# Health Canada approves Novartis' KISQALI® for HR+/HER2- early breast cancer patients at high risk of recurrence

Jun 18, 2025

- *Despite endocrine therapy (ET), the risk of recurrence for people diagnosed with hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) early breast cancer (eBC) remains high, in addition to the possibility of an incurable metastatic relapse.*[1]
- *Health Canada approval is based on the pivotal Phase III NATALEE trial data, which demonstrated a clinically meaningful invasive disease-free survival (iDFS) benefit for KISQALI® plus adjuvant aromatase inhibitor (AI) in patients with stage II or III HR+/HER2- eBC.*[2]
- *KISQALI is currently the only CDK4/6 inhibitor that has demonstrated statistically significant improvement in overall survival in three Phase III trials in advanced breast cancer.*[3,4,5]

**Montreal, QC [June 18, 2025]** – Novartis Canada is pleased to announce that Health Canada has granted a Notice of Compliance (NOC) for KISQALI® (ribociclib tablets) in combination with an aromatase inhibitor (AI) for the adjuvant treatment of adult patients with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) stage II-III early breast cancer (eBC) at high risk of recurrence.[2]

Breast cancer is one of the most common cancers globally,[6] with HR+/HER2- being the most prevalent subtype, accounting for approximately 70% of cases.[7,8,9] Over 40% of HR+/HER2- breast cancer cases are diagnosed at stage II or III, with a high risk of recurrence for up to 20 years.[8,9] If cancer recurs, it is often metastatic which in most cases is considered incurable.[10,11] This progression significantly increases the burden on patients, caregivers, and healthcare systems, both financially and emotionally.[11,12] On average, 15 Canadian women will die from breast cancer every day.[13]

“Over our years supporting younger patients, we’ve seen far too many with HR+ breast cancer become metastatic even while on maintenance endocrine therapy,” said MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer. “Breast cancer is often more aggressive in younger patients, and they have higher rates of recurrence despite early treatment. So, we were thrilled to see that the positive results for KISQALI for early breast cancer are the same for patients of all ages, regardless of stage and nodal status. Our community desperately wants more effective tools to help improve their chances against this challenging disease that’s turned their life plans upside-down. This Health Canada approval is an exciting step forward.”

The Health Canada approval is based on the global Phase III NATALEE trial, which included a broad patient population with HR+/HER2- stage II and III eBC. At the final analysis, this clinical trial demonstrated a statistically significant and clinically meaningful reduction in the risk of disease recurrence with ribociclib plus AI compared to AI alone. Among patients with stage II and stage III eBC, ribociclib added to AI demonstrated a 25.1% relative reduction in the risk of an invasive disease-free survival (iDFS) event compared with AI alone[1], with a well-tolerated safety profile seen across all subgroups in pivotal Phase III NATALEE trial.[2,4,14,15]

“In the NATALEE trial, ribociclib demonstrated significant efficacy for a broad population of patients with early breast cancer,[2] said Dr. Stephen Chia, Medical Oncologist, BC Cancer and Steering Committee member of the NATALEE trial. “This approval provides a new and expanded treatment option for these patients to help reduce their risk of cancer returning. Patients deserve access to the most effective treatment options, and their individual needs should always be at the centre of shared decision making. In every situation, it’s critical to have an open, balanced risk-benefit discussion, in order to make the appropriate treatment decision that’s best suited for the patient to reduce the risk of their cancer returning.”

“While the risk of cancer returning peaks in the first five years after diagnosis, more than half of recurrences occur after this period, and the majority are metastatic and incurable,”[16,17] said Dr. Katarzyna Jerzak, Medical Oncologist, Sunnybrook Health Sciences Centre. “Ribociclib provides a new treatment option to help reduce the risk of recurrence and improve outcomes, particularly for patients at elevated risk. This approval expands our treatment arsenal with a targeted therapy that will have a meaningful impact on improving the care of patients diagnosed with early breast cancer in Canada.”

