Ibrance® (palbociclib) – Expanded indication, label update

- On March 31, 2017, Pfizer announced the FDA approval of Ibrance (palbociclib) for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor (AI) as initial endocrine based therapy in postmenopausal women.
    - Previously, Ibrance was only approved for use in combination with Femara® (letrozole) for this indication.
    - The FDA approval broadens the range of anti-hormonal therapy that may be administered with Ibrance.
- Ibrance is also approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with Faslodex® (fulvestrant) in women with disease progression following endocrine therapy.
- The expanded indication is based on data from a placebo-controlled clinical study (PALOMA-2) of 666 women with estrogen-receptor positive, HER2-negative breast cancer, who had not received prior treatment for advanced disease. The primary end point was progression-free survival (PFS).
    - The median PFS was 24.8 months in the Ibrance-Femara group vs. 14.5 months in the Ibrance-placebo group (hazard ratio for disease progression or death = 0.58; 95% CI, 0.46 to 0.72; $p < 0.001$).
- The recommended dose of Ibrance is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete 28 day cycle.
    - The recommended dose of an AI should be administered with Ibrance. Refer to the drug label for dosing information for the AI being used.
- Additionally, pulmonary embolism was removed from the *Warnings and Precautions* section of the Ibrance drug label.