

Novartis Kisqali® significantly reduced the risk of recurrence by 25% across a broad population of patients with early breast cancer; clinically meaningful benefit was consistent across subgroups

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Kisqali is the first and only CDK4/6 inhibitor to demonstrate a consistent, clinically meaningful benefit across a broad population of patients with HR+/HER2- early breast cancer, regardless of disease stage, menopausal or nodal status¹

Results were also consistent across all secondary endpoints, including distant disease-free survival and recurrence-free survival, with a trend for improved overall survival*¹

The safety profile of Kisqali was favorable at 400 mg with low rates of symptomatic adverse events and limited treatment modifications when administered up to three years¹

Collectively, NATALEE results have the potential to more-than-double the number of patients who could benefit from treatment with a CDK4/6 inhibitor in the adjuvant setting²

EAST HANOVER, N.J., June 2, 2023 -- Novartis today presents positive primary endpoint data from the pivotal Phase III NATALEE trial at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. Data showed that Kisqali® (ribociclib) plus endocrine therapy (ET), compared to ET alone, lowered the risk of cancer recurrence by 25.2% in patients with stage II and III hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) early breast cancer (HR=0.748; 95% CI: 0.618, 0.906; p=0.0014) along with a consistent, clinically meaningful invasive disease-free survival (iDFS) benefit across key pre-specified subgroups (see table below)¹.

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Kisqali iDFS benefit across key pre-specified subgroups¹:

	Hazard Ratio 95% CI	
Intention-To-Treat Population	0.748	0.618, 0.906 (p=0.0014)
AJCC Tumor Stage II	0.761	0.525, 1.103
AJCC Tumor Stage III	0.740	0.592, 0.925
Node-positive disease	0.771	0.630, 0.944
Node-negative disease	0.630	0.341, 1.165
Pre-menopausal women and men	0.722	0.530, 0.983
Post-menopausal women	0.781	0.613, 0.997

Kisqali data across all secondary efficacy endpoints was also consistent, including distant disease-free survival (DDFS) (26% risk reduction) and recurrence-free survival (RFS) (28% risk reduction), with a trend for improvement in overall survival (OS) (HR=0.759; 95% CI: 0.539, 1.068)*¹.

The safety profile of Kisqali at 400 mg was favorable with low rates of symptomatic adverse events (AEs) and limited need for dose modifications when administered up to three years¹. The most frequently reported AEs of special interest (grade 3 or higher) were neutropenia (43.8%) and liver-related AEs (e.g. elevated transaminases) (8.3%)¹. Grade 3 or higher QT interval prolongation and diarrhea were low for Kisqali at 1.0% and 0.6%, respectively¹.

"These landmark results will fundamentally change how we treat patients with stage II and III HR+/HER2- early breast cancer who are in need of new, well-tolerated options that prevent their cancer from coming back," said Dennis J. Slamon, M.D., Director of Clinical/Translational Research, UCLA Jonsson Comprehensive Cancer Center and Chairman and Executive Director of Translational Research In Oncology (TRIO) and NATALEE trial lead investigator. "Addressing this unmet need across such a broad patient population could help streamline treatment decisions for healthcare providers and keep many more at-risk patients cancer-free without disrupting their daily lives."

"Patients diagnosed with HR+/HER2- early breast cancer remain at risk of cancer recurrence, given that one-third of patients diagnosed with stage II and more than half of those diagnosed with stage III will unfortunately experience a return of their cancer," said Shreeram Aradhye, M.D., President, Global Drug Development and Chief Medical Officer, Novartis. "The compelling data from NATALEE highlight the potential of Kisqali to reduce the risk of cancer recurrence in this at-risk population, including node-negative patients, while maintaining a favorable safety profile. These potentially practice-changing results reinforce the unique and well-established profile of Kisqali as a proven treatment in HR+/HER2- metastatic breast cancer."

"After an early breast cancer diagnosis, patients live with a persistent and lifelong worry that their cancer will return," said Fran Visco, President, National Breast Cancer Coalition, and member of the NATALEE Steering Committee. "The National Breast Cancer Coalition partners with industry and scientists to help find

treatments that will make certain that does not happen. Educated patient advocate participation in all phases of research, especially in designing and implementing clinical trials, is critical to making certain patients have meaningful options, and we are grateful that Novartis welcomed our collaboration and participation in all aspects of the NATALEE trial."

Novartis plans to submit these Phase III data to regulatory authorities in the US and Europe before end of year.

About NATALEE

NATALEE is a global Phase III multi-center, randomized, open-label trial to evaluate the efficacy and safety of Kisqali with ET as adjuvant treatment versus ET alone in patients with HR+/HER2- EBC, being conducted in collaboration with TRIO¹. The adjuvant ET in both treatment arms was a non-steroidal aromatase inhibitor (NSAI; anastrozole or letrozole) and goserelin if applicable¹. The primary endpoint of NATALEE is iDFS as defined by the Standardized Definitions for Efficacy End Points (STEEP) criteria¹. A total of 5,101 adult patients with HR+/HER2- EBC across 20 countries were randomized in the trial¹.

Results showed Kisqali plus ET, compared to ET alone, lowered the risk of cancer recurrence by 25.2% (HR=0.748; 95% CI: 0.618, 0.906; p=0.0014), along with consistent clinically meaningful iDFS benefit across key pre-specified subgroups: AJCC Tumor Stage II (HR=0.761; 95% CI: 0.525, 1.103), AJCC Tumor Stage III (HR=0.740; 95% CI: 0.592, 0.925), node-negative disease (HR=0.630; 95% CI: 0.341, 1.165), node-positive disease (HR=0.771; 95% CI: 0.630, 0.944), pre-menopausal women and men (HR=0.722; 95% CI: 0.530, 0.983), post-menopausal women (HR=0.781; 95% CI: 0.613, 0.997)¹. Kisqali data across all secondary efficacy endpoints was also consistent, including DDFS (26% risk reduction) and RFS (28% risk reduction), with a trend for improvement in OS (HR=0.759; 95% CI: 0.539, 1.068)^{*1}.

