



MEET  
ERIN

PATIENT  
PROFILE

KISQALI + AI for patients with stage II/III  
HR+/HER2- eBC at high risk of recurrence

## She was recently diagnosed with stage II (T2N0) HR+/HER2- eBC

**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.<sup>1</sup>

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

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.<sup>1,2</sup>

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.<sup>1</sup>

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.



Patient  
portrayal.

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Patient portrayal.

# MEET ERIN

**DIAGNOSIS:** Stage II (T2N0)  
HR+/HER2- eBC with high genomic risk

Erin is 43 years old and lives in St Louis with her husband, 2 daughters, and their dog, Ozzie. She loves working as a real estate agent, but is happiest when cooking and enjoying movie nights at home with her family.

- She first noticed a lump in her left breast after a self-examination and immediately reached out to her doctor
- Erin is in remission after undergoing a lumpectomy followed by adjuvant chemotherapy and radiation and has been on hormone therapy for 11 months

## 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for KISQALI.





## ERIN'S CLINICAL EVALUATION

<b>Age</b>	43	<b>Gene expression profile assay results</b>	34 (Oncotype DX®)
<b>Menopausal status</b>	Premenopausal		
<b>Clinical features</b>	<ul style="list-style-type: none"> <li>• Size and location: 3.5-cm tumor in left breast</li> <li>• Nodal involvement: sentinel nodes negative</li> <li>• Grade: 2</li> </ul>	<b>ECOG PS</b>	0
		<b>Prior therapy</b>	Lumpectomy; adjuvant chemotherapy; adjuvant radiation
<b>Hormone receptor assay status</b>	ER+/PR-/HER2-	<b>Current therapy</b>	Hormone therapy (11 months)

ECOG PS, Eastern Cooperative Oncology Group performance status; ER+, estrogen receptor-positive; PR-, progesterone receptor-negative.

### 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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Patient profile

**Clinical characteristics**

Risk of recurrence



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In stage II/III HR+/HER2- eBC at high risk of recurrence,

**In the NATALEE-eligible population, patients with high-risk N0 disease had a similar risk of recurrence as patients with N1 disease, demonstrating the unmet need in the high-risk N0 population**



KISQALI is approved for all patients with T4N0 and T3N0 disease; if T2N0: grade 3, or grade 2 with Ki-67  $\geq 20\%$  or high genomic risk.<sup>4</sup>

Risk of recurrence data reflect outcomes reported in a US electronic health record (EHR)-derived database of patients with HR+/HER2- eBC who may be appropriate for treatment with adjuvant 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.**<sup>2,3,5,6</sup>

5-year risk of recurrence is based on relapse-free survival (RFS) outcomes from a US EHR-derived database analysis of 2534 NATALEE-eligible stage II/III HR+/HER2- eBC patients who received adjuvant ET, including 604 with N0 disease and 1462 with N1 disease.<sup>3</sup>

**Limitations:** Findings are based on a real-world study of data from the Flatiron Health US EHR-derived database and should be interpreted with caution given the observational and descriptive nature of the study and potential data limitations.

**Disclaimers:** Liz Santarsiero and Fen Ye are employees of Novartis Pharmaceuticals Corporation, and Murat Akdere and Henry Owusu are employees of Novartis Pharma AG.

ET, endocrine therapy.

#### **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 NSAID, 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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## iDFS : OVERALL POPULATION

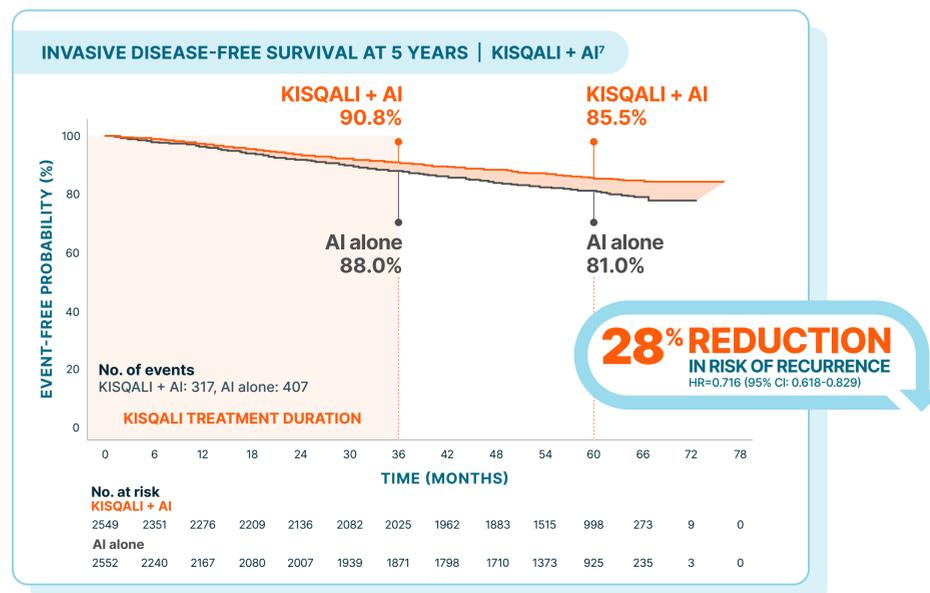
In patients with stage II/III HR+/HER2- eBC,

