Kisqali® (ribociclib), Kisqali Femara® Co-Pack – Expanded indication

- On December 10, 2021, the FDA approved Novartis' Kisqali (ribociclib), for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (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 in postmenopausal women or in men.

- Kisqali was previously approved in combination with:
    - An aromatase inhibitor for the treatment of *pre/perimenopausal or postmenopausal women* with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or
    - Fulvestrant for the treatment of *postmenopausal women* with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

- The approval of Kisqali for the expanded indication was based on COMPLEEMENT-1, an open-label study in 39 men with HR-positive, HER2-negative, advanced breast cancer who received no prior hormonal therapy for advanced disease. Patients received Kisqali in combination with letrozole and either goserelin or leuprolide. Patients were treated until disease progression or unacceptable toxicity occurred. Overall response rate (ORR) and duration of response (DOR) were assessed.
    - The ORR was 46.9% (95% CI: 29.1, 65.3).
    - The median DOR was not reached (95% CI: 21.3, not reached).

- The indication for Kisqali Femara Co-Pack, which co-packages ribociclib and letrozole, was also updated as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer.

- 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.
    - Pre/perimenopausal women, or men, treated with the combination Kisqali plus an aromatase inhibitor should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards.
    - Men treated with the combination of Kisqali plus fulvestrant should be treated with a LHRH agonist according to current clinical practice standards.

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