Health Canada approves Kesimpta®, the first and only self-administered targeted B-cell therapy for relapsing remitting multiple sclerosis (RRMS)

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- Kesimpta® (ofatumumab) delivers superior efficacy with a favourable safety profile and can be self-administered at home, addressing a significant unmet need for people living with relapsing remitting multiple sclerosis (RRMS)[1]
- Approval is based on two Phase III studies (ASCLEPIOS I & II) demonstrating significant reductions in risk of relapses, confirmed disability worsening and MRI lesions[1]
- With Kesimpta®, people with RRMS have a novel treatment option that has a favourable safety profile, is effective and convenient

Dorval, Quebec, March 23, 2021 — Novartis Pharmaceuticals Canada Inc. is pleased to announce that Health Canada has approved Kesimpta® (ofatumumab) for the treatment of adults with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features. Kesimpta® is the first and only targeted B-cell therapy that can be self-administered subcutaneously once a month via the Sensoready® autoinjector pen[2].

Multiple sclerosis (MS), typically diagnosed in a person's prime of life (age 20 to 40 years), substantially impacts their health, quality of life, productivity, and employment over many years[2]. A key goal of managing RRMS is to preserve neurological function to slow down the worsening of disability[3]. Early initiation of high-efficacy treatment can help improve long-term outcomes for people with RRMS3.

"MS is a disease that can easily run away and produce significant impairment if not kept in check as early as possible," says Dr. Mark S. Freedman, Professor of Medicine, Department of Medicine, University of Ottawa. "Having a highly effective treatment option with a favorable safety profile available like Kesimpta® for treating more aggressive disease up front, offers MS patients a better chance at leading a more normal life, for a longer time."

B-cell treatments, which bind to CD20 and deplete circulating B-cells, including those associated with disease activity in MS have only been available in hospitals or infusion treatment centres[2,3]. This mode of administration can be inconvenient for some people with MS and adds costs to the healthcare system[7]. Kesimpta® provides the flexibility of self-administration, eliminating the need to travel for treatment to an infusion centre.

"This approval represents another advancement in available treatment options for people living with MS," says Dr. Pamela Valentine, President and CEO, MS Society of Canada. "This means that there is now an option of a B-cell therapy that can be self-administered at home, allowing for flexibility and convenience, which is especially meaningful now, more than ever. We are hopeful that this will provide increased access to effective treatments for all Canadians living with MS, no matter where they live."

"From the introduction of the first oral treatment for RRMS, Novartis continues to be a global leader in

neuroscience by providing renewed hope and advancing care for the MS Community so they can live their lives as fully as possible," says Andrea Marazzi, Country Pharma Organization (CPO) Head, Novartis Pharmaceuticals Canada. "The development and approval of Kesimpta® is an important example of our commitment to supporting and meeting the needs of those who live with MS by offering a targeted treatment that can significantly improve patient outcomes and increase the convenience of self-managing the disease at home, eliminating the need to travel for treatment."

The approval of Kesimpta® is based on results from the Phase III ASCLEPIOS I and II studies, in which Kesimpta® demonstrated superiority versus teriflunomide in significantly reducing the annualized relapse rate (ARR, primary endpoint), 3-month confirmed disability progression (CDP), and the number of gadolinium-enhancing (Gd+) T1 and new or enlarging T2 lesions[1].

Kesimpta® has received a positive recommendation by the Canadian Agency for Drugs and Technologies in Health (CADTH) and by the Institut national d'excellence en santé et en services sociaux (INESSS). CADTH and INESSS are both recommending that Kesimpta® should be reimbursed by public drug plans for the treatment of adult patients with RRMS with active disease defined by clinical and imaging features , . Novartis is ready to work collaboratively with the Pan-Canadian Pharmaceutical Alliance (pCPA) to ensure patients have access to Kesimpta as soon as possible.

About Kesimpta®

Kesimpta® is a targeted, precisely dosed and delivered B-cell therapy that provides the flexibility of self-administration for adults with RRMS. It is a recombinant and fully human monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously[1,6]. Initial loading doses of Kesimpta® are given at Weeks 0, 1 and 2, with the first injection performed under the guidance of an experienced healthcare professional. Kesimpta® is thought to work by binding to distinct epitopes–the parts of an antigen where an antibody binds–on the CD20 molecule[1]. This binding induces B-cell lysis (cell membrane breakdown) and depletion[7]. The selective mechanism of action and subcutaneous (under the skin) administration of Kesimpta® allows precise delivery to the lymph nodes, where B-cell depletion in MS is needed, and preclinical studies have shown that it may preserve the B-cells in the spleen[8]. Once-monthly dosing of Kesimpta® also allows faster repletion of B-cells and offers more flexibility[9]. Ofatumumab was originally developed by Genmab and licensed to GlaxoSmithKline. Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RRMS, in December 2015[10].

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 It affects over 90,000 Canadians – one of the highest prevalence rates in the world[12]. MS can be characterized into four main types: clinically isolated syndrome (CIS), relapsing remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS)[13]. 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[17].

About Novartis Pharmaceuticals 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. In 2020, the company invested $45 million in research and development in Canada. Located in Dorval, Quebec, Novartis

Pharmaceuticals Canada Inc. employs approximately 1000 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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