

## MEET ERIN

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

**Find out if KISQALI is right for her**

**NCCN**  
**CATEGORY 1**  
**UPDATE**

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>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>

### 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.

 **KISQALI**<sup>®</sup>  
ribociclib 200 mg  
tablets



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EFFICACY

SAFETY

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REFERENCES

ISI



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.

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Patient profile

Clinical characteristics



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## ERIN'S CLINICAL EVALUATION

Age	43	Gene expression profile assay results	34 (Oncotype DX)
Menopausal status	Premenopausal		
Clinical features	<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>	ECOG PS	0
		Prior therapy	Lumpectomy; adjuvant chemotherapy; adjuvant radiation
Hormone receptor assay status	ER+/PR-/HER2-	Current therapy	Hormone therapy (11 months)

**Patients like Erin with node-negative eBC 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/III, NO HR+/HER2- eBC**

up to **11%** risk of recurrence within 3 years, despite ET<sup>3</sup>

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.**<sup>2,4</sup>

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.<sup>3</sup>

### 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.

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

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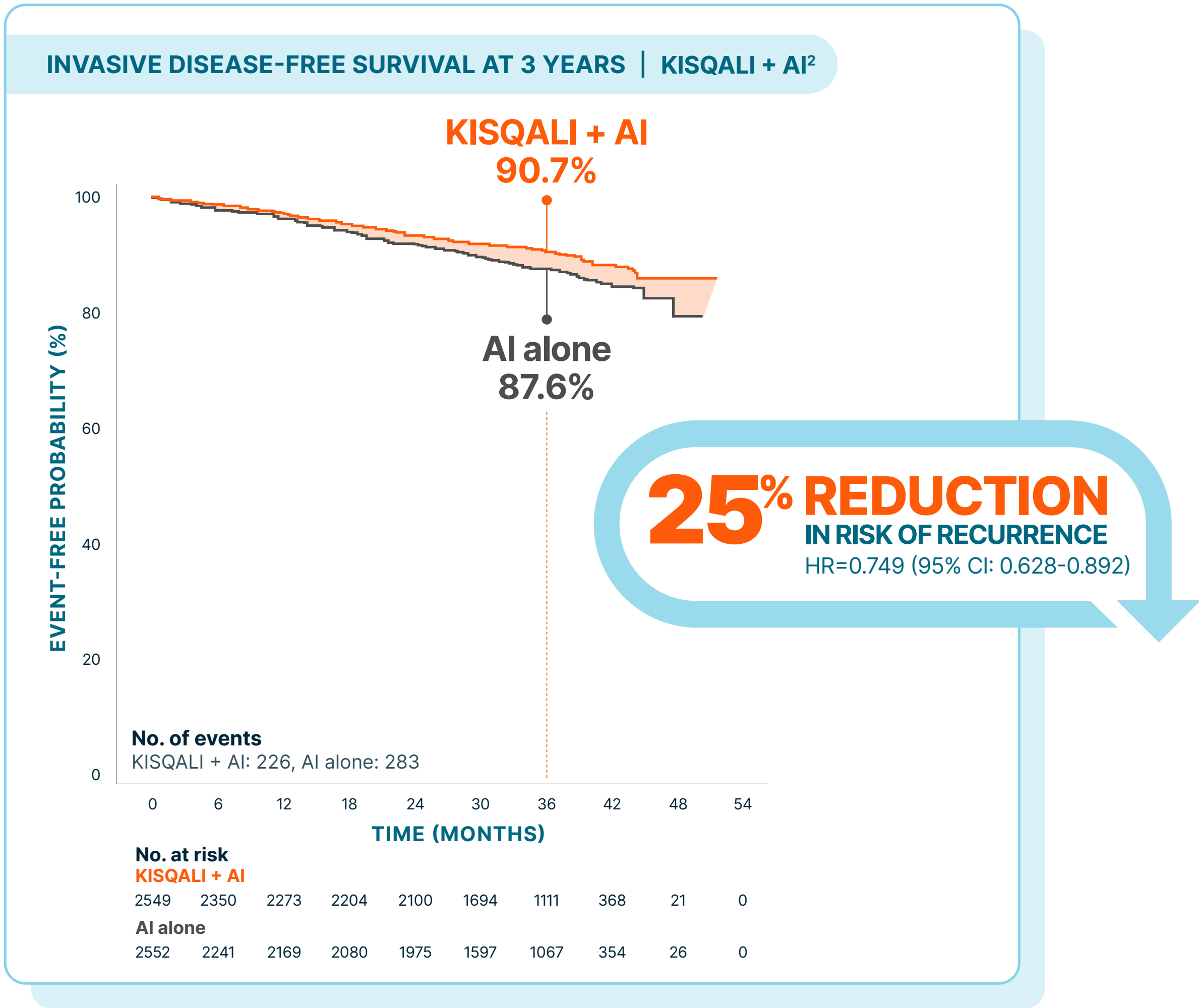


