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MEDIA & INVESTOR RELEASE

New Novartis data demonstrate only Kisqali® offers more life in the first-line setting for postmenopausal HR+/HER2- advanced breast cancer patients

- *With further follow-up of MONALEESA-3, Kisqali plus fulvestrant achieved a median overall survival (OS) of more than five-and-a-half years (67.6 months) in the first-line (1L) setting for postmenopausal women living with HR+/HER2- aBC*[1]

- *When used 1L, Kisqali plus fulvestrant added nearly 16 months of survival benefit to the lives of patients compared to fulvestrant alone, with a 33% relative reduction in the risk of death*[1]

- *Kisqali is the only CDK4/6 inhibitor-fulvestrant combination to demonstrate an OS benefit in this 1L setting*[1]

- *Kisqali remains the CDK4/6 inhibitor with the longest median OS reported and with consistent OS benefit across three Phase III trials, regardless of combination partner, line of therapy, menopausal status, or site and number of metasteses*[1-10]

Basel, May 4, 2022 — Novartis today announced updated median overall survival (OS) results for Kisqali® (ribociclib) in combination with fulvestrant in the first-line subgroup of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer. The analysis of patients treated in first-line with Kisqali plus fulvestrant demonstrated a significant OS benefit of nearly 16 months compared to those treated with fulvestrant alone. This updated exploratory OS analysis from the Phase III MONALEESA-3 study will be presented as a late-breaker mini-oral presentation at the 2022 European Society of Medical Oncology (ESMO) Breast Cancer Congress (Abstract #LBA4).

“MONALEESA-3 results continue to demonstrate the survival benefit of treatment with ribociclib for postmenopausal women with advanced breast cancer,” said Dennis J. Slamon, MD, Director of Clinical/Translational Research, University of California, Los Angeles Jonsson Comprehensive Cancer Center. “Whether partnered with fulvestrant or an aromatase inhibitor in the first-line setting, ribociclib offers oncologists a CDK4/6 inhibitor with consistent benefit in providing women with HR+/HER2- advanced breast cancer more quality time, regardless of their disease characteristics.”

In this MONALEESA-3 exploratory analysis, patients were further evaluated for a median of 71 months, more than two-and-a-half years of additional follow-up since the final key

secondary endpoint OS analysis, which was presented at ESMO Congress 2019 and published in the *New England Journal of Medicine.* The final OS analysis demonstrated a statistically significant OS benefit for Kisqali in combination with fulvestrant and a relative reduction in the risk of death by 28% compared to fulvestrant alone in the full population (HR=0.72; 95% CI: 0.568-0.924; p=0.00455)[1,5-6].

This new updated analysis with a median follow-up of five years found that in the first-line setting, Kisqali plus fulvestrant (n=237) achieved 67.6 months median OS as compared to 51.8 months for those treated with fulvestrant alone (n=128) (HR=0.673; 95% CI: 0.504-0.899)[1]. Patients treated with Kisqali plus fulvestrant compared to those on fulvestrant alone in the first-line setting experienced over one-and-a-half years of additional delay to subsequent use of chemotherapy (49.2 months versus 29.0 months, respectively; HR=0.624; 95% CI: 0.481-0.810)[1].

With this extended follow-up, the estimated survival rate at five years was 56.5% (95% CI: 49.5-62.9) for women who received Kisqali in combination with fulvestrant in first-line compared to 42.1% (95% CI: 33.2-50.7) for women who received fulvestrant alone[1]. Additionally, 16.5% of patients in the Kisqali plus fulvestrant arm (n=39) compared to 8.6% of those in the fulvestrant only arm (n=11) were still ongoing on therapy at this longer follow-up[1]. No new adverse events were observed.

“It is a tremendous achievement to see such remarkable, consistent overall survival results from the MONALEESA clinical trial program, demonstrating how Novartis is transforming care for people with breast cancer as we continue to work toward cures,” said Jeff Legos, Executive Vice President, Global Head of Oncology & Hematology Development. “The unique profile of Kisqali continues to be reinforced, with results from MONALEESA-3 pushing the boundaries of how using a Kisqali-combination treatment regimen can extend lives of postmenopausal women living with HR+/HER2- advanced breast cancer without compromising quality of life.”

The MONALEESA-3 overall survival data from ESMO Congress 2019 are featured in a media release[6].

About Kisqali® (ribociclib)
Kisqali is the only CDK4/6 inhibitor with proven overall survival benefit across all three Phase III advanced trials[1-10], and is recognized by the National Comprehensive Cancer Network (NCCN) guidelines as the only CDK4/6 inhibitor with overall survival benefit in first-line HR+/HER2- advanced breast cancer[11]. Additionally, Kisqali has the highest rating of any CDK4/6 inhibitor on the ESMO Magnitude of Clinical Benefit Scale, achieving a score of five out of five for first-line premenopausal patients with HR+/HER2- advanced breast cancer[12.] Further, Kisqali in combination with either letrozole or fulvestrant has received a score of four out of five for first-line postmenopausal patients with HR+/HER2- advanced breast cancer[13].

Kisqali has been approved in more than 95 countries worldwide, including by the United States Food and Drug Administration (FDA) and the European Commission, for the treatment of women with HR+/HER2- advanced or metastatic breast cancer in combination either with an aromatase inhibitor or with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy[14-15]. Kisqali in combination with fulvestrant is approved as initial endocrine-based therapy or following disease progression on endocrine therapy in men by the FDA[14].

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)[16]. Novartis is collaborating with SOLTI, who is leading HARMONIA to test the hypothesis whether Kisqali changes tumor biology to enable a better response to

endocrine-based therapy compared to Ibrance®* for patients with advanced HR+/HER2-, HER2-enriched subtype.

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

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

Disclaimer

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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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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