MEET **KATRICE** | **PATIENT PROFILE** | KISQALI + AI for patients with stage II/III HR+/HER2- eBC at high risk of recurrence

She was recently diagnosed with **stage III (T2N2) HR+/HER2- eBC**

Patient portrayal.

NCCN CATEGORY 1

National Comprehensive Cancer Network® (NCCN®) recognizes ribociclib (KISQALI®) as a **Category 1 Preferred** CDK4/6 inhibitor in combination with an AI for appropriate patients with HR+/HER2- eBC—**the only one to receive this designation for both high-risk node-negative and any node-positive disease**.[1]

KISQALI is approved for use in combination with an AI; node-positive disease excludes patients with microscopic nodal involvement.[1,2]

High-risk node-negative disease is defined as either tumor size >5 cm, or if tumor size 2-5 cm, either grade 2 (with high genomic risk or Ki-67 ≥20%), or grade 3.[1,2]

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.[1]

AI, aromatase inhibitor; CDK, cyclin-dependent kinase; eBC, early breast cancer; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; N, nodal status; T, tumor size.

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.

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

KISQALI® ribociclib 200 mg tablets

Patient portrayal.

MEET KATRICE

DIAGNOSIS: Stage III (T2N2) HR+/HER2- eBC

Katrice is 63 years old and lives a well-rounded life as a daughter, wife, and colleague. She's busy with a DIY home renovation project but stays grounded through a consistent yoga practice and quality time with friends.

- Katrice found a small lump in one of her breasts. She immediately called her primary care doctor, who ordered a mammogram
- A biopsy confirmed she had HR+/HER2- breast cancer that had spread to her lymph nodes
- She had a mastectomy and rang the bell after completing chemotherapy; she is now on hormone therapy

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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KATRICE'S CLINICAL EVALUATION

Age	63	**ECOG PS**	1
Menopausal status	Postmenopausal		
Clinical features	• Size and location: 2.5-cm primary tumor in right breast • Nodal involvement: 5 axillary lymph nodes positive for tumor cells • Grade: 2	**Prior therapy**	Mastectomy, adjuvant chemotherapy
Hormone receptor assay status	ER+/PR+/HER2-	**Current therapy**	Hormone therapy

Patients like Katrice with stage III 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 III HR+/HER2- eBC

up to 21% risk of recurrence within 3 years, despite ET[3,4]

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.**[2-4]

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. The 3-year data listed for stage III also include some patients with stage IIB disease, due to differentiated data breakouts between trials.[3,4]

ECOG PS, Eastern Cooperative Oncology Group performance status; ER+, estrogen receptor-positive; ET, endocrine therapy; iDFS, invasive disease-free survival; PR+, progesterone receptor-positive.

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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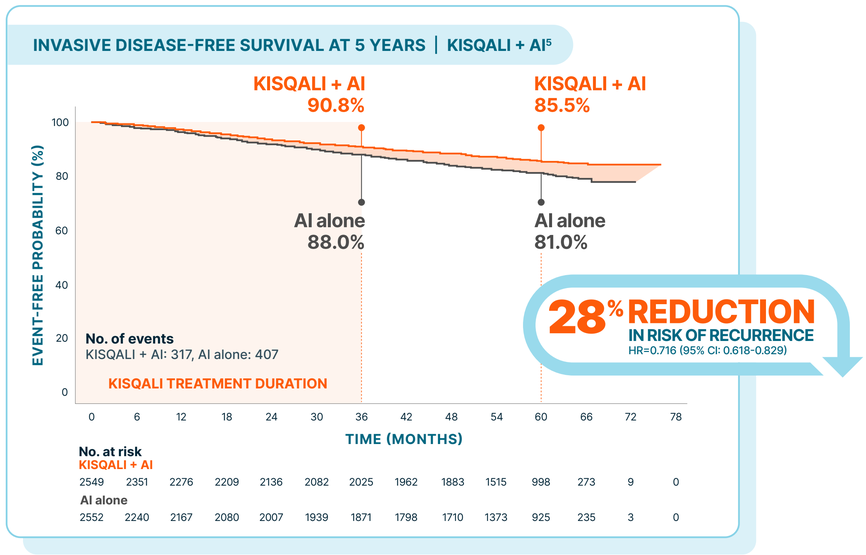
In patients with stage II/III HR+/HER2- eBC,

Over 5 years, KISQALI delivered a 28% reduction in the risk of recurrence

The iDFS benefit deepened over time with KISQALI + AI, beyond the 3-year treatment period[5]

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 55.4 months



Hazard ratio is based on stratified Cox model.[6]

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).[2]

