Kisqali ® (ribociclib) – Expanded indications and new warning

- On July 18, 2018, the FDA announced the approval of Novartis' Kisqali (ribociclib), for the following indications:
    - In combination with an aromatase inhibitor (AI) for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.
    - In combination with Faslodex® (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.

- Previously, Kisqali was only approved for use in combination with an AI for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer as initial endocrine therapy.

- This is the first approval that the FDA has granted using the Real-Time Oncology Review Pilot Program and the Assessment Aid Pilot Project, two new pilot programs that collectively aim to make the development and review of cancer drugs more efficient, while improving FDA's rigorous standard for evaluating efficacy and safety.
    - The Real-Time Oncology Review program allows the FDA to start evaluating clinical data as soon as the trial results become available, enabling the FDA review team to be in a better position to conduct a more efficient, timely, and thorough review once the sponsor submits the formal application.
    - The Assessment Aid is a new template that the applicant uses to organize its submission to facilitate and streamline the FDA's review of the application.
    - Currently these two programs are only being used for supplemental applications for already approved cancer drugs, but may later be expanded to original drugs and biologics.

- The expanded indications for Kisqali were based on safety and efficacy data from the MONALEESA-7 and MONALEESA-3 clinical studies, in women with HR-positive, HER2-negative advanced breast cancer. MONALEESA-7 included 495 pre/perimenopausal women who were randomized to receive either Kisqali or placebo. Patients also received goserelin and either an AI or tamoxifen. MONALEESA-3 included 726 postmenopausal women who were randomized to receive either Kisqali plus fulvestrant or placebo plus fulvestrant. The primary endpoint in both studies was progression-free survival (PFS).
    - In MONALEESA-7, the median PFS was 27.5 months for patients who received Kisqali vs.13.8 months with placebo (HR = 0.569 [95% CI: 0.436, 0.743]).
    - In MONALEESA-3, the median PFS was 20.5 months for patients who received Kisqali vs. 12.8 months with placebo (HR = 0.593 [95% CI: 0.480, 0.732]; $p < 0.0001$).
    - In both studies, overall survival data were not mature at the time of final PFS analysis.

- In addition, a new warning has been added to the Kisqali drug label regarding QT prolongation with concomitant use of tamoxifen.

- The recommended dose of Kisqali for all indications is 600 mg (three 200 mg tablets) taken orally once daily, with or without food, for 21 consecutive days followed by 7 days off treatment in a complete cycle of 28 days.

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- The recommended dose of an AI or fulvestrant should be administered with Kisqali. Refer to the drug label for dosing information for the AI or fulvestrant being used.
- Dose interruption, reduction, and/or discontinuation may be required based on individual safety and tolerability.

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