Novartis presents new Kisqali® data showing longest median overall survival ever reported in HR+/HER2- advanced breast cancer

Sep 19, 2021

- With the MONALEESA-2 final analysis, only Kisqali has reported statistically significant overall survival (OS) benefit with an aromatase inhibitor for postmenopausal women with HR+/HER2- advanced breast cancer in the first-line (1L) setting[2]
- Kisqali plus letrozole achieved median OS of over five years (63.9 months), a survival benefit of over 12 months vs. placebo plus letrozole in postmenopausal women (HR=0.76; p=0.004)[2]
- Kisqali is the only CDK4/6 inhibitor with proven OS benefit across all three Phase III trials of the MONALEESA program with different endocrine therapy partners, regardless of menopausal status or line of therapy[2-4]
- MONALEESA-2 OS data to be presented at ESMO Congress 2021 as a late-breaker in an oral session

EAST HANOVER, N.J., Sept. 19, 2021 /PRNewswire/ -- Novartis today announced results of the final overall survival (OS) analysis of the Phase III MONALEESA-2 study, which 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. These data will be presented as a late-breaker oral presentation at the European Society for Medical Oncology (ESMO) Congress 2021 on September 19 (#LBA17).

Kisqali in combination with letrozole met its key secondary endpoint of OS, 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)[2]. 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 over one year[2]. 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)[2].

"These remarkable ribociclib overall survival data are highly encouraging and represent the longest reported median survival from a randomized trial in HR+/HER2- advanced 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."

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 alone[2]. With this longer follow-up, no new safety signals were observed; adverse events were consistent with previously reported Phase III trial results for Kisqali.

"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 breast 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, the primary endpoint progression-free survival (PFS) was met at the initial analysis [median PFS; 95% CI (19.3 months - not reached) vs. 14.7 months (13.0 - 16.5 months); HR=0.556; p=0.00000329][5]. 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 to support label updates.

"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).

Visit https://www.hcp.novartis.com/virtual-congress/esmo-2021/ for the latest information from Novartis, including our commitment to the Oncology community, and access to our ESMO2021 Virtual Scientific Program data presentations (for registered participants).

About Kisqali® (ribociclib)

Kisqali is the CDK4/6 inhibitor with the largest body of clinical trial 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[3,4,6,7].

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. 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[9]. Kisqali is approved in over 95 countries[1].

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-enriched[1].

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

Important Safety Information

KISQALI can cause severe or life-threatening inflammation of the lungs. Patients should tell their health care provider right away if they experience breathing problems or chest pains. KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. KISQALI is not indicated for concomitant use with tamoxifen due to an increased risk of QT prolongation. Patients should tell their health care provider right away if they have a change in their heartbeat (a fast or irregular heartbeat), or if they feel dizzy or faint. KISQALI can cause serious liver problems. Patients should tell their health care provider right away if they get any of the following signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), dark or brown (tea-colored) urine, feeling very tired, loss of appetite, pain on the upper right side of the stomach area (abdomen), and bleeding or bruising more easily than normal. Low white blood cell counts are very common when taking KISQALI and may result in infections that may be severe. Patients should tell their health care provider right away if they have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Before taking KISQALI, patients should tell their health care provider if they are pregnant, or plan to become pregnant as KISQALI can harm an unborn baby. 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. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI.

Patients should tell their health care provider about all of the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements since they may interact with KISQALI. Patients should avoid grapefruit or grapefruit juice while taking KISQALI.

The most common side effects (incidence ≥20%) include white blood cell count decreases, nausea, infections, tiredness, diarrhea, vomiting, hair loss, headache, constipation, rash, and cough. The most common grade 3/4 side effects (incidence >5%) were low neutrophils, low leukocytes, abnormal liver function tests, and low lymphocytes. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

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

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.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of Novartis – is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis employs nearly 15,500 people in the United States. For more information, please visit https://www.novartis.us.

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References

1. Novartis Data on File. Novartis Pharmaceuticals Corp: 2021.
2. Hortobagyi, et al. Overall survival (OS) results from the phase III MONALEESA (ML)-2 trial of postmenopausal patients with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2–) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib. Presented at the European Society of Medical Oncology (ESMO) Congress, September 16-21, 2021, (Abstract #LBA17).
3. Im, S. A. et al. Overall Survival with Ribociclib plus Endocrine Therapy in Breast Cancer. N Engl J Med 2019; 381:307-316.
4. Slamon DJ, Neven P, Chia S, Fasching PA, De Laurentiis M, Im S-A, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. N Engl J Med. 2020;382(6):514–24.
5. Hortobagyi G, Stemmer S, Burris H, et al. Ribociclib as First-Line Therapy for HR-Positive, Advanced Breast Cancer. N Engl J Med. 2016;375:1738-1748.
6. Slamon D, Neven P, Chia S, et al. Updated overall survival (OS) results from the Phase III MONALEESA-3 trial of postmenopausal patients (pts) with HR+/HER2– advanced breast cancer (ABC) treated with fulvestrant (FUL) ± ribociclib (RIB. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, June 5, 2021, (Abstract #1001).
7. Tripathy D, Im S-A, Colleoni M, et al, Updated overall survival (OS) results from the phase III MONALEESA-7 trial of pre- or perimenopausal patients with HR+/HER2– advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib. Presented at the San Antonio Breast Cancer Symposium, December 9, 2020. Abstract #PD2-04.
8. Ferlay, J, et al. Global Cancer Observatory: Cancer Today. International Agency for Research on Cancer. Available at: https://gco.iarc.fr/today/online-analysis-table?v=2020&mode=cancer&mode_population=continents&population=900&populations=900&key=asr&sex=2&cancer=39&type=1&statistic=5&prevalence=0&population_group=0 accessed August 18, 2021.
9. Kisqali (ribociclib) Prescribing information. East Hanover, New Jersey, USA: Novartis Pharmaceuticals Corporation; July 2020.
10. Novartis Pharmaceuticals and Translational Research in Oncology (2018, December 7 - 2026, May 29). A Trial to Evaluate Efficacy and Safety of Ribociclib With Endocrine Therapy as Adjuvant Treatment in Patients With HR+/HER2- Early Breast Cancer (NATALEE). Identifier NCT03701334. https://clinicaltrials.gov/ct2/show/NCT03701334 .

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- https://clinicaltrials.gov/ct2/show/NCT03701334