



IBRANCE™ (palbociclib) Availability: Fact Sheet

IBRANCE™ is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women living with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer as initial endocrine-based therapy for their metastatic disease.¹

Metastatic Breast Cancer (mBC)

- When breast cancer spreads to other parts of the body, it's called metastatic.²
- Despite improvements made with early detection and treatment, there is no cure for mBC.³
- It is estimated that in 2015, about 25,000 Canadian women were diagnosed with breast cancer.⁴
- It is estimated that approximately 5,000 Canadian women died from breast cancer in 2015, representing about 14% of all cancer deaths in women.⁴
- In Canada, about 5-10% of new breast cancers are diagnosed metastatic.^{5,6}
- Approximately 20-30% of women first diagnosed with early stage breast cancer will go on to develop mBC in their lifetime, the majority being hormone sensitive.^{7,5}
- Advanced breast cancer has a five-year survival rate of approximately 20%.⁸ Despite significant advances, mBC still remains an incurable disease associated with a 24-month median overall survival.^{3,9}

Health Canada Approval of IBRANCE (palbociclib)

- IBRANCE is a new first line treatment conditionally approved by Health Canada as initial therapy for estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) mBC patients.¹
- IBRANCE received a Notice of Compliance with conditions (NOC/c) from Health Canada on March 16, 2016, based on the final results of the Phase 2 PALOMA-1/TRIO 18 trial. This approval is contingent upon verification and description of clinical benefit in a confirmatory Phase 3 trial (PALOMA-2).¹
- The Health Canada approval of IBRANCE provides mBC patients with a new therapeutic option, while raising awareness and inspiring conversations about this incurable but treatable disease.³

PALOMA-1 / TRIO 18 Trial:

- The Health Canada approval of IBRANCE is based on the final results of the Phase 2 PALOMA-1/TRIO 18 trial (n=165), which studied whether IBRANCE in combination with letrozole prolonged progression-free survival (PFS) compared with letrozole alone in postmenopausal women with ER+/HER2- locally advanced or mBC who had not received previous systemic treatment for their advanced disease.¹
- IBRANCE has been studied extensively in Canada with clinical trial participation from 114 patients at more than 27 Canadian centres to-date.¹⁰ Participation in other Canadian clinical trials will continue on an ongoing basis.



- Pfizer also conducted a Canadian Expanded Access Program clinical trial prior to the approval of IBRANCE for postmenopausal women with ER+/HER2- advanced breast cancer who were deemed appropriate for letrozole therapy. The trial included nine Canadian centres.¹⁰

References

¹ IBRANCE. Product Monograph. March 15, 2016.

² Canadian Cancer Society. Metastatic Cancer. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/metastatic-cancer/metastatic-cancer/?region=on>. Accessed March 9, 2016.

³ O'Shaughnessy J. Extending survival with chemotherapy in metastatic breast cancer. *The Oncologist*. 2005; 10(3):20-29.

⁴ Canadian Cancer Society. Breast Cancer Statistics. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/breast/statistics/?region=bc>. Accessed March 31, 2016.

⁵ Canadian Partnership Against Cancer. Breast Cancer Control in Canada: A System Performance Special Focus Report. September 2002. Available at: http://www.cancerview.ca/idc/groups/public/documents/webcontent/breast_cancer_control_rep.pdf. Accessed April 4, 2016.

⁶ Canadian Breast Cancer Foundation. Metastatic Breast Cancer. Available at: <http://www.cbfc.org/central/AboutBreastCancerMain/MetastaticBreastCancer/Pages/Metastatic-Breast-Cancer.aspx>. Accessed March 31, 2016.

⁷ Metastatic Breast Cancer Network. 13 Facts Everyone Should Know about Metastatic Breast Cancer. Available at: <http://mbcn.org/developing-awareness/category/13-things-everyone-should-know-about-metastatic-breast-cancer>. Accessed April 5, 2016.

⁸ Canadian Cancer Society. Survival Statistics for Breast Cancer. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/breast/prognosis-and-survival/survival-statistics/?region=on>. Accessed April 7, 2016.

⁹ Martino, M, Ballestrero, A, Zambelli, A, et al. Long-term survival in patients with metastatic breast cancer receiving intensified chemotherapy and stem cell rescue: data from the Italian registry. *Bone Marrow Transplantation*. 2013;48: 414–418.

¹⁰ Pfizer data on file.