Median study duration of follow up was 34 months (range 21-48 months) with clinical benefits observed after approximately two years¹. NATALEE explored a lower starting dose (400 mg) of Kisqali than the dose approved for treatment in metastatic breast cancer (MBC) (600 mg) with the goal to minimize disruptions to patient quality of life without compromising efficacy. The safety profile of Kisqali at 400 mg was favorable with low rates of symptomatic AEs and limited need for dose modifications when administered up to three years¹. The most frequently reported AEs of special interest (grade 3 or higher) were neutropenia (43.8%) and liver-related AEs (e.g. elevated transaminases) (8.3%)¹. Grade 3 or higher QT interval prolongation and diarrhea were low for Kisqali at 1.0% and 0.6%, respectively¹.

*Results based on pre-specified interim analysis for OS at time of primary iDFS analysis; additional follow up is planned to obtain more mature OS data¹.

About Early Breast Cancer

More than 90% of patients diagnosed with breast cancer have EBC³. Despite standard-of-care adjuvant therapy, approximately one-third of those diagnosed with stage II and more than half of those diagnosed with stage III HR+/HER2- EBC experience cancer recurrence^{4,5}. The risk of recurrence continues over decades with more than half of breast cancer recurrences occurring five or more years after diagnosis^{4,6}. For many of these patients, there are currently no targeted therapeutic options outside of the standard chemotherapy and ET⁷.

About Kisqali® (ribociclib)

Kisqali has consistently demonstrated OS benefit while preserving or improving quality of life across three Phase III trials in MBC⁸⁻¹⁹. Updates to the NCCN Guidelines® for breast cancer, released in January 2023, recommend ribociclib (Kisqali) as the only Category 1 preferred CDK4/6 inhibitor for first-line treatment of patients with HR+/HER2- MBC when combined with an aromatase inhibitor (AI)²⁰. Additionally, Kisqali has the highest rating of any CDK4/6 inhibitor on the ESMO Magnitude of Clinical Benefit Scale, achieving a score of five out of five for first-line pre-menopausal patients with HR+/HER2- advanced breast cancer²¹. Further, Kisqali in combination with either letrozole or fulvestrant has uniquely, among other CDK4/6 inhibitors, received a score of four out of five for post-menopausal patients with HR+/HER2- advanced breast cancer treated in the first line²².

Kisqali has been approved in 99 countries worldwide, including by the United States Food and Drug Administration (FDA) and the European Commission. In the U.S., Kisqali is approved for the treatment of adult patients with HR+/HER2- advanced or MBC in combination with an AI as initial ET or fulvestrant as initial ET or following disease progression on ET in post-menopausal women or in men. In the EU, Kisqali is approved for the treatment of women with HR+/HER2- advanced or MBC in combination with either an AI or fulvestrant as initial ET or following disease progression. In pre- or peri-menopausal women, the ET should be combined with a luteinizing hormone-releasing hormone agonist¹⁹.

Novartis is committed to continuing to study Kisqali in breast cancer. Novartis is collaborating with SOLTI, which is leading the HARMONIA study to test whether Kisqali changes tumor biology to enable a better response to ET compared to Ibrance®** (palbociclib) for patients with HR+/HER2-, HER2-enriched subtype²³ MBC, and with the Akershus University Hospital in Norway on the NEOLETRIB trial, a neoadjuvant Phase II trial studying the effects of Kisqali in HR+/HER2- EBC to discover the potentially unique underlying mechanism of action²⁴.

Kisqali was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

Please see full Prescribing Information for Kisqali, available at www.Kisqali.com

Indications

KISQALI® (ribociclib) is a prescription medicine used to treat adults with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer that has gotten worse or has spread to other parts of the body (metastatic), in combination with:

- an aromatase inhibitor as the first endocrine-based therapy; or
- fulvestrant as the first endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

It is not known if KISQALI is safe and effective in children.

Important Safety Information

What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

Lung problems. KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your health care provider right away if you have any new or worsening symptoms, including:

- trouble breathing or shortness of breath

- cough with or without mucus
- chest pain

Severe skin reactions. Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse; reddened skin; flu-like symptoms; skin pain/burning; blistering of the lips, eyes, or mouth; or blisters on the skin or skin peeling, with or without fever.

Heart rhythm problems (QT prolongation). KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your health care provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.

Liver problems (hepatobiliary toxicity). KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark or brown (tea-colored) urine
- feeling very tired
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Low white blood cell counts (neutropenia). Low white blood cell counts are very common during treatment with KISQALI and may result in infections that may be severe. Your health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your health care provider may tell you to decrease your dose, temporarily stop, or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

What should I tell my health care provider before taking KISQALI?

Before you take KISQALI, tell your health care provider if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby
 - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.
 - Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
 - Talk to your health care provider about birth control methods that may be right for you during this time.
 - If you become pregnant or think you are pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other, causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and avoid drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

The most common side effects of KISQALI include:

- decreased white blood cell counts
- decreased red blood cell counts
- abnormal liver function tests
- infections
- nausea
- increased kidney function test
- tiredness
- decreased platelet counts
- diarrhea
- vomiting
- headache
- constipation
- hair loss
- cough
- rash
- back pain
- low blood sugar level

KISQALI may cause fertility problems if you are male and take KISQALI. This may affect your ability to father a child. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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About Novartis

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