

Supplemental Figures for:

Palbociclib in Combination With Fulvestrant in Women With Hormone Receptor–Positive/HER2-Negative Advanced Metastatic Breast Cancer: Detailed Safety Analysis
From a Multicenter, Randomized, Placebo-Controlled, Phase 3 Study (PALOMA-3)

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Table S1. Summary of treatment-emergent serious adverse events (>1 case, all causalities): as-treated population^a

Preferred term, ^b n (%)	Palbociclib + fulvestrant (N = 345)						Placebo + fulvestrant (N = 172)					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade
Any adverse event	1 (0.3)	8 (2.3)	24 (7.0)	7 (2.0)	4 (1.2)	44 (12.8)	0	8 (4.7)	16 (9.3)	3 (1.7)	3 (1.7)	30 (17.4)
Infections ^c	0	2 (0.6)	4 (1.2)	1 (0.3)	0	7 (2.0)	0	3 (1.7)	4 (2.3)	0	0	7 (4.1)
Neutropenia ^c	0	0	2 (0.6)	2 (0.6)	0	4 (1.2)	0	0	0	0	0	0
Pyrexia	3 (0.9)	0	1 (0.3)	0	0	4 (1.2)	1 (0.6)	0	0	0	0	1 (0.6)
Pulmonary embolism ^c	0	0	3 (0.9)	0	0	3 (0.9)	0	0	0	0	0	0
Pleural effusion	0	2 (0.6)	1 (0.3)	0	0	3 (0.9)	0	2 (1.2)	1 (0.6)	0	0	3 (1.7)
Deep vein thrombosis	0	1 (0.3)	1 (0.3)	0	0	2 (0.6)	0	0	0	0	0	0
Disease progression	0	0	0	0	2 (0.6)	2 (0.6)	0	0	0	0	0	0
Febrile neutropenia	0	0	2 (0.6)	0	0	2 (0.6)	0	0	0	0.6	0	1 (0.6)
Suicide attempt	0	0	1 (0.3)	1 (0.3)	0	2 (0.6)	0	0	0	0	0	0
Pneumonia	0	0	1 (0.3)	0	0	1 (0.3)	0	1 (0.6)	1 (0.6)	0	0	2 (1.2)
Ascites	0	0	0	0	0	0	0	0	3 (1.7)	0	0	3 (1.7)
Pathologic fracture	0	0	0	0	0	0	0	0	1 (0.6)	1 (0.6)	0	2 (1.2)

^aIncludes data up to 28 days after last dose of study drug.

^bAdverse events were graded in accordance with Common Terminology Criteria for Adverse Events version 4.0 and the Medical Dictionary for Regulatory Activities version 18.0 (MedDRA).

^cPreferred terms (PTs) are listed according to MedDRA. Infection includes any reported PTs that are part of the System Organ Class infections and infestations. Neutropenia includes the following PTs: neutropenia, neutrophil count decreased. Pulmonary embolism includes the following PTs: pulmonary artery thrombosis, pulmonary embolism.

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Table S2. Multivariate analysis of grade 3 and/or 4 neutropenia^a vs infection status,^b treatment arm, and key baseline factors

Factors ^c	Odds ratio ^d	95% CI	<i>p</i> value
Infection status, no vs yes	0.682	0.396–1.174	.17
Treatment arm, palbociclib arm vs placebo arm	>999.999	151.036–>999.999	<.0001
Immediate prior chemotherapy, no vs yes	0.643	0.243–1.700	.37
Age, y			
50–70 vs ≥70	1.300	0.690–2.451	.83
<50 vs ≥70	1.503	0.632–3.574	.46
ECOG PS, 0 vs 1	0.963	0.558–1.663	.89
Number of disease sites			
1 vs ≥3	0.858	0.459–1.604	.42
2 vs ≥3	1.174	0.616–2.237	.43
Race, Asian vs Non-Asian	10.972	4.355–27.645	<.0001
Bone metastasis, no vs yes	0.840	0.464–1.520	.56
Baseline ANC, <median value vs ≥median value	7.223	4.088–12.761	<.0001

^aNeutropenia, any event having a PT equivalent to neutropenia/neutrophil count decreased; ^bInfections, any event having a PT part of the SOC infections and infestations. ^cControlled for baseline/prognostic factors and treatment arm simultaneously in multivariate analysis. ^dAn odds ratio of A:B (ie, A vs B) >1 with a *p* value <.05 means that the level A of a specific variable is significantly associated with the increased probability of experiencing grade 3–4 neutropenia compared with level B of the same variable in this multivariate analysis.

Abbreviations: ANC, absolute neutrophil count; ECOG PS, Eastern Cooperative Oncology Group performance status; PT, preferred term; SOC, System Organ Class.

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