MEET **JASMINE**

She was recently diagnosed with **stage II (T2N1) HR+/HER2- eBC**

Patient portrayal.

Find out if KISQALI is right for her

Indications

KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC) at high risk of recurrence.

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.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

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 KISQALI immediately and evaluate the patient. Permanently discontinue KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

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KISQALI® ribociclib 200 mg tablets

Patient portrayal.

MEET JASMINE

DIAGNOSIS: Stage II (T2N1) HR+/HER2- eBC

Jasmine is a 54-year-old dentist and a beloved wife, daughter, sister, and friend. In her free time, she enjoys visiting local food and music fairs.

- During a routine exam, her gynecologist discovered a lump in her left breast and ordered a mammogram
- A biopsy revealed her diagnosis of HR+/HER2- eBC
- After surgery and radiation, she is now in remission

IMPORTANT SAFETY INFORMATION (continued)

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. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

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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JASMINE'S CLINICAL EVALUATION

Age	54	**Gene expression profile assay results**	21 (Oncotype DX)
Menopausal status	Postmenopausal		
Clinical features	• Size and location: 4-cm primary tumor in left breast • Nodal involvement: 2 axillary lymph nodes positive for tumor cells • Grade: 2	**ECOG PS**	0
		Prior therapy	Lumpectomy, adjuvant radiation
Hormone receptor assay status	ER+/PR+/HER2-	**Current therapy**	Hormone therapy

Patients like Jasmine with stage II disease remain at risk of recurrence—including recurrence with incurable metastatic disease—despite treatment with adjuvant ET

Estimated risk of recurrence for patients with stage II HR+/HER2- eBC

up to 12% risk of recurrence within 3 years, despite ET[1,2]

Risk of recurrence data reflect recent outcomes published for patients with HR+/HER2- eBC who may be appropriate for treatment with CDK4/6 inhibitors, who were treated with standard ET, including tamoxifen. **KISQALI is not indicated for concomitant use with tamoxifen due to an increased risk for QT prolongation.**[1-3]

3-year risk of recurrence rate is based on iDFS outcomes among patients with HR+/HER2- eBC who received ET in select CDK4/6 inhibitor clinical trials. Data are from control arms only; no comparisons should be made between results from CDK4/6 inhibitor trial arms.[1,2]

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

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3-YEAR iDFS

Patients like Jasmine with stage II HR+/HER2- eBC need a treatment option that helps reduce their risk of recurrence

SUBGROUP ANALYSIS

In the NATALEE trial, patients with stage II disease saw a

30% REDUCTION IN RISK OF RECURRENCE

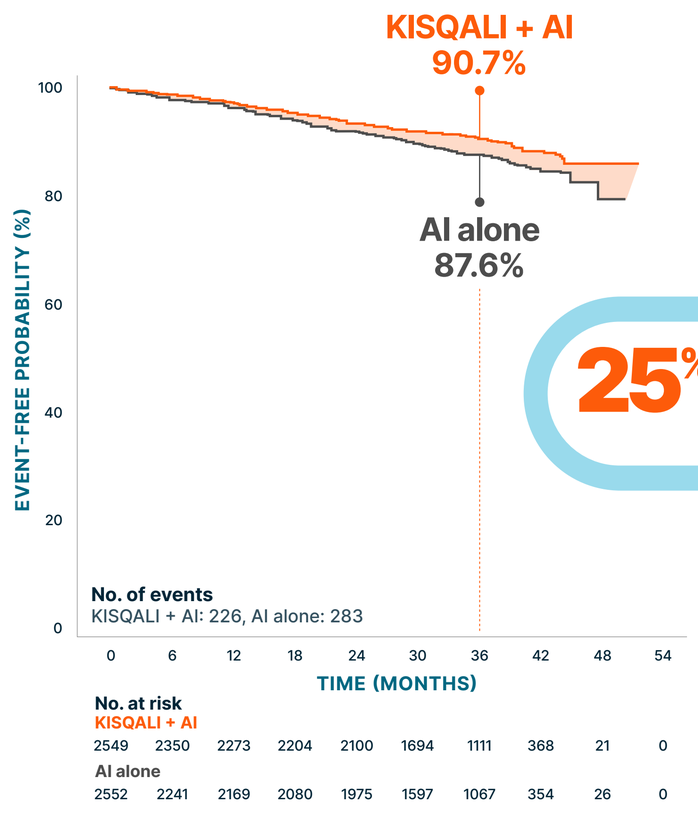
The absolute difference in iDFS values in the stage II subgroup was 1.6%

