Health Sciences Authority approves Novartis Kisqali®, the first and only CDK4/6 inhibitor that significantly extends life in women with HR+/ HER2- advanced breast cancer

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- *Kisqali is the only CDK4/6 inhibitor indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of pre-, peri-, or postmenopausal women with HR+/HER2- advanced or metastatic breast cancer in Singapore*[1]
- *Kisqali is also indicated with fulvestrant for the treatment of postmenopausal women with HR+/HER2- advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy*
- *HSA approval is based on MONALEESA-3 and MONALEESA-7 clinical trials, which demonstrated robust efficacy of Kisqali combination therapy in multiple treatment partners and settings*[1]

Singapore, June 20, 2019 – The Health Sciences Authority has approved Novartis Kisqali® (ribociclib, LEE011), earlier this year for women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in Singapore. Kisqali is now the only CDK4/6 inhibitor indicated for use with an aromatase inhibitor for first line treatment of pre-, peri- or postmenopausal women, and is also indicated for use in combination with fulvestrant as both first- or second-line therapy in postmenopausal women.[1]

“With this new approval, Kisqali has the potential to provide even more women with a treatment option that allow them to live a longer life without progression of disease from this incurable form of breast cancer” said Susanne Schaffert, Ph.D., CEO, Novartis Oncology. “The MONALEESA Phase III program enrolled more than 2,000 women, giving Kisqali by far, the most extensive first-line evidence in clinical trials among any of the CDK4/6 indicators.”

This approval is based on the pivotal MONALEESA-7 and MONALEESA-3 Phase III clinical trials that demonstrated prolonged progression-free survival (PFS) and improvements as early as eight weeks for Kisqali-based regimens compared to endocrine therapy alone.[1]

In MONALEESA-7, Kisqali plus an aromatase inhibitor and goserelin nearly doubled the median PFS compared to an aromatase inhibitor and goserelin alone (27.5 months compared to 13.8 months; HR=0.569; 95% CI: 0.436-0.743) in pre- or perimenopausal women.[2]

In MONALEESA-3, Kisqali plus fulvestrant demonstrated a median PFS of 20.5 months compared to 12.8 months for fulvestrant alone (HR=0.593; 95% CI: 0.480-0.732) across the overall population of first-line and second-line postmenopausal women.[3] Across the two trials, the most common adverse reactions (incidences ≥ 20%) were neutropenia, nausea, infections, fatigue, diarrhoea, leukopenia, vomiting, alopecia, headache, constipation, rash and cough.[2,3]

Susanne Schaffert, Ph.D., CEO, Novartis Oncology, added, “These exciting results add to the proven efficacy and safety profile of Kisqali, solidifying it as a standard of care for people living with HR+/HER2- metastatic breast cancer and inspiring us to continue to reimagine medicine.”

Globally, an estimated 267,000 women are diagnosed with advanced breast cancer each year and up to one-third of patients with early-stage breast cancer will subsequently develop advanced disease, for which there is currently no cure.[4,5] In Singapore, breast cancer remains as the number one cause of death for women diagnosed with cancers. Based on the Singapore Cancer Registry Annual Report in 2015, 9,634 women were diagnosed with breast cancer, accounting for nearly 1 in 3 incident cancers in females. From 2006 to 2015, Singapore saw a 32% increase in Singaporean women diagnosed with the disease and 62% of those diagnosed with advanced breast cancer are younger than 49 years old.[6] Premenopausal breast cancer is a biologically distinct and more aggressive disease than postmenopausal breast cancer, and it is the leading cause of cancer death in women 20-59 years old.[6,7] These young women face unique challenges as they are met with an incurable illness at the prime of their lives. This includes the induction of premature menopause, emotional distress, and strain on their professional and personal lives.[8,9,10]

Novartis is committed to providing novel treatment options for breast cancer patients around the world through the robust MONALEESA clinical trial program.

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 alone.

About Novartis in Advanced Breast Cancer

Novartis tackles breast cancer with superior science, collaboration and a passion for transforming patient care. We have 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 SINGAPORE PI[1]

KISQALI® (ribociclib) is a prescription medicine used in combination with an aromatase inhibitor as initial endocrine-based therapy to treat pre/peri- and postmenopausal women and in combination with 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. 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 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 white blood cell count decreases, nausea, infections, tiredness, diarrhea, vomiting, hair loss, headache, constipation, rash, and cough. The most common Grade 3/4 side effects (incidence >5%) were low neutrophils, low leukocytes, abnormal liver function tests, and low lymphocytes. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

Please see full Prescribing Information for KISQALI for more information.

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 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at

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