

Scemblix™, a first-in-class CML treatment with new mechanism of action approved in Canada

Aug 31, 2022

- *Scemblix provides a new option for chronic myeloid leukemia (CML) patients who have had two or more previous tyrosine kinase inhibitor (TKI) treatments¹*
- *New mechanism of action with Scemblix reinforces Novartis' more than 20-year commitment to bring transformative therapies to people living with CML*

Dorval, QC, August 31, 2022 – Novartis Pharmaceuticals Canada Inc. is pleased to announce that Health Canada has approved Scemblix™ (asciminib tablets) for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) previously treated with two or more tyrosine kinase inhibitors (TKIs)¹.

Scemblix represents an important development for patients who experience resistance and/or intolerance to currently available TKI therapies.

“Despite the developments in CML over the last quarter of a century, there are some patients who do not respond well or tolerate the options available and become more difficult to treat. As treating physicians when we move through the lines of therapy, the options become more limited,” said Dr. Jeff Lipton, a Toronto-based medical oncologist. “Having a new therapy like asciminib with a different target in CML cells, expands the armamentarium available to us, giving us a new option to use in certain circumstances of advanced disease. Having choices to allow patients response opportunities is always a more satisfying treatment approach both for the physician and the patient.”

Scemblix is a first-in-class STAMP (Specifically Targeting the ABL Myristoyl Pocket) inhibitor that works through a different mechanism of action than other therapies used to treat CML. It blocks the action of a protein called BCR::ABL1 of the abnormal white blood cells by specifically targeting the ABL myristoyl pocket to stop their division and growth¹ and is a promising advance for patients in need of further innovation.

“Novartis has been at the forefront of advancements in CML for over two decades and is committed to continued investment in research to meet the needs of patients and further reimagine CML care,” said Andrea Marazzi, Country President, Novartis Canada. “Patients and physicians have waited a long time for something new in CML and we are proud to have pushed the boundaries of innovation to support the continued evolution of the standard of care and help even more CML patients. The positive reimbursement recommendation from the Canadian Agency for Drugs and Technology in Health reinforces the clinical evidence and foundation for the Scemblix approval in Canada. Novartis looks forward to working with payors so that eligible CML patients can access this new option.”

The Health Canada approval of Scemblix is based on results from the Phase III pivotal ASCEMBL trial which randomized patients with Ph+ CML-CP who had experienced resistance or intolerance to at least two TKIs¹.

The full product monograph for Scemblix can be found at <https://www.novartis.com/ca-en/>.

Novartis has a long-standing scientific commitment to patients living with CML. For more than 20 years, our bold science has helped transform CML into a chronic disease for many patients. Despite these advancements, we're not standing still. We continue to research ways to target the disease, seeking to address the challenges with treatment resistance and/or intolerance that many patients face. Novartis also continues to reimagine CML care through its commitment to sustainable access for patients and collaboration with the global CML community.

About Novartis in Canada

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. Over the last 5 years, our average annual research and development investment in Canada was \$47 million. 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. The company prides itself on its commitment to diversity and to nurturing an inclusive and inspiring environment. Novartis is recognized as a Great Place to Work[®], ranked among the Top 50 Best Workplaces[™] in the country and is proudly named on the 2021 Best Workplaces[™] for Women in Canada and Best Workplace[™] for Mental Wellness lists. 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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com/>.

Scemblix is a trademark.

Novartis Media Relations

Maureen Miller

Novartis Pharmaceuticals Communications

+ 1 514 633 7873

E-mail: camlph.communications@novartis.com

References

1. Novartis Pharmaceuticals Canada, Inc. Scemblix Product Monograph. June 21, 2022

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