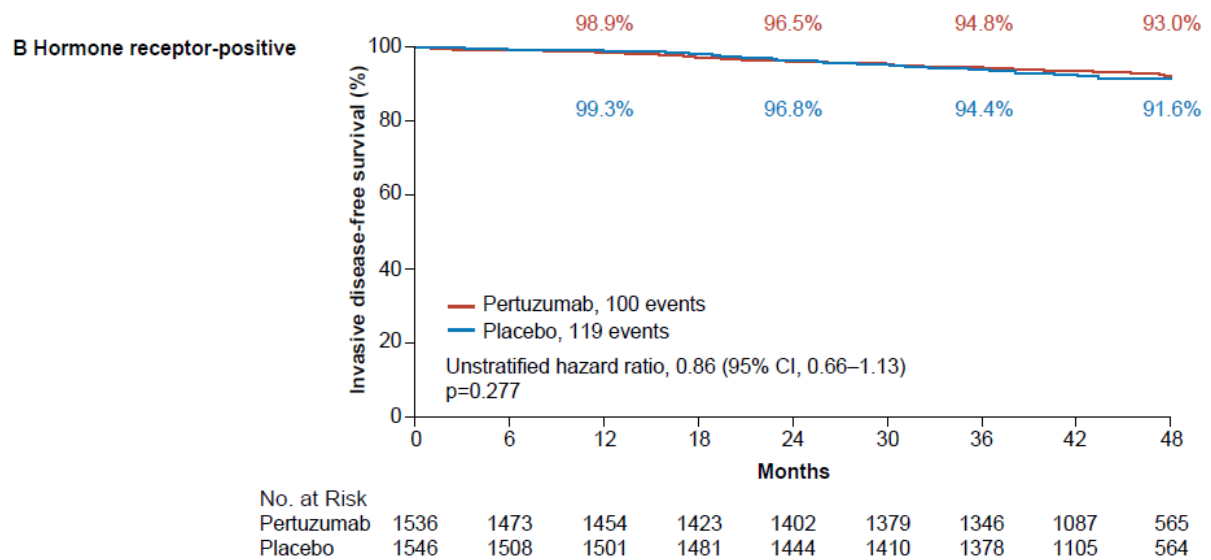
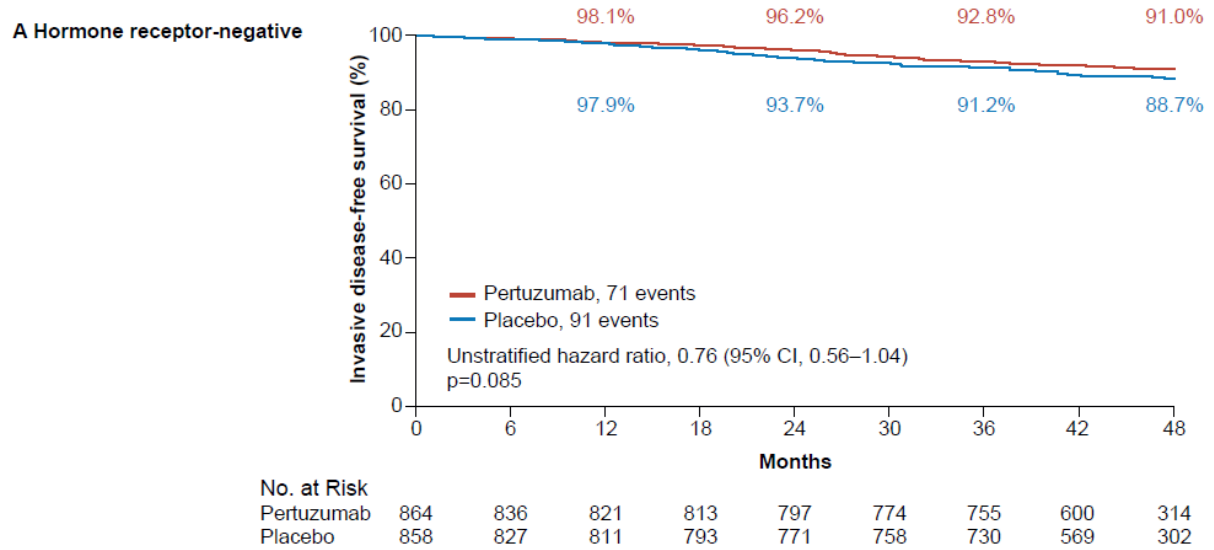