**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<sup>7</sup>

### NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 55.4 months



Hazard ratio is based on stratified Cox model.<sup>8</sup>

**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).<sup>2</sup>

### 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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In the 5-year prespecified analysis<sup>7</sup>:

- 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<sup>7</sup>
- 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)<sup>2,9</sup>:

- 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<sup>†</sup> (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.<sup>2,10</sup>

iDFS, invasive disease-free survival; HR, hazard ratio.

\*The difference between percentages does not equal 2.7 due to rounding.<sup>7</sup>

<sup>†</sup>Men and premenopausal women also received goserelin.<sup>10</sup>

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iDFS    DDFS    iDFS NO subgroup

## DDFS : OVERALL POPULATION

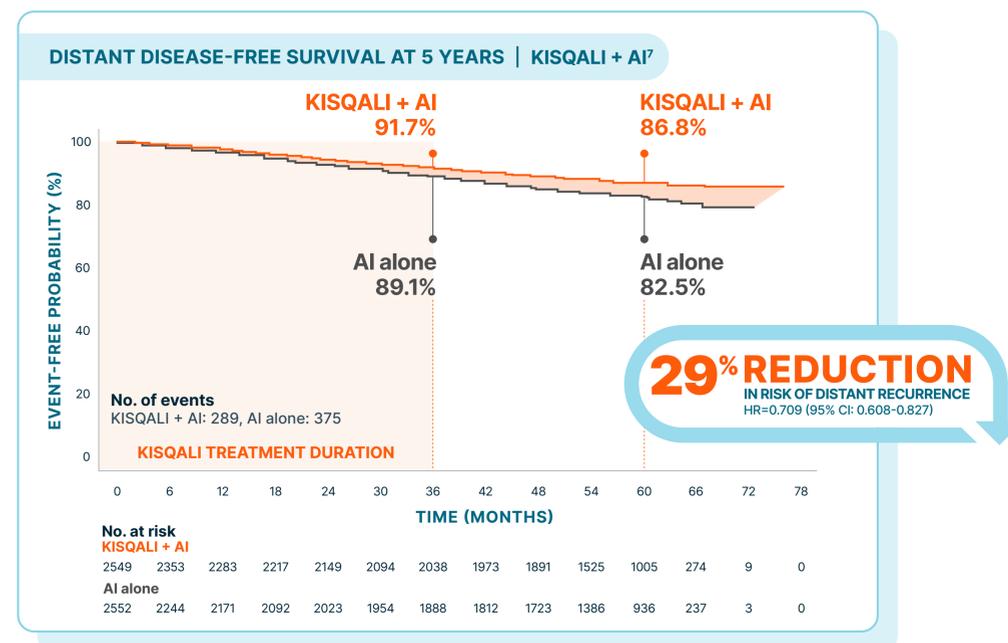
In patients with stage II/III HR+/HER2- eBC,

**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<sup>7</sup>

### NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 55.5 months



In the 5-year prespecified analysis<sup>7</sup>:

- 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<sup>7</sup>
- 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).<sup>8</sup>

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

Hazard ratio is based on stratified Cox model.<sup>8</sup>

DDFS, distant disease-free survival.