# Patients like Erin need a treatment option that helps reduce their risk of recurrence

## OVERALL POPULATION

### NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 33.3 months



Hazard ratio is based on stratified Cox model.<sup>5</sup>

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

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>

- At 3 years, the absolute difference in iDFS was 3.1%<sup>2</sup>
- 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<sup>2</sup>
- In an interim analysis, a statistically significant reduction in risk was achieved despite the greater challenge of showing clinical benefit in a broad range of patients<sup>2,6</sup>

**KISQALI is proven to help reduce the risk of recurrence in patients with stage II or III HR+ /HER2- eBC—including those with high-risk node-negative disease, like Erin**

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.<sup>2,6</sup>

\*Men and premenopausal women also received goserelin.<sup>6</sup>

**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.

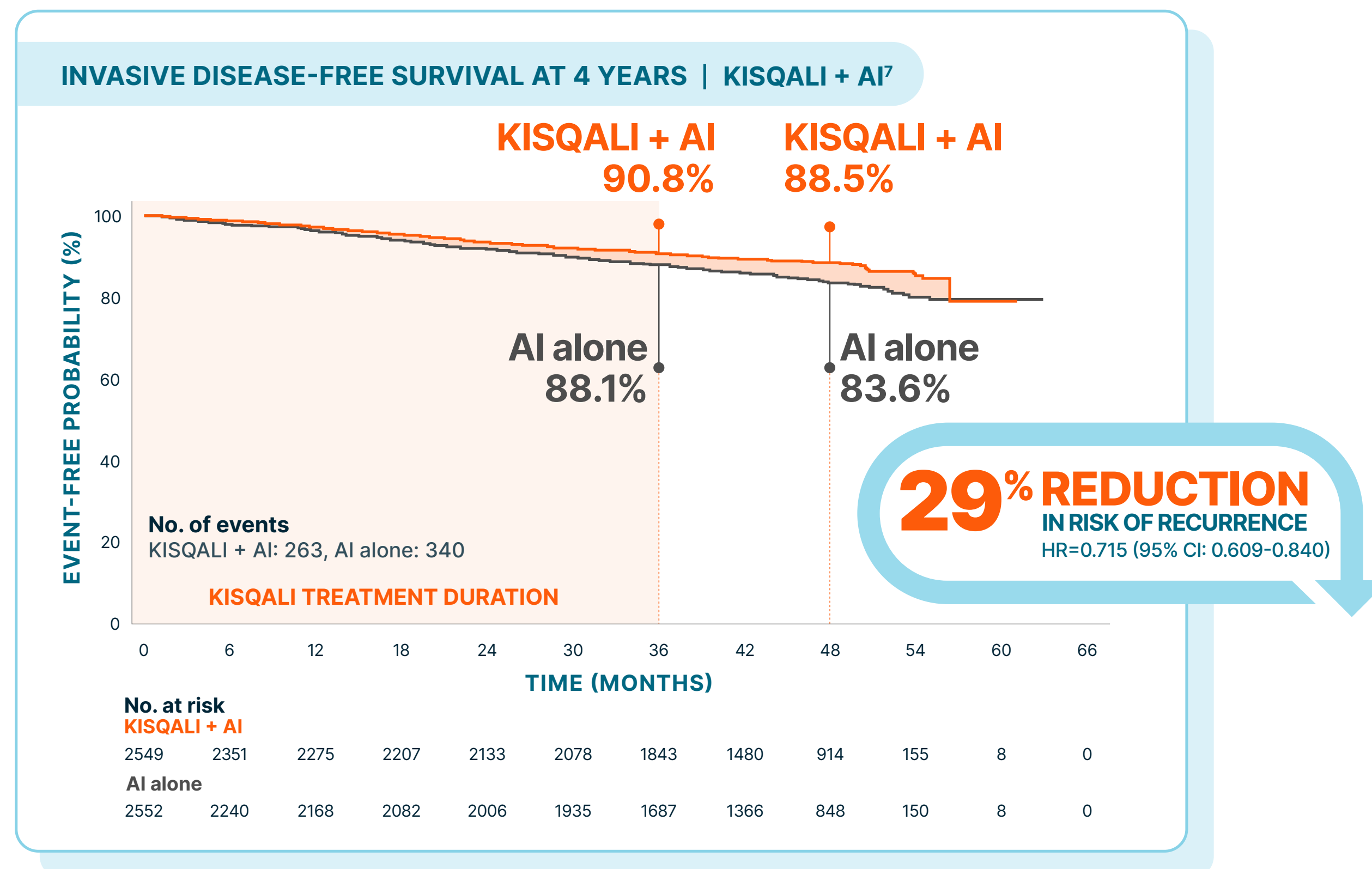


# The iDFS benefit increased over time with KISQALI for patients with HR+/HER2- eBC—beyond the 3-year treatment period

## 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%<sup>7</sup>
- 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<sup>7</sup>
- 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
- In an interim analysis, a statistically significant reduction in risk was achieved despite the greater challenge of showing clinical benefit in a broad range of patients<sup>2,6</sup>

**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.<sup>5</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.

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

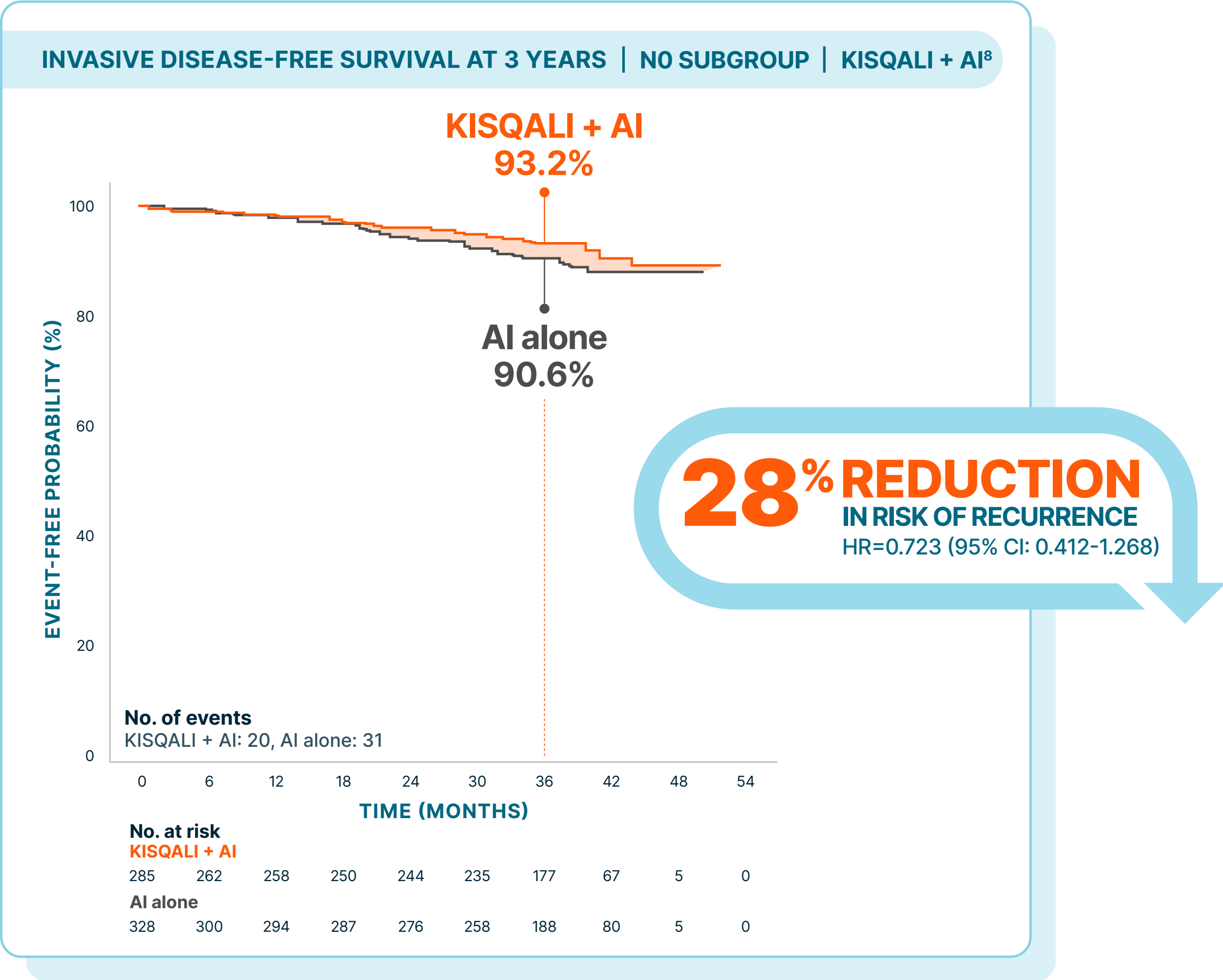
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# KISQALI—the only CDK4/6 inhibitor approved for patients like Erin who have stage II NO HR+/HER2- eBC with high genomic risk

