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PRESS RELEASE

1 in 4 metastatic breast cancer patients treated with Novartis Kisqali® remain progression-free beyond 4 years

- *Progression-free response stayed consistent across age, BMI, and menopausal status in MONALEESA pooled analysis*[1]
- *KISQALI is only CDK4/6i to demonstrate statistically significant overall survival (OS) in MBC across all Phase III trials*[2-12]
- *New NATALEE 5-year sub-analysis data reinforce sustained reduction in distant disease-free survival in broadest population of EBC patients*[13]

Basel, December 9, 2025 – Novartis today announced results showing that one in four patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced breast cancer (ABC) remained progression-free for four or more years following treatment with Kisqali® (ribociclib) plus endocrine therapy (ET)[1]. Results were from a pooled, post-hoc exploratory analysis of first-line patients in the MONALEESA trials and will be presented at the 2025 San Antonio Breast Cancer Symposium® (SABCS) on December 11, 2025.

Metastatic breast cancer is cancer that has spread beyond the breasts to other parts of the body. Long-term progression-free survival benefit with Kisqali was observed in patients regardless of their menopausal status and was achieved even in a proportion of patients with unfavorable prognostic factors (liver involvement, ≥ 3 metastatic sites)[1]. Patients had a median progression-free survival of 6.8 years[1]. The median overall survival was not estimable.

Kisqali has demonstrated statistically significant overall survival (OS) across all three Phase III MONALEESA trials[2-12].

“The latest MONALEESA analysis shows that 1 in 4 patients with metastatic disease remained progression-free for four years or more. Our biomarker analyses demonstrate clinical and genomic factors potentially associated with these outstanding responses, highlighting the importance of precision medicine in identifying which patients may derive the greatest benefit from CDK4/6 inhibitors,” said Dr. Pedram Razavi, Breast Medical Oncologist and Director of Translational Oncology Partnership Program at Memorial Sloan Kettering Cancer Center, who is the author and presenter of the analysis at SABCS.

“Kisqali continues to deliver on its promise of potentially offering more time for people living with advanced breast cancer,” said Mark Rutstein, Global Head of Oncology Development at Novartis. “The results from the long-term analysis provide continued confidence in the clinical benefit of Kisqali for metastatic breast cancer patients.”

Patient and Biomarker Characteristics Associated with Long-Term Response
The post-hoc exploratory analysis of the MONALEESA-2, -3 and -7 trials in first-line HR+/HER2- MBC aimed to identify clinical characteristics and biomarkers of patients who experienced long-term response with Kisqali[1].

Characteristic	Long-term Responders (LTR) (n=153)	Non-LTR (n=349)	Directional insight
Median age (years)	59.3	58.0	Comparable across groups
Postmenopausal (%)	78	78	Balanced by menopausal status
De novo disease (%)	43	40	Similar baseline disease presentation
≥ 3 metastatic sites (%)	30	43	Fewer high-burden cases among LTRs
Liver involvement (%)	16	26	Less frequent among LTRs
Bone-only disease (%)	24	20	Slightly more common among LTRs
Mean ctDNA fraction	0.05	0.13	Lower circulating tumor DNA in LTRs
***CCND1* alteration (%)**	2	10	Less frequent among LTRs
***TP53* alteration (%)**	3	12	Less frequent among LTRs
Luminal A subtype (%)	38	25	Higher prevalence among LTRs

NATALEE 5-year Data Reinforce Sustained Benefit in Reducing Distant Recurrence
Additionally, Novartis is presenting a sub-analysis from the five-year NATALEE trial that showed Kisqali plus a nonsteroidal aromatase inhibitor (NSAI) continues to result in improved distant disease-free survival (DDFS) compared to NSAI alone[13]. This was consistent across key subgroups with node-positive and node-negative disease, reinforcing Kisqali plus NSAI as a treatment option to help reduce the risk of recurrence for the broadest population of HR+/HER2- early breast cancer (EBC) patients[13,14].

About Novartis in Breast Cancer
For more than 30 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.

About Kisqali® (ribociclib)
Kisqali® (ribociclib) is a selective cyclin-dependent kinase inhibitor, helping slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated, enable cancer cells to grow and divide quickly. Targeting CDK4/6 with enhanced precision plays a role in tumor control.

Kisqali has been approved as a treatment for breast cancer by regulatory authorities in more than 100 countries worldwide, including the U.S. FDA and the European Commission[15,16]. In the US, Kisqali is indicated in combination with an AI as an adjuvant treatment for adults with HR+/HER2- stage II and III early breast cancer at high risk of recurrence, as well as for the treatment of adults with HR+/HER2- metastatic breast cancer or ABC as initial ET; Kisqali is also approved in the metastatic indication in combination with fulvestrant as initial ET or following disease progression on ET[15].

In EBC, Kisqali is the only CDK4/6 inhibitor recommended by the NCCN Guidelines® for breast cancer as Category 1 preferred for both all node-positive disease as well as for patients with no nodal involvement with high-risk disease characteristics, such as tumor size >5 cm, or for tumors sized 2-5 cm, either Grade 2 with high genomic risk/Ki-67 ≥20% or Grade 3[17]. Kisqali approvals in EBC from regulatory authorities worldwide are ongoing, including recent approval from China's National Medical Products Administration[18]. In MBC, Kisqali has consistently demonstrated statistically significant overall survival benefit across three Phase III trials[2-12]. The NCCN Guidelines® also recommend Kisqali as the only Category 1 preferred CDK4/6 inhibitor for first-line treatment of people living with HR+/HER2- MBC when combined with an AI, making Kisqali the preferred first-line treatment of choice for US prescribers in HR+/HER2- MBC[17].

In addition, Kisqali has achieved the highest score (A) on the European Society for Medical Oncology-Magnitude of Clinical Benefit Scale (ESMO-MCBS) for EBC and has the highest rating of any CDK4/6 inhibitor on the ESMO Magnitude of Clinical Benefit Scale, achieving a score of four out of five for first-line pre-menopausal patients with HR+/HER2- advanced breast cancer[19,20]. 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 line[21].

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

Disclaimer

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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 nearly 300 million people worldwide.

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

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