PS1-12-28 • Real-world outcomes of first line palbociclib combined with endocrine treatment in HR+/HER2- metastatic breast cancer: 5-year data from the French ESME cohort

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BACKGROUND

- CDK4/6 inhibitors (CDK4/6i) are the standard of care in first line (1L) treatment for HR+/HER2- metastatic breast cancer (MBC) patients.
- This study aimed to characterize patient profiles and outcomes in the French ESME real-world (RW) cohort for patients in academic centers receiving 1L palbociclib combined with endocrine therapy (ET).

METHODS

Datasource

- ESME MBC database (NCT03275311), a multicenter real-world cohort collecting data from patients treated for MBC across 18 French academic Comprehensive Cancer Centers from 2008 onwards.

Patient selection

- Patients aged ≥18 years with newly diagnosed HR+/HER2- MBC who initiated in 1L palbociclib within 90 days after ET initiation, between 2018 and 2023 outside a clinical trial.

Statistical analysis

- Overall survival (OS) and time to next treatment (TTNT) were assessed using Kaplan-Meier estimations.
- OS was defined as the time from 1L start date to the date of death for any cause. Patients still alive were censored at the date of the last medical information (LMI). TTNT was defined as the time from the 1L start date to the 2L start date. Patients who did not receive 2L were censored at the date of LMI or death.
- Multivariable modelling (Cox-regression) was performed to identify independent prognostic factors

RESULTS

- Among 3,587 patients treated in 1L by CDK4/6i combined with ET for HR+/HER2- MBC, **2,267 patients initiated palbociclib**, combined with an aromatase inhibitor (AI) for 1,651 (72.8%) patients and with fulvestrant in 449 (19.8%) patients **(Table 1)**. Patients who received other ET regimen (n=167, 7.4%) were excluded from the analyses.
- Palbociclib was combined with AI mostly in ET-sensitive disease (1,297/1,651 of de novo or treatment-free interval (TFI) >12 months) and with fulvestrant mainly for ET-resistant disease (323/449 of TFI ≤12 months) **(Table 1)**.

Table 1. Patients' characteristics

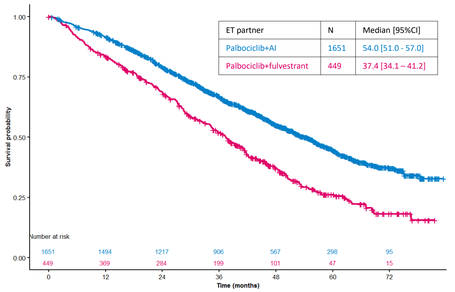
	Total (N = 2,267)	Palbociclib+AI (N = 1,651)	Palbociclib+fulvestrant (N = 449)
Men, n (%)	7 (0.3)	3 (0.2)	2 (0.4)
Premenopausal women, n (%)	340 (15.0)	236 (14.3)	64 (14.3)
missing	7 (0.3)	7 (0.4)	0
Age (year) at 1L start date			
median (range)	69 (29-95)	69 (38-95)	69 (41-93)
< 65, n (%)	807 (35.6)	571 (34.6)	174 (38.8)
65-74 years, n (%)	794 (35.0)	597 (36.2)	138 (30.7)
≥ 75 years, n (%)	666 (29.4)	483 (29.3)	137 (30.5)
ECOG score at 1L start date, n (%)			
0-1	1141 (50.3)	872 (52.8)	209 (46.6)
2+	324 (14.3)	228 (13.8)	77 (17.1)
missing	802 (35.4)	551 (33.4)	163 (36.3)
Endocrine sensitivity, n (%)			
De novo MBC	750 (33.1)	713 (43.2)	5 (1.1)
TFI ≤12 months	511 (22.5)	119 (7.2)	323 (71.9)
TFI >12 months	718 (31.7)	584 (35.4)	95 (21.2)
missing	288 (12.7)	235 (14.2)	26 (5.8)
Nb of metastatic sites, n (%)			
1	1204 (53.1)	833 (50.5)	256 (57.0)
2	510 (22.5)	388 (23.5)	95 (21.2)
3+	553 (24.4)	430 (26.0)	98 (21.8)
Type of disease, n (%)			
Visceral	862 (38.0)	638 (38.6)	174 (38.8)
Bone-only	857 (37.8)	610 (36.9)	168 (37.4)

1L, first-line treatment in metastatic setting; AI, aromatase inhibitor; MBC, metastatic breast cancer; TFI, treatment-free interval defined as the time interval between the end of (neo)adjuvant treatment and 1L start date

- The median follow-up was 54.9 months [95% CI 52.9-56.8].
- Median OS was 49.9 months [47.4-52.3] and median TTNT was 21.3 months [19.8–22.3] in the overall population.
- These results varied by ET partner (AI versus fulvestrant) (**Figure 1**) and according to different subgroups (**Table 2**).
- Multivariable Cox regression analyses in the overall cohort identified age, number of metastatic sites at 1L, TFI and menopausal status as independent prognostic factors for OS. In contrast, the ET partner was not significantly associated with OS (p=0.067) (**Figure 2A**)
- Similarly, in models assessing TTNT, age, number of metastatic sites at 1L, and TFI were independent prognostic factors, while ET partner showed no significant association with TTNT (p=0.118) (**Figure 2B**)