OVERALL POPULATION

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 33.3 months

INVASIVE DISEASE-FREE SURVIVAL AT 3 YEARS | KISQALI + AI[2,4]



25% REDUCTION IN RISK OF RECURRENCE
HR=0.749 (95% CI: 0.628-0.892)

Hazard ratio is based on stratified Cox model.[4]

iDFS was defined as the time from randomization to the date of the first event of local invasive breast cancer recurrence, regional invasive recurrence, distant recurrence, contralateral invasive breast cancer, second primary non-breast invasive cancer (excluding basal and squamous cell carcinomas of the skin), or death (any cause).[3]

- **At 3 years, the absolute difference in iDFS was 3.1%[3]**
- At the time of data cutoff, only 8.9% of patients receiving KISQALI + AI had experienced an iDFS event vs 11.1% of patients treated with AI alone[3]
- A statistically significant reduction in risk was achieved despite the greater challenge of showing clinical benefit in a broad range of patients[3,6]

NATALEE was a randomized, multicenter, open-label, phase III study of KISQALI 400 mg (dosed orally, once daily for the first 21 days followed by 7 days off, resulting in a complete cycle of 28 days) + letrozole or anastrozole* (n=2549) vs letrozole or anastrozole (n=2552) for the adjuvant treatment of men and women with stage II/III HR+/HER2- eBC. iDFS was the primary end point.[3,5]

Results from the subgroup analysis included no prespecified statistical procedure controlling for type 1 error.

*Men and premenopausal women also received goserelin.[5]

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation (continued). Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus NSAI, 8 out of 2494 patients (0.3%) had > 500 ms post-baseline QTcF interval value and 50 out of 2494 patients (2%) had > 60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes.

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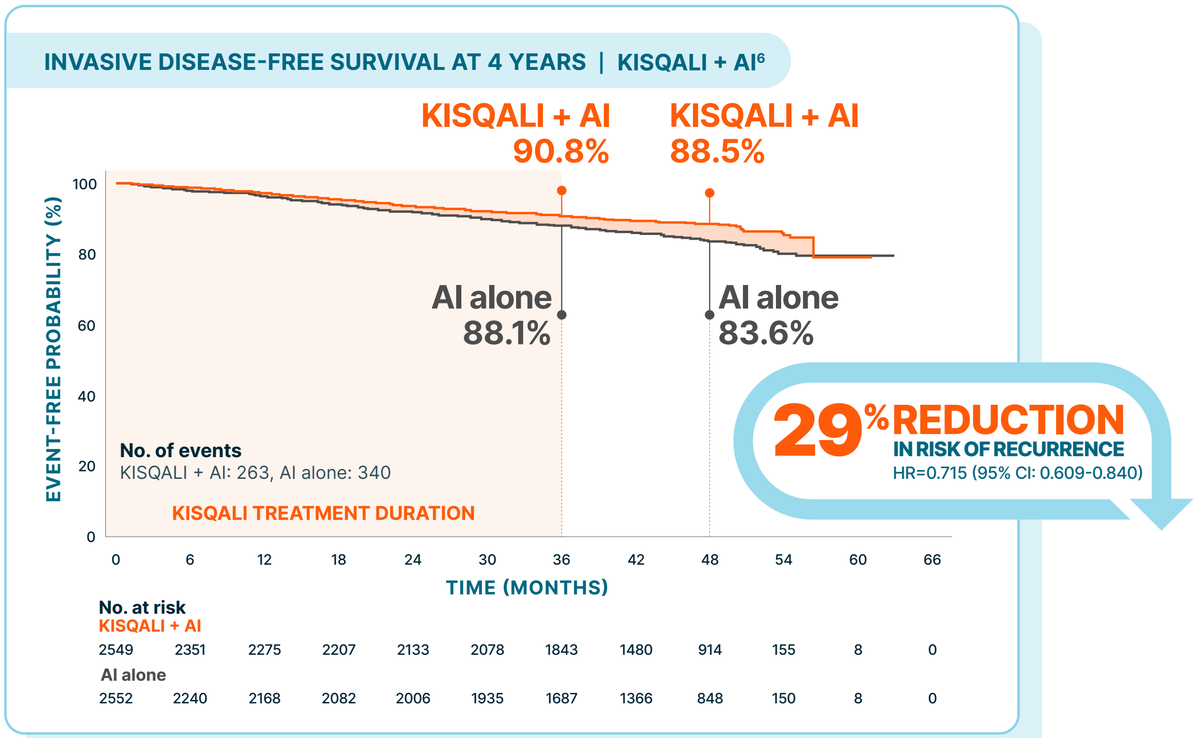
The iDFS benefit increased over time with KISQALI for patients with HR+/HER2- eBC—beyond the 3-year treatment period

