Verzenio® (abemaciclib) – Expanded indication

- On March 3, 2023, 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.
    - This expanded adjuvant indication removes the previous Ki-67 score requirement for patient selection.
- The approval of Verzenio for the expanded indication was based on updated data from 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. Patients were randomized to receive 2 years of Verzenio plus physician's choice of standard endocrine therapy or standard endocrine therapy alone. The major efficacy outcome measure was invasive disease–free survival (IDFS).
    - At four years, 85.5% of patients remained recurrence-free with Verzenio plus endocrine therapy vs. 78.6% with endocrine therapy alone. The addition of Verzenio reduced the risk of recurrence by 35% compared to endocrine therapy alone (hazard ratio 0.653, 95% CI: 0.567, 0.753).
- In addition to the expanded indication for early breast cancer, the FDA also approved an expanded indication for Verzenio in metastatic breast cancer (MBC). Verzenio is now approved in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or MBC.
    - This updated MBC indication now includes all adult patients, with the expanded indication including pre-/perimenopausal women. Verzenio was previously approved for this use in postmenopausal women and men only.
- In addition to the expanded indications, Verzenio is also approved:
    - In combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or MBC with disease progression following endocrine therapy;
    - As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or MBC with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
- When used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, the recommended dose of Verzenio is 150 mg taken orally twice daily. When used as monotherapy, the recommended dose of Verzenio is 200 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.
    - For advanced or MBC, Verzenio treatment should be continued until disease progression or unacceptable toxicity.