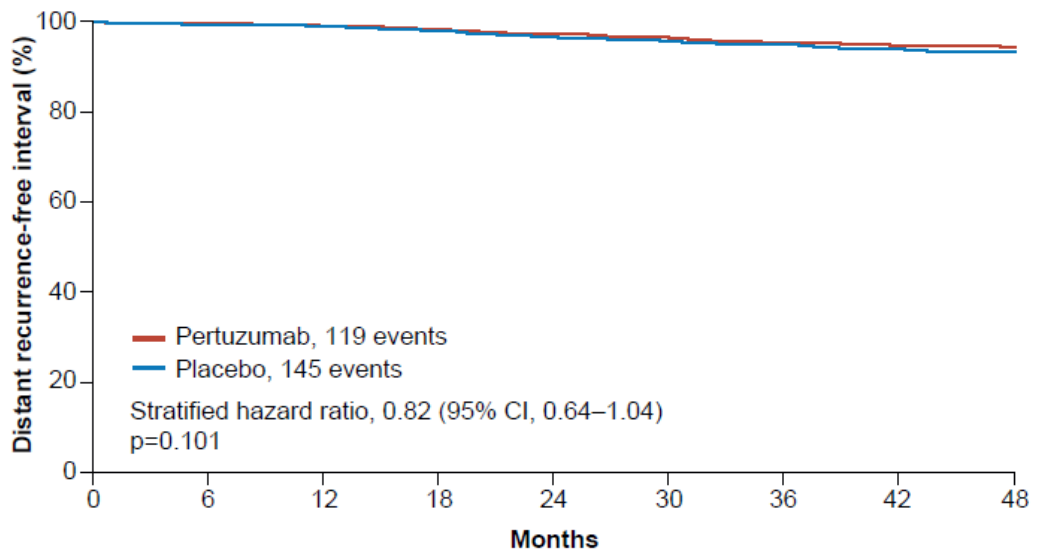