In the 5-year prespecified analysis[5]:

- **At 3 years: 2.7% absolute difference***
- **At 5 years: 4.5% absolute difference**
- At the time of data cutoff, only 12.4% of patients receiving KISQALI + AI had experienced an iDFS event vs 15.9% of patients treated with AI alone
- The 5-year analysis was prespecified and observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error

In the 3-year final analysis (median follow-up of 33.3 months)[2,7]:

- **iDFS at 3 years was 90.7% for KISQALI + AI vs 87.6% for AI alone (absolute difference 3.1%)**
- **There was a 25.1% relative reduction in the risk of an iDFS event; HR=0.749 (95% CI: 0.628-0.892)**

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, including all those with node-positive or high-risk node-negative disease (eligible stages and nodal status include: anatomic stage group IIB-III, or anatomic stage group IIA that is either node positive, or node negative with histologic grade 3, or histologic grade 2 with Ki-67 ≥20% and/or high risk by gene signature testing). iDFS was the primary end point. In an interim analysis, a statistically significant improvement in iDFS was observed.[2,8]

HR, hazard ratio.

*The difference between percentages does not equal 2.7 due to rounding.[5]

†Men and premenopausal women also received goserelin.[8]

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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DDFS : OVERALL POPULATION

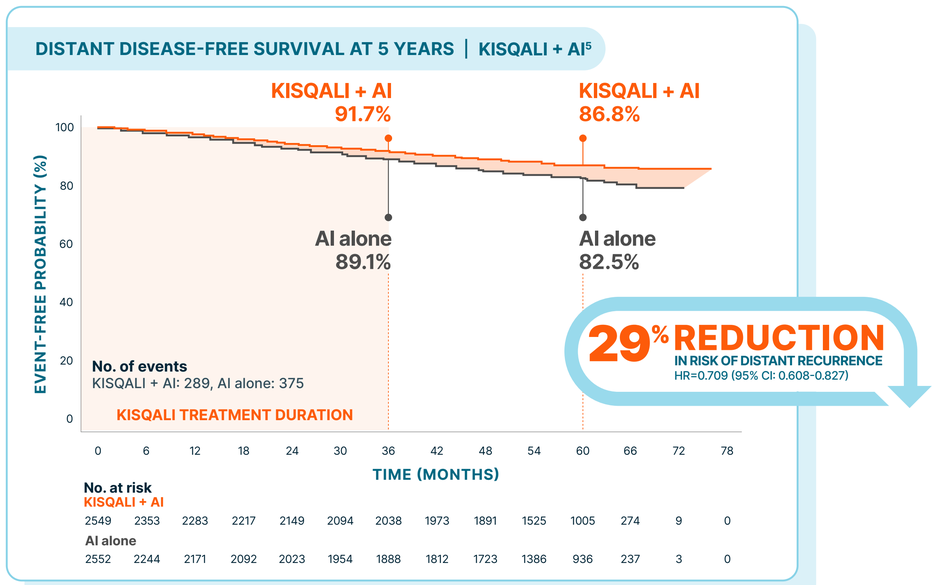
In patients with stage II/III HR+/HER2- eBC,

Over 5 years, KISQALI showed a 29% reduction in the risk of distant recurrence

The DDFS benefit was consistent with iDFS and increased over time with KISQALI + AI, beyond the treatment period[5]

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 55.5 months



Hazard ratio is based on stratified Cox model.[6]

In the 5-year prespecified analysis[5]:

- **At 3 years: 2.6% absolute difference**
- **At 5 years: 4.3% absolute difference**
- At the time of data cutoff, only 11.3% of patients receiving KISQALI + AI had experienced a DDFS event vs 14.7% of patients treated with AI alone
- The 5-year analysis was prespecified and observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error

DDFS was defined as the time from randomization to the date of the first event of distant recurrence, second primary non-breast invasive cancer (excluding basal and squamous cell carcinomas of the skin), or death (any cause).[6]

KISQALI can help reduce the risk of distant recurrence with incurable metastatic disease

DDFS, distant disease-free survival.