### 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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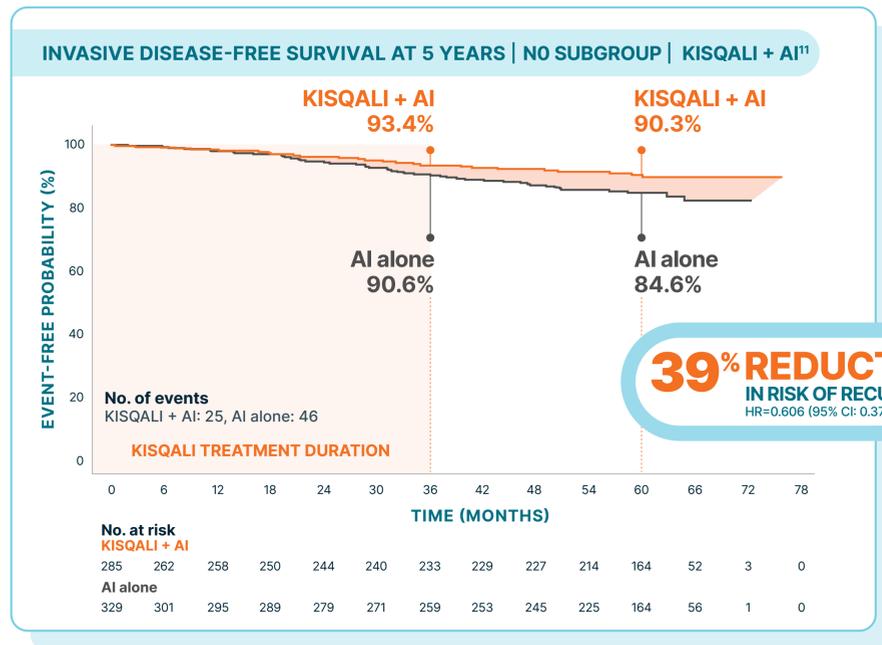
iDFS    **DDFS**    iDFS NO subgroup

**iDFS SUBGROUP: NO**

**For Erin, and other patients with stage II or III NO 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 60.1 months



The NATALEE trial assessed patients with stage II/III HR+/HER2- eBC— including those who had node-negative disease with high-risk features<sup>2</sup>

In the 5-year prespecified analysis<sup>11</sup>:

- At 3 years: 2.8% absolute difference
- At 5 years: 5.7% absolute difference
- Results from the NO subgroup are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error

**The increased iDFS benefit seen in the NO subgroup was consistent with the iDFS benefit increase seen in the overall population**

KISQALI is approved for all patients with T4N0 and T3N0 disease; if T2N0: grade 3, or grade 2 with Ki-67 ≥20% or high genomic risk.<sup>4</sup>

**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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iDFS    DDFS    **iDFS NO subgroup**

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<sup>2</sup>**

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

**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<sup>2</sup>
- 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<sup>2</sup>
- 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%)<sup>2</sup>
- In the NATALEE trial, no new safety signals were observed at 5 years of follow-up<sup>7</sup>

Grading according to CTCAE version 4.03.

\*Infections included urinary and respiratory tract infections.<sup>2</sup>

<sup>†</sup>Only includes grade 3 ARs.<sup>2</sup>

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

### 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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Adverse reactions    Reductions and discontinuations    Diarrhea



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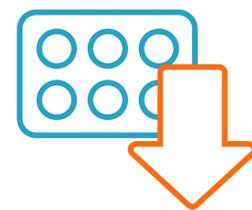
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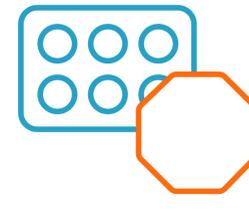
In stage II/III HR+/HER2- eBC,

**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<sup>12</sup>**

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



**Rate of discontinuation due to ARs<sup>12</sup>**

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

• Median time to KISQALI discontinuation was 4.2 months<sup>13</sup>

**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%).<sup>2</sup>

**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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Adverse reactions   **Reductions and discontinuations**   Diarrhea



