

Ontario and Quebec become the first provinces to list Kesimpta® (ofatumumab) for the treatment of adults with relapsing remitting multiple sclerosis (RRMS)

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- Kesimpta® is the first and only B-cell therapy for RRMS that can be administered by patients in the safety and convenience of their home
- Kesimpta® delivers superior efficacy with a favourable safety profile¹
- Two Phase III studies (ASCLEPIOS I and II) demonstrated significant reductions in risk of relapses, confirmed disability worsening and MRI lesions^{1,2}

Dorval, QC, April 25, 2022/CNW/ — Novartis Pharmaceuticals Canada Inc. is pleased to announce that Kesimpta® (ofatumumab) is now covered under the Ontario Exceptional Access Program (EAP) and included on the Régie de l'assurance maladie du Québec (RAMQ) List of Medications as an Exceptional Medication for the treatment of adults living with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features.

"We commend the Governments of Ontario and Quebec for their leadership in making Kesimpta® rapidly accessible after the pan-Canadian Pharmaceutical Alliance confirmed its Letter of Intent for this innovative medicine on March 2, 2022," said Andrea Marazzi, Country Pharma Organization Head, Novartis Pharmaceuticals Canada Inc. "We are committed to continuing our collaboration with the remaining provinces to make Kesimpta® available as quickly as possible to all eligible Canadians who rely on public coverage."

In Ontario, the listing aligns with the recommendation from the Canadian Agency for Drugs and Technologies in Health (CADTH), which reported that people living with MS place high value in having a choice to select the administration, dosing schedule, side effect profile, and level of medication monitoring that best fit their lifestyle and personal preference, and are looking for a treatment that would result in fewer relapses requiring hospitalization, decrease work absenteeism, and which allows them to remain active within their social networks.³

"This is an important development for the MS communities in Ontario and Quebec, and I hope more provinces will follow shortly. People living with relapsing MS desire convenient options, so being able to offer patients a safe and highly efficacious treatment that can also be self-administered with a monthly subcutaneous injection moves us closer to achieving both the clinical goals of reducing disability and delaying progression while meeting the lifestyle needs and wishes of our patients," said Dr. Warren Berger, Neurologist, Department of Clinical Neurological Sciences, University of Western Ontario, London Health Sciences Centre, University Hospital, London.

"This is welcome news for people living with RRMS in Ontario and Quebec who rely on public reimbursement for their medications. We encourage other provinces to move swiftly in doing the same, as the more treatment options available to people living with MS, the more they can work with their care teams to effectively manage this chronic, disabling disease," said Dr. Pamela Valentine, President and CEO, MS Society of Canada.

The Quebec listing aligns with the recommendation from the Institut national d'excellence en santé et en services sociaux (INESSS), noting that Kesimpta® is currently the only available monoclonal antibody for the treatment of RRMS that can be administered subcutaneously at home, allowing patients to avoid travel to specialized clinics,⁴ which, especially in the context of a pandemic, has the potential to alleviate the burden on the health care system.

"Having a highly effective treatment option accessible to eligible patients in Quebec to treat their disease in the safety and convenience of their home is positive news. This development allows us to now offer our RRMS patients who meet the therapeutic criteria a choice that addresses the need to reduce the risk of relapses and slow progression, while providing the flexibility they want to live their lives on their terms," said Dr. François Grand'Maison, Neurologist, Charles LeMoine Hospital, Université de Sherbrooke and Neuro Rive-Sud Multiple Sclerosis Clinic.

"We are pleased that the province of Quebec has prioritized the needs of people living with RRMS by making this high efficacy treatment available to those eligible. This unpredictable disease carries physical, emotional and financial burdens, so having additional options is welcome news," said Louis Adam, President, Quebec and Atlantic Divisions, MS Society of Canada.

About Kesimpta®

Kesimpta® is a targeted, precisely dosed and delivered B-cell therapy that provides the flexibility of self-administration for adults living with RRMS. It is a recombinant and fully human monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously.¹

Kesimpta® received Health Canada approval on January 22, 2021 for the treatment of adult patients with RRMS with active disease defined by clinical and imaging features based on findings from the pivotal ASCLEPIOS Phase III studies.¹

The full prescribing information for Kesimpta® can be found at <https://www.novartis.com/ca-en/>.

About Multiple Sclerosis

MS is a chronic, often disabling immune disease that attacks the central nervous system (CNS), made up of the brain, spinal cord and optic nerve.⁵ It affects over 90,000 Canadians – one of the highest prevalence rates in the world.⁵ MS can be characterized into four main types: clinically isolated syndrome (CIS), relapsing remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS).⁶ These forms can be distinguished based on whether someone experiences relapses (clearly defined acute inflammatory attacks of worsening neurological function), and/or whether they experience progression of neurologic damage and disability from the onset of the disease.⁶

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. 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. 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/>.

Kesimpta is a registered trademark.

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