Figure S4. Kaplan–Meier Plots of Distant Recurrence-Free Interval.

CI denotes confidence interval.



No. at Risk	Months								
Pertuzumab	2400	2320	2293	2256	2225	2185	2126	1704	887
Placebo	2404	2344	2325	2289	2239	2203	2145	1701	881

Figure S5. Kaplan–Meier Plots of Overall Survival.

CI denotes confidence interval.

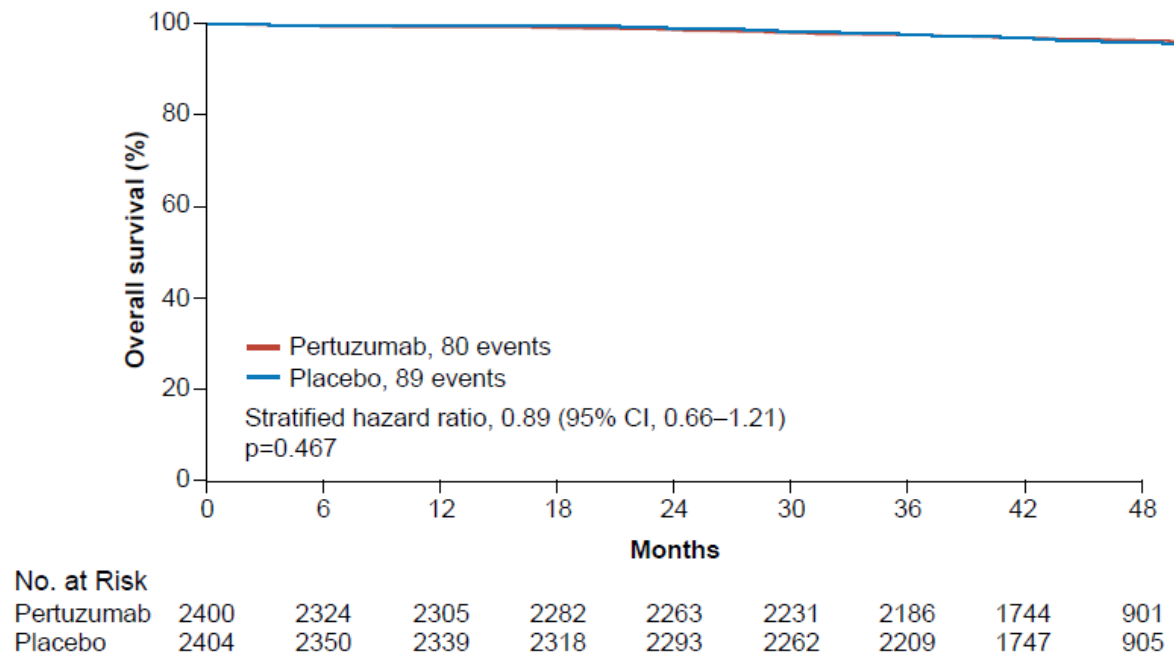
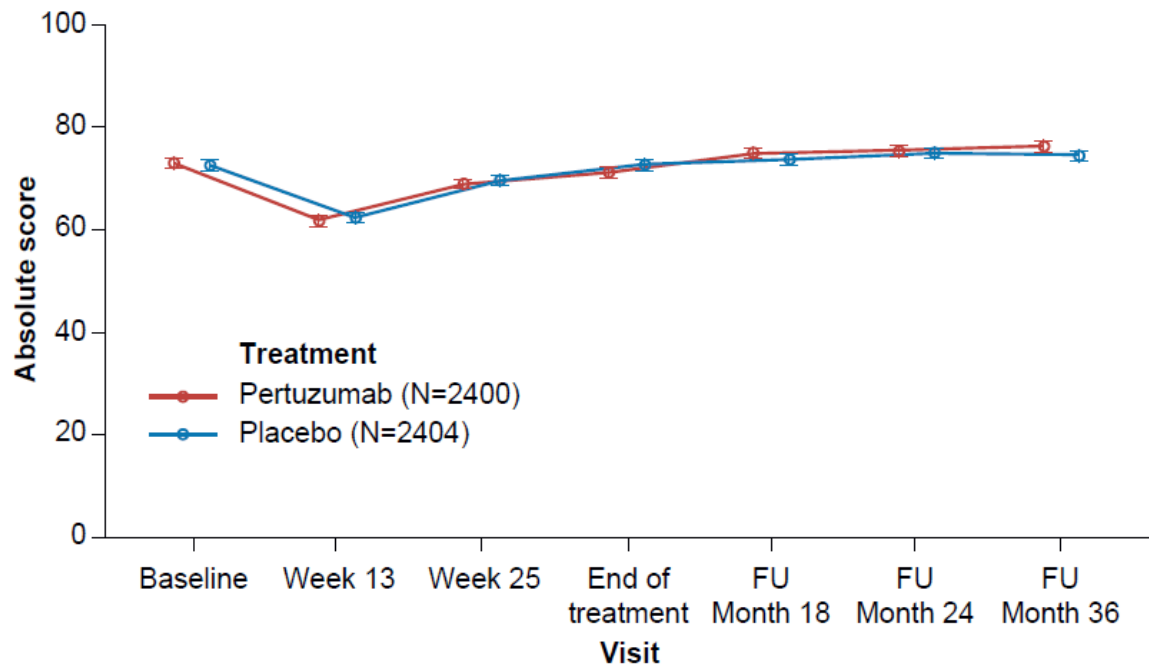


Figure S6. Plot of Mean EORTC QLQ-C30 global health status by treatment regimen, ITT population



Clinically meaningful decrease defined as below 10pts from BL; Osoba *et al*

Baseline questionnaires were completed prior to physician assessment and prior to receiving treatment. Week 13 assessment corresponds to end of taxane treatment for all patients, regardless of whether they received 3, 4 or 6 cycles of taxane (corresponding to week 10, 13 or 19 of targeted treatment).

