Start your patients on KISQALI with confidence

A guide to a seamless treatment journey

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.

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

KISQALI® ribociclib 200 mg tablets

Ensure patients start right away with only a few standard assessments

- Complete blood count (CBC)[1]
- Liver function tests (LFTs)[1,*]
- Electrolyte levels[1,†]
- Electrocardiogram (ECG)[1,‡]

Simple and straightforward ECG testing

- **Only 3 ECGs are required**—and all are completed within the first 30 days of treatment[1]
- If you are unable to perform ECGs in office, speak with your Novartis Oncology Specialist about a simple solution for fast, easy, and accurate ECG testing

Only 1.4% (15/1054) of patients taking KISQALI
had a >500 ms postbaseline QTcF value[1,§]

6% had a >60 ms increase from baseline in QTcF intervals (61/1054)[1,§]

*Monitor LFTs prior to the initiation of treatment, every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. For LFTs, if grade ≥2 abnormalities are noted, more frequent monitoring is recommended.[1]
†Monitor serum electrolytes prior to the initiation of treatment, at the beginning of the first 6 cycles, and as clinically indicated. Correct any electrolyte abnormalities before initiating treatment.[1]
‡KISQALI should only be initiated in patients with QTcF <450 ms.[1]
§In a pooled analysis across 3 phase III trials of 1054 pre- and postmenopausal patients treated with KISQALI + an AI or fulvestrant, there were no reported cases of torsades de pointes. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner. In MONALEESA-2, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation.[1]

IMPORTANT SAFETY INFORMATION (continued)

Interstitial lung disease/pneumonitis (continued). Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt treatment with KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with recurrent symptomatic or severe ILD/pneumonitis.

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.

If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

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KISQALI® ribociclib 200 mg tablets

Count on favorable access and strong financial support for your patients

Commercial insurance

- **$0** co-pay‖
- **Bridge Program** (up to **5 free** treatment cycles¶)
- **One free** treatment cycle voucher#

Government insurance

- **One free** treatment cycle voucher#

Patient Support Services

- Novartis Patient Navigator Program**
- Specialized support brought to you by Novartis Patient Support (NPS)

9 out of 10 patients have favorable coverage for KISQALI for all approved indications††

‖**Limitations apply.** This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Use of this offer for FEMARA (or generic letrozole) does not require a KISQALI prescription. Offer is NOT valid for purchases of FEMARA **only** by Massachusetts patients or California patients that do not meet additional eligibility criteria. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit CoPay.NovartisOncology.com or call 1-877-577-7756.

¶**Limitations apply.** Eligible patients must have commercial insurance, a completed Service Request Form, and be experiencing a delay in obtaining coverage for KISQALI. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. No purchase necessary. Participation is not a guarantee of insurance coverage. Once coverage is approved, patients will no longer be eligible. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this program without notice.

#Your patients are eligible to receive a 1-treatment-cycle supply of KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole **at no cost**. No purchase required of KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole. This offer is available for patients with a valid prescription for KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole, including patients who have not been prescribed KISQALI or another Novartis product. Please see your sales representative for vouchers. You can also visit **www.FreeTreatmentVoucher.com** or call **1-800-282-7630**.

**The Novartis Patient Navigator Program is available for select Novartis Oncology products. Patient Navigator services do not involve the practice of nursing or provide clinical advice and counseling.

††Unrestricted or single-step edit coverage from MMIT data as of July 2023.[2]

IMPORTANT SAFETY INFORMATION (continued)

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 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. These electrocardiogram (ECG) changes were reversible with dose interruption and most occurred within the first 4 weeks of treatment. No cases of torsades de pointes were reported. 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. No cases of sudden death were reported in MONALEESA-7 or MONALEESA-3.

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

KISQALI® ribociclib 200 mg tablets

Overall survival maintained regardless of dose adjustments

MONALEESA-2[3,4]:

- **Median OS was 66.0 months** (95% CI: 57.6-75.7) for patients with ≥1 dose reduction vs 60.6 months (95% CI: 42.5-79.2) for patients without dose reduction; HR=0.87 (95% CI: 0.65-1.18)
- 62.6% of patients (209/334) had ≥1 dose reduction

MONALEESA-7[5,6]:

- **Median OS was not reached** (95% CI: NR-NR) for patients with ≥1 dose reduction vs not reached (95% CI: NR-NR) for patients without dose reduction; HR=0.79 (95% CI: 0.46-1.36)
- 40.7% of patients (101/248) had ≥1 dose reduction

MONALEESA-3[6,7]:

- **Median OS was not reached** (95% CI: 43-NR) for patients with ≥1 dose reduction vs not reached (95% CI: 41.1-NR) for patients without dose reduction; HR=0.88 (95% CI: 0.64-1.21)
- 40.7% of patients (197/484) had ≥1 dose reduction

Results are based on a post hoc analysis; efficacy in the placebo comparator arms was not assessed.