## NODE-NEGATIVE SUBGROUP

### NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 38.7 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>

- At 3 years, the absolute difference in iDFS values for the NO subgroup was 2.6%<sup>8</sup>

The iDFS benefit seen in the NO subgroup was consistent with the overall 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. Results from the node-negative subgroup are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.<sup>6</sup>

### 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.

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

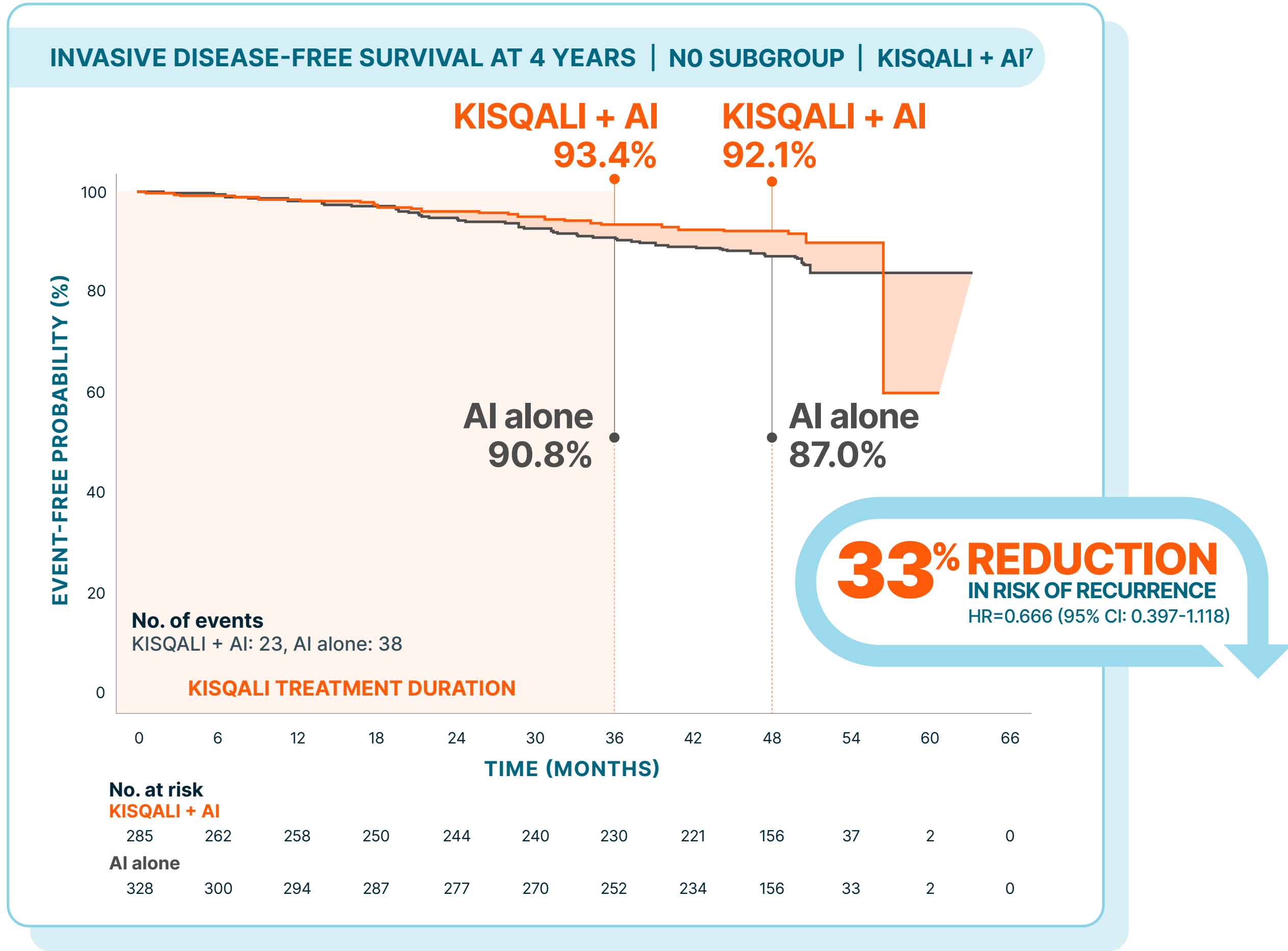


For patients with stage II/III N0 HR+/HER2- eBC, the iDFS benefit increased over time with KISQALI—beyond the 3-year treatment period

NODE-NEGATIVE SUBGROUP

NATALEE: KISQALI + AI vs AI alone

At a median follow-up of 49.1 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>

- At 4 years, the absolute difference in iDFS values for the N0 subgroup was 5.1%<sup>7</sup>

The increased iDFS benefit seen in the N0 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. Results from the node-negative subgroup are exploratory and hypothesis-generating; as such, there was no statistical procedure controlling for type 1 error.<sup>6</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%).

