

MITSUBISHI TANABE PHARMA CANADA ANNOUNCES THAT COMPANY'S ORAL TREATMENT FORMULATION FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) HAS BEEN ADDED TO THE PROVINCIAL DRUG PLAN IN SASKATCHEWAN

TORONTO, ON, September 1, 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 Saskatchewan Drug Plan Formulary (Exception Drug Status) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.¹

“We’d like to thank the Government of Saskatchewan for making RADICAVA® Oral Suspension available to those who are eligible for coverage under the province’s public formulary,” said Andy Zylak, President, MTP-CA. “Today’s announcement is excellent news for the ALS community in this province and 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.

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}

“Due to the swift progression of this disease, it is imperative that people living with ALS have publicly funded access to all approved therapies that could help slow the loss of physical function,” said Denis Simard, Executive Director, ALS Society of Saskatchewan. “That’s why today’s news is an important milestone for people living with ALS in the province, their families and loved ones.”

In addition to Saskatchewan, RADICAVA® Oral Suspension, is also listed on the public drug plans in Ontario, Alberta, Quebec, British Columbia, New Brunswick, and Nova Scotia. 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](#).

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, Piro 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.