

Verzenio[™] (abemaciclib) – New drug approval

- On September 28, 2017, the [FDA announced](#) the approval of Eli Lilly's [Verzenio \(abemaciclib\)](#), for use in combination with [Faslodex[®] \(fulvestrant\)](#) for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
- Breast cancer is the most common form of cancer in the U.S. According to the [National Cancer Institute](#), an estimated 252,710 women will be diagnosed with breast cancer in 2017, and 40,610 will die of the disease.
 - Approximately 72% of breast cancer patients have tumors that are HR-positive and HER2-negative.
- Verzenio is a cyclin-dependent kinase-4 and -6 (CKD-4/6) inhibitor. CDK-4/6 are enzymes involved in the growth promotion of cancer cells.
 - Related products include [Ibrance[®] \(palbociclib\)](#) and [Kisqali[®] \(ribociclib\)](#). Both Ibrance and Kisqali are indicated in HR-positive, HER2-negative advanced or metastatic breast cancer in combination with other agents.
- The safety and efficacy of Verzenio in combination with fulvestrant were studied in 669 patients with HR-positive, HER2-negative breast cancer that had progressed after prior therapy. The primary endpoint was progression-free survival (PFS).
 - The median PFS was 16.4 months for patients taking Verzenio and fulvestrant vs. 9.3 months for patients taking placebo and fulvestrant (p < 0.0001).
- The safety and efficacy of Verzenio as monotherapy treatment were studied in a single-arm trial involving 132 patients with HR-positive, HER2-negative breast cancer that had progressed after prior therapy. The primary endpoint was the objective response rate (ORR).
 - Based on an independent review, the ORR was 17.4% (95% CI: 11.4, 25.0) for a median of 7.2 months.
 - The investigator-assessed ORR was 19.7% (95% CI: 13.3, 27.5) for a median of 8.6 months.
- Warnings and precautions of Verzenio include diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Verzenio use were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, and thrombocytopenia.
- The recommended dosage of Verzenio in combination with fulvestrant is 150 mg orally twice daily. When used as monotherapy, the recommended dose of Verzenio is 200 mg orally twice daily.
 - Treatment should be continued until disease progression or unacceptable toxicity.
 - Refer to the Verzenio drug label for the appropriate dosing of fulvestrant.

- Eli Lilly's launch plans for Verzenio are pending. Verzenio will be available as 50 mg, 100 mg, 150 mg, and 200 mg tablets.



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