Figure 1. OS (A) and TTNT (B) by ET partner

A. Overall survival



B. Time to next treatment

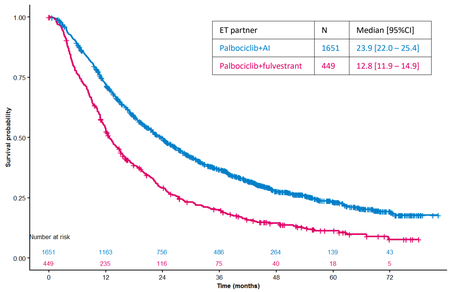


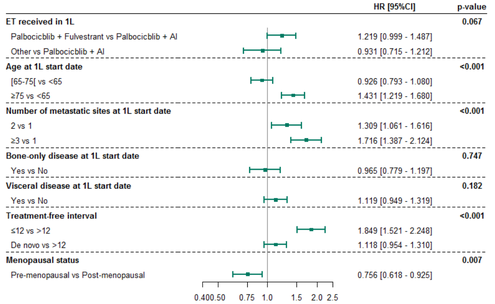
Table 2. OS and TTNT in selected subgroups by ET partner

	n	n	median OS [95%CI] Palbociblib+AI (N= 1,651)	median OS [95%CI] Palbociclib+Fulvestrant (N= 449)	median TTNT [95%CI] Palbociblib+AI (N= 1,651)	median TTNT [95%CI] Palbociclib+Fulvestrant (N= 449)
Age						
<65	571	174	56.5 [52.3 - 63.3]	38.3 [34.1 - 45.8]	21.2 [18.2 - 23.7]	12.0 [10.5 - 13.5]
65-74	597	138	58.3 [53.1 - 64.0]	41.6 [36.5 - 46.6]	26.3 [22.6 - 29.9]	12.8 [11.1 - 16.1]
≥75	483	137	44.5 [40.0 - 47.5]	29.5 [24.9 - 37.0]	24.5 [21.2 - 27.2]	16.3 [11.9 - 23.0]
Menopausal status						
Pre-menopausal	236	64	57.0 [50.3 - 73.0]	49.9 [36.5 - 53.4]	26.2 [21.3 - 28.5]	13.3 [10.8 - 21.8]
Post-menopausal	1405	174	53.1 [50.2 - 56.7]	36.3 [30.1 - 39.8]	23.5 [21.7 - 25.3]	12.7 [11.7 - 15.0]
Nb of metastatic sites						
1	833	256	62.7 [58.6 - 68.1]	43.1 [39.2 - 47.9]	31.6 [27.9 - 36.6]	15.2 [12.4 - 18.9]
2	388	95	50.4 [45.7 - 55.3]	30.7 [27.2 - 35.5]	20.1 [18.0 - 23.5]	10.8 [8.9 - 13.5]
3+	430	98	37.1 [33.9 - 43.3]	27.3 [20.5 - 34.1]	16.5 [14.6 - 18.4]	11.0 [9.0 - 13.5]
Type of disease						
Visceral	638	174	44.5 [39.3 - 49.1]	28.5 [24.7 - 34.5]	18.2 [16.5 - 21.2]	10.9 [9.2 - 12.4]
Bone-only	610	168	62.7 [57.3 - 69.7]	46.3 [37.9 - 50.9]	30.0 [27.3 - 33.4]	17.2 [13.3 - 21.0]
Endocrine sensitivity						
De novo MBC	713	5	51.7 [47.0 - 57.3]	NA (n<30)	23.5 [20.4 - 26.5]	NA (n<30)
TFI ≤ 12 months	119	323	36.2 [27.8 - 45.7]	34.8 [29.9 - 39.2]	12.1 [10.2 - 13.8]	11.6 [10.3 - 12.8]
TFI > 12 months	584	95	59.1 [54.8 - 64.0]	41.8 [37.9 - 54.9]	24.8 [22.2 - 28.5]	27.3 [14.9 - 34.1]

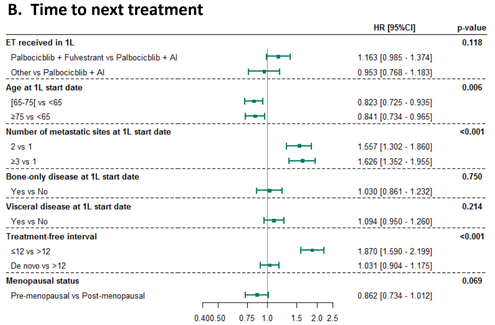
AI, aromatase inhibitor; CI, confidence interval; MBC, metastatic breast cancer; ET, endocrine therapy; OS, overall survival; TFI, treatment-free interval; TTNT, time to next treatment

Figure 2. Multivariable analysis of OS (A) and TTNT (B)

A. Overall survival



B. Time to next treatment



Note: P-value displayed is the global p-value.
Patients with TFI or menopausal status not available (n=302) were excluded from the analysis.
Sensitivity analyses adjusting for ECOG performance status (for patients with available data) confirmed the robustness of the results.

CONCLUSION

In this large real-world cohort from French academic centers, first-line palbociclib + endocrine therapy achieved overall survival and treatment duration comparable to those reported in randomized trials and other observational studies. On multivariable analysis, the effectiveness outcomes appear to be primarily driven by treatment-free interval rather than by the choice of ET partner, which is itself directly associated with TFI. These results reinforce the benefit of palbociclib-based regimens in routine clinical practice.

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