MONALEESA-2 was a randomized, double-blind, placebo-controlled phase III study of KISQALI + letrozole (n=334) vs placebo + letrozole (n=334) in postmenopausal patients with HR+/HER2- mBC who received no prior therapy for advanced disease. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 80 months, median OS was 63.9 months with KISQALI + letrozole (95% CI: 52.4-71.0) vs 51.4 months with letrozole (95% CI: 47.2-59.7); HR=0.765 (95% CI: 0.628-0.932); *P*=0.004.[1,8-10]

MONALEESA-7 was a randomized, double-blind, placebo-controlled phase III study of KISQALI + ET (NSAI or tamoxifen) + goserelin vs placebo + ET (NSAI or tamoxifen) + goserelin (ITT) in premenopausal patients with HR+/HER2- mBC who received no prior ET for advanced disease. **KISQALI is not indicated for concomitant use with tamoxifen.** Efficacy results are from a prespecified subgroup analysis of 495 patients who received KISQALI (n=248) or placebo (n=247) with an NSAI + goserelin and were not powered to show statistical significance. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 35 months, statistical significance was established for overall survival in the ITT population; HR=0.71 (95% CI: 0.54-0.95); *P*=0.00973, with similar results observed in the NSAI subgroup. At a median follow-up of 35 months, median OS was not reached with KISQALI + NSAI + goserelin (95% CI: NR-NR) vs 40.7 months with placebo + NSAI + goserelin (95% CI: 37.4-NR); HR=0.699 (95% CI: 0.501-0.976).[1,11,12]

MONALEESA-3 was a randomized, double-blind, placebo-controlled phase III study of KISQALI + fulvestrant (n=484) vs placebo + fulvestrant (n=242) for the treatment of postmenopausal patients with HR+/HER2- mBC who have received no or only 1 line of prior ET for advanced disease. OS was a secondary end point; PFS was the primary end point. At a median follow-up of 39 months, statistical significance was established for overall survival in the ITT population; median OS was not reached with KISQALI + fulvestrant (95% CI: 42.5-NR) vs 40.0 months with placebo + fulvestrant (95% CI: 37.0-NR); HR=0.724 (95% CI: 0.568-0.924); *P*=0.00455.[1,13,14]

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation (continued). Assess ECG prior to initiation of treatment. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, at the beginning of the second cycle, and as clinically indicated. Monitor serum electrolytes (including potassium, calcium, phosphorus, and magnesium) prior to the initiation of treatment, at the beginning of each of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting therapy with KISQALI.

Avoid the use of KISQALI in patients who already have or who are at significant risk of developing QT prolongation, including patients with:

- long QT syndrome
- uncontrolled or significant cardiac disease including recent myocardial infarction, congestive heart failure, unstable angina, and bradyarrhythmias
- electrolyte abnormalities

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.

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

KISQALI® ribociclib 200 mg tablets

So you can manage adverse reactions with confidence

One tablet strength for simple dose reduction[1]

Recommended starting dose

3 

tablets (600 mg)

1st reduction

2 

tablets (400 mg)

2nd reduction

1 

tablet (200 mg)

KISQALI is given as 600 mg (3 x 200-mg tablets) orally once daily (3 weeks on, 1 week off) with either: an AI (an LHRH agonist should be administered according to current clinical practice guidelines for premenopausal patients and men), or fulvestrant 500 mg intramuscularly on Days 1, 15, and 29, and once monthly thereafter, in postmenopausal patients or men (an LHRH agonist should be administered according to current clinical practice guidelines for male patients). Dose adjustments for adverse reactions should be made stepwise by reducing the number of tablets taken. Dose modification is recommended based on individual safety and tolerability. If dose reduction below 200 mg/day is required, discontinue treatment. KISQALI can be taken with or without food.[1]

Adverse reactions which resulted in permanent discontinuation of KISQALI in ≥2% of patients were alanine aminotransferase increased, aspartate aminotransferase increased, and vomiting. Adverse reactions which required dose reductions in ≥2% of patients included neutropenia, neutrophils decreased, and alanine aminotransferase increased.[1]

