

MITSUBISHI TANABE PHARMA CANADA CONCLUDES LETTER OF INTENT WITH PAN-CANADIAN PHARMACEUTICAL ALLIANCE FOR ^{PR}RADICAVA[®] ORAL SUSPENSION (EDARAVONE)

TORONTO, ON, July 20, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced that it has entered into a Letter of Intent with the pan-Canadian Pharmaceutical Alliance (pCPA) regarding RADICAVA[®] Oral Suspension (edaravone), for the treatment of people with amyotrophic lateral sclerosis (ALS), which was authorized by Health Canada on November 8, 2022.

“This is an important milestone in our efforts to secure coverage for RADICAVA[®] Oral Suspension under publicly funded drug plans in Canada,” said Andy Zylak, President, MTP-CA. “We would like to thank the pCPA negotiating team for its collaboration and consideration. We look forward to commencing discussions with the participating provinces, territories, and federal agencies across Canada that will enable access to this new formulation of edaravone for people living with ALS as soon as possible.”

The authorization 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.^{1,2}

According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS, an incurable disease that affects the nerve cells in the brain and spinal cord.^{3,4} The majority of people with ALS die within two to five years of diagnosis.⁵ 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.^{6,7}

“Today’s news is a positive step towards providing Canadians living with ALS with publicly funded access to this new treatment formulation option,” said Tammy Moore, CEO, ALS Society of Canada. “Because of the speed with which this fatal disease progresses, with a life expectancy of two to three years following diagnosis, timely access to treatments is crucial. We hope that decision-makers throughout the reimbursement process will move with urgency to provide the ALS community across Canada with equitable access to this new treatment formulation option.”

With a Letter of Intent with the pCPA now in place, MTP-CA will undertake the necessary steps to enter into discussions with participating provinces, territories, and federal agencies regarding the listing of RADICAVA[®] Oral Suspension under publicly funded drug programs. To date, it is estimated that approximately 85% of private insurance plans in the country cover RADICAVA[®] Oral Suspension.

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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). MTPC is the pharma arm of Mitsubishi Chemical Group (MCG). It was established by MTPC to 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:

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- ² 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.
- ³ Benchmarking Survey, Federation of ALS Societies of Canada, 2016.
- ⁴ 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.
- ⁵ Mehta P., et al. Prevalence of Amyotrophic Lateral Sclerosis - United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2018;67:1285-1289.
- ⁶ Richards D, Morren JA, Pioro EP. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. *J Neurol Sci.* 2020;417:117054.
- ⁷ Hodgkinson VL, Lounsbury J, Mirian A, Genge A, Benstead T, Briemberg H, Grant I, Hader W, Johnston WS, Kalra S, Linassi G, Massie R, Melanson M, O'Connell C, Schellenberg K, Shoesmith C, Taylor S, Worley S, Zinman L, Korngut L. Provincial Differences in the Diagnosis and Care of Amyotrophic Lateral Sclerosis. *Can J Neurol Sci.* 2018;45:652-659.