Table S1. Demographic and Baseline Disease Characteristics of the Patients

(Extended).

	Pertuzumab + trastuzumab + chemotherapy N = 2400	Placebo + trastuzumab + chemotherapy N = 2404
Nodal status – no. (%)	n = 2400	n = 2404
0 positive nodes and tumor ≤1 cm*	90 (3.8)	84 (3.5)
0 positive nodes and tumor >1 cm*	807 (33.6)	818 (34.0)
1–3 positive nodes	907 (37.8)	900 (37.4)
≥4 positive nodes	596 (24.8)	602 (25.0)
Adjuvant chemotherapy regimen (randomized) – no. (%)	n = 2400	n = 2404
Anthracycline-containing regimen	1865 (77.7)	1877 (78.1)
Non-anthracycline-containing regimen	535 (22.3)	527 (21.9)
Hormone receptor status (central) – no. (%)	n = 2400	n = 2404
Negative (ER- and PgR-negative)	864 (36.0)	858 (35.7)
Positive (ER- and/or PgR-positive)	1536 (64.0)	1546 (64.3)
Protocol version – no. (%)	n = 2400	n = 2404
Protocol A	1828 (76.2)	1827 (76.0)
Protocol Amendment B	572 (23.8)	577 (24.0)
Age – yr	n = 2400	n = 2404

Mean (SD)	51.7 (10.9)	51.4 (10.7)
Median	51.0	51.0
Range	22–86	18–85
Age – yr – no. (%)	n = 2400	n = 2404
<35	149 (6.2)	144 (6.0)
35–39	177 (7.4)	183 (7.6)
40–49	708 (29.5)	702 (29.2)
50–64	1051 (43.8)	1082 (45.0)
65–74	285 (11.9)	267 (11.1)
≥75	30 (1.3)	26 (1.1)
Sex – no. (%)	n = 2400	n = 2404
Female	2397 (99.9)	2396 (99.7)
Male	3 (0.1)	8 (0.3)
Menopausal status at screening – no. (%)	n = 2397	n = 2395
Pre-menopausal	1152 (48.1)	1173 (49.0)
Post-menopausal	1242 (51.8)	1220 (50.9)
Unknown	3 (0.1)	2 (<0.1)
Pathologic tumor size – cm	n = 2400 tumors	n = 2405 tumors
Mean (SD)	2.4 (1.5)	2.5 (1.5)
Median	2	2
Range	0–18	0–14

Pathologic tumor size – cm – no. (%)	n = 2400 tumors	n = 2405 tumors
0–<2	978 (40.8)	948 (39.4)
≥2–<5	1275 (53.1)	1283 (53.3)
≥5	147 (6.1)	174 (7.2)

* Protocol A only.

Patients with bilateral tumors will report pathologic characteristics for both tumors; therefore, pathologic tumor characteristics are summarized on the tumor level.

ER denotes estrogen receptor, PgR progesterone receptor, and SD standard deviation.

Table S2. Site of First Invasive Disease-Free Survival Event by Hormone Receptor Status.

A Hormone Receptor-Negative Cohort.

No. (%)	Pertuzumab + trastuzumab + chemotherapy N = 864	Placebo + trastuzumab + chemotherapy N = 858
Total patients with IDFS event	71 (8.2)	91 (10.6)
Category of first IDFS event		
Distant recurrence	43 (5.0)	60 (7.0)
CNS metastases	20 (2.3)	20 (2.3)
Locoregional recurrence	12 (1.4)	12 (1.4)
Contralateral breast cancer	3 (0.3)	4 (0.5)
Death without prior event	13 (1.5)	15 (1.7)

Patients who experience additional IDFS event(s) within 61 days of their first IDFS event are reported in the category according to the following hierarchy: [1] Distant recurrence; [2] locoregional recurrence; [3] contralateral breast cancer; [4] death without prior event.

