Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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MEDIA & INVESTOR RELEASE

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

- *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]

Basel, December 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.

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.

Disclaimer
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.

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

Anja von Treskow
Novartis External Communications
+41 79 392 8697
anja.von_treskow@novartis.com

Julie Masow
Novartis Oncology Media Relations
+1 862 579 8456
julie.masow@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 778 5052
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		