Novartis Kisqali® demonstrates nearly five years median overall survival in metastatic breast cancer

Dec 09, 2020

- MONALEESA-7 median overall survival (OS) results reinforce Kisqali as the CDK4/6 inhibitor with unrivaled OS evidence[1]
- Kisqali plus endocrine therapy had a median OS of nearly five years (58.7 months), the longest ever reported for premenopausal women with HR+/HER2- metastatic breast cancer (MBC), after a median of 53.5 months follow-up[1]
- Kisqali offers the chance for more life for younger women with HR+/HER2- MBC, which remains the leading cause of cancer death in women 20-59 years old[2,3]

EAST HANOVER, N.J., Dec. 9, 2020 -- Novartis today announced updated median overall survival (OS) results for Kisqali® (ribociclib) in combination with endocrine therapy, marking the longest survival data ever reported in premenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+HER2-) metastatic breast cancer. The Phase III MONALEESA-7 trial evaluated Kisqali plus endocrine therapy (goserelin plus either an aromatase inhibitor or tamoxifen) as initial treatment compared to endocrine therapy alone in pre- and perimenopausal women with HR+/HER2- metastatic breast cancer. These updated median OS data will be presented today at the 2020 San Antonio Breast Cancer Virtual Symposium.

After a median of 53.5 months follow-up, median OS for patients taking Kisqali in combination with endocrine therapy was 58.7 months vs. 48.0 months for endocrine therapy alone (HR=0.76 [95% CI: 0.61-0.96])[1]. Additionally, a similar median OS benefit of 58.7 months was observed with Kisqali plus an aromatase inhibitor subgroup vs. 47.7 months in the placebo plus aromatase inhibitor subgroup (HR=0.80 [95% CI, 0.62-1.04]), and the survival benefit shown in subgroup analyses was consistent with the intent-to-treat (ITT) population[1]. This exploratory ad hoc analysis follows the previously reported MONALEESA-7 OS analysis presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and published in the New England Journal of Medicine, which demonstrated statistically significant OS results for Kisqali in combination with endocrine therapy. After a median of 42 months follow-up, the estimated survival rate was 70.2% [95% CI: 63.5 to 76.0] for women who received Kisqali in combination with endocrine therapy compared to 46.0% [95% CI, 32.0 to 58.9] for women who received endocrine therapy alone (HR=0.71 [95% CI: 0.54 to 0.95]) p=0.00973)[4].

"These longer-term data showing ribociclib can help women with metastatic breast cancer live longer are remarkable and emphasize the progress we've made in treating this disease, which until now, had an estimated median survival of just three years," said Debu Tripathy, M.D., chair of Breast Medical Oncology, MD Anderson Cancer Center. "I'm hopeful the proven overall survival benefit with ribociclib will shift the standard for those with metastatic breast cancer, and that patients are empowered to ask their doctors about which treatments give them the best chance of living longer with the best quality of life."

The need for chemotherapy was delayed by more than four years (50.9 months) in patients taking Kisqali in combination with endocrine therapy (HR=0.69; 95% CI: 0.56-0.87)[1]. No new adverse events were observed. Kisqali is not indicated for use with tamoxifen.

"We're proud to be able to provide the CDK4/6 inhibitor with the longest ever reported median overall survival benefit of nearly five years in younger women," said Susanne Schaffert, Ph.D., President, Novartis Oncology. "It is our vision to develop therapies that give patients the longest life possible, and these best-in-class data help us realize that vision by proving Kisqali extends the lives of younger premenopausal women with metastatic breast cancer, who typically have more aggressive disease and unique needs."

Metastatic breast cancer in premenopausal women is biologically distinct, more aggressive and the leading cause of cancer death in women 20-59 years old[2,3].

About Kisqali® (ribociclib)

Kisqali was initially approved by the US Food and Drug Administration (FDA) in March 2017 and by the European Commission (EC) in August 2017, 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 was 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 in July 2018 and by the EC in December 2018. Regulatory filings are underway with other health authorities worldwide.

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

Approved Uses

KISQALI® (ribociclib) is a prescription medicine used in combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced or metastatic breast cancer, as initial endocrine-based therapy; or fulvestrant for the treatment of postmenopausal women with HR+/HER2- advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. It is not known if Kisqali is safe and effective in children or adolescents.

Important Safety Information

KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Patients should contact their doctor right away if they have trouble breathing or shortness of breath, chest pain, cough with or without mucus. Severe skin reactions skin reactions have been reported with Kisqali. Patients should get medical help right away if they have a severe rash or rash that keeps getting worse.

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 highly 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 infections, white blood cell count decreases, headache, cough, nausea, tiredness, diarrhea, vomiting, constipation, hair loss and rash. The most common Grade 3/4 side effects (incidence >5%) were infections, low neutrophils, low leukocytes, low red blood cells, abnormal liver function tests, low lymphocytes, low phosphate levels and vomiting. 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 more than 15,000 people in the United States. For more information, please visit https://www.novartis.us.

Novartis and Novartis US is on Twitter. Sign up to follow @Novartis at https://twitter.com/novartisnews and @NovartisUS at https://twitter.com/NovartisUS.

For Novartis multimedia content, please visit https://www.novartis.com/news/media-library

For questions about the site or required registration, please contact media.relations@novartis.com.

# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Eric Althoff	**Jamie Bennett**
Head, US Corp & Country External Comms,	Director, US Media Relations
Global Media & Corp Communications	+1 862-217-3976
+1 646 438 4335	jamie.bennett@novartis.com
eric.althoff@novartis.com	

Novartis Investor Relations
E-mail: investor.relations@novartis.com

Sloan Simpson +1 862 778 5052

References

1. 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.
2. Benz CC. Impact of aging on the biology of breast cancer. Crit Rev Oncol Hematol. 2008; 66:65-74.
3. World Health Organization. Top cancer per country, estimated age-standardized mortality rates (World) in 2018, females, all ages. 2018. Available at http://gco.iarc.fr/today/home. Accessed May 2019.
4. Tripathy D et al. Overall Survival with Ribociclib plus Endocrine Therapy in Breast Cancer. N Engl J Med 2019; 381:307-316.
5. "Survival Rates." Metastatic Breast Cancer Network, mbcn.org/3957-2/.

List of links present in page

1. https://qa1.novartis.us/news/media-releases/novartis-kisqali-demonstrates-nearly-five-years-median-overall-survival-metastatic-breast-cancer
2. https://www.kisqali.com/
3. https://qa1.novartis.us/home
4. https://twitter.com/novartisnews
5. https://twitter.com/NovartisUS
6. https://www.novartis.com/news/media-library
7. mailto:media.relations@novartis.com
8. mailto:media.relations@novartis.com
9. mailto:jamie.bennett@novartis.com
10. mailto:eric.althoff@novartis.com
11. mailto:investor.relations@novartis.com
12. https://gco.iarc.fr/today/home