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MEDIA & INVESTOR RELEASE

Novartis ribociclib (Kisqali®) recognized as Category 1 preferred breast cancer adjuvant treatment by NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

- *Ribociclib (Kisqali) plus aromatase inhibitor (AI) recommended for HR+/HER2- early breast cancer (EBC) node-positive and high-risk node-negative patients, as studied in the NATALEE trial and indicated by the FDA*[1]
- *Recommendation comes after recent FDA approval and positive CHMP Opinion for ribociclib (Kisqali) to help reduce the risk of recurrence in EBC*
- *Ribociclib (Kisqali) is also the only Category 1 preferred CDK4/6 inhibitor for first-line treatment of patients with HR+/HER2- metastatic breast cancer in combination with an AI*[1]

Basel, October 24, 2024 – This month, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for breast cancer were updated to recommend ribociclib (Kisqali®) as a Category 1 preferred CDK4/6 inhibitor (CDK4/6i) adjuvant therapy for patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) early breast cancer (EBC) in combination with an aromatase inhibitor (AI)[1]. Ribociclib (Kisqali) is the only CDK4/6i recommended 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[1].

“These evidence-based guidelines are helpful to clinicians when determining optimal treatment options for patients,” said Shreeram Aradhye, M.D., President, Development and Chief Medical Officer, Novartis. “Importantly, the NCCN Guideline recommendation of ribociclib in this broad population reaffirms the importance of offering eligible patients with early breast cancer, including those with limited nodal involvement and high-risk N0 disease, a CDK4/6i treatment like ribociclib in addition to endocrine therapy to reduce their risk of recurrence.”

A Category 1 recommendation by the NCCN Guidelines indicates high levels of clinical evidence and uniform consensus among NCCN on ribociclib (Kisqali) as an appropriate treatment for these patients. This recommendation comes after the presentation of longer-term results from the Phase III NATALEE trial at the European Society for Medical Oncology (ESMO) Congress 2024, which showed a deepening efficacy benefit beyond the Kisqali treatment duration in a broad population of patients, including those with node-negative disease; as well as the recent FDA approval and CHMP positive opinion for Kisqali in the EBC indication[2].

The updated guidelines, consistent with the FDA indication per the NATALEE trial, approximately double the number of patients that could benefit from treatment with a CDK4/6i in the adjuvant setting[3].

NCCN Guidelines also continue to recommend ribociclib (Kisqali) as the only Category 1 preferred CDK4/6i for first-line treatment of patients with HR+/HER2- metastatic breast cancer in combination with an AI; ribociclib (Kisqali) is also recommended as a Category 1 preferred regimen for first- and subsequent-line therapies** in HR+/HER2- MBC in combination with fulvestrant[1].

To access NCCN Guidelines, visit www.nccn.org.

* Adjuvant treatment with Kisqali has only been studied in high-risk patients.
** If CDK4/6 inhibitor was not previously used.

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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.

In addition to the recent FDA approval of Kisqali for EBC patients in the US and CHMP positive opinion in Europe, regulatory reviews for Kisqali as an EBC treatment are ongoing worldwide.

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[4,5]. 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[4]. 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 agonist[5].

In MBC, Kisqali has consistently demonstrated statistically significant overall survival benefit across three Phase III trials[6-16]. In addition to being included in the NCCN Guidelines® for breast cancer[1], 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 cancer[17]. 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[18].

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.

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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 connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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