Kisqali® (ribociclib) – Updated indication

- On July 22, 2024, the FDA approved Novartis' Kisqali (ribociclib), for treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy or with disease progression following endocrine therapy.
    - Kisqali was previously approved for this indication in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy *in postmenopausal women or in men*.
- Kisqali is also approved for treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy.
- The recommended dose of Kisqali is 600 mg (three 200 mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.
    - When given with Kisqali, the recommended dose of fulvestrant is 500 mg administered on days 1, 15, 29, and once monthly thereafter.
    - Refer to the Kisqali drug label for complete dosing and administration recommendations.