FDA approves Novartis Kisqali® to reduce risk of recurrence in people with HR+/HER2- early breast cancer

Sep 17, 2024

- *Broad indication in HR+/HER2- stage II and III early breast cancer (EBC) at high risk of recurrence approximately doubles population eligible for CDK4/6 inhibitor adjuvant therapy[1,2]*
- *Kisqali® (ribociclib) significantly reduced the risk of recurrence by 25% vs. endocrine therapy (ET) alone; consistent benefit and a well-tolerated safety profile seen across all sub-groups in pivotal Phase III NATALEE trial, including patients with node-negative disease[3-6]*
- *Late-breaking NATALEE data recently presented at ESMO provides additional confidence, with deepening of invasive disease-free survival benefit after completion of the three-year treatment period across all patient subgroups[7]*
- *People with stage II or III HR+/HER2- EBC face significant risk of recurrence – often as incurable metastatic disease – despite adjuvant ET and regardless of nodal involvement[8,9]*
- *Already a proven treatment in HR+/HER2- metastatic breast cancer[1,10-20], Kisqali is under regulatory review worldwide, including in the EU, for the EBC indication*

East Hanover, N.J., Sept. 17, 2024 -- Novartis today announced that the US Food and Drug Administration (FDA) has approved Kisqali® (ribociclib) in combination with an aromatase inhibitor (AI) for the adjuvant treatment of people with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) stage II and III early breast cancer (EBC) at high risk of recurrence, including those with node-negative (N0) disease[1].

The approval is based on results from the pivotal Phase III NATALEE trial, which showed a significant and clinically meaningful 25.1% (HR=0.749; 95% CI: 0.628, 0.892; P=0.0006) reduction in risk of disease recurrence in a broad population of patients with HR+/HER2- stage II and III EBC treated with adjuvant Kisqali plus endocrine therapy (ET) compared to ET alone, including those with high-risk N0 disease[3-6]. The invasive disease-free survival (iDFS) benefit was consistently observed across all patient subgroups[3-6].

"The FDA approval of Kisqali for this early breast cancer population, including those with N0 disease, is a pivotal moment in improving our approach to care," said Dennis J. Slamon, M.D., Director of Clinical/Translational Research, UCLA Jonsson Comprehensive Cancer Center and Chairman of the Board of Translational Research In Oncology (TRIO) and NATALEE trial lead investigator. "Today's approval allows us to offer treatment with a CDK4/6 inhibitor to a significantly broader group of people as a powerful tool that, combined with endocrine therapy, can help further minimize their risk of cancer returning."

In EBC, Kisqali is taken with or without food as a once-daily oral dose of 400 mg (two 200 mg tablets) for three weeks, followed by one week off treatment, in combination with four weeks of any AI[1]. Patients should take Kisqali for three years. The NATALEE trial showed the safety profile of Kisqali at the 400 mg dose was well tolerated, with discontinuations mainly driven by asymptomatic laboratory findings[3]. Adverse events (AEs) of special interest in the Kisqali + ET arm of the NATALEE trial include (all Grades, and Grades 3/4, respectively): neutropenia (62.5%, 44.3%), liver-related AEs (26.4%, 8.6%), QT interval prolongation (5.3%, 1.0%), and interstitial lung disease/pneumonitis (1.5%, 0.0%)[4].

An updated analysis from the NATALEE trial recently presented at the European Society for Medical Oncology (ESMO) Congress 2024 reinforces the data analyzed by the FDA. Results showed a deepening benefit beyond the three-year treatment period and reduced the risk of recurrence by 28.5% (HR=0.715; CI 95% 0.609-0.840; P<0.0001), compared to ET alone, in patients with stage II and III HR+/HER2- EBC[7]. Novartis will continue evaluating NATALEE patients for longer-term outcomes, including overall survival.

Raising the bar for EBC survivors

Approximately 90% of breast cancer cases in the US are diagnosed early (stages I-III) and treated promptly with curative intent – sometimes with adjuvant ET[21,22]. In spite of this, people with stage II and III HR+/HER2- EBC remain at risk of cancer coming back – in most cases, as incurable metastatic disease[8,9]. Recurrence remains a lifelong concern, though most tumors return within the first years, even in cases with no lymph node involvement[8,23]. Despite ET, 10% of people with high-risk N0 disease may face recurrence within the first three years after diagnosis[24].

"With this approval, we are redefining treatment options for a broader population of people impacted by breast cancer and facing the persistent risk of recurrence," said Victor Bultó, President, US, Novartis. "We continue to transform cancer care with Kisqali, building on its established profile in the metastatic setting and now helping a wide range of people as they strive to stay cancer-free following an early-stage diagnosis."