OVERALL POPULATION

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 44 months



- **At 4 years, the absolute difference in iDFS was 4.9%[6]**
- At the time of data cutoff, only 10.3% of patients receiving KISQALI + AI had experienced an iDFS event vs 13.3% of patients treated with AI alone[6]
- A statistically significant reduction in risk was achieved despite the greater challenge of showing clinical benefit in a broad range of patients[5,6]
- Results from the exploratory 4-year analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error

For patients with HR+/HER2- eBC, KISQALI can help reduce the risk of recurrence, including recurrence with incurable metastatic disease

Hazard ratio is based on stratified Cox model.[4]

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation (continued). Perform electrocardiogram (ECG) in all patients prior to starting KISQALI. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle and as clinically indicated.

Monitor serum electrolytes (including potassium, calcium, phosphorus and magnesium) prior to the initiation of KISQALI, at the beginning of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting KISQALI.

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3-year iDFS | 4-year iDFS | 3-year iDFS subgroups

MEET JASMINE | EFFICACY | SAFETY | NOVARTIS PATIENT SUPPORT | REFERENCES | ISI

KISQALI + AI consistently improved iDFS across subgroups, regardless of stage, nodal or menopausal status, age, or grade

iDFS results favored KISQALI across prespecified subgroups, including grade 1 disease or no nodal involvement[7,8]

ANATOMIC STAGE		
Stage II	✓	HR=0.700 (95% CI: 0.496-0.986)
Stage III	✓	HR=0.755 (95% CI: 0.616-0.926)
NODAL STATUS*		
N0	✓	HR=0.723 (95% CI: 0.412-1.268)
N1, N2, N3	✓	HR=0.759 (95% CI: 0.631-0.912)
MENOPAUSAL STATUS		
Premenopausal/men	✓	HR=0.688 (95% CI: 0.519-0.913)
Postmenopausal	✓	HR=0.806 (95% CI: 0.645-1.007)
AGE		
<45 years	✓	HR=0.652 (95% CI: 0.443-0.959)
45 to 54 years	✓	HR=0.799 (95% CI: 0.578-1.104)
55 to 64 years	✓	HR=0.871 (95% CI: 0.636-1.193)
≥65 years	✓	HR=0.662 (95% CI: 0.444-0.986)
HISTOLOGICAL GRADE†		
Grade 1	✓	HR=0.708 (95% CI: 0.303-1.657)
Grade 2	✓	HR=0.696 (95% CI: 0.548-0.885)
Grade 3	✓	HR=0.890 (95% CI: 0.658-1.204)

Grade 1 subgroup did not include patients with T2N0 disease. Results from the subgroup analysis included no prespecified statistical procedure controlling for type 1 error.[3]

In the NATALEE trial, KISQALI consistently reduced the threat of recurrence in the broadest range of patients, including those like Jasmine

Hazard ratios reported as KISQALI + AI vs AI alone.

