

MITSUBISHI TANABE PHARMA CANADA ANNOUNCES THAT COMPANY'S ORAL TREATMENT FORMULATION FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) HAS BEEN ADDED TO THE PROVINCIAL DRUG PLANS IN PRINCE EDWARD ISLAND, NEWFOUNDLAND AND LABRADOR

TORONTO, ON, November 7, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced that RADICAVA® Oral Suspension (edaravone) is now covered under the Prince Edward Island (PEI) Pharmacare Formulary (special authorization) and the Newfoundland and Labrador Prescription Drug Program (NLPDP) (special authorization) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.¹

“We would like to thank the Governments of Prince Edward Island and Newfoundland and Labrador for supporting eligible patients living with ALS to have publicly funded access to RADICAVA® Oral Suspension,” said Andy Zylak, President, MTP-CA. “To date, RADICAVA® Oral Suspension is listed on the majority of provincial public drug plans. MTP-CA will continue to work with the remaining provincial, territorial and federal drug plans to help ensure that RADICAVA® Oral Suspension is listed on all public formularies across the country.”

The efficacy of RADICAVA® Oral Suspension, is based on a bioavailability/bioequivalence study comparing it to RADICAVA® IV, which was authorized by Health Canada for the treatment of people with ALS in October 2018 and has shown in a pivotal trial to slow the loss of physical function in ALS by 33%.^{2,3} RADICAVA® IV Infusion is currently available and reimbursed through public formularies in all provinces and territories across Canada, as well as Veterans Affairs Canada and Indigenous Services Canada.

“Today’s news is good news for the ALS community in Newfoundland and Labrador”, said Dr. Alan Goodridge, Neurologist with NL Health Services based in St. John’s and Professor of Medicine (Neurology) at Memorial University. “Given the rapid progression of ALS, it is important that patients have access to all approved therapies to treat this disease.”

According to the ALS Society of Canada, an estimated 3,000 Canadians are currently living with ALS⁴, an incurable disease that affects the nerve cells in the brain and spinal cord.⁵ The majority of people with ALS die within two to five years of diagnosis.⁶ Symptoms of the condition can be subtle at first, and it can take an average of 21 months to receive a diagnosis of ALS in Canada.^{7,8}

“We commend the Government of Prince Edward Island for making RADICAVA® Oral Suspension available on the province’s drug plan,” said Kathy MacNeill, Past-President, ALS Society of Prince Edward Island. “Access to new treatments plays a key role in helping people and their families live their best possible life in the face of an ALS diagnosis.”

“People living with ALS do not have the luxury of time to wait for access to new medications to slow the progression of their disease,” said Cheryl Power, Executive Director of the ALS Society of Newfoundland and Labrador. “For this reason, we’re pleased that people impacted by ALS in this province will now have publicly funded access to RADICAVA® Oral Suspension.”

In addition to Prince Edward Island and Newfoundland and Labrador, RADICAVA® Oral Suspension, is listed on the public drug plans in Ontario, Alberta, Quebec, British Columbia, New Brunswick, Nova Scotia and Saskatchewan. To date, it is estimated that the majority of private insurance plans in the country cover RADICAVA® Oral Suspension. MTP-CA continues to have discussions with the territories and federal agencies regarding the listing of RADICAVA® Oral Suspension under additional publicly funded drug programs.

About RADICAVA® IV and RADICAVA® Oral Suspension (edaravone)

RADICAVA® IV and RADICAVA® Oral Suspension are indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) through an iterative clinical development platform over a 13-year period. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. RADICAVA® was approved by the U.S. Food and Drug Administration (FDA) in May of 2017. Marketing authorization for RADICAVA® IV Infusion was granted in Canada (October 2018), Switzerland (January 2019), Indonesia (July 2020), Thailand (April 2021), and Malaysia (December 2021).

RADICAVA® ORS (edaravone) was approved by the U.S. FDA in May 2022. RADICAVA® Oral Suspension (edaravone) was authorized by Health Canada in November 2022.

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](#).

Media Inquiries:

Media_MTPA@mt-pharma-us.com

References:

¹ Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health. Available at: <https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet>. Accessed on June 6, 2023.

² RADICAVA® Product Monograph. Mitsubishi Tanabe Pharma America, Inc.; 2022.

³ Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol.* 2017;16:505-512.

⁴ Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

⁵ Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health. Available at: <https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet>. Accessed on June 6, 2023.

⁶ Mehta P, Kaye W, Raymond J, Punjani R, Larson T, Cohen J, et al. Prevalence of Amyotrophic Lateral Sclerosis - United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2018;67:1285-1289.

⁷ Richards D, Morren JA, Pioro EP. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. *J Neurol Sci.* 2020;417:117054.

⁸ Hodgkinson VL, Lounsbury J, Mirian A, Genge A, Benstead T, Briemberg H, et al. Provincial Differences in the Diagnosis and Care of Amyotrophic Lateral Sclerosis. *Can J Neurol Sci.* 2018;45:652-659.