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Novartis Kisqali significantly prolongs life in women with HR+/HER2- advanced breast cancer now in two distinct Phase III trials

- *In MONALEESA-3, Kisqali plus fulvestrant achieved statistically significant improvement in overall survival in post-menopausal women in first- and second-line setting*
- *Kisqali is the only CDK4/6 inhibitor proven to prolong life with multiple combination partners*
- *These results build on the unique MONALEESA-7 data presented at ASCO 2019 showing overall survival benefit of Kisqali plus aromatase inhibitor in pre-/peri-menopausal women*
- *Full results will be presented at an upcoming medical congress and submitted to global health authorities*

Basel, July 31, 2019 – Novartis today announced Kisqali® (ribociclib) achieved statistically significant improvement in overall survival in the Phase III MONALEESA-3 clinical trial. This is the second Phase III clinical trial in which Kisqali combination therapy met the key secondary endpoint of overall survival at the pre-planned interim analysis. MONALEESA-3 evaluated efficacy and safety of Kisqali plus fulvestrant in postmenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in both the first-line and second-line settings.

“We are thrilled that Kisqali combination therapy again has demonstrated improved overall survival for patients with HR+/HER2- advanced breast cancer – first in pre-menopausal and peri-menopausal women in MONALEESA-7, and now in post-menopausal women in MONALEESA-3,” said Susanne Schaffert, PhD, President, Novartis Oncology. “We will continue to reimagine cancer to help patients live longer, and also improve quality of life as we work towards finding a cure for this incurable disease.”

No new safety signals were observed; adverse events were consistent with previously reported Phase III trial results. Kisqali is approved for use in various indications in more than 75 countries around the world.

Novartis will present the full results at an upcoming medical congress and submit the data to global health authorities.

About Kisqali® (ribociclib)

Kisqali® (ribociclib) is the CDK4/6 inhibitor with the largest body of first-line clinical trial evidence demonstrating consistent and sustained efficacy compared to endocrine therapy alone¹. Kisqali is the only CDK4/6 inhibitor to achieve statistically significant overall survival in

two Phase III trials with two distinct patient populations¹. Overall survival follow-up is ongoing for the Phase III MONALEESA-2 trial.

Novartis is continuing to reimagine cancer by investigating Kisqali in early breast cancer. The NATALEE study is a Phase III 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)¹.

Kisqali is approved for use in more than 75 countries around the world, including the United States and European Union member states. 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 worldwide¹.

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.

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 $\geq 20\%$) 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.

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 “build on,” “upcoming,” “work towards,” “continuing,” “investigating,” “potential,” “will,” “expectations,” “investigational,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Kisqali, or regarding potential future revenues from Kisqali. 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 Kisqali 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 Kisqali will be commercially successful in the future. In particular, our expectations regarding Kisqali 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 and economic conditions; safety, quality 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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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1. Novartis Data on File.

2. Slamon J, et al. Ribociclib (RIB) + fulvestrant (FUL) in postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2-) advanced breast cancer (ABC): Results from MONALEESA-3. Journal of Clinical Oncology 2018.

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