*Nodal status classification according to AJCC staging. Nodal status is from the worst stage derived per surgical specimen or at diagnosis.[7]

†At time of surgery.[7]

IMPORTANT SAFETY INFORMATION (continued)

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. Avoid use of tamoxifen with KISQALI. In MONALEESA-7, the observed mean QTcF increase from baseline was >10 ms higher in the tamoxifen + placebo subgroup compared with the nonsteroidal 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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In the adjuvant setting, for patients with stage II/III HR+/HER2- eBC,

No new safety signals were observed with KISQALI

ADVERSE REACTIONS (≥10% AND ≥2% HIGHER THAN AI-ALONE ARM) IN NATALEE[3]

	KISQALI + AI (n=2526)		AI alone (n=2441)	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
INFECTIONS AND INFESTATIONS				
Infections*	37	2	27	0.9
NERVOUS SYSTEM DISORDERS				
Headache	23	0.4†	17	0.2†
GASTROINTESTINAL DISORDERS				
Nausea	23	0.2†	8	0.1†
Diarrhea	15	0.6†	6	0.1†
Constipation	13	0.2†	5	0
Abdominal pain	11	0.5†	7	0.4†
GENERAL DISORDERS AND ADMINISTRATION-SITE CONDITIONS				
Fatigue	22	0.8†	13	0.2†
Asthenia	17	0.6†	12	0.1†
Pyrexia	11	0.2†	6	0.1†
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
Alopecia	15	0	4.6	0
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS				
Cough	13	0.1†	8	0.1†

Grading according to CTCAE version 4.03.

*Infections included urinary and respiratory tract infections.[3]

†Only includes grade 3 ARs.[3]

The NATALEE trial was designed to maximize the efficacy benefit of KISQALI while minimizing dose-dependent ARs and adherence issues related to tolerability

- The most common ARs (occurring in ≥20% of patients treated with KISQALI), including laboratory abnormalities, were decrease in lymphocytes, decrease in leukocytes, decrease in neutrophils, decrease in hemoglobin, increase in ALT, increase in AST, infections, increase in creatinine, decrease in platelets, headache, nausea, and fatigue[3]
- The most common grade ≥3 ARs, including laboratory abnormalities, occurring in ≥5% of patients were decrease in neutrophils, decrease in leukocytes, decrease in lymphocytes, increase in ALT, and increase in AST[3]
- Fatal ARs occurred in 0.6% of patients who received KISQALI. Fatal ARs in ≥0.1% of patients receiving KISQALI included COVID-19 or COVID-19 pneumonia (0.2%) and pulmonary embolism (0.1%)[3]
- In the NATALEE trial, no new safety signals were observed at 4 years of follow-up[6]

IMPORTANT SAFETY INFORMATION (continued)

Hepatotoxicity. In patients with eBC, drug-induced liver injury and increases in transaminases occurred with KISQALI.

In patients with eBC (NATALEE) treated with KISQALI, drug-induced liver injury was reported in 9 patients (0.4%), of which 5 were grade ≥3 and 8 had resolved as of the data cutoff. There were 8 (0.3%) clinically confirmed Hy's Law cases (including 4 out of 9 drug-induced liver injury mentioned above), 6 of which had resolved within 303 days and 2 were resolving, all after discontinuation of KISQALI. Grade 3/4 increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) occurred in 8% and 4.7%, respectively, and grade 4 increases in ALT (1.5%) and AST (0.8%).