“Novartis has been advancing innovative research and medical practice in breast cancer care for over 35 years, developing one of the most comprehensive pipelines in the field. Over 100,000 people with HR+/HER2- metastatic breast cancer have been treated with KISQALI globally,[18] and now we’re focused on expanding its use to those with stage II or III HR+/HER2- early breast cancer to reduce risk of recurrence,” said Mark Vineis, Country President, Novartis Canada. “We are actively committed to working with our health system partners to ensure timely access to KISQALI and supporting Canadians and healthcare professionals to improve health outcomes.”

**About early breast cancer (eBC)**

Breast cancer is the most commonly diagnosed cancer among Canadian women, with approximately 70% of cases diagnosed in the early stages of the disease.[7,8,11] However, despite existing treatment options, people with stage II and III HR+/HER2- eBC remain at significant risk of recurrence.[11,12]

The risk of recurrence is influenced by factors such as lymph node involvement, tumor size, age at diagnosis, and biomarkers. While patients without lymph node involvement typically have a lower risk, nearly 25% of those with HR+/HER2- eBC may experience recurrence within 20 years,[1] peaking after the first five years.[19] However, more than half of recurrences still happen after five years and more than 80% of these cases are metastatic and incurable.[20]

**About KISQALI® (ribociclib tablets)**

KISQALI was previously approved by Health Canada on March 2, 2018, for the treatment of patients with HR+/HER2- advanced or metastatic breast cancer.[20]

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 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably.[2]

In eBC, KISQALI is the only CDK4/6 inhibitor recommended for both all node-positive disease and patients with no nodal involvement with high-risk disease characteristics.[20,21] The National Comprehensive Cancer Network (NCCN) guidelines recommend ribociclib (KISQALI) as a Category 1 preferred CDK4/6 inhibitor for breast cancer patients.[21] KISQALI, in combination with an AI, has the highest score (A) on the ESMO-

Magnitude of Clinical Benefit Scale for the adjuvant treatment of adults with stage II and III HR+/HER2- eBC, at high risk of recurrence.[22]

The most common Adverse Drug Reactions across the NATALEE study (>20% and exceeding the frequency for AI alone) were neutropenia (62.5% vs. 4.6%), infections (36.3% vs. 26.3%), nausea (23.3% vs.7.8%, headache (23.0% vs. 17.1%), fatigue (22.3% vs. 13.2%), leukopenia (22.3% vs. 3.6%), and abnormal liver function tests (22.3% vs. 7.6%).[2]

Please see the Product Monograph for KISQALI, available at https://www.novartis.com/ca-en/kisqalimonograph.

**About NATALEE**

NATALEE is a global Phase III multi-centre, randomized, open-label trial to evaluate the efficacy and safety of KISQALI with an AI as an investigational adjuvant treatment versus AI alone in patients with stage II and III HR+/HER2- eBC. The adjuvant ET in both treatment arms was a non-steroidal aromatase inhibitor (NSAI; anastrozole or letrozole) and goserelin, if applicable. The primary endpoint of NATALEE was invasive disease-free survival (iDFS) as defined by the Standardized Definitions for Efficacy End Points (STEEP) criteria. A total of 5,101 adult patients with HR+/HER2- eBC across 20 countries were randomized in the trial.[13,23]

**About Novartis**

Novartis is a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

In Canada, Novartis Pharmaceuticals Canada Inc. employs approximately 600 people to serve the evolving needs of patients and the healthcare system and invests over $30 million in R&D yearly in the country. For more information visit www.novartis.ca.

