Verzenio™ (abemaciclib) – Expanded indication

- On February 26, 2018, Eli Lilly announced the FDA approval of Verzenio (abemaciclib) tablets, for use in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

    — Previously, Verzenio was only approved for use in combination with Faslodex® (fulvestrant) for the treatment of women with HR-positive, 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.

- The expanded indication approval for Verzenio was based on the MONARCH 3 study, a placebo-controlled trial involving 493 postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer. Patients were randomized to receive an aromatase inhibitor plus either Verzenio or placebo. The primary endpoint was progression-free survival (PFS).

    — The median PFS in the Verzenio arm was 28.2 months vs. 14.8 months in the placebo arm (HR = 0.540 [95% CI: 0.418, 0.698, p < 0.0001]).
    — At the time of analysis, the overall survival data were immature and could not be reported.

- The recommended dose of Verzenio when used in combination with an aromatase inhibitor (or with Faslodex) is 150 mg orally twice daily until disease progression or unacceptable toxicity.

- The recommended dose of Verzenio when used as monotherapy is 200 mg orally twice daily until disease progression or unacceptable toxicity.