Verzenio® (abemaciclib) – New indication, expanded indication

- On October 13, 2021, Eli Lilly announced the FDA approval of Verzenio (abemaciclib), in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥ 20% as determined by an FDA approved test.

- Verzenio is also approved for various uses in advanced or metastatic breast cancer.

- Concurrent with the new indication approval, the FDA also has expanded the use of Verzenio in all indications, when given in combination with endocrine therapy, to include men.

- It is estimated that 90% of all breast cancers are detected at an early stage. Although the prognosis for HR+, HER2- early breast cancer is generally positive, 20% of patients will experience recurrence potentially to incurable metastatic disease. Risk of recurrence is greatest within the initial two to three years post-diagnosis, particularly in patients with node-positive, high risk early breast cancer.

    — One factor associated with high risk of recurrence includes high rate of cellular proliferation (Ki-67 score ≥ 20%).

- The approval of Verzenio for the new indication was based on monarchE, a randomized, open-label, two cohort study in adult women and men with HR-positive, HER2-negative, node-positive, resected, early breast cancer with clinical and pathological features consistent with a high risk of disease recurrence. Cohort 1 included 2,003 patients with a Ki-67 score ≥ 20%. Additionally, cohort 1 included patients with ≥ 4 positive axillary lymph nodes (ALN), or 1 to 3 positive ALN and either Grade 3 disease or tumor size ≥ 5 cm. Patients were randomized to receive 2 years of Verzenio plus physician's choice of standard endocrine therapy or standard endocrine therapy alone. The primary endpoint was invasive disease–free survival (IDFS). IDFS was defined as the time from randomization to the first occurrence of: ipsilateral invasive breast tumor recurrence, regional invasive breast cancer recurrence, distant recurrence, contralateral invasive breast cancer, second primary non-breast invasive cancer, or death attributable to any cause.

    — An IDFS event occurred in 10.2% of patients in the Verzenio combination arm vs. 16.0% for the standard endocrine therapy arm (hazard ratio 0.626, 95% CI: 0.488, 0.803; p = 0.0042).

- When used in combination with tamoxifen or an aromatase inhibitor, the recommended dose of Verzenio in early breast cancer is 150 mg taken orally twice daily. For early breast cancer, Verzenio should be continued until completion of 2 years of treatment or until disease recurrence, or unacceptable toxicity.

    — Patients should be selected for treatment of early breast cancer with Verzenio in combination with endocrine therapy based on a Ki-67 score ≥ 20% in tumor specimens. Information on FDA-approved tests for the measurement of Ki-67 score is available at http://www.fda.gov/CompanionDiagnostics.
    — Refer to the tamoxifen or aromatase inhibitor drug labels for the recommended dose of the product being used.

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— Refer to the Verzenio drug label for additional dosing recommendations in metastatic or advanced breast cancer.

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