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Real-world effectiveness of 1st line palbociclib + endocrine therapy and subsequent treatments in patients with HR+/HER2- advanced breast cancer: Interim results from the PERFORM study

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Background

CDK4/6 inhibition (CDK4/6i) plus endocrine therapy (ET) is the first-line (1L) standard of care for patients (pts) with HR+/HER2- advanced breast cancer (ABC). Real-world (RW) evidence is an important complement to clinical trials. Today, the evolving therapeutic landscape raises questions about optimal treatment post CDK4/6i + ET failure. The PERFORM study can help to address these gaps by providing RW data on 1L palbociclib + ET and subsequent treatments.

Methods

PERFORM is a German/Austrian prospective non-interventional study of pts with HR+/HER2- ABC treated with 1L palbociclib + ET. Primary endpoint is progression-free survival (PFS) in 1L. Secondary endpoints include second line (2L) PFS, time to next treatment and chemotherapy (TTNT, TTC) and overall survival (OS). Tumor assessments follow local medical standards. Pts characteristics, treatment patterns, and outcomes in 1L and 2L were analyzed. Time-to-event endpoints were estimated with the Kaplan-Meier method.

Results

At database cutoff (Sep 30th 2024), 1,171 pts were included in interim analysis 4; of these, 683 stopped 1L treatment (due to progression 428, (S)AE 110; 56 pts LTFU, 34 pts informed consent withdrawal, other 55). 402 pts had documented 2L treatment. Median 1L PFS was 25.7 mos [95% CI: 22.8, 28.9] with a median FU of 27.0 mos. The OS rate at 12 and 24 mos was 90.3% and 78.4%, respectively. Median OS was not reached (23.2% events). Patients already in 2L (n=402) received chemotherapy (47.5%), further CDK4/6i based therapy (19.4%), other ET combination therapy (17.2%), ET monotherapy (12.9%), or other therapies (3%). Median 2L PFS (13.9 mos median FU) was 6.3 mos [95% CI: 5.3, 8.1].

Conclusions

PERFORM highlights the real-world effectiveness of 1L palbociclib + ET in HR+/HER2- ABC, with PFS outcomes consistent with clinical trial data and demonstrates the variability of options in 2L. These are interim results; additional follow-up is needed for mature 2L and time to subsequent treatment data. However, these data and future in depth (interim) analyses will provide valuable insights for optimizing 2L treatment in routine clinical practice.

Clinical trial identification

NCT04767594.

Legal entity responsible for the study

Pfizer Pharma GmbH, Germany.

Funding

Pfizer Pharma GmbH, Germany.

Disclosure

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