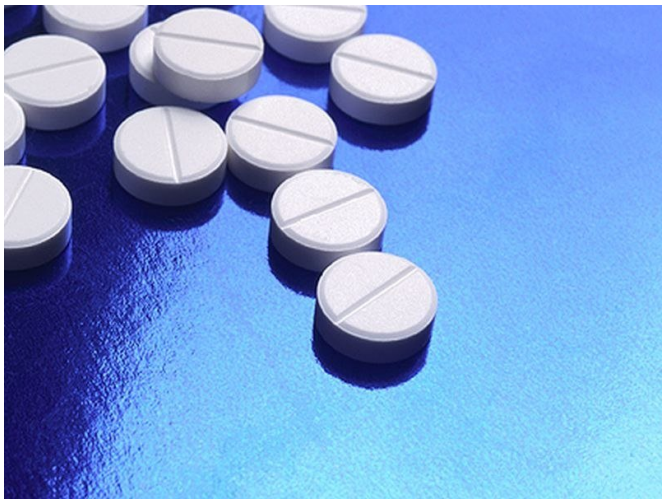
FDA grants first approval for CA drug under new pilot programs

24 July 2018



(HealthDay)—The U.S. Food and Drug Administration has approved ribociclib (Kisqali) in combination with an aromatase inhibitor (AI) as an initial endocrine-based therapy 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.

Ribociclib has also been approved with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy for postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer. This approval is the first that the FDA has granted as part of two new pilot programs that aim to make the development and review of cancer drugs more efficient and improve its standard for evaluating efficacy and safety.

The efficacy of ribociclib was demonstrated for pre/perimenopausal women in a clinical trial involving 495 participants who received ribociclib and an AI or placebo and an AI; progression-free survival was longer for patients taking ribociclib versus placebo (median, 27.5 versus 13.8 months). For treating advanced or metastatic breast cancer, a trial involving 726 participants who received ribociclib and fulvestrant or placebo and fulvestrant showed that the median progression-free survival was longer for those taking ribociclib (median, 20.5 versus 12.8 months, respectively). Common adverse effects of ribociclib include infections, neutropenia, leukopenia, headache, cough, nausea, fatigue, diarrhea, vomiting, and constipation.

"The approval adds a new treatment choice for patients with breast cancer," Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence, said in a statement.

More information: More Information