

Supplementary material

Relationship of prior anticancer treatments with palbociclib clinical outcomes in patients with HR+/HER2– advanced breast cancer in real-world settings

Authors: Gabrielle B. Rocque,¹ Joanne L. Blum,² Yan Ji,³ Timothy Pluard,⁴ John Migas,⁵ Shailendra Lakhanpal,⁶ Erin Jepsen,⁷ Yao Wang,⁸ Monica Z. Montelongo,⁹ Zhe Zhang,¹⁰ Eric Gauthier,¹¹ Debu Tripathy¹²

Affiliations: ¹Department of Medicine, Division of Hematology/Oncology, University of Alabama at Birmingham, Birmingham, AL, USA; ²Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, TX, USA; ³Hematology/Oncology, Health Partners Institute, Saint Paul, MN, USA; ⁴St. Luke's Hospital Koontz Center for Advanced Breast Cancer, Kansas City, MO, USA; ⁵Mid-Illinois Hematology & Oncology Associates, Normal, IL, USA; ⁶Alabama Oncology, Birmingham, AL, USA; ⁷Medical Oncology, Hematology, Novant Health Cancer Institute, Winston-Salem, NC, USA; ⁸Oncology Pfizer Biopharma, Pfizer Inc, New York, NY, USA; ⁹ICON plc, Blue Bell, PA, USA; ¹⁰Oncology Clinical Statistics, Pfizer Inc, La Jolla, CA, USA; ¹¹Pfizer Inc, South San Francisco, CA, USA; ¹²Department of Breast Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

Table S1. Per-label population: patient baseline demographic and disease characteristics by prior treatment and palbociclib LOT

Palbociclib LOT	1LOT (n = 712)					≥ 2LOT (n = 149)			
Treatments received prior to palbociclib	None (n = 272)	ET alone (n = 123)	CT alone (n = 65)	ET + CT (n = 238)	Other^a (n = 14)	ET alone (n = 41)	CT alone (n = 0)	ET + CT (n = 77)	Other^a (n = 31)
Age at enrollment									
n (missing)	272 (0)	123 (0)	65 (0)	237 (1)	14 (0)	41 (0)	0	77 (0)	31 (0)
Median (range), years	64 (30–97)	69 (22–91)	56 (28–95)	63 (29–88)	67 (54–79)	70 (48–88)	0	62 (36–88)	64 (45–92)
Distribution, n (%)									
< 50 years	39 (14.3)	7 (5.7)	18 (27.7)	34 (14.3)	0	1 (2.4)	0	11 (14.3)	2 (6.5)
≥ 50 to < 70 years	151 (55.5)	55 (44.7)	34 (52.3)	129 (54.4)	8 (57.1)	19 (46.3)	0	41 (53.2)	18 (58.1)
≥ 70 years	82 (30.1)	61 (49.6)	13 (20.0)	74 (31.2)	6 (42.9)	21 (51.2)	0	25 (32.5)	11 (35.5)
Female sex, n (%)	269 (98.9)	123 (100.0)	65 (100.0)	233 (97.9)	14 (100.0)	39 (95.1)	0	75 (97.4)	31 (100.0)
Race, n (%)									
White	223 (82.0)	104 (84.6)	54 (83.1)	198 (83.2)	8 (57.1)	35 (85.4)	0	65 (84.4)	22 (71.0)
Black or African American	34 (12.5)	12 (9.8)	7 (10.8)	25 (10.5)	5 (35.7)	3 (7.3)	0	7 (9.1)	6 (19.4)
Asian	2 (0.7)	2 (1.6)	0	4 (1.7)	0	0	0	2 (2.6)	1 (3.2)
American Indian or Alaska Native	1 (0.4)	1 (0.8)	0	2 (0.8)	1 (7.1)	1 (2.4)	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0	3 (1.3)	0	0	0	0	0
Other	2 (0.7)	2 (1.6)	4 (6.2)	3 (1.3)	0	0	0	3 (3.9)	1 (3.2)
Not reported or missing	10 (3.7)	2 (1.6)	0	3 (1.3)	0	2 (4.9)	0	0	1 (3.2)
Ethnicity, n (%)									
Not Hispanic or Latino	249 (91.5)	108 (87.8)	57 (87.7)	211 (88.7)	13 (92.9)	40 (97.6)	0	72 (93.5)	25 (80.6)
Hispanic or Latino	12 (4.4)	13 (10.6)	7 (10.8)	19 (8.0)	1 (7.1)	0	0	5 (6.5)	4 (12.9)

