Abemaciclib as initial therapy for advanced breast cancer: MONARCH 3 updated results in prognostic subgroups

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In MONARCH 3, continuous dosing of abemaciclib with an aromatase inhibitor (AI) conferred significant clinical benefit to postmenopausal women with HR+, HER2- advanced breast cancer. We report data for clinically prognostic subgroups: liver metastases, progesterone receptor status, tumor grade, bone-only disease, ECOG performance status, and treatment-free interval (TFI) from an additional 12-month follow-up (after final progression-free survival [PFS] readout). In the intent-to-treat population, after median follow-up of approximately 39 months, the updated PFS was 28.2 versus 14.8 months (hazard ratio [HR], 0.525; 95% confidence interval, 0.415-0.665) in abemaciclib versus placebo arms, respectively. Time to chemotherapy (HR, 0.513), time to second disease progression (HR, 0.637), and duration of response (HR, 0.466) were also statistically significantly prolonged with the addition of abemaciclib to AI. Treatment benefit was observed across all subgroups, as evidenced by objective response rate change from the addition of abemaciclib to AI, with the largest effects observed in patients with liver metastases, progesterone receptor-negative tumors, high-grade tumors, or TFI < 36 months. Extended follow-up in the MONARCH 3 trial further confirmed that the addition of abemaciclib to AI conferred significant treatment benefit to all subgroups, including those with poorer prognosis.

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