Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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MEDIA UPDATE

New CDK4/6i data at ASCO reinforce Novartis Kisqali® as only drug in class with consistently proven overall survival benefit in HR+/HER2- metastatic breast cancer

- *Kisqali is the only CDK4/6 inhibitor with consistent overall survival (OS) benefit seen across all three Phase III trials, with the longest median OS benefit ever reported for HR+/HER2- mBC*[1-10]
- *OS benefit from Kisqali in combination with letrozole was maintained in 1L treatment of postmenopausal women with HR+/HER2- mBC, following Kisqali dose reduction when recommended*[11]
- *A matching-adjusted indirect comparison analysis shows Kisqali plus an aromatase inhibitor (AI) is associated with better symptom-related quality of life when compared to Verzenio®* plus AI when used in 1L*[12]

Basel, June 3, 2022 — Novartis today announced new overall survival (OS) and quality of life (QoL) analyses which evaluated Kisqali® (ribociclib) plus endocrine therapy for patients with hormone receptor-positive/human epidermal growth factor receptor-negative (HR+/HER2-) advanced or metastatic breast cancer. These data will be presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.

In a new exploratory analysis of data from the Phase III MONALEESA-2 study, Kisqali plus letrozole maintained an OS benefit for postmenopausal patients with HR+/HER2- metastatic breast cancer treated in the first-line, including for those patients who required dose modification of Kisqali (Abstract #1017). Median OS seen in this analysis was 66.0 months in patients with at least one Kisqali dose reduction from the 600mg starting dose compared to 60.6 months in patients who did not have a dose reduction (95% CI: 57.6-75.7 and 42.5-79.2, respectively). Additionally, an OS benefit was observed in all patient subgroups treated with Kisqali and letrozole[11].

“Kisqali is the only CDK4/6 inhibitor to have consistently demonstrated statistically significant overall survival across its entire Phase III program,” said Reshema Kemps-Polanco, Executive Vice President, US Oncology at Novartis. “Overall survival is the ultimate goal of oncology clinical trials and what patients hope for—to live longer, and to thrive. We are extremely proud of our quality of life data and that Kisqali has the longest median overall survival ever reported in HR+/HER2- metastatic breast cancer.”

A matching-adjusted indirect comparison (MAIC), a method used to estimate the comparative effectiveness of treatments after adjusting for differences in the patient populations where head-to-head trials do not exist, indicated that treatment with Kisqali plus aromatase inhibitor is associated with better symptom-related QoL when indirectly compared to Verzenio®* plus an aromatase inhibitor in the first-line setting for postmenopausal patients with HR+/HER2- metastatic breast cancer

(Abstract #1015). Results from the MAIC favored the Kisqali-aromatase inhibitor combination in time to sustained deterioration (TTSD), including appetite loss (HR=0.46; 95% CI: 0.27-0.81), diarrhea (HR=0.23; 95% CI: 0.23-0.79), fatigue (HR=0.63; 95% CI: 0.41-0.96) and arm symptoms (HR=0.49; 95% CI: 0.30-0.79)[12].

“As a clinician and clinical researcher who treats patients with metastatic breast cancer, I always strive to find a therapy that gives patients more time while also maintaining the quality of that time,” said Dr. Hope S. Rugo, Professor of Medicine and Director, Breast Oncology and Clinical Trials Education, University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center. “Our indirect comparison of ribociclib plus aromatase inhibitor gives initial insight into variations in symptoms that may impact quality of life and may vary between different treatment options.”

About Kisqali® (ribociclib)
Kisqali is the only CDK4/6 inhibitor with proven overall survival benefit across all three Phase III metastatic trials[1-9], 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- metastatic breast cancer[13]. 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- metastatic breast cancer[14]. 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- metastatic breast cancer[15].

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[10,16]. Kisqali in combination with fulvestrant is approved as initial endocrine-based therapy or following disease progression on endocrine therapy in men by the FDA[16].

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)[17]. 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 metastatic 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.

About Novartis in Metastatic 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 metastatic breast cancer.

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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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*Verzenio® is a registered trademark of Eli Lilly & Company.
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Novartis Media Relations
E-mail: media.relations@novartis.com

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

Ashley Buford
Novartis Oncology Communications
+1 201 953 4364
ashley.buford@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
julie.masow@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	+1 862 345 4440
Nicole Zinsli-Somm	+41 61 324 3809	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973 876 4912