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.

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