Ibrance® (palbociclib) – New formulation approval

- On November 1, 2019, the FDA approved an oral tablet formulation of Pfizer's Ibrance (palbociclib), for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
    - An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or
    - Fulvestrant in patients with disease progression following endocrine therapy.
- Ibrance was previously approved as a capsule formulation. The tablets and capsules share the same indication.
    - Ibrance tablets can be taken orally with or without food whereas the capsules had to be taken with food.
- Warnings and precautions of Ibrance include neutropenia, interstitial lung disease/pneumonitis, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 10%) with Ibrance use were neutropenia, infections, leukopenia, fatigue, nausea, stomatitis, anemia, alopecia, diarrhea, thrombocytopenia, rash, vomiting, decreased appetite, asthenia, and pyrexia.
- The recommended dosage of Ibrance is 125 mg taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days.
    - Refer to the drug labels for the aromatase inhibitor used or fulvestrant for additional dosing recommendations for those products.
- Pfizer's launch plans for the tablet formulation are pending. The new formulation will be available as 75 mg, 100 mg, and 125 mg tablets.