"Breast cancer treatment can take a toll on your physical and mental health, and you may worry about the risk of your cancer coming back. This risk is different for everyone, depending on many factors, but should not be underestimated," said Valarie Worthy, Co-Founder & Vice President of Community Outreach and Engagement, Touch, The Black Breast Cancer Alliance. "The FDA approval of Kisqali for more people with breast cancer is welcome news and empowers people diagnosed with early breast cancer with a new option to help manage and control their risk of cancer coming back."

Novartis prioritizes patient access by offering the Kisqali patient support program. This resource assists eligible patients in navigating treatment initiation, providing educational materials, clarifying insurance coverage, and identifying potential financial assistance options. For additional information, patients and healthcare professionals can call 1-800-282-7630.

About NATALEE

NATALEE is a global Phase III multi-center, randomized, open-label trial to evaluate the efficacy and safety of Kisqali® (ribociclib) with ET as an investigational adjuvant treatment versus ET alone in patients with stage II and III HR+/HER2- EBC, being conducted in collaboration with TRIO[25]. The adjuvant ET in both treatment arms was a non-steroidal AI (NSAI; anastrozole or letrozole) and goserelin if applicable[25]. The primary endpoint of NATALEE is iDFS as defined by the Standardized Definitions for Efficacy End Points (STEEP) criteria[25]. A total of 5,101 adult patients with HR+/HER2- EBC across 20 countries were randomized in the trial[25].

About Kisqali® (ribociclib)

Kisqali® (ribociclib) is a selective cyclin-dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated, can enable cancer cells to grow and divide too quickly. Targeting CDK4/6 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably.

Beyond today's FDA approval of Kisqali for EBC patients in the US, regulatory reviews for Kisqali as an EBC treatment are ongoing worldwide, including in the EU and China.

Kisqali has been approved as a treatment for metastatic breast cancer (MBC) patients in 99 countries worldwide, including by the US FDA and the European Commission[1,26]. In the US, Kisqali is indicated for the treatment of adults 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[1].

In MBC, Kisqali has consistently demonstrated statistically significant overall survival benefit across three Phase III trials[10-20]. The NCCN Guidelines® for breast cancer recommend ribociclib (Kisqali) as the only Category 1 preferred CDK4/6 inhibitor for first-line treatment of people living with HR+/HER2- when combined with an AI, making Kisqali the preferred first-line treatment of choice for US prescribers in HR+/HER2- MBC[27].

Kisqali was developed by Novartis under a research collaboration with Astex Pharmaceuticals.

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

About Novartis in Breast Cancer
For more than 35 years, Novartis has been at the forefront of driving scientific advancements for people touched by breast cancer and improving clinical practice in collaboration with the global community. With one of the most comprehensive breast cancer portfolios and pipeline, Novartis leads the industry in discovery of new therapies and combinations in HR+/HER2- breast cancer, the most common form of the disease.

Indication

What is KISQALI?

KISQALI® (ribociclib) is a prescription medicine used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer:

- in combination with an aromatase inhibitor for stage II and III early breast cancer with a high risk of coming back
- that has gotten worse or has spread to other parts of the body (advanced or metastatic breast cancer) 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

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

IMPORTANT SAFETY INFORMATION

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 or burning, blistering of the lips, eyes, or mouth, 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. 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 upper 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 high blood pressure that is not controlled
- have decreased thyroid gland (hypothyroidism)
- 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 kidney problems
- 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 in people with early breast cancer include:

- decreased white blood cell counts
- decreased red blood cell counts
- increased liver function tests
- infections
- increased kidney function test
- decreased platelet counts
- nausea
- headache
- tiredness

The most common side effects of KISQALI in people with advanced or metastatic breast cancer include:

- decreased white blood cell counts
- decreased red blood cell counts
- increased 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 in males, which 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.

Please see accompanying full Prescribing Information including Patient Information.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," "to reduce," "remains," "continue," "transform," "evaluate," "likelihood," "ensuring," "updates," "should," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Kisqali in combination with an aromatase inhibitor (AI), or regarding potential future revenues from such product. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Kisqali in combination with an AI will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Kisqali in combination with an AI will be commercially successful in the future. In particular, our expectations regarding Kisqali in combination with an AI could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

Reimagine medicine with us: Visit us at https://www.novartis.com and https://www.novartis.us, and connect with us on LinkedIn, LinkedIn US, Facebook, X/Twitter, X/Twitter US and Instagram.

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