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MEDIA & INVESTOR RELEASE

Novartis Kisqali® reports longest median overall survival in postmenopausal HR+/HER2- metastatic breast cancer patients

- *MONALEESA-3 median overall survival (OS) results of 53.7 months underscore that Kisqali offers more life to postmenopausal women with HR+/HER2- metastatic breast cancer (MBC) in addition to the OS benefit demonstrated for premenopausal women as shown in MONALEESA-7*[1,2]

- *The relative risk reduction of death by 36% in the MONALEESA-3 first-line (1L) postmenopausal population highlights that Kisqali is the only CDK4/6i with proven OS for 1L in combination with fulvestrant*[1]

- *Time to chemotherapy was delayed to 4 years (48.1 months) in postmenopausal women taking Kisqali in combination with fulvestrant compared to 2.4 years (28.8 months) for women receiving fulvestrant only*[1]

- *MBC takes a life in the US approximately every 12 minutes, creating an urgent need for treatment proven to extend life while preserving quality of life*[3-6]

Basel, June 2, 2021 — Novartis today announced updated median overall survival (OS) results for Kisqali® (ribociclib) in combination with fulvestrant in postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) metastatic breast cancer. The exploratory analysis of OS after an additional 16.9 months of follow-up of the Phase III MONALEESA-3 trial evaluated Kisqali plus fulvestrant as first- or second-line treatment compared to fulvestrant alone in postmenopausal women with HR+/HER2- metastatic breast cancer[1]. The analysis found that with extended follow-up of more than four years, Kisqali in combination with fulvestrant continued to demonstrate a clinically relevant OS benefit of more than a year compared with fulvestrant alone[1]. These updated median OS data (Abstract #1001) will be presented in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Successfully demonstrating overall survival improvements in an incurable disease like metastatic breast cancer is a significant achievement, and is what we ultimately strive for in most clinical trials,” said Dennis J. Slamon, MD, Director of Clinical/Translational Research, University of California, Los Angeles Jonsson Comprehensive Cancer Center. “When the MONALEESA-7 trial achieved median OS of nearly five years at SABCS 2020, it was the first time we saw a median survival this long with a CDK4/6 inhibitor in the metastatic setting. It is encouraging to see median OS results of nearly 4.5 years in the MONALEESA-3 study, underscoring that ribociclib offers hope for patients to have a longer life while preserving quality of life.”

After a median follow-up of 56.3 months, median OS for patients taking Kisqali in combination with fulvestrant was 53.7 months vs. 41.5 months for fulvestrant alone (HR=0.73; 95% CI: 0.59-0.90)[1]. Additionally, Kisqali plus fulvestrant had prolonged OS in the first-line (median, not reached vs. 51.8 months; HR=0.64; 95% CI: 0.46-0.88) and second-line (median, 39.7 vs. 33.7 months; HR=0.78; 95% CI: 0.59-1.04) treatment subgroups[1]. This exploratory ad hoc analysis follows the previously reported MONALEESA-3 OS analysis presented at the European Society of Medical Oncology (ESMO) Congress 2019 and published in the *New England Journal of Medicine*, which demonstrated statistically significant OS results for Kisqali in combination with fulvestrant with a 28% reduction in the risk of death (HR=0.72; 95% CI: 0.568-0.924; p=0.00455)[6,7]. Results from the subgroup analyses were consistent with the survival data seen with the intent-to-treat (ITT) population[1].

“As overall survival data mature, we’re proud that Kisqali continues to distinguish itself, offering more life for both younger and older women living with metastatic breast cancer,” said Susanne Schaffert, Ph.D., President, Novartis Oncology. “These data confirming the sustained efficacy of Kisqali for a broad range of people with HR+/HER2- metastatic breast cancer regardless of line of therapy are unique and inspiring. Our exploration of the benefits of Kisqali continues as we evaluate its potential in the adjuvant setting.”

The need for chemotherapy was delayed to 4 years (48.1 months) in patients taking Kisqali in combination with fulvestrant and 28.8 months in the patients taking fulvestrant alone (HR=0.70; 95% CI: 0.57-0.88). Adverse events were consistent with previously reported Phase III trial results[1].

“Breast cancer has recently emerged as the most common cancer among females worldwide. The decrease in screenings due to COVID-19 creates a potential threat to improvements in breast cancer survival,” said Jean A. Sachs, MSS, MLSP, CEO of Living Beyond Breast Cancer. “What gives me hope is the continued focus on driving science for our community, and to see progress being made in metastatic breast cancer research as we work toward cures.”

Visit https://www.hcp.novartis.com/virtual-congress/a-2021/ for the latest information from Novartis, including our commitment to the Oncology community, and access to our ASCO21 Virtual Scientific Program data presentations (for registered participants).

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.

Important Safety Information from the Kisqali EU SmPC
Kisqali® (ribociclib) is a prescription medicine approved in combination with an aromatase inhibitor as initial endocrine-based therapy in women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. It is not known if Kisqali is safe and effective in children or adolescents. 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.

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This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or

maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and 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 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 products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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