Ibrance® (palbociclib) – Expanded indications

- On April 4, 2019, the FDA announced the approval of Pfizer's Ibrance (palbociclib), for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or men; or in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy.
    - Previously, the first indication was approved only in postmenopausal women and the second indication was approved only in women.
- Breast cancer is rare in males with 2,670 cases of male breast cancer estimated in 2019. The majority of breast tumors in male patients express HRs. Men are more likely to be diagnosed at an older age, with a more advanced stage of disease.
- The expanded indications for breast cancer in men are based on limited data from post-marketing reports and real-world data from electronic health records showing the safety profile for men treated with Ibrance is consistent with the safety profile in women treated with Ibrance.
- The recommended dose of Ibrance is a 125 mg capsule taken orally once daily with food for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days.
    - For men treated with combination Ibrance plus aromatase inhibitor therapy, consider treatment with a luteinizing hormone-releasing hormone agonist according to current clinical practice standards.
    - Refer to prescribing information for Faslodex and specific aromatase inhibitors for further dosing recommendations.