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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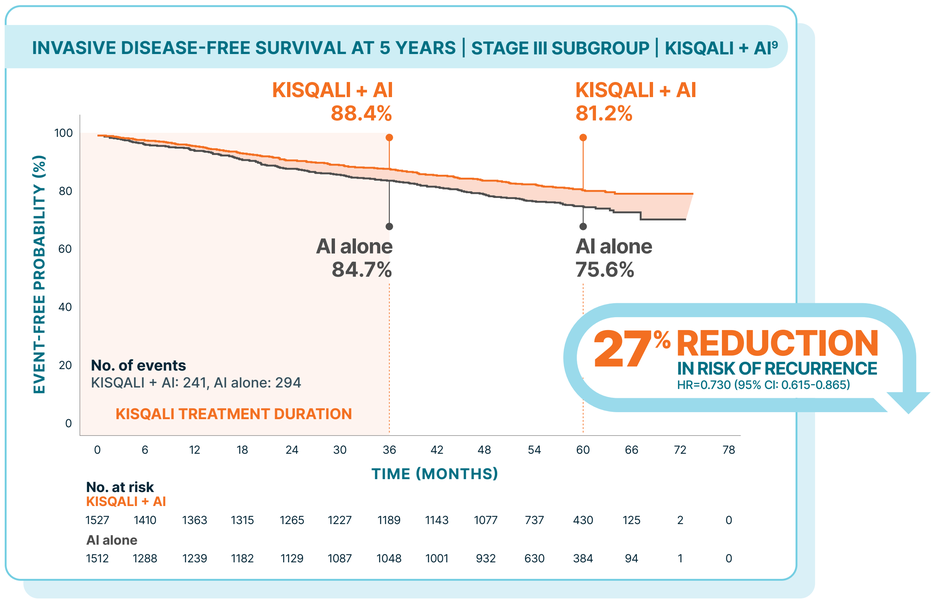
iDFS SUBGROUP: STAGE III

For patients like Katrice, with stage III HR+/HER2- eBC, the reduction in risk of recurrence was consistent with the overall population

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 50.0 months



In the 5-year prespecified analysis[9]:

- **At 3 years: 3.7% absolute difference**
- **At 5 years: 5.6% absolute difference**
- Results from the stage III subgroup are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error

For patients with stage III HR+/HER2- eBC, KISQALI improved iDFS over time, beyond the 3-year treatment period

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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With 33.3 months of follow-up, 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[2]

	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.[2]
†Only includes grade 3 ARs.[2]

ALT, alanine aminotransferase; AR, adverse reaction; AST, aspartate aminotransferase; CTCAE, Common Terminology Criteria for Adverse Events.

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[2]
- 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[2]
- 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%)[2]
- In the NATALEE trial, no new safety signals were observed at 5 years of follow-up[5]

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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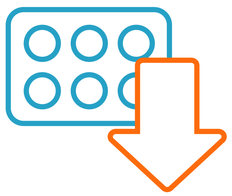
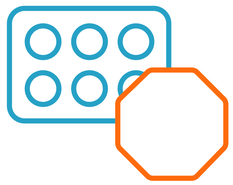
In stage II/III HR+/HER2- eBC,

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[10]

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



Rate of discontinuation due to ARs[10]

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

- Median time to KISQALI discontinuation was 4.2 months[11]

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%).[2]

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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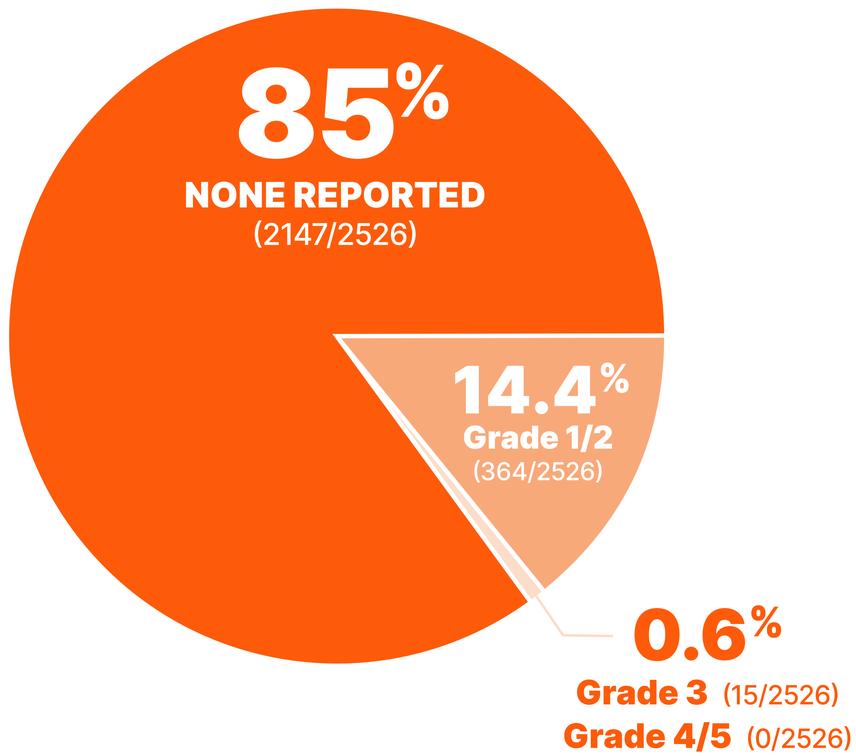
In the NATALEE clinical trial,