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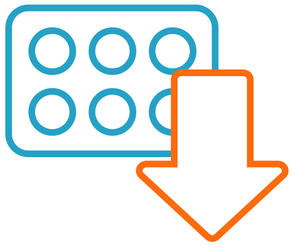
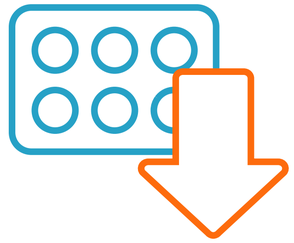
With KISQALI, most adverse reactions were manageable and reversible with dose reduction, which may have helped patients remain on therapy



Rate of dose reductions due to ARs[8]

KISQALI + AI: 23.2% | **AI alone: 0%**



Rate of discontinuation due to ARs[8]

KISQALI + AI: 20.8% | **AI alone: 5.5%**

- Median time to KISQALI discontinuation was 4.2 months[9]

In NATALEE, the leading cause of discontinuation was asymptomatic laboratory findings such as increases in ALT or AST, not symptomatic ARs such as diarrhea, fatigue, and nausea

In NATALEE, the leading causes of KISQALI + AI discontinuation (occurring in ≥2% of patients) were increases in ALT or AST (8%).[3]

IMPORTANT SAFETY INFORMATION (continued)

Hepatotoxicity (continued). Perform liver function tests (LFTs) before initiating 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.

Neutropenia. KISQALI causes concentration-dependent neutropenia. In patients with eBC (NATALEE) who received KISQALI plus NSAI, 94%, including 45% of grade 3/4, had a decrease in neutrophil counts (based on laboratory findings), 63% had an adverse drug reaction of neutropenia, and 0.3% had febrile neutropenia. The median time to grade ≥2 neutropenia was 18 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 10 days. Treatment discontinuation due to neutropenia was required in 1.1% of patients.

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Novartis Patient Support™—a dedicated team for you and your patients

Novartis Patient Support is a comprehensive program that is designed to help your eligible patients start, stay, and save on KISQALI.

Your practice and patients will have access to a Novartis Patient Support team committed to providing the support you need, including:

Insurance Support

Help navigating the insurance process, including benefits verification

Financial Support

Assistance with relevant savings options for your eligible patients

Clinical Testing and Support

Workflow support and options for testing

Ongoing Support

Dedicated assistance from our team and educational resources

To learn more, contact your dedicated Novartis Patient Support team at 1-866-433-8000
Monday-Friday, 8:00 AM - 8:00 PM ET, excluding holidays

Help your patients get started with KISQALI today

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KISQALI® ribociclib 200 mg tablets

Patient portrayal.

KISQALI is proven in the broadest range of patients with stage II/III HR+/HER2- eBC—including patients like Jasmine who have stage II (T2N1) disease and low genomic risk

KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. Patients with stage IIA, T2N0 HR+/HER2- eBC must meet the following criteria to be eligible for treatment with KISQALI: grade 3, or grade 2 with Ki-67 ≥20% or high genomic risk.[3]

Regardless of tumor size, nodal status, grade, age (≥18 years), or menopausal status—consider KISQALI for your patients with stage II/III disease

Explore more patient profiles at KISQALI-HCP.COM

AI=aromatase inhibitor; AJCC=American Joint Committee on Cancer; ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; CDK=cyclin-dependent kinase; CTCAE=Common Terminology Criteria for Adverse Events; eBC=early breast cancer; ECOG PS=Eastern Cooperative Oncology Group performance status; ER+=estrogen receptor-positive; ET=endocrine therapy; HR=hazard ratio; iDFS=invasive disease-free survival; PR+=progesterone receptor-positive.

