**Quality of life (QoL) in patients with hormone receptor–positive (HR+)/human epidermal growth factor receptor 2–negative (HER2‒) advanced breast cancer (ABC) treated with palbociclib in real-world practice settings**

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**Introduction:** Palbociclib plus endocrine therapy (ET) is a standard of care for patients with HR+/HER2− ABC. The PALOMA clinical trials have shown that patients receiving palbociclib plus ET maintained stable QoL;no QoL data are currently available from real-world settings.

**Methods:** This noninterventional, prospective, multicenter study evaluated men and women with HR+/HER2– ABC treated with palbociclib as indicated by the attending physician during routine care. The European Organization for the Research and Treatment of Cancer Quality-of-Life Questionnaire Core 30 (EORTC QLQ-C30) was collected at enrollment before receiving palbociclib (baseline), monthly for the first 3 months of treatment, and then every 3 months until the end of treatment or patient withdrawal or death. Here we report demographic characteristics and QoL assessments using descriptive analyses.

**Results:** 522 patients who completed ≥6 months of palbociclib treatment as of May 20, 2019, were included in this interim analysis; 394 were prescribed palbociclib as first-line and 128 patients as ≥second line treatment. Median age was 64 years, 98% were women, and 83% were white; >50% of all patients (n=285) received palbociclib plus letrozole or anastrozole; 218 received palbociclib plus fulvestrant and 19 received palbociclib plus exemestane. Mean (SD) EORTC QLQ-C30 scores remained similar at baseline (66.2 [22.6]), 3 months (68.3 [19.7]), and 6 months (70.2 [21.3]). Mean EORTC QLQ-C30 functional and symptom scale scores remained stable over the first 6 months (**Table**). Except pain scores (which declined by 7 points), change from baseline at 6 months generally was <5 points across the different EORTC QLQ-C30 subscales.

**Conclusions:** Patients experienced stable to modestly improved QoL from baseline to 6 months after starting palbociclib. Changes from baseline in EORTC QLQ-C30 scores generally were below the 10-point clinically meaningful threshold. These early findings indicate that patients maintained their baseline QoL with palbociclib.

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| **EORTC QLQ-C30** | **Baseline** | **3 Months** | **6 Months** |
| Global Health/Quality of Life\* |  |  |  |
| n (missing)  | 474 (48) | 292 (230) | 409 (113) |
| Mean (SD) score | 66.2 (22.6) | 68.3 (19.7) | 70.2 (21.3) |
| Functional scales score, mean (SD)\* |  |  |  |
| Physical functioning | 75.6 (23.3) | 75.8 (21.9) | 77.2 (21.4) |
| Role functioning | 72.5 (31.9) | 76.7 (26.1) | 77.1 (26.8) |
| Emotional functioning | 74.8 (22.8) | 77.7 (22.3) | 79.7 (20.5) |
| Cognitive functioning | 78.8 (24.6) | 82.7 (20.6) | 80.1 (22.0) |
| Social functioning | 76.4 (28.3) | 79.5 (25.5) | 81.5 (24.7) |
| Symptom scales score, mean (SD)† |  |  |  |
| Fatigue | 34.3 (25.7) | 35.0 (23.6) | 33.7 (22.2) |
| Nausea and vomiting | 11.3 (20.2) | 10.4 (16.4) | 10.6 (19.3) |
| Pain | 33.5 (30.0) | 27.3 (27.2) | 26.5 (26.9) |
| Dyspnea | 22.2 (28.3) | 18.7 (22.5) | 18.8 (24.1) |
| Insomnia | 29.3 (30.1) | 27.5 (31.7) | 27.4 (27.9) |
| Appetite loss | 21.1 (27.9) | 19.4 (26.4) | 17.9 (26.5) |
| Constipation | 18.4 (26.6) | 15.2 (23.8) | 16.0 (23.8) |
| Diarrhea | 12.3 (22.1) | 12.0 (20.8) | 12.6 (22.0) |
| Financial difficulties | 25.0 (32.4) | 23.9 (30.4) | 22.1 (29.5) |

\*Higher scores indicate a better level of functioning.

†Higher scores indicate more severe symptoms.

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