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Quality of life from the Penelope-B study on high-risk HR+/HER2- early breast cancer patients treated with endocrine therapy with or without palbociclib

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Background

The PENELOPE-B trial did not demonstrate improved invasive disease-free survival with the addition of one year of palbociclib to endocrine therapy (ET) compared to placebo plus ET in high risk HR+/HER2- early breast cancer patients with residual invasive breast cancer following neoadjuvant therapy. This analysis compared patient-reported outcomes (PROs) between the two treatment groups.

Methods

Patients were randomized 1:1 to receive palbociclib 125 mg/day (n=631) or placebo (n=619) orally for 3 weeks followed by 1 week off plus ET per standard of care. PROs were assessed during screening, on day 1 of cycles 1, 3, 5, 7, 9, 11, then, every 6 months after end of treatment visit using the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ-C30) and its breast cancer (BR23) and fatigue (FA13) modules. Higher scores of C30 and FA13 (range 0-100) indicate better functioning and global health status/quality of life (GHS/QoL) or worse symptom severity, respectively. Repeated-measures mixed-effects models were used to evaluate differences in PRO between treatment groups, changes of PRO over time, and treatment-by-time interactions.

Results

Overall, 924 of 1250 patients (73.9%) completed the baseline and at least one post baseline questionnaire of all PRO instruments. GHS/QoL by the EORTC QLQ-C30 was generally high in both treatment arms (mean [SD]: palbociclib 70.1 [19.3], placebo 71.4 [18.8]) and was slightly higher in the placebo arm (LeastSquare mean difference: 0.82, $p<0.001$), especially during the active treatment phase of the study. Higher fatigue was reported in the palbociclib compared to placebo arm (mean [SD]: 30.3 [23.8] vs. 28.3 [22.7]; $p<0.001$). In contrast, no statistically significant differences were observed among the FA13 physical, cognitive, and emotional fatigue subscales.

Conclusions

In general, patient-reported QoL and fatigue was maintained during the study in both treatment arms. Statistically significant differences were observed between treatments in favor of the placebo arm; however, none were clinically relevant.

Clinical trial identification

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Legal entity responsible for the study

German Breast Group.

Funding

Pfizer Inc.

Disclosure

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