CNS metastases is a subset of distant recurrence.

CNS denotes central nervous system and IDFS invasive disease-free survival.

B Hormone Receptor-Positive Cohort.

No. (%)	Pertuzumab + trastuzumab + chemotherapy N = 1536	Placebo + trastuzumab + chemotherapy N = 1546
Total patients with IDFS event	100 (6.5)	119 (7.7)
Category of first IDFS event		
Distant recurrence	69 (4.5)	79 (5.1)
CNS metastases	25 (1.6)	24 (1.6)
Locoregional recurrence	14 (0.9)	22 (1.4)
Contralateral breast cancer	2 (0.1)	7 (0.5)
Death without prior event	15 (1.0)	11 (0.7)

Patients who experience additional IDFS event(s) within 61 days of their first IDFS event are reported in the category according to the following hierarchy: [1] Distant recurrence; [2] locoregional recurrence; [3] contralateral breast cancer; [4] death without prior event.

CNS metastases is a subset of distant recurrence.

CNS denotes central nervous system and IDFS invasive disease-free survival.

Table S3. Summary of First Distant Recurrence.

No. (%)	Pertuzumab + trastuzumab + chemotherapy N = 2400	Placebo + trastuzumab + chemotherapy N = 2404
Patients with a distant recurrence at any time	119 (5.0)	145 (6.0)
Site of first distant recurrence		
CNS	46 (1.9)	45 (1.9)
Lung/liver/pleural effusion	43 (1.8)	61 (2.5)
Other	9 (0.4)	9 (0.4)
Bone	21 (0.9)	30 (1.2)

The first distant recurrence may occur after a prior IDFS event.

CNS includes brain metastasis and meningitis carcinomatosa. If a patient experiences a distant recurrence in more than one site within 61 days of the date of their first recurrence, they are counted in the category according to the following hierarchy: [1] CNS; [2] lung/liver/pleural effusion; [3] other; [4] bone.

CNS denotes central nervous system.

Table S4. Summary of Secondary Efficacy Endpoints

	Pertuzumab + trastuzumab + chemotherapy N = 2400	Placebo + trastuzumab + chemotherapy N = 2404
IDFS (STEEP definition)		
Patients with an event	189 (7.9)	230 (9.6)
3-year event-free rate – %	93.5	92.5
95% CI	92.5–94.5	91.4–93.6
Stratified hazard ratio	0.82	
95% CI	0.68-0.99	
p-value (log-rank)	0.043	
Disease-Free Survival		
Patients with an event	192 (8.0%)	236 (9.8%)
3-year event-free rate – %	93.4	92.3
Stratified hazard ratio	0.81	
95% CI	(0.67, 0.98)	
p-value (log-rank)	0.033	
Recurrence-Free Interval		
Patients with an event	138 (5.8%)	173 (7.2%)
3-year event-free rate – %	95.2	94.3
Stratified hazard ratio	0.79	
95% CI	(0.63, 0.99)	
p-value (log-rank)	0.043	

Distant recurrence-free interval		
Patients with an event	119 (5.0%)	145 (6.0%)
3-year event-free rate – %	95.7	95.1
Stratified hazard ratio	0.82	
95% CI	(0.64, 1.04)	
p-value (log-rank)	0.101	

CI denotes confidence interval and STEEP standardized efficacy endpoints.

Table S5. Patient Disposition.

