

Media Release

More time for people with advanced breast cancer : New Novartis Kisqali® data demonstrates more than five years and longest ever median overall survival in HR+/HER2- advanced breast cancer

- *With the new MONALEESA-2 data, only Kisqali has shown statistically significant overall survival (OS) benefit with an aromatase inhibitor for postmenopausal women with HR+/HER2- advanced breast cancer in the first-line (1L) setting¹*
- *Kisqali plus letrozole achieved median OS of over 5 years (63.9 months), a survival benefit of over 12 months vs. placebo plus letrozole in postmenopausal women (HR=0.76; p=0.004)¹*
- *Kisqali is the only CDK4/6 inhibitor with proven OS benefit across all three Phase III trials with multiple treatment combination partners, regardless of menopausal status or line of therapy¹⁻³*
- *MONALEESA-2 median overall survival (OS) results reinforce Kisqali as the CDK4/6 inhibitor with unrivaled OS evidence⁶*

Vilvoorde, September 21, 2021 — Despite various breakthrough technological advancements, breast cancer continues to kill more women in Europe than any other type of cancer.⁷ In Belgium 45 women die of breast cancer every week, most of them because of advanced metastatic disease.^{8,9} At the European Society for Medical Oncology (ESMO) Congress 2021, Novartis announced the results of the final overall survival (OS) analysis of the Phase III MONALEESA-2 study demonstrating a statistically significant and clinically meaningful improvement in survival (median 63.9 vs. 51.4 months; HR=0.76; 95% CI: 0.63-0.93; p=0.004)¹. The study evaluated Kisqali® (ribociclib) in combination with letrozole compared to placebo plus letrozole in postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced or metastatic breast cancer with no prior systemic treatment for advanced disease.

The analysis found that after a median follow-up of over six and a half years, the longest for any CDK4/6 inhibitor trial to date, the improvement in the median OS was greater than one year¹. MONALEESA-2 showed that after five years, patients treated with Kisqali in combination with letrozole had more than a 50% chance of survival (52.3% vs. 43.9%; 95% CI: 46.5-57.7 vs. 38.3-49.4)¹.

“These remarkable ribociclib overall survival data are highly encouraging and represent the longest reported median survival from a randomized trial in any type of breast cancer. This extension of life is great news for our patients and the building block for further progress.,” said

Gabriel N. Hortobagyi, MD, FACP, professor of medicine with The University of Texas MD Anderson Cancer Center. “I have spent the last 45 years researching and increasing our scientific understanding of breast cancer, so it is incredibly rewarding to see just how far we’ve come.”

“As we reimagine medicine and strive for cures, our MONALEESA program continues to push boundaries by demonstrating that Kisqali is unique in its ability to give people living with advanced cancer more time,” said Susanne Schaffert, PhD, President, Novartis Oncology.

“Our mission is to improve and extend the lives of those with cancer. For people with HR+/HER2- advanced breast cancer, these data are not just numbers and may mean more life milestones — yet, we will not rest as we continue to investigate the full potential that Kisqali can bring to patients.”

In MONALEESA-2, a 12-month delay in time to chemotherapy was observed with Kisqali (median 50.6 vs. 38.9 months; HR=0.74; 95% CI: 0.61-0.91) compared to those taking letrozole alone¹. With this longer follow-up, no new safety signals were observed; adverse events were consistent with previously reported Phase III trial results for Kisqali. These new OS results mark the third statistically significant and clinically meaningful survival benefit achieved by Kisqali in the MONALEESA program. Novartis will submit the data to global health authorities.

“When treatment offers long overall survival—and in this case, the longest ever reported in HR+/HER2- advanced breast cancer—patients have more time to be with family and loved ones and to pursue whatever makes them happy. These data offer new hope for people with advanced or metastatic breast cancer, which remains the leading cause of cancer death in women worldwide,” said Shirley A. Mertz, President, Metastatic Breast Cancer Network (MBCN).

About Kisqali® (ribociclib)

Kisqali is the CDK4/6 inhibitor with the largest body of Phase III clinical trials evidence demonstrating consistent and superior overall survival benefit compared to endocrine therapy alone. Overall survival results from MONALEESA-7 and MONALEESA-3 were presented at ASCO 2019 and ESMO 2019 respectively, as well as published in the New England Journal of Medicine, with updated exploratory analyses presented at SABCS 2020 and ASCO 2021, demonstrating Kisqali plus endocrine therapy significantly extends life in pre/perimenopausal or postmenopausal women with HR+/HER2- advanced breast cancer ^{2,3, 5,6}.

Kisqali is approved by the US Food and Drug Administration (FDA) and by the European Commission (EC) as initial endocrine-based therapy for postmenopausal women with HR+/HER2- locally advanced or metastatic breast cancer in combination with an aromatase inhibitor based on findings from the pivotal MONALEESA-2 trial. Kisqali in combination with an aromatase inhibitor is approved for the treatment of pre-, peri- or postmenopausal women as initial endocrine-based therapy, and also indicated for use in combination with fulvestrant as both first- or second-line therapy in postmenopausal women by the FDA and by the EC. Kisqali is approved in over 95 countries.

Novartis is continuing to reimagine cancer with additional trials of Kisqali. NATALEE is a large confirmatory clinical trial of Kisqali with endocrine therapy in the adjuvant treatment of HR+/HER2- early breast cancer being conducted in collaboration with Translational Research In Oncology (TRIO)¹⁰. Novartis is also collaborating with SOLTI, who is leading the Phase III HARMONIA clinical trial evaluating Kisqali compared to palbociclib in patients with HR+/HER2- advanced breast cancer with aggressive tumor biology, defined as HER2-enriched¹¹.

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

About Novartis in Advanced Breast Cancer

Novartis tackles breast cancer with superior science, collaboration and a passion for transforming patient care. We've taken a bold approach to our research by including patient populations often neglected in clinical trials, identifying new pathways or mutations that may play a role in disease progression and developing therapies that not only maintain, but also improve, quality of life for patients. Our priority over the past 30 years and today is to deliver treatments proven to improve and extend lives for those diagnosed with advanced breast cancer.

References

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