Not reported or missing	11 (4.0)	2 (1.6)	1 (1.5)	8 (3.4)	0	1 (2.4)	0	0	2 (6.5)
Disease stage at enrollment, n (%)									
Locally advanced	9 (3.3)	6 (4.9)	6 (9.2)	7 (2.9)	1 (7.1)	3 (7.3)	0	2 (2.6)	3 (9.7)
Metastatic	263 (96.7)	115 (93.5)	59 (90.8)	231 (97.1)	13 (92.9)	38 (92.7)	0	75 (97.4)	28 (90.3)
Not reported	0	2 (1.6)	0	0	0	0	0	0	0
Diagnosis at enrollment, n (%)									
Recurrent from earlier stage, stages 0–III	77 (28.3)	118 (95.9)	60 (92.3)	232 (97.5)	14 (100.0)	16 (39.0)	0	51 (66.2)	21 (67.7)
De novo, ^b newly diagnosed stage IV	180 (66.2)	4 (3.3)	2 (3.1)	1 (0.4)	0	24 (58.5)	0	17 (22.1)	9 (29.0)
Not reported	15 (5.5)	1 (0.8)	3 (4.6)	5 (2.1)	0	1 (2.4)	0	9 (11.7)	1 (3.2)
Bone-only disease at MBC diagnosis, ^c n (%)	101 (38.4)	42 (36.5)	24 (40.7)	90 (39.0)	4 (30.8)	15 (39.5)	0	17 (22.7)	6 (21.4)
Visceral disease ^d at MBC diagnosis, ^c n (%)	77 (29.3)	57 (49.6)	19 (32.2)	103 (44.6)	5 (38.5)	16 (42.1)	0	41 (54.7)	13 (46.4)
HR status ^e									
HR+ (any ER+, any PR+)	272 (100.0)	123 (100.0)	65 (100.0)	238 (100.0)	14 (100.0)	41 (100.0)	0	77 (100.0)	31 (100.0)
HER2 status ^e									
HER2–	272 (100.0)	123 (100.0)	65 (100.0)	238 (100.0)	14 (100.0)	41 (100.0)	0	77 (100.0)	31 (100.0)
HER2–/HR+	272 (100.0)	123 (100.0)	65 (100.0)	238 (100.0)	14 (100.0)	41 (100.0)	0	77 (100.0)	31 (100.0)

^a Includes experimental therapies or therapies other than ET or chemotherapy.

^b A subset of these patients (n = 7) was designated as having received an initial breast cancer diagnosis of “de novo MBC” despite having records of prior treatment.

^c Among patients with metastatic disease at study enrollment.

^d Metastases of the brain, liver, and/or lung/pleura.

^e At most recent recurrence diagnosis prior to enrollment date or initial diagnosis if no recurrence.

CT, chemotherapy; ER, endocrine receptor; ET, endocrine therapy; HR, hormone receptor; LOT, line of therapy; MBC, metastatic breast cancer; PR, progesterone receptor.

Table S2. Per-label population: TFI by prior treatment in patients who received palbociclib in the 1LOT

TFI^a	ET alone (n = 123)	CT alone (n = 65)	ET + CT (n = 238)	Other^b (n = 14)
n (missing) ^a	117 (6)	61 (4)	237 (1)	14 (0)
Mean, months (SD)	38.6 (47.5)	88.2 (99.0)	35.5 (50.3)	24.1 (38.4)
Median, months (range)	15.8 (0.0–212.6)	52.3 (0.0–422.5)	7.7 (0.0–310.6)	11.0 (0.0–146.6)
TFI ≤ 12 months, n (%)	52 (42.3)	15 (23.1)	127 (53.4)	8 (57.1)
TFI > 12 months, n (%)	65 (52.8)	46 (70.8)	110 (46.2)	6 (42.9)

^a A subset of these patients (n = 7) was designated as having received an initial breast cancer diagnosis of “de novo MBC” despite having records of prior treatment and therefore have been excluded from the TFI calculation.

^b Includes experimental therapies or therapies other than ET or chemotherapy.

1LOT, first line of therapy; CT, chemotherapy; ET, endocrine therapy; MBC, metastatic breast cancer; SD, standard deviation; TFI, treatment-free interval.