Reported rates of diarrhea were low with KISQALI

Diarrhea rates in NATALEE[2]



Diarrhea can be disruptive in many ways—from a daily, unpredictable inconvenience to a debilitating, even life-threatening condition[12]

- **Grade 1:** <4 stools per day over baseline; mild increase in ostomy output
- **Grade 2:** 4 to 6 stools per day over baseline; moderate increase in ostomy output; limiting instrumental ADL
- **Grade 3:** ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output; limiting self-care ADL
- **Grade 4:** Life-threatening; urgent intervention indicated
- **Grade 5:** Death

ADL, activities of daily living.

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.

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KISQALI® ribociclib 200 mg tablets

KISQALI—broad access and coverage to help make treatment available for more of your patients

For the majority of patients with prescription drug insurance coverage, all or nearly all of the cost of KISQALI is covered, and prior authorizations are approved within 1 day

For Medicare members, nearly

85% of KISQALI out-of-pocket costs were between **$0** and **$20** per month[13]

For patients with commercial insurance, nearly

80% of KISQALI out-of-pocket costs were between **$0** and **$50** per month[13]

More than

85% of KISQALI PAs are approved in less than **24 hours**[14]

More than 9 out of 10 patients
have preferred formulary coverage for KISQALI[15]

Unrestricted coverage from MMIT data as of July 2025.

PA, prior authorization.

Novartis does not guarantee payment or coverage for any product or service. Actual coverage and reimbursement decisions are made by individual payers following receipt of claims. Coverage is subject to change by the relevant payer.

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Novartis Patient Support™—a dedicated team for your patients

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

We support your patient's journey with:

Insurance Support

Help navigating the insurance process, including benefits verification

Financial Support

Assistance with connecting patients to relevant savings options

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 866-433-8000
Monday-Friday, 8:00 AM - 8:00 PM ET, excluding holidays

Help your patients get started with KISQALI today

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

KISQALI® ribociclib 200 mg tablets

Patient portrayal.

KISQALI + AI is proven in the broadest range of patients with stage II/III HR+/HER2- eBC—including patients like Katrice who have stage III (T2N2) disease

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.[2]

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

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.5.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed December 1, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Kisqali. Prescribing information. Novartis Pharmaceuticals Corp. **3.** 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 **4.** 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 **5.** Crown J, Stroyakovskii D, Yardley DA, et al. Adjuvant ribociclib plus nonsteroidal aromatase inhibitor therapy in patients with HR-positive/HER2-negative early breast cancer: 5-year follow-up of NATALEE efficacy outcomes and updated overall survival. *ESMO Open.* 2025;10(11):105858. doi:10.1016/j.esmoop.2025.105858 **6.** 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 **7.** Hortobagyi GN, Lacko A, Sohn J, et al. A phase III trial of adjuvant ribociclib plus endocrine therapy versus endocrine therapy alone in patients with HR-positive/HER2-negative early breast cancer: final invasive disease-free survival results from the NATALEE trial. *Ann Oncol.* 2025;36(2):149-157. doi:10.1016/j.annonc.2024.10.015 **8.** 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. doi:10.1056/NEJMoa2305488 **9.** Crown J, Stroyakovskii D, Yardley DA, et al. Adjuvant ribociclib plus nonsteroidal aromatase inhibitor therapy in patients with HR-positive/HER2-negative early breast cancer: 5-year follow-up of NATALEE efficacy outcomes and updated overall survival. *ESMO Open.* 2025;10(11):105858;(suppl). doi:10.1016/j.esmoop.2025.105858 **10.** Data on file. CLEE011O12301C (NATALEE) final iDFS analysis results. Novartis Pharmaceuticals Corp; 2023. **11.** 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. **12.** US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0. Published November 27, 2017. Accessed December 2, 2025. https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v5-8x11.pdf **13.** Data on file. Kisqali IQVIA data through May 2025. Novartis Pharmaceuticals Corp; 2025. **14.** Data on file. Kisqali CMM AMP data review May 2025. Novartis Pharmaceuticals Corp; 2025. **15.** Data on file. Kisqali MMIT data July 2025. Novartis Pharmaceuticals Corp; 2025.

IMPORTANT SAFETY INFORMATION (continued)

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.

KISQALI® ribociclib 200 mg tablets

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 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.

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

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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%).

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**.

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