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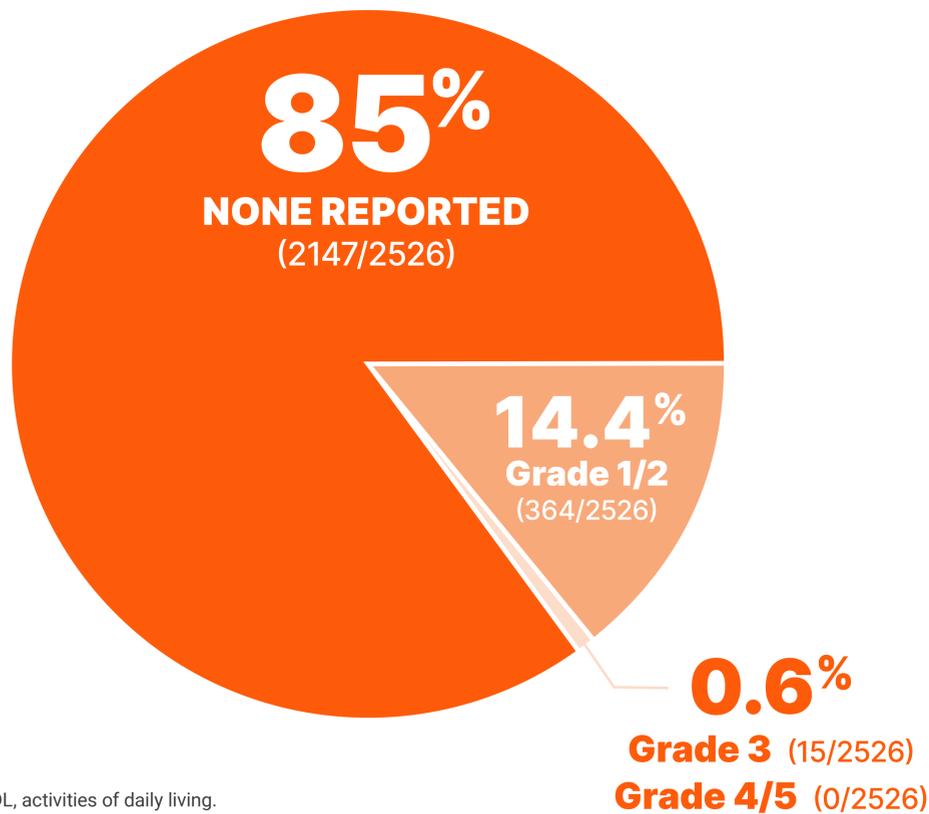
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In the NATALEE clinical trial,

## Reported rates of diarrhea were low with KISQALI

### Diarrhea rates in NATALEE<sup>2</sup>



ADL, activities of daily living.

Diarrhea can be disruptive in many ways— from a daily, unpredictable inconvenience to a debilitating, even life-threatening condition<sup>14</sup>

- **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

#### 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.

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Adverse reactions    Reductions and discontinuations    **Diarrhea**



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## 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<sup>15</sup>

For patients with commercial insurance, nearly

**80%** of KISQALI out-of-pocket costs were between **\$0** and **\$50** per month<sup>15</sup>

More than

**85%** of KISQALI PAs are approved in less than **24 hours**<sup>16</sup>

More than **9** out of **10** patients  
have preferred formulary coverage for KISQALI<sup>17</sup>



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**

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Patient portrayal.

## For patients like Erin who have N0 disease with tumor size >2 cm and ≤5 cm and G3 or G2 + Ki-67 ≥20% or high genomic risk, KISQALI is the only FDA-approved CDK4/6 inhibitor

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.<sup>2</sup>

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](https://KISQALI-HCP.COM)

FDA, US Food and Drug Administration; G, grade.

**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. Tarantino P, Rugo HS, Curigliano G, et al. Risk of recurrence in real-world (RW) NATALEE- and monarchE-eligible populations of patients with HR+/HER2- early breast cancer (EBC) in an electronic health record (EHR)-derived database. Poster presented at: San Antonio Breast Cancer Symposium; December 10-13, 2024; San Antonio, TX. 4. 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 5. 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 6. 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 7. 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 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;(protocol). doi:10.1056/NEJMoa2305488 9. 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 10. 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 11. 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 12. Data on file. CLEE011012301C (NATALEE) final iDFS analysis results. Novartis Pharmaceuticals Corp; 2023. 13. 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. 14. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0. Published November 27, 2017. Accessed December 1, 2025. <https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v5-8x11.pdf> 15. Data on file. Kisqali IQVIA data through May 2025. Novartis Pharmaceuticals Corp; 2025. 16. Data on file. Kisqali CMM AMP data review May 2025. Novartis Pharmaceuticals Corp; 2025. 17. Data on file. Kisqali MMIT data July 2025. Novartis Pharmaceuticals Corp; 2025.

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### 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.

**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 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)

**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  $\geq 3$  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  $\geq 2$  neutropenia was 18 days. The median time to resolution of grade  $\geq 3$  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  $\geq 20\%$ ) 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  $\geq 20\%$ ) were **lymphocytes decreased, leukocyte decreased, neutrophil decreased, hemoglobin decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, and platelets decreased.**

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