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



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 (%)
INFECTIONS AND INFESTATIONS				
Infections*	37	2	27	0.9
NERVOUS SYSTEM DISORDERS				
Headache	23	0.4 <sup>†</sup>	17	0.2 <sup>†</sup>
GASTROINTESTINAL DISORDERS				
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>
GENERAL DISORDERS AND ADMINISTRATION-SITE CONDITIONS				
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>
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
Alopecia	15	0	4.6	0
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS				
Cough	13	0.1 <sup>†</sup>	8	0.1 <sup>†</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>

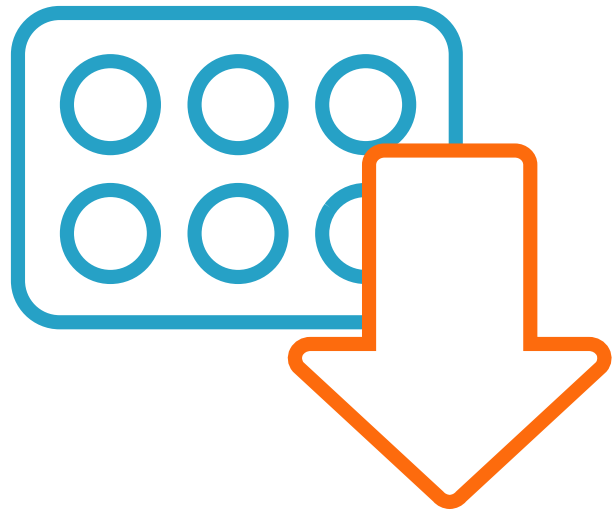
The NATALEE trial was designed to maximize the efficacy benefit of KISQALI while minimizing dose-dependent ARs and adherence issues related to tolerability

- 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 4 years of follow-up<sup>7</sup>

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

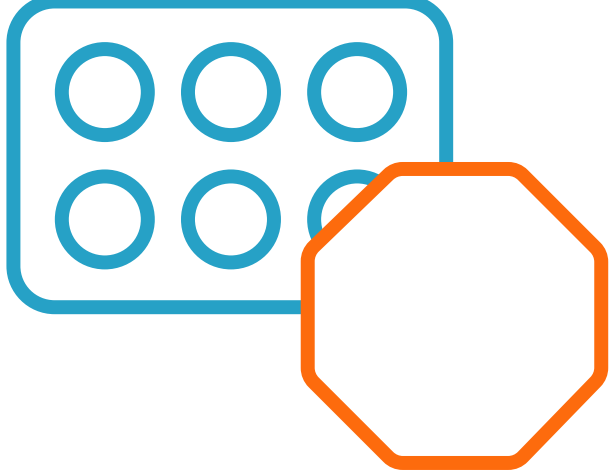


**With KISQALI, most adverse reactions were manageable and reversible with dose reduction, which may have helped patients remain on therapy**



**Rate of dose reductions due to ARs<sup>9</sup>**

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



**Rate of discontinuation due to ARs<sup>9</sup>**

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

• Median time to KISQALI discontinuation was 4.2 months<sup>10</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)**

**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.

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



Adverse reactions      Reductions and discontinuations



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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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Patient  
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## KISQALI is proven in the broadest range of patients with stage II/III HR+/HER2- eBC—including patients like Erin who have stage II (T2N0) disease and high 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  $\geq 20\%$  or high genomic risk.<sup>2</sup>

Regardless of tumor size, nodal status, grade, age ( $\geq 18$  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)

AI, aromatase inhibitor; 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-negative.

**References:** 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) for Breast Cancer V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed February 5, 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. 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 6. 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 7. 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. 8. 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. 9. Data on file. CLEE011012301C (NATALEE) final iDFS analysis results. Novartis Pharmaceuticals Corp; 2023. 10. 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 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.

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



## 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.

**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.

**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.**

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



Novartis Pharmaceuticals Corporation  
East Hanover, New Jersey 07936-1080

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