Generic Name:
Ribociclib
Trade Name:
Kisqali
Company:
Novartis
Notes:

FDA approved ribociclib in combination with an aromatase inhibitor 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.

FDA also approved ribociclib in combination with 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.

This is the first approval that FDA has granted as part of two new pilot programs announced earlier this year 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. With this real-time review, FDA was able to start evaluating the clinical data as soon as the trial results become available, enabling FDA to be ready to approve the new indication upon filing of a formal application with the agency.

Currently the two pilot programs are being used for supplemental applications for already approved cancer drugs and could later be expanded to original drugs and biologics.

Ribociclib was first approved in March 2017 for use with an AI to treat HR-positive, HER2-negative breast cancer in postmenopausal women whose cancer is advanced or has spread to other parts of the body.

Medication Monitor Categories:
Supplemental Approvals