Faslodex® (fulvestrant) – Expanded indication

- On August 28, 2107, AstraZeneca announced the FDA approval of Faslodex (fulvestrant) injection, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
    - Faslodex is also approved for HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy; and treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with Ibrance® (palbociclib) in women with disease progression after endocrine therapy.
- The expanded indication approval for Faslodex was based on the FALCON trial, which compared Faslodex to Arimidex® (anastrozole) in 462 postmenopausal women with HR-positive, metastatic or locally advanced breast cancer. The primary endpoint was progression-free survival (PFS).
    - A statistically significant increase in median PFS was shown with Faslodex vs. Arimidex (16.6 months vs. 13.8 months), representing a 20% reduction in the risk of disease progression or death (HR = 0.797 [95% CI: 0.637, 0.999], p = 0.049).
- The recommended dose of Faslodex is 500 mg intramuscularly on days 1, 15, 29, and once monthly thereafter.
- Refer to the Faslodex drug label for the dosing of Ibrance when used in combination with Faslodex.