Canadian-Developed AI Technology Aims to Support Early Detection of ALS

~ MNd-5 algorithm screens electronic medical records to assist physicians in identifying individuals for which follow-up investigations for ALS may be appropriate ~

TORONTO, ON, September 20, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA) is proud to support the development of a new artificial intelligence (AI) program designed to analyze de-identified electronic medical records (EMRs) and identify individuals for which follow-up investigations for Amyotrophic Lateral Sclerosis (ALS), or referral to a specialty centre may be clinically appropriate. *Process for Progress in ALS: An EMR-based practice enhancement initiative* utilizes a clinical algorithm, MNd-5, and is intended to support healthcare professionals (HCPs) in making timely decisions regarding follow-up testing or referral to a specialist.

"Early diagnosis and treatment of ALS can improve outcomes, but the disease can be difficult to diagnose in its early stages. The more time that passes before diagnosis, the less opportunities exist for disease-management for someone living with ALS," said Dr. Angela Genge, Executive Director, ALS Centre of Excellence at The Neuro in Montreal. "*Process for Progress in ALS* is a unique advancement in AI medical technology which can help HCPs identify patients who present multiple warning signs for ALS so that they can receive expedited follow-ups, diagnoses, and treatment if needed."

ALS, also known as Lou Gehrig's disease, is a neurodegenerative disease that currently has no cure and can progress rapidly.[1] The disease is challenging to diagnose because symptoms of the condition can be subtle at first and no test can provide a definitive diagnosis. In Canada, it takes an average of 21 months to receive a diagnosis of ALS.[2,3] The majority of people with ALS die within three years from symptom onset.[2]

"As a participant in the *Process for Progress in ALS* initiative, I believe it is a significant step forward to assist in our ability to identify ALS symptoms in the early stages and confidently refer people for further testing or to an ALS centre," said Dr. Hamza Jalal, neurologist at Oakville Valley Health, who is participating in the program. "By intervening in patients' journeys earlier in the course of their disease, we can provide access to multidisciplinary care, approved therapies or clinical trials that can slow the progression of the disease and enhance the quality of their lives."

The MNd-5 algorithm* is intended for use as a clinical decision support tool to aid community neurologists in identifying individuals in which follow-up investigations for ALS or referral to a specialty centre may be clinically appropriate. It prioritizes patients for clinical review by comparing their presenting characteristics and EMG findings to a reference population of patients diagnosed with ALS, in which ALS has been ruled out and consecutive community neurology patients in which ALS and other motor neuron diseases have not previously been suspected. The algorithm is applied to electronic health records at the Toronto Data Lab of Ensho Health as a service. The service is available to approximately 80% of community neurologists through integrations with the Epic, Cerner, Accuro, OscarPro, Indivicare, Mediquest and other electronic medical record systems.

"We know that time is of the essence for people living with ALS, and initiatives like *Process for Progress in ALS* are critical in helping to ensure a timely diagnosis for people impacted by this devastating disease," said Andy Zylak, President, Mitsubishi Tanabe Pharma Canada. "We are proud to support the introduction of this important AI technology as part of our long-standing commitment to leading scientific innovation, collaborating with HCPs, and working tirelessly to meet the needs of the ALS community."

The *Process for Progress in ALS* initiative is a collaboration between MTP-CA and the program's Steering Committee: Dr. Angela Genge, Executive Director, Clinical Research Unit at The Neuro in Montreal, Dr. Amer A. Ghavanini, Division Head of Neurology, Trillium Health Partners, and Dr. Amanda Fiander, Neurologist at Maritime Neurology.

For more information on *Process for Progress in ALS: An EMR-based practice enhancement initiative,* please visit: https://www.alsprogress.ca.

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About Mitsubishi Tanabe Pharma Canada, Inc.
Based in Toronto, Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) with a goal to provide therapies for some of the most difficult-to-treat diseases, including ALS. For more information, please visit www.mt-pharma-ca.com.

About Mitsubishi Tanabe Pharma America, Inc.
Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America, Inc. (MTPA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). It was established by MTPC to develop and advance our pipeline as well as commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com or follow us on Twitter, Facebook and LinkedIn.

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*The MNd-5 algorithm is a process for converting input parameters to a likelihood estimate. It is deployed at the Toronto, Canada data lab of Ensho Health through the MNd-5 CDL Module ("CDL Module"). The CDL Module is comprised of the MNd-5 Likelihood Estimator ("Likelihood Estimator") which encodes it in software and a graphical user interface called the MNd-5 Controller ("Controller"). The CDL Module was developed to the ISO 13485:2016 standard for medical devices in compliance with Ensho's Quality Management System. The MNd-5 CDL Module is registered as medical device software in Canada under the Medical Device Establishment License of Ensho Health (license 16208). The software that encodes the MNd-5 algorithm and applies it to EHR data is Class I medical device software in Canada developed and deployed under the Medical Device Establishment License of Ensho Health.

References:

[1] Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health, June 2013, https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet

[2] Richards D, et al. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. J Neurol Sci. 2020;417:117054.

[3] Hodgkinson VL, et al. Provincial differences in the diagnosis and care of amyotrophic lateral sclerosis. Can J Neurol Sci. 2018;45:652-659.