FDA Approves Verzenio as Initial Therapy for Metastatic Breast Cancer

Abemaciclib approved for first-line treatment of HR-positive, HER2-negative breast cancer that has spread.

February 26, 2018 By Food and Drug Administration (FDA)

FDA approves abemaciclib as initial therapy for HR-positive, HER2-negative metastatic breast cancer

On February 26, 2018, the Food and Drug Administration approved abemaciclib (Verzenio™, Eli Lilly and Company) in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Approval was based on MONARCH 3, a randomized (2:1), double-blinded, placebo-controlled, multicenter clinical trial in postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer. A total of 493 patients were randomized to receive either abemaciclib 150 mg or placebo orally twice daily, plus physician's choice of letrozole or anastrozole. The estimated median progression-free survival (PFS) (RECIST 1.1) was 28.2 months (95% CI: 23.5, Not reached) for patients receiving abemaciclib and 14.8 months (95% CI: 11.2, 19.2) for those receiving placebo (HR 0.540; 95% CI: 0.418, 0.698; $p<0.0001$).

The most common adverse reactions in at least 20% of patients receiving abemaciclib in MONARCH 3 and more than 2% higher than the placebo arm were diarrhea, neutropenia, fatigue, infections, nausea, abdominal pain, anemia, vomiting, alopecia, decreased appetite, and leukopenia.

The recommended starting dose of abemaciclib in combination with an aromatase inhibitor is 150 mg twice daily orally with or without food.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208855s000lbl.pdf.

FDA granted this application priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: FDA approves abemaciclib as initial therapy for HR-positive, HER2-negative metastatic breast cancerhttp://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/

ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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