Health Canada grants approval of the Eye-Tracking Neurological Assessment for Multiple Sclerosis (ETNA™-MS) for use in tracking disease progression in people living with MS

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- *More than 90,000 Canadians—or one in 400 people across Canada—live with multiple sclerosis (MS),[1] a neurodegenerative, chronic condition that affects the central nervous system.[2]*
- *Despite decades of progress on the therapeutics front, the way disease progression is detected remains vastly unchanged.*
- *Approval of ETNA™-MS has the potential to advance a new generation of care in MS, empower clinicians with a tool to identify disease progression earlier and facilitate more efficient healthcare access and delivery for people living with MS.*

Montréal, QC, March 25, 2024 – Health Canada has granted approval of the Eye-Tracking Neurological Assessment for Multiple Sclerosis (ETNA™-MS). Developed by Innodem Neurosciences (Innodem), ETNA™-MS is a software as a medical device (SaMD, class II) intended to administer a non-invasive test and provide an Expanded Disability Status Scale (EDSS) score in the range between 1.0 and 4.5 for use in tracking disease progression in people living with MS.

ETNA™-MS turns an iPad Pro into a medical device capable of capturing and analyzing several hundreds of eye movement parameters. This patented, mobile, software technology could offer a modernized approach to care and a way to make informed, real-time treatment decisions for people living with MS. The approval of ETNA™-MS is based on data collected through a validation study performed by Innodem.

An ongoing longitudinal observational trial supported by Novartis Pharmaceuticals Canada Inc. (Novartis Canada) aims to investigate the potential utility of biomarkers in monitoring MS disease status. The work between Novartis Canada and Innodem seeks to accelerate the path towards a reliable, non-invasive, sensitive, and accessible marker of disease progression in MS.

“This approval brings us one step further in closing the gap in care for people living with MS and marks a shift to a more proactive approach to disease management,” said Erin Keith, Vice President, Neuroscience at Novartis Canada. “Through our commitment to reimagine medicine and cross-sector collaboration, we are taking innovation in MS beyond therapeutics, paving a path to much needed solutions that Canadians deserve. I am excited to see what the future holds.”

Canada has one of the highest rates of MS in the world,[2] with more than 90,000 Canadians—or one in 400 people across Canada—living with it. MS is a complex and unpredictable disease, in which the severity and duration of symptoms can vary from person to person and evolve as the disease progresses.[2] As such, people living with MS require tailored, personalized, and adaptive treatment strategies based on individual needs and the rate of disease evolution.[3]

“We’ve learned a lot about MS and its progressive nature over the years, but we still hadn’t established a

reliable and accessible means through which to monitor subtle changes in disease status in near real-time," said Dr. Giacomini, MS Clinic Director at the Montreal Neurological Institute and Chief Medical Officer at Innodem Neurosciences. "This approval brings us one step closer to giving clinicians a tool that could help inform better clinical decision-making and offer more positive outcomes for people living with MS."

The necessity of using biomarkers in studying major diseases such as cancer and heart disease has been widely discussed,[4] and today, there is an increased interest to develop disease-specific biomarkers that could estimate disease severity and cognitive status in people living with MS. In recent years, there has been a remarkable increase in the number of available treatments for MS,[5] but how disease progression is detected and monitored has remained vastly unchanged.

"When someone is diagnosed with MS, it changes their life," said Diego Mena Martínez, Executive Director, Quebec Division of MS Canada. "It can be a challenging condition to manage given its unpredictable nature, so I welcome the progress happening in this space as an important step towards a more proactive care approach which has the potential of positively impacting people living with this disease."

As a leader in life sciences, Novartis Canada is pushing the boundaries of innovation beyond the traditional confines of therapeutics, focusing on the expansion of research to support the identification of novel biomarkers in MS. Having signed a multimillion, multi-year commercial framework agreement with Innodem to continue advancing research into the application of ETNA™-MS, with additional milestones anticipated in the future, Novartis Canada is committed to helping advance a more proactive care approach in MS.

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. Reimagine medicine with us: Visit us at https://www.novartis.com and connect with us on LinkedIn, Facebook, X/Twitter and Instagram.

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.

About Innodem Neurosciences
Innodem Neurosciences is a leading digital biomarker and AI company specializing in the development of a proprietary, mobile, non-invasive eye-tracking technology called ETNA™ (Eye Tracking Neurological Assessment). ETNA™-MS is software as a medical device (SaMD, class II) that can be used in clinic or remotely through patient self-testing. ETNA™-MS captures patient responses to brief oculomotor tests displayed on the screen of an iPad Pro within 10 minutes. These tasks are designed to assess several key neurological functions known to be affected by multiple sclerosis, and to capture several hundred eye movement parameters in response to visually presented stimuli during specifically designed eye-tracking tests. The eye movement data is then analyzed by powerful machine learning algorithms to provide an EDSS score (between 1 and 4.5) that is correlated to the EDSS score obtained by a specialized MS clinician, potentially improving efficiencies and access to care. The ETNA™ technology is also being further validated in ongoing observational trials with participants diagnosed with other neurodegenerative and mental disorders, such as Parkinson's disease, Alzheimer's disease, Friedreich's ataxia, and cancer-related cognitive disorders ("chemo brain"). Innodem's core team, led by cognitive neurologist and CEO Dr. Étienne de Villers-Sidani, is made up of an intersectional group of neuroscientists, software engineers, data scientists, healthcare professionals and serial entrepreneurs. The company's mission is to become the leading digital biomarker and AI company to better serve the needs of the global health system. For further information, please consult www.innodemneurosciences.com.

Media Contact
Katia Kononova
Communications & Engagement Lead
E-mail: camlph.communications@novartis.com
+ 1 514 633 7873

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