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BREAST CANCER, METASTATIC

2900 Patient-reported outcomes (PROs) in advanced breast cancer (ABC) treated with ribociclib + fulvestrant: Results from MONALEESA-3

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Background: In the MONALEESA-3 trial (NCT02422615), ribociclib + fulvestrant significantly improved progression-free survival (PFS) vs placebo + fulvestrant in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative BC who had received no or only 1 line of prior endocrine therapy for ABC. Here, we present PROs from the trial, including health-related quality of life (HRQoL).

Methods: Patients were randomized (2:1) to receive ribociclib (600 mg/day, 3-weeks-on/1-week-off) + fulvestrant (500 mg on Day 1 of every cycle and Cycle 1 Day 15; n = 484) or placebo + fulvestrant (n = 242). Time to definitive 10% deterioration from baseline (TTD) in HRQoL (global health status/quality of life scale score of the EORTC QLQ-C30 questionnaire [GHS/QLS]) and pain (BPI-SF questionnaire) were compared between treatment arms using a stratified log-rank test; a stratified Cox regression was used to estimate the hazard ratio with 95% confidence intervals (CI). PROs were also assessed using the EQ-5D-5L questionnaire.

Results: Questionnaire compliance rates were high (>90% at baseline for each measure). Mean GHS/QLS was maintained or improved during every cycle of treatment in both arms (mean change from baseline up to Cycle 19 [n ≥ 50 in both arms]: ribociclib + fulvestrant 3.6–4.9; placebo + fulvestrant 1.3–4.3). At the end of treatment, addition of ribociclib to fulvestrant had not negatively impacted GHS/QLS (mean change from baseline: −5.2 points in the ribociclib arm [n = 184] vs −5.5 points in the placebo arm [n = 113]). Median TTD in GHS/QLS was not reached (NR) in the ribociclib arm (95% CI 22.1–NR) vs 19.4 months in the placebo arm (95% CI 16.6–NR); hazard ratio: 0.80 (95% CI 0.60–1.05). Using the BPI-SF scale, median TTD was 25.4 months in the ribociclib arm vs NR in the placebo arm for worst pain (hazard ratio: 0.81; 95% CI 0.58–1.11), 25.4 months vs NR for pain severity index (hazard ratio: 0.81; 95% CI 0.60–1.11), and NR vs NR for pain interference index (hazard ratio: 0.87; 95% CI 0.63–1.21).

Conclusions: As well as significantly prolonging PFS compared with placebo + fulvestrant, adding ribociclib to fulvestrant maintains quality of life.

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