Status – no (%)	Pertuzumab + trastuzumab + chemotherapy N = 2400	Placebo + trastuzumab + chemotherapy N = 2404
Completed pertuzumab/placebo treatment	2028 (84.5)	2100 (87.4)
Discontinued pertuzumab/placebo treatment	372 (15.5)	304 (12.6)
Safety	186 (7.8)	155 (6.4)
Adverse event	176 (7.3)	149 (6.2)
Death	9 (0.4)	6 (0.2)
Pregnancy	1 (<0.1)	0
Non-safety	186 (7.8)	149 (6.2)
Lost to follow-up	0	1 (<0.1)
Non-compliance with study drug	44 (1.8)	29 (1.2)
Physician decision	30 (1.3)	15 (0.6)
Protocol violation	1 (<0.1)	3 (0.1)
Recurrence of disease	20 (0.8)	29 (1.2)
Contralateral breast cancer	2 (<0.1)	0
Withdrawal by subject	55 (2.3)	47 (2.0)
Other	34 (1.4)	25 (1.0)

Table S6 Summary of Adverse Events by Chemotherapy Regimen (Safety Analysis Population)

	Pertuzumab + trastuzumab + anthracycline N = 1834	Placebo + trastuzumab + anthracycline N = 1894	Pertuzumab + trastuzumab + non-anthracycline N = 528	Placebo + trastuzumab + non-anthracycline N = 510
At least 1 Grade \geq 3 Adverse Event	1133 (61.8%)	1080 (57.0%)	384 (72.7%)	299 (58.6%)
Neutropenia	301 (16.4%)	304 (16.1%)	84 (15.9%)	73 (14.3%)
Febrile Neutropenia	235 (12.8%)	204 (10.8%)	51 (9.7%)	62 (12.2%)
Neutrophil count decreased	193 (10.5%)	197 (10.4%)	35 (6.6%)	33 (6.5%)
Diarrhoea	137 (7.5%)	59 (3.1%)	95 (18.0%)	31 (6.1%)
Anaemia	74 (4.0%)	56 (3.0%)	89 (16.9%)	57 (11.2%)
Fatal Adverse Event	12 (0.7%)	16 (0.8%)	6 (1.1%)	4 (0.8%)
Primary Cardiac Event	15 (0.8%)	7 (0.4%)	2 (0.4%)	1 (0.2%)
Treatment difference (pertuzumab – placebo) 95% CI*	0.4 (-0.1, 1.0)		0.2 (-0.6, 0.9)	
Heart failure (NYHA III or IV) and significant LVEF decline	13 (0.7%)	5 (0.3%)	2 (0.4%)	1 (0.2%)
Cardiac death (definite or probable)	2 (0.1%)	2 (0.1%)	0	0

Secondary Cardiac Event	55 (3.0%)	60 (3.2%)	9 (1.7%)	7 (1.4%)
Treatment difference (pertuzumab – placebo) 95% CI*	-0.2 (-1.3, 1.0)		0.3 (-1.3, 1.9)	
Identified automatically from LVEF assessments	46 (2.5%)	44 (2.3%)	4 (0.8%)	3 (0.6%)
Identified by CAB	9 (0.5%)	16 (0.8%)	5 (0.9%)	4 (0.8%)

Percentages are based on N in the column headings;

The summary of grade ≥ 3 adverse events includes AEs with onset from first dose of any study treatment through 28 days after last dose of study treatment. The incidence of all other grade ≥ 3 AEs was $< 5\%$ in both safety analysis population arms.

Primary cardiac events are counted over the whole study period, including post-treatment follow-up.

Secondary cardiac events are counted up to the date of recurrence or end of post-treatment follow-up, whichever occurs earlier

Secondary cardiac events are only counted for patients who have not experienced a primary cardiac event

Significant LVEF decline defined as a decline of $\geq 10\%$ points to a value $< 50\%$

* 95% confidence interval with Hauck-Anderson correction

Table S7. Summary of Incidence of Grade ≥ 3 Diarrhea (Safety Analysis Population).

No. (%)	Pertuzumab + trastuzumab + chemotherapy N = 2364	Placebo + trastuzumab + chemotherapy N = 2405
Study treatment period*	232 (9.8)	90 (3.7)
Targeted therapy (post-chemotherapy period)[†]	12 (0.5)	4 (0.2)

* Includes grade ≥ 3 adverse events with onset from first dose of any study treatment through 28 days after last dose of study treatment.

[†] Includes grade ≥ 3 adverse events with onset during the targeted therapy post-chemotherapy treatment period.

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