# 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 NEW BRUNSWICK AND NOVA SCOTIA

**TORONTO, ON, August 29, 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 New Brunswick Drug Plan (NBDP) formulary (special authorization) and the Nova Scotia Formulary (exceptional status) 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 New Brunswick and Nova Scotia for supporting eligible patients living with ALS in the Atlantic provinces to have publicly-funded access to RADICAVA® Oral Suspension," said Andy Zylak, President, MTP-CA. "We will continue to collaborate with decision makers to help ensure that RADICAVA® Oral Suspension is made available through all publicly funded drug plans."

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 announcement is an important step forward for people living with ALS in New Brunswick because it gives greater access to a new and less burdensome treatment shown to slow the decline of physical function in ALS," said Dr. Colleen O'Connell, Physical Medicine and Rehabilitation specialist and Professor at Dalhousie University. "As an ALS clinic physician this is good news. We need our patients to have access to approved therapies that have demonstrated benefit in treating this devastating disease."

"Over time, ALS weakens the muscles, which impacts physical function of the body and the activities of daily living for people living with this progressive neurodegenerative disease," said Dr. Amanda Fiander, neurologist, Maritime Neurology in Halifax. "Given the rapid progression of this disease, it is important that patients have access to all approved therapies that can help slow the progression."

According to the ALS Society of Canada, an estimated 3,000 Canadians are currently living with ALS[4], 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 Governments of New Brunswick and Nova Scotia for prioritizing the needs of people living with ALS in Atlantic Canada," said Kimberly Carter, President and CEO, ALS Society of New Brunswick and Nova Scotia. "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. We urge the remaining provinces to provide the same commitment by ensuring access to all approved therapies for ALS patients, no matter where they live."

In addition to New Brunswick and Nova Scotia, RADICAVA® Oral Suspension is also listed on the public drug plans in Ontario, Alberta, Québec and British Columbia. 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 other provinces, territories and federal agencies regarding the listing of RADICAVA® Oral Suspension under additional publicly funded drug programs.

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**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.

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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, Lounsberry 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.