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Pooled analysis of patient (pt)-reported quality of life (QOL) in the MONALEESA (ML)-2, -3, and -7 trials of ribociclib (RIB) plus endocrine therapy (ET) to treat hormone receptor–positive, HER2-negative (HR+/HER2–) advanced breast cancer (ABC)

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Background

Pt-reported QOL results have been presented separately for each phase III ML trial, which tested efficacy and safety of RIB with different ET combination partners as first- or second-line treatment for HR+/HER2– ABC. Pooling the ML trial data enables a robust analysis of QOL that includes pre- and postmenopausal pts receiving different ET combination partners.

Methods

Health-related QOL and pain were evaluated using EORTC QLQ-C30 questionnaires. QOL was assessed for all pts in ML-2, pts receiving treatment as initial ET for ML-3, and pts receiving RIB or placebo (PBO) plus a nonsteroidal aromatase inhibitor as ET for ML-7. A linear effects model was used to determine least squares (LS) mean change from baseline (BL) in pain and global health status (GHS).

Results

QOL was assessed in 1528 pts from the ML trials. Time to definitive deterioration (TTDD) ≥ 10% for GHS, pain, and emotional functioning was delayed with RIB. Median TTDD ≥ 10% for GHS was 39.6 mo for RIB and 33.1 mo for PBO (hazard ratio [HR], 0.79 [95% CI, 0.66-0.94]). Median TTDD ≥ 10% for pain was not reached for RIB or PBO (HR, 0.77 [95% CI, 0.61-0.97]). Median TTDD ≥ 10% for emotional functioning was 46.9 mo for RIB and 35.9 mo for PBO (HR, 0.71 [95% CI, 0.59-0.85]). HRs for TTDD ≥ 10% for social and physical functioning and fatigue favored RIB but had wide 95% CIs (will be reported in detail at the congress). GHS/QOL was maintained from BL during treatment, but decreased at end of treatment (EOT) in both arms (LS mean change from BL at cycle 3 and EOT for RIB vs. PBO: +2.9 vs. +4.8 points and –3.7 vs. –2.7 points, respectively). Pain was improved from BL to cycle 3, maintained throughout treatment, and worsened at EOT (LS mean change from BL at cycle 3 and EOT for RIB vs. PBO: –4.3 vs. –3.2 points and +1.0 vs. +1.6 points, respectively).

Conclusions

In pts receiving first-line ET across the ML trials, RIB delayed deterioration in QOL. TTDD for GHS, pain, and emotional functioning scores was longer with RIB vs. PBO. Overall, this large, robust analysis demonstrated favorable QOL results with the addition of RIB to ET in patients with HR+/HER2– ABC.

Clinical trial identification

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