

# Novartis' KISQALI® (ribociclib) product monograph in Canada now includes MONALEESA-3 data demonstrating statistically significant improvement in overall survival in postmenopausal women with HR+/HER2- advanced breast cancer

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- KISQALI® is currently the only CDK4/6 inhibitor that has demonstrated statistically significant improvement in overall survival (key secondary endpoint) with various endocrine treatment partners and the broadest spectrum of patients in two Phase III trials in advanced breast cancer.<sup>1</sup>
- At the time of the second interim overall survival analysis, the MONALEESA-3 study met its key secondary endpoint demonstrating a statistically significant improvement in overall survival for the overall population.<sup>1</sup>
- In Canada, 88% of all new breast cancer cases are diagnosed in individuals over the age of 50, and approximately 10% of women diagnosed will have an initial diagnosis of metastatic breast cancer.<sup>2,3</sup>

**Dorval, Quebec, March 18, 2021** – Novartis Pharmaceuticals Canada Inc. (Novartis) is pleased to announce that statistically significant overall survival (OS) results for KISQALI® (ribociclib) in combination therapy have been approved within the KISQALI® Product Monograph. This is the second Phase III trial in which KISQALI® combination therapy met the secondary endpoint of OS at the pre-planned interim analysis.<sup>1</sup>

The pivotal Phase III MONALEESA-3 was a randomized double-blind, placebo-controlled study of KISQALI® in combination with fulvestrant for the treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer who had received no or only one line of prior endocrine treatment. These OS results have now been approved within the KISQALI® Product Monograph.

At the time of the second interim OS analysis, the study met its key secondary endpoint demonstrating a statistically significant improvement in OS for the overall population and was consistent for the prior endocrine therapy subgroups and across all other subgroups.<sup>1</sup>

"It is compelling to see consistently significant overall survival findings among pre-, peri-, and postmenopausal women," said Dr. Christine Brezden-Masley, Medical Oncologist, Mount Sinai Hospital. "These results lend an added level of confidence to help oncologists make more informed treatment decisions for their advanced or metastatic breast cancer patients."

For women living with metastatic breast cancer, also known as Stage IV breast cancer, the cancer has spread beyond the breast to other areas of the body. Cancerous cells can spread anywhere in the body, but they most commonly spread to the bones or other common sites such as, the liver, brain, lungs and skin. This may happen before or after treatment, or it may develop from reoccurring breast cancer.<sup>4</sup> Although there have been advancements in early detection and treatment, there is still no cure for metastatic breast cancer.<sup>5</sup>

"The element of time is front-and-centre for all women living with advanced or metastatic breast cancer, but for women diagnosed at an older age, navigating their disease may require different considerations which can impose an additional layer of concern and worry," said Cathy Ammendolea, Chair of the Board of Directors, Canadian Breast Cancer Network. "Increased overall survival benefit in postmenopausal women offers new hope to many."

KISQALI® is indicated in combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with HR+/HER2- advanced or metastatic breast cancer, as initial endocrine-based therapy. In pre/perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone releasing hormone (LHRH) agonist. KISQALI® is also indicated in combination 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.<sup>1</sup>

"At Novartis, we are proud of the previously shared MONALEESA-7 and the recently added MONALEESA-3 overall survival data," said Daniel Hébert, Vice-President, Medical Affairs, Oncology, Novartis Pharmaceuticals Canada Inc. "In a world where 5-year survival rates in metastatic breast cancer remain persistently low, these data sets represent additional steps toward a future in which we hope to envision advanced or metastatic breast cancer as a chronic disease."

KISQALI® is now reimbursed in [Ontario](#), [Alberta](#) and British Columbia under the respective provincial drug programs, in addition to [Quebec](#), [New Brunswick](#), [Nova Scotia](#), [Manitoba](#) and Saskatchewan. Novartis continues to work towards securing coverage across the country.

## About KISQALI® (ribociclib)

KISQALI® is a selective cyclin-dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated, can enable cancer cells to grow and divide too quickly.

Targeting CDK4/6 may play a role in ensuring that cancer cells do not continue to replicate uncontrollably. KISQALI<sup>®</sup> was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

KISQALI<sup>®</sup> first received Health Canada approval for use with letrozole on March 2, 2018, for the treatment of postmenopausal women with HR+/HER2- advanced or metastatic breast cancer as first-line endocrine-based therapy based on findings from the pivotal MONALEESA-2 trial.

### About Novartis in Advanced Breast Cancer

Novartis tackles breast cancer with advanced 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.

### About Novartis Pharmaceuticals Canada Inc.

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. In 2020, the company invested \$45 million in research and development in Canada. Located in Dorval, Quebec, Novartis Pharmaceuticals Canada Inc. employs approximately 1,000 people in Canada and is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. For further information, please consult <https://www.novartis.com/ca-en/>.

### 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 800 million people globally and we are finding 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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KISQALI is a registered trademark.

### References

1. KISQALI<sup>®</sup> Product Monograph, December 22, 2020. Available at: [https://www.novartis.com/ca-en/sites/novartis\\_ca/files/kisqali\\_scrip\\_e.pdf](https://www.novartis.com/ca-en/sites/novartis_ca/files/kisqali_scrip_e.pdf) (PDF, 2.0 MB). Accessed on March 9, 2021.
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### List of links present in page

1. <https://prod1.novartis.ca/ca-fr/ca-fr/en/news/media-releases/novartis-kisqali-ribociclib-product-monograph-canada-now-includes-monaleesa-3-data-demonstrating-statistically-significant-improvement-overall-survival-postmenopausal-women-hrher2-advanced-breast-cancer>
2. [http://health.gov.on.ca/en/pro/programs/drugs/docs/frequently\\_requested\\_drugs.pdf](http://health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf)
3. <https://www.albertahealthservices.ca/assets/programs/ps-1025651-drug-benefit-list.pdf>
4. <https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-08-19-en.pdf>
5. <https://novascotia.ca/dhw/pharmacare/pharmacare-news-bulletins.asp>
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14. <https://www.cbcn.ca/web/default/files/public/Reports/Metastatic%20Breast%20Cancer%20In%20Canada%20Report%20June%202013%20-%20English.pdf>