## Kisqali® (ribociclib) – New indication

- On September 17, 2024, Novartis announced the FDA approval of Kisqali (ribociclib), in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

- Kisqali is also approved for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with:

    - An aromatase inhibitor as initial endocrine-based therapy; or
    - Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

- The approval of Kisqali for the new indication was based on NATALEE, a randomized, open-label study in 5,101 adults with HR-positive, HER2-negative early breast cancer. Patients were randomized to receive Kisqali plus a non-steroidal aromatase inhibitor (letrozole or anastrozole) or non-steroidal aromatase inhibitor only, and goserelin as indicated. The main efficacy measure was invasive disease-free survival (iDFS). iDFS was defined as the time from randomization to the first occurrence of: local invasive breast recurrence, regional invasive recurrence, distant recurrence, death (any cause), contralateral invasive breast cancer, or second primary non-breast invasive cancer (excluding basal and squamous cell carcinomas of the skin). Overall survival (OS) was an additional outcome measure.

    - The iDFS at 36 months was 90.7% in the Kisqali arm vs. 87.6% in the comparator arm (hazard ratio 0.749, 95% CI: 0.628, 0.892).
    - At the time of the iDFS final analysis, OS was immature, and a total of 172 (3.5%) of patients had died across both study arms.

- The most common adverse reactions (≥ 20%) with Kisqali use in patients with early breast cancer, including laboratory abnormalities, were decreased lymphocytes, decreased leukocytes, decreased neutrophils, decreased hemoglobin, increased alanine aminotransferase, increased aspartate aminotransferase, infections, increased creatinine, decreased platelets, headache, nausea, and fatigue.

- The recommended dose of Kisqali for early breast cancer is 400 mg (two 200 mg film-coated tablets) orally once daily for 21 consecutive days followed by 7 days off in 28-day treatment cycles. Kisqali should be given in combination with an aromatase inhibitor. In patients with early breast cancer, treatment with Kisqali should continue for 3 years or until disease recurrence or unacceptable toxicity occurs.

- Refer to the Kisqali drug label for dosing for advanced or metastatic breast cancer.