Ibrance® (palbociclib) – Updated label

- On December 13, 2022, the FDA approved 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.
    - Ibrance was previously approved for this use in postmenopausal women or in men. The indication was updated to include pre-/perimenopausal women.
- Ibrance is also approved for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with fulvestrant in patients with disease progression following endocrine therapy.
- The recommended dose of Ibrance is a 125 mg tablet or capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days.
- Pre/perimenopausal women treated with the combination Ibrance plus an aromatase inhibitor or fulvestrant therapy should also be treated with luteinizing hormone-releasing hormone agonists according to current clinical practice standards.