6.5 months longer on therapy

In MONALEESA-2, managing adverse reactions with dose reductions helped patients stay on therapy an average of 6.5 months longer than those without dose reductions[4]

IMPORTANT SAFETY INFORMATION (continued)

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. In MONALEESA-7, the observed mean QTcF increase from baseline was ≥10 ms higher in the tamoxifen + placebo subgroup compared with the non-steroidal aromatase inhibitor (NSAI) + placebo subgroup. In the placebo arm, an increase of >60 ms from baseline occurred in 6/90 (7%) of patients receiving tamoxifen, and in no patients receiving an NSAI. An increase of >60 ms from baseline in the QTcF interval was observed in 14/87 (16%) of patients in the KISQALI and tamoxifen combination and in 18/245 (7%) of patients receiving KISQALI plus an NSAI.

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IMPORTANT SAFETY INFORMATION (continued)

Hepatobiliary toxicity. Across KISQALI treatment groups, 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.

Among the patients who had grade ≥3 ALT/AST elevation, the median time to onset was 92 days and median time to resolution to grade ≤2 was 21 days for the KISQALI treatment groups.

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.

Perform liver function tests (LFTs) before initiating therapy with KISQALI. Monitor LFTs every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation. Recommendations for patients who have elevated AST/ALT grade ≥3 at baseline have not been established.

Neutropenia. Across KISQALI treatment groups 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. Among the patients who had grade 2, 3, or 4 neutropenia, the median time to grade ≥2 was 17 days. The median time to resolution of grade ≥3 (to normalization or grade <3) was 12 days 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%.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction, or discontinuation.

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. In animal reproduction studies, administration of KISQALI to pregnant rats and rabbits during organogenesis caused embryo-fetal toxicities at maternal exposures that were 0.6 and 1.5 times the human clinical exposure, respectively, based on area under the curve. 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%) adverse reactions 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.**

AI=aromatase inhibitor; ET=endocrine therapy; HR=hazard ratio; ITT=intent to treat; LHRH=luteinizing hormone-releasing hormone; mBC=metastatic breast cancer; NR=not reached; NSAI=nonsteroidal aromatase inhibitor; OS=overall survival; PFS=progression-free survival; QTcF=QT interval corrected by Fridericia's formula.

References: 1. Kisqali. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. Kisqali MMIT data July 2023. Novartis Pharmaceuticals Corp; 2023. **3.** Data on file. ML2 OS by dose reduction. Novartis Pharmaceuticals Corp; 2021. **4.** Data on file. CLEE011A2301 additional analysis. Novartis Pharmaceuticals Corp; 2021. **5.** Data on file. CLEE011E2301 additional analysis. Novartis Pharmaceuticals Corp; 2020. **6.** Data on file. OS by dose reduction poster. Novartis Pharmaceuticals Corp; 2020. **7.** Data on file. CLEE011F2301 additional analysis. Novartis Pharmaceuticals Corp; 2020. **8.** Hortobagyi GN, Stemmer SM, Burris HA, et al. Overall survival with ribociclib plus letrozole in advanced breast cancer. *N Engl J Med*. 2022;386(10):942-950. doi:10.1056/NEJMoa2114663 **9.** Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. *N Engl J Med*. 2016;375(18):1738-1748. doi:10.1056/NEJMoa1609709 **10.** Data on file. CLEE011A2301. Novartis Pharmaceuticals Corp; 2021. **11.** Tripathy D, Im S-A, Colleoni M, et al. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor-positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial. *Lancet Oncol*. 2018;19(7):904-915. doi:10.1016/S1470-2045(18)30292-4 **12.** Im S-A, Lu Y-S, Bardia A, et al. Overall survival with ribociclib plus endocrine therapy in breast cancer. *N Engl J Med*. 2019;381(4):307-316. doi:10.1056/NEJMoa1903765 **13.** Slamon DJ, Neven P, Chia S, et al. Phase III randomized study of ribociclib and fulvestrant in hormone receptor–positive, human epidermal growth factor receptor 2–negative advanced breast cancer: MONALEESA-3. *J Clin Oncol*. 2018;36(24):2465-2472. doi:10.1200/JCO.2018.78.9909 **14.** Slamon DJ, Neven P, Chia S, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. *N Engl J Med*. 2020;382(6):514-524. doi:10.1056/NEJMoa1911149

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Your Novartis representative is available to answer any questions you may have

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