Supplementary Materials:

Patient-Reported Outcomes of Palbociclib Plus Exemestane with GnRH Agonist versus Capecitabine in Premenopausal Women with Hormone Receptor-Positive Metastatic Breast Cancer: A Prospective, Open-Label, Randomized Phase ll Trial (KCSG-BR 15-10)

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Table S1. Baseline characteristics between palbociclib plus exemestane with GnRH agonist and capecitabine arm.

	Palbociclib plus Endocrine therapy (*n* = 92)	Capecitabine (*n* = 86)
Age in years; median (range)	44 (31–58)	44 (28–53)
BMI; median (range)	22 (15–30)	22 (14–35)
Hormone receptor status		
ER+/PR+	70 (76.1%)	64 (74.4%)
ER+/PR−	22 (23.9%)	22 (25.6%)
ECOG performance status		
0	54 (58.7%)	48 (55.8%)
1–2	38 (41.3%)	38 (44.2%)
Metastatic sites		
Bone only	22 (23.9%)	18 (20.9%)
Visceral organs	45 (48.9%)	43 (50.0%)
lung	29 (31.5%)	22 (25.6%)
Liver	17 (18.5%)	19 (22.1%)
DFS from the 1st diagnosis of stage I–III BC (*N* = 124)	*N* = 64	*N* = 60
<24 months	12 (13.0%)	15 (17.4%)
≥24 months	52 (56.5%)	45 (52.3%)
Initially stage IV	28 (30.4%)	26 (30.2%)
Tamoxifen resistance (including recurrence within 1 year after completion of adjuvant tamoxifen)		
Yes	76 (82.6%)	77 (89.5%)
No	16 (17.4%)	9 (10.5%)
Prior cytotoxic chemotherapy for MBC		
Yes	22 (23.9%)	18 (20.9%)
No	70 (76.1%)	68 (79.1%)
Previous lines of treatment for MBC		
0	46 (50.0%)	45(51.2%)
1	30 (32.6%)	30(52.3%)
2	16 (17.4%)	11 (12.8%)

Prior (neo)adjuvant treatment (N = 124)	N = 64	N = 60
Cytotoxic chemotherapy	58 (90.1%)	50 (83.3%)
Anthracycline based	16 (25.0%)	11 (18.3%)
Anthracycline and taxane based	40 (62.5%)	36 (60.0%)
Others	2 (3.1%)	3 (5.0%)
Endocrine treatment	60 (93.8%)	55 (91.7%)
Tamoxifen	43 (67.2%)	47 (78.3%)
Tamoxifen + GnRH agonist	17 (26.6%)	8 (13.3%)

BMI = body mass index; ER = estrogen receptor; PR = progesterone receptor; DFS = disease free survival; BC = breast cancer; MBC = metastatic breast cancer.

Table S2. Comparison between two treatment arms of change pattern according to time of each subscale scores by analysis using generalized estimating equations.

	Parameter	Level1	Estimate	Standard Error	p value
Global health status	ARMCD	ArmA vs ArmB	5.3442	2.9061	0.0659
	week_i		0.0064	0.0565	0.9100
	week_i × RMCD	ArmA vs ArmB	−0.0333	0.0678	0.6230
Physical functioning	ARMCD	ArmA vs ArmB	3.6421	2.7033	0.1779
	week_i		0.0225	0.0474	0.6353
	week_i × ARMCD	ArmA vs ArmB	0.0095	0.0549	0.8619
Role functioning	ARMCD	ArmA vs ArmB	5.8515	3.5271	0.0971
	week_i		−0.0189	0.0598	0.7524
	week_i × ARMCD	ArmA vs ArmB	0.0028	0.0696	0.9675
Emotional functioning	ARMCD	ArmA vs ArmB	1.3662	2.6889	0.6114
	week_i		−0.0707	0.073	0.3332
	week_i × ARMCD	ArmA vs ArmB	0.0775	0.0813	0.3405
Cognitive functioning	ARMCD	ArmA vs ArmB	2.593	2.4358	0.2871
	week_i		0.0234	0.0501	0.6412
	week_i × ARMCD	ArmA vs ArmB	−0.0769	0.0601	0.2010
Social functioning	ARMCD	ArmA vs ArmB	7.199	3.3151	0.0299
	week_i		−0.0246	0.0743	0.7409
	week_i × ARMCD	ArmA vs ArmB	0.0068	0.0901	0.9396
Fatigue	ARMCD	ArmA vs ArmB	−3.2795	3.0029	0.2748
	week_i		0.0595	0.0633	0.3471
	week_i × ARMCD	ArmA vs ArmB	−0.0569	0.0709	0.4222
Nausea and vomiting	ARMCD	ArmA vs ArmB	−7.081	2.1759	0.0011
	week_i		−0.0745	0.0405	0.0660
	week_i × ARMCD	ArmA vs ArmB	0.0695	0.0482	0.1493
Pain	ARMCD	ArmA vs ArmB	−6.8937	3.3473	0.0394
	week_i		−0.1107	0.0525	0.0349
	week_i × ARMCD	ArmA vs ArmB	0.0804	0.0658	0.2215
Dyspnea	ARMCD	ArmA vs ArmB	−0.8068	2.9748	0.7862
	week_i		−0.0292	0.0498	0.5573
	week_i × ARMCD	ArmA vs ArmB	−0.0126	0.0637	0.8430
Insomnia	ARMCD	ArmA vs ArmB	4.102	3.8952	0.2923
	week_i		0.0937	0.072	0.1933
	week_i × ARMCD	ArmA vs ArmB	−0.0626	0.0866	0.4702

Appetite loss	ARMCD	ArmA vs ArmB	−4.7466	3.0746	0.1226
	week_i		−0.0667	0.0544	0.2204
	week_i × ARMCD	ArmA vs ArmB	−0.0155	0.0647	0.8112
Constipation	ARMCD	ArmA vs ArmB	−1.3192	2.9857	0.6586
	week_i		−0.0357	0.0546	0.5131
	week_i × ARMCD	ArmA vs ArmB	0.0438	0.0692	0.5261
Diarrhea	ARMCD	ArmA vs ArmB	−8.3505	2.1837	0.0001
	week_i		0.1238	0.0547	0.0237
	week_i × ARMCD	ArmA vs ArmB	−0.1153	0.0635	0.0696
Total Score	ARMCD	ArmA vs ArmB	3.7713	2.1344	0.0772
	week_i		−0.0022	0.039	0.9553
	week_i × ARMCD	ArmA vs ArmB	0.0068	0.0455	0.8806

ARMCD = planned arm code.