

Abemaciclib Plus AI in Postmenopausal Patients With Advanced Breast Cancer: Final Overall Survival Analysis From MONARCH 3

By The ASCO Post Staff

Posted: 12/8/2023 11:28:00 AM

Last Updated: 12/8/2023 12:27:52 PM



Final overall survival results from the MONARCH 3 trial were reported in a late-breaking presentation during the 2023 San Antonio Breast Cancer Symposium (Abstract GS01-12). MONARCH 3 evaluated abemaciclib in combination with an aromatase inhibitor (AI) compared with an AI alone as initial endocrine-based therapy for postmenopausal patients with hormone receptor–positive, HER2-negative advanced or metastatic breast cancer. At 8 years of follow-up, MONARCH 3 showed women taking abemaciclib and an AI had a median overall survival of more than 5.5 years—an increase of 13.1 months compared with the control arm in the intent-to-treat (ITT) population (66.8 vs 53.7 months)—although statistical significance for the overall survival outcome was not reached (hazard ratio [HR] = 0.804, 95% confidence interval [CI] = 0.637–1.015, $P = .0664$).

For women with visceral organ metastases, data showed a median overall survival of more than 5 years, with an increase in median overall survival of 14.9 months in the abemaciclib arm compared with the control arm (63.7 vs 48.8 months). This result included those women whose breast cancer had spread to the liver or lungs. The overall survival results for this subpopulation were also not statistically significant (HR = 0.758, 95% CI = 0.558–1.030, $P = .0757$).

Stephen R.D.
Johnston, MD, PhD

“At 8 years of follow-up, when the natural history of metastatic breast cancer starts to substantially impact patient survival, it is highly encouraging to see abemaciclib combined with AI therapy deliver a meaningful survival difference of 13 months in the ITT population and more than 14 months in women at even higher risk due to visceral disease,” said **Stephen R.D. Johnston, MD, PhD**, Professor of Breast Cancer Medicine and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust and

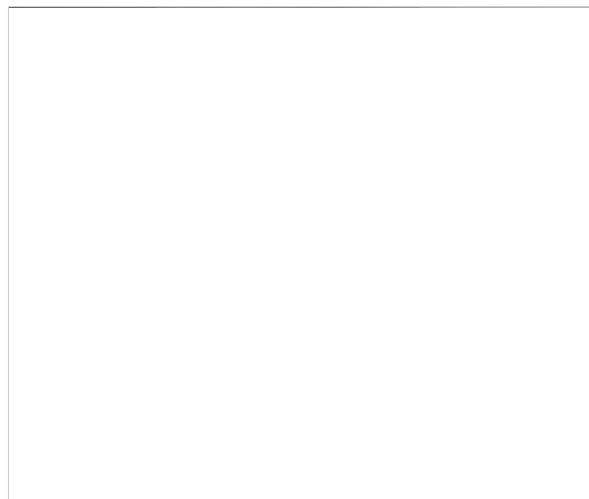


an investigator on the MONARCH 3 trial. “Despite missing statistical significance, these data are clinically relevant and highly consistent with the overall body of evidence for abemaciclib in advanced or metastatic breast cancer.”

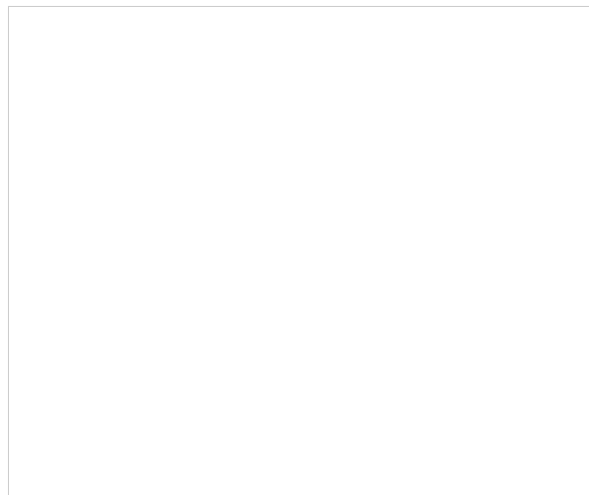
The median progression free survival benefit—the primary endpoint of the MONARCH 3 study—was maintained (29.0 vs 14.8 months; HR = 0.535, 95% CI = 0.429–0.668, nominal $P < .0001$), with a substantial difference in 6-year progression-free survival rates (23.3% in the abemaciclib arm vs 4.3% in the control arm). Progression-free survival statistical significance was achieved in an interim analysis in 2017, leading to regulatory approvals for this indication in 2018. No new safety signals were observed with longer-term use.

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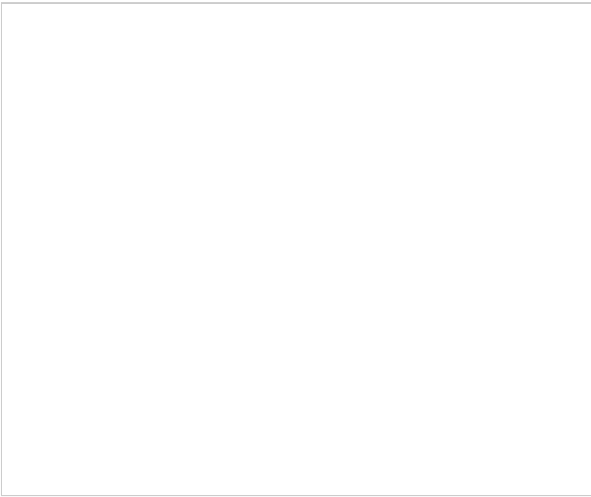
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