Straightforward monitoring with KISQALI

The majority of scheduled monitoring occurs **within the first 2 cycles of therapy**

There is **no scheduled monitoring** beyond Cycle 6

The 3 required ECGs all take place during the **first 30 days** of treatment

Use this checklist to help _____ start and stay on therapy with KISQALI.
Patient name

Take the following readings at the points of therapy noted below and mark the date in the space provided:

BASELINE
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes
- ☐ QTcF

CYCLE 1 Day 14
- ☐ CBC _____ Date
- ☐ LFT
- ☐ QTcF

CYCLE 2 Day 1
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes
- ☐ QTcF **(final scheduled)**

CYCLE 2 Day 14
- ☐ CBC _____ Date
- ☐ LFT

CYCLE 3 Day 1
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes

CYCLE 4 Day 1
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes

CYCLE 5 Day 1
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes

CYCLE 6 Day 1
- ☐ CBC _____ Date
- ☐ LFT
- ☐ Electrolytes

Additional monitoring may be required as clinically indicated.

CBC=complete blood count; ECG=electrocardiogram; LFT=liver function test; QTcF=QT interval corrected by Fridericia's formula.

Plan ahead and use this calendar as a guide to help you place monitoring orders in advance

Unable to perform ECGs in your office? Click here or scan to learn more about a simple solution for **fast**, **easy**, and **accurate** monitoring, or contact your Novartis representative.

Indications

KISQALI is indicated 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.

IMPORTANT SAFETY INFORMATION

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

Across clinical trials in patients with advanced or metastatic breast cancer treated with KISQALI in combination with an aromatase inhibitor or fulvestrant ("KISQALI treatment groups"), 1.6% of patients treated with KISQALI had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have been observed in the postmarketing setting, with fatalities reported.

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for KISQALI.

KISQALI® ribociclib 200 mg tablets

IMPORTANT SAFETY INFORMATION (continued)

Severe cutaneous adverse reactions (continued). If SCARs is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation. Across clinical trials in patients with advanced or metastatic breast cancer treated with KISQALI in combination with an aromatase inhibitor or fulvestrant ("KISQALI treatment groups"), 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms increase from baseline in QTcF intervals. In MONALEESA-2, on the KISQALI + letrozole treatment arm, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation.

Avoid the use of KISQALI in patients who already have or who are at significant risk of developing QT prolongation. Avoid using KISQALI with drugs known to prolong the QT interval and/or strong CYP3A inhibitors, as this may lead to prolongation of the QTcF interval.

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen.

Hepatobiliary toxicity. Across clinical trials in patients with advanced or metastatic breast cancer, increases in transaminases were observed. Across all trials, grade 3/4 increases in alanine aminotransferase (ALT) (11% vs 2.1%) and aspartate aminotransferase (AST) (8% vs 2%) were reported in the KISQALI and placebo arms, respectively.

In MONALEESA-2 and MONALEESA-3, concurrent elevations in ALT or AST greater than 3 times the upper limit of normal (ULN) and total bilirubin greater than 2 times the ULN, with normal alkaline phosphatase, in the absence of cholestasis occurred in 6 (1%) patients and all patients recovered after discontinuation of KISQALI. No cases occurred in MONALEESA-7.

Neutropenia. Across trials, neutropenia was the most frequently reported adverse reaction (AR) (75%), and a grade 3/4 decrease in neutrophil count (based on laboratory findings) was reported in 62% of patients in the KISQALI treatment groups. Febrile neutropenia was reported in 1.7% of patients in the KISQALI treatment groups. Treatment discontinuation due to neutropenia was 1%.

Embryo-fetal toxicity. Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose.

Adverse reactions. Most common (incidence ≥20%) ARs include infections, nausea, fatigue, diarrhea, vomiting, headache, constipation, alopecia, cough, rash, and back pain.

Laboratory abnormalities. Across clinical trials of patients with advanced or metastatic breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, AST increased, gamma-glutamyl transferase increased, ALT increased, creatinine increased, platelets decreased, and glucose serum decreased.**

Reference: Kisqali. Prescribing information. Novartis Pharmaceuticals Corp.

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