**Media Contact Information**

Aimee Sulliman, Communications and Patient Advocacy Lead
Email: aimee.sulliman@novartis.com
Phone: +1 416 254 6450

**References**

---

[1]Pan H, Gray R, Braybrooke J, et al. 20-Year Risks of Breast-Cancer Recurrence after Stopping Endocrine Therapy at 5 Years (incl. supplementary appendix). N Engl J Med. 2017;377(19):1836-1846. doi:10.1056/NEJMoa1701830

[2]Novartis. (2025). KISQALI Product Monograph. Accessed June 2025. https://www.novartis.com/us-en/sites/novartis_us/files/kisqali.pdf

[3]Hortobagyi G, Stroyakovskiy D. Yardley DA, et al. Ribociclib (RIB) + nonsteroidal aromatase inhibitor (NSAI) as adjuvant treatment in patients with HR+/HER2– early breast cancer: final invasive disease–free survival (iDFS) analysis from the NATALEE trial. Presented at: San Antonio Breast Cancer Symposium 2023 on December 5–9, 2023 San Antonio, TX.

[4]Bardia A, Hortobagyi GN, Lipatov O, et al. LBA23: Invasive disease–free survival (iDFS) across key subgroups from the Phase III NATALEE study of ribociclib (RIB) + a nonsteroidal aromatase inhibitor (NSAI) in patients (pts) with HR+/HER2– early breast cancer (EBC). Presented at: European Society for Medical Oncology (ESMO) Congress on 23 October 2023. Madrid, Spain.

[5]Slamon D, Stroyakovskiy D, Yardley D, et al. Ribociclib and endocrine therapy as adjuvant treatment in patients with HR+/HER2– early breast cancer: primary results from the Phase III NATALEE trial. Presented at: the American Society of Clinical Oncology Annual Meeting on June 2, 2023. Chicago, USA.

[6]International Agency for Research on Cancer (IARC). Accessed April 2025. https://gco.iarc.fr/today/en/dataviz/pie?mode=cancer&group_populations=1.

[7]American Cancer Society. Breast Cancer Facts & Figures 2019-2020. 2019. Accessed April 2025. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf.

[8]Howlader N, Altekruse SF, Li CI, et al. US incidence of breast cancer subtypes defined by joint hormone receptor and HER2 status. J Natl Cancer Inst. 2014;106(5):dju055. doi:10.1093/jnci/dju055

[9]Criscitiello C, Spurden D, Piercy J, et al. Health-Related Quality of Life Among Patients With HR+/HER2- Early Breast Cancer. Clin Ther. 2021;43(7):1228-1244.e4. doi:10.1016/j.clinthera.2021.04.020

[10]Mayo Clinic. Recurrent breast cancer. July 2, 2022. Accessed April 2025. https://www.mayoclinic.org/diseases-conditions/recurrent-breast-cancer/symptoms-causes/syc-20377135.

[11]Breast Cancer Now. Breast cancer recurrence. May 2019. Accessed April 2025. https://breastcancernow.org/about-breast-cancer/diagnosis/breast-cancer-recurrence/.

[12]FDA Approval. Available from https://www.novartis.com/news/media-releases/fda-approves-novartis-kisqali-reduce-risk-recurrence-people-hrher2-early-breast-cancer. Accessed April 2025

[13]Government of Canada. Breast cancer in Canada. Accessed June 2025. https://www.canada.ca/en/public-health/services/publications/diseases-conditions/breast-cancer.html

[14]Slamon D et al. Ribociclib plus Endocrine Therapy in Early Breast Cancer. N Engl J Med. 2024;390:1080-1091. doi: 10.1056/NEJMoa2305488

[15]Yardley D, Untch M, et al. Baseline (BL) characteristics and efficacy endpoints for patients (pts) with node-negative (N0) HR+/HER2– early breast cancer (EBC) in NATALEE. Presented at the American Society of Clinical Oncology Annual Meeting; May 31, 2024; Chicago, USA.