References: 1. Mayer EL, Dueck AC, Martin M, et al. Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study. *Lancet Oncol.* 2021;22(2):212-222. doi:10.1016/S1470-2045(20)30642-2 **2.** Johnston SRD, Toi M, O'Shaughnessy J, et al. Abemaciclib plus endocrine therapy for hormone receptor-positive, HER2-negative, node-positive, high-risk early breast cancer (monarchE): results from a preplanned interim analysis of a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2023;24(1):77-90. doi:10.1016/S1470-2045(22)00694-5 **3.** Kisqali. Prescribing information. Novartis Pharmaceuticals Corp. **4.** Slamon D, Lipatov O, Nowecki Z, et al. Ribociclib plus endocrine therapy in early breast cancer. *N Engl J Med.* 2024;390(12):1080-1091;protocol. doi:10.1056/NEJMoa2305488 **5.** Slamon DJ, Fasching PA, Hurvitz S, et al. Rationale and trial design of NATALEE: a phase III trial of adjuvant ribociclib + endocrine therapy versus endocrine therapy alone in patients with HR+/HER2− early breast cancer. *Ther Adv Med Oncol.* 2023;15:1-16. doi:10.1177/17588359231178125 **6.** Fasching PA, Stroyakovskiy D, Yardley DA, et al. Adjuvant ribociclib plus nonsteroidal aromatase inhibitor in patients with HR+/HER2- early breast cancer: 4-year outcomes from the NATALEE trial. Presented at: ESMO Congress 2024; September 13-17, 2024; Barcelona, Spain. **7.** Hortobagyi GN, Stroyakovskiy D, Yardley DA, et al. Ribociclib + nonsteroidal aromatase inhibitor as adjuvant treatment in patients with HR+/HER2- early breast cancer: final invasive disease-free survival analysis from the NATALEE trial. Presented at: San Antonio Breast Cancer Symposium; December 5-9, 2023; San Antonio, TX. **8.** Data on file. CLEE011O12301C (NATALEE) final iDFS analysis results. Novartis Pharmaceuticals Corp; 2023. **9.** Barrios C, Harbeck N, Hortobagyi G, et al. NATALEE update: safety and treatment duration of ribociclib + nonsteroidal aromatase inhibitor in patients with HR+/HER2- early breast cancer. Presented at: ESMO Breast Cancer 2024; May 15-17, 2024; Berlin, Germany.

IMPORTANT SAFETY INFORMATION (continued)

Neutropenia (continued). 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. 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.

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

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Indications

KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC) at high risk of recurrence.

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.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

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 KISQALI immediately and evaluate the patient. Permanently discontinue KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson sSevere 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. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

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.

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus NSAI, 8 out of 2494 patients (0.3%) had > 500 ms post-baseline QTcF interval value and 50 out of 2494 patients (2%) had > 60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes.

Perform electrocardiogram (ECG) in all patients prior to starting KISQALI. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle and as clinically indicated.

Monitor serum electrolytes (including potassium, calcium, phosphorus and magnesium) prior to the initiation of KISQALI, at the beginning of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting KISQALI.

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. Avoid use of tamoxifen with KISQALI. In MONALEESA-7, the observed mean QTcF increase from baseline was >10 ms higher in the tamoxifen + placebo subgroup compared with the nonsteroidal 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)

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Perform liver function tests (LFTs) before initiating 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.

Neutropenia. KISQALI causes concentration-dependent neutropenia. In patients with eBC (NATALEE) who received KISQALI plus NSAI, 94%, including 45% of grade 3/4, had a decrease in neutrophil counts (based on laboratory findings), 63% had an adverse drug reaction of neutropenia, and 0.3% had febrile neutropenia. The median time to grade ≥2 neutropenia was 18 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 10 days. Treatment discontinuation due to neutropenia was required in 1.1% of patients.

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. 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, headache, and fatigue.

Laboratory abnormalities. In a clinical trial of patients with early breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were lymphocytes decreased, leukocyte decreased, neutrophil decreased, hemoglobin decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, and platelets decreased**.

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

NOVARTIS

KISQALI® ribociclib 200 mg tablets

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