FDA Expands Kisqali Indication for Advanced or Metastatic Breast Cancer

Ribociclib now approved for pre- and perimenopausal women with HR-positive, HER2-negative breast cancer.

July 18, 2018 By Food and Drug Administration (FDA)

On July 18, 2018, the Food and Drug Administration expanded the indication for ribociclib (Kisqali, Novartis Pharmaceuticals Corporation) in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.

FDA also approved ribociclib in combination with fulvestrant for postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

Ribociclib was previously approved for postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine therapy.

The efficacy of ribociclib in combination with an aromatase inhibitor for pre/perimenopausal women was based on MONALEESA-7 (NCT02278120), a randomized, double-blind, placebo-controlled trial. Pre/perimenopausal women were randomized to ribociclib plus either a non-steroidal aromatase inhibitor (NSAI) or tamoxifen and goserelin versus placebo plus either an NSAI or tamoxifen and goserelin. Results from the pre-specified NSAI-only subgroup of 495 pre/peri-menopausal women with HR-positive, HER2-negative, advanced breast cancer who received no prior endocrine therapy for advanced disease showed an estimated median progression-free survival (PFS, RECIST 1.1) of 27.5 months for patients on the ribociclib arm compared with 13.8 months for those on the placebo arm (HR 0.569; 95% CI: 0.436, 0.743). Ribociclib is not indicated for concomitant use with tamoxifen.

The efficacy of ribociclib in combination with fulvestrant was demonstrated in MONALEESA-3 (NCT02422615), a randomized double-blind, placebo-controlled trial of ribociclib in combination with fulvestrant in 726 postmenopausal women with HR-positive, HER2-negative, advanced breast cancer who received no or only one line of prior endocrine treatment. The estimated median PFS was 20.5 months for patients taking ribociclib compared with 12.8 months for those who received placebo (HR 0.593; 95% CI: 0.480, 0.732; $p<0.0001$).

The most common adverse reactions in at least 20% of patients were neutropenia, nausea, infections, fatigue, diarrhea, leukopenia, vomiting, alopecia, headache, constipation, rash and cough.

The recommended starting ribociclib dose is 600 mg orally (three 200 mg tablets) once daily with or without food for 21 consecutive days followed by 7 days off treatment.

View full prescribing information for Kisqali.

This is the first FDA approval using the Real Time Oncology Review and the Assessment Aid, pilot programs that enabled the FDA review team to begin analyzing data before the application submission. The FDA was able to approve the application less than one month after it was submitted.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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