FDA expands indication for use of abemaciclib with early, high-risk breast cancer

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Abemaciclib (Verzenio) with endocrine therapy (tamoxifen or an aromatase inhibitor) is now approved for the adjuvant treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk for recurrence, the U.S. Food and Drug Administration announced on March 3.

This priority approval expands the indication by removing the Ki-67 testing requirement to identify high-risk patients (defined as having either at least four pathologic axillary lymph nodes or one to three pathologic axillary lymph nodes and either tumor grade 3 or a tumor size ≥50 mm).

This approval was based on a randomized trial of two years of abemaciclib plus physician's choice of standard endocrine therapy (tamoxifen or an aromatase inhibitor) or standard endocrine therapy alone. The study showed a statistically significant difference in the intent-to-treat population for invasive disease-free survival (hazard ratio, 0.653). At 48 months, invasive disease-free survival was 85.5 percent for abemaciclib plus standard endocrine therapy and 78.6 percent for standard endocrine therapy alone.

Diarrhea, infections, neutropenia, fatigue, leukopenia, nausea, anemia, and headache were the most common adverse reactions (≥20 percent).

The expanded approval of abemaciclib was granted to Eli Lilly.

More information: FDA expanded approval

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