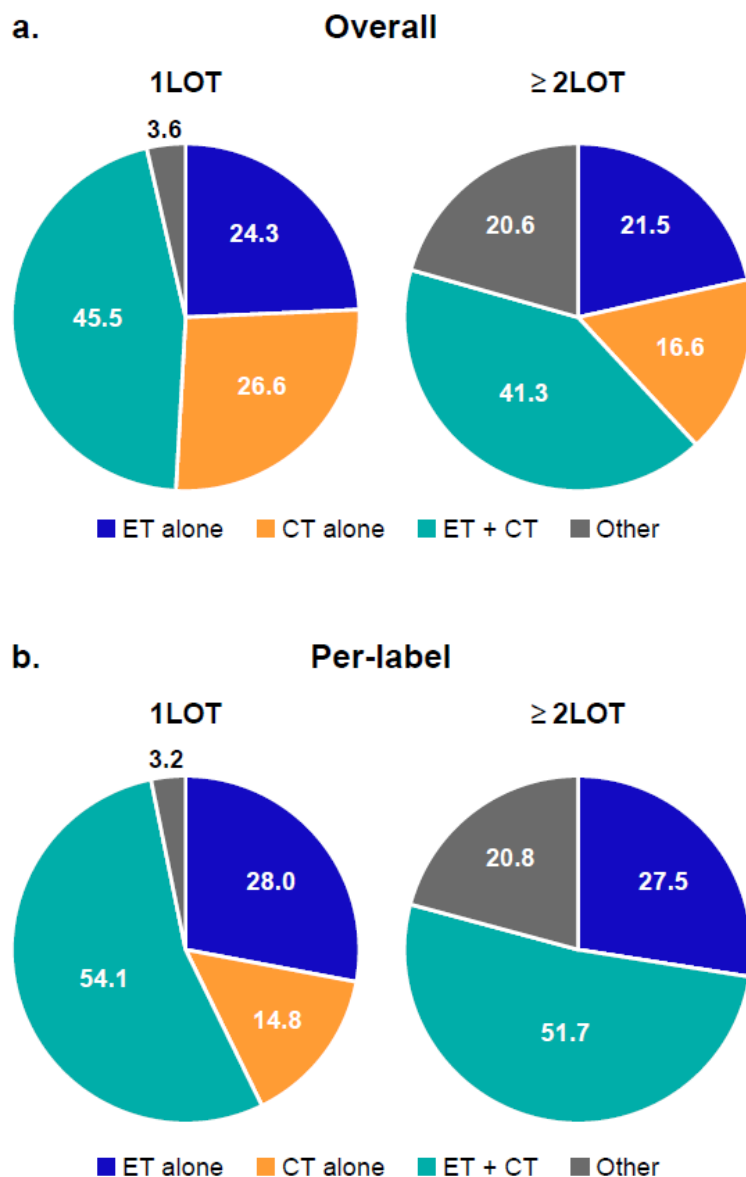
Table S3. Per-label population: clinical outcomes by prior treatment and palbociclib LOT

		1LOT (n = 712)		≥ 2LOT (n = 149)	
		Median, months (95% CI)		Median, months (95% CI)	
	Prior treatment	n		n	
rwPFS	None	272	26.7 (20.3–31.9)	–	–
	ET alone	123	30.4 (22.0–40.5)	41	19.8 (9.9–33.8)
	CT alone	65	25.8 (16.2–30.0)	0	–
	ET + CT	238	17.7 (15.9–21.8)	77	11.1 (7.4–19.5)
	Other ^a	14	9.4 (3.5–19.0)	31	10.8 (2.8–13.7)
OS	None	272	53.3 (39.2–NE)	–	–
	ET alone	123	NR (42.4–NE)	41	39.5 (28.4–NE)
	CT alone	65	48.8 (35.5–NE)	0	–
	ET + CT	238	46.9 (39.3–NE)	77	31.7 (23.1–44.3)
	Other ^a	14	17.3 (9.3–NE)	31	26.3 (13.2–35.2)

^a Includes experimental therapies or therapies other than ET or chemotherapy.

CI, confidence interval; CT, chemotherapy; ET, endocrine therapy; LOT, line of therapy; NE, not estimable; NR, not reached; OS, overall survival; rwPFS, real-world progression-free survival.

Fig. S1 Prior anticancer treatments by palbociclib LOT in the overall study population (a) and per-label population (b)



CT, chemotherapy; ET, endocrine therapy; LOT, line of therapy.