[16]Geurts YM, Witteveen A, Bretveld R, et al. Patterns and predictors of first and subsequent recurrence in women with early breast cancer. Breast Cancer Res Treat. 2017;165(3):709-720. doi:10.1007/s10549-017-4340-3

[17]Wangchinda P, Ithimakin S. Factors that predict recurrence later than 5 years after initial treatment in operable breast cancer. World J Surg Oncol. 2016;14(1):223. Published 2016 Aug 24. doi:10.1186/s12957-016-0988-0

[18]Novartis Data on File.

[19]Bushnell GG, Deshmukh AP, den Hollander P, et al. Breast cancer dormancy: need for clinically relevant models to address current gaps in knowledge. NPJ Breast Cancer. 2021;7(1):66. Published 2021 May 28. doi:10.1038/s41523-021-00269-x

[20]Health Canada Approval. Available from https://www.newswire.ca/news-releases/health-canada-approves-kisqali-for-the-treatment-of-hr-positive-and-her2-negative-metastatic-breast-cancer-in-postmenopausal-women-in-combination-with-letrozole-as-an-initial-endocrine-based-therapy-681481661.html. Accessed April 2025

[21]NCCN Guidelines. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) - Breast Cancer. Accessed May 2025. https://www.nccn.org

[22]European Society of Medical Oncology (ESMO). ESMO MCBS scorecards; NATALEE. Available at https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards/scorecard-468-1. Accessed April 2025.

[23]Clinicaltrials.gov. NCT03701334. A Trial to Evaluate Efficacy and Safety of Ribociclib With Endocrine

Therapy as Adjuvant Treatment in Patients With HR+/ HER2- Early Breast Cancer (NATALEE). Updated October 10, 2024. Available at https://clinicaltrials.gov/study/NCT03701334. Accessed April 2025.

---

**Source URL:** *https://prod1.novartis.ca/ca-fr/news/media-releases/health-canada-approves-novartis-kisqali-hrher2-early-breast-cancer-patients-high-risk-recurrence*

**List of links present in page**

1. https://prod1.novartis.ca/ca-fr/ca-fr/en/news/media-releases/health-canada-approves-novartis-kisqali-hrher2-early-breast-cancer-patients-high-risk-recurrence
2. #1
3. #2
4. #3
5. #4
6. #5
7. #2
8. #6
9. #7
10. #8
11. #9
12. #8
13. #9
14. #10
15. #11
16. #11
17. #12
18. #13
19. #1
20. #2
21. #4
22. #14
23. #15
24. #2
25. #16
26. #17
27. #18
28. #7
29. #8
30. #11
31. #11
32. #12
33. #1
34. #19
35. #20
36. #20
37. #2
38. #20
39. #21
40. #21
41. #22
42. https://www.novartis.com/ca-en/kisqalimonograph
43. #13
44. #23
45. http://www.novartis.ca
46. mailto:aimee.sulliman@novartis.com
47. https://www.novartis.com/us-en/sites/novartis_us/files/kisqali.pdf
48. https://gco.iarc.fr/today/en/dataviz/pie?mode=cancer&group_populations=1
49. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-

and-figures/breast-cancer-facts-and-figures-2019-2020.pdf
50. https://www.mayoclinic.org/diseases-conditions/recurrent-breast-cancer/symptoms-causes/syc-20377135
51. https://breastcancernow.org/about-breast-cancer/diagnosis/breast-cancer-recurrence/
52. https://www.novartis.com/news/media-releases/fda-approves-novartis-kisqali-reduce-risk-recurrence-people-hrher2-early-breast-cancer.%20Accessed%20April%202025
53. https://www.canada.ca/en/public-health/services/publications/diseases-conditions/breast-cancer.html
54. https://www.newswire.ca/news-releases/health-canada-approves-kisqali-for-the-treatment-of-hr-positive-and-her2-negative-metastatic-breast-cancer-in-postmenopausal-women-in-combination-with-letrozole-as-an-initial-endocrine-based-therapy-681481661.html
55. https://www.nccn.org
56. https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards/scorecard-468-1
57. https://clinicaltrials.gov/study/NCT03701334