

PRADICAVA® (EDARAVONE) ORAL SUSPENSION RECEIVES POSITIVE RECOMMENDATION FROM CADTH FOR THE TREATMENT OF PATIENTS WITH ALS

TORONTO, Canada – January 18, 2023 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) is pleased to announce a positive recommendation from the CADTH Canadian Drug Expert Committee (CDEC) for RADICAVA® Oral Suspension, the oral formulation of RADICAVA® IV (edaravone), for the treatment of patients with Amyotrophic Lateral Sclerosis (ALS). Full details on the recommendation by CADTH, including recommended criteria for reimbursement, are available on the [CADTH website](#).

“The positive recommendation from CADTH is an important first step in ensuring access to RADICAVA® Oral Suspension for all eligible Canadians living with ALS,” said Atsushi Fujimoto, President, MTP-CA. “While we are delighted by this milestone, we know there is more work to do, and we look forward to continued discussions with stakeholders to secure coverage for RADICAVA® Oral Suspension on public formularies.”

RADICAVA® Oral Suspension, the oral form of edaravone, is authorized by Health Canada for the treatment of patients with ALS. RADICAVA® Oral Suspension was developed to have similar efficacy to RADICAVA® IV Infusion, which was authorized by Health Canada for the treatment of patients with ALS in October 2018 and has shown in a pivotal trial to slow the loss of physical function in ALS.^{1,2}

MTP-CA is continuing to work closely with stakeholders to make RADICAVA® Oral Suspension accessible to patients through private insurance and public formularies.

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. It is important ALS patients begin the most appropriate treatment available to them as soon as possible, regardless of mode of delivery.³

About ALS

ALS, also known as Lou Gehrig’s disease, is a neurodegenerative disease that currently has no cure and can progress rapidly.⁴ According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS,⁵ a disease that affects the nerve cells in the brain and spinal cord.⁴ The majority of patients 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}

About RADICAVA® Oral Suspension (edaravone)

RADICAVA® Oral Suspension is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).¹ 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 in May of 2017. Marketing authorization for RADICAVA® IV Infusion was granted in Canada (October 2018),

Switzerland (January 2019), China (July 2019), Indonesia (July 2020), Thailand (April 2021), and Malaysia (December 2021).

RADICAVA ORS™ (edaravone oral suspension) was approved by the FDA in May 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's (MTPC) 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. It was established by MTPC to commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com.

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¹ RADICAVA® Product Monograph. Mitsubishi Tanabe Pharma America, Inc.; 2022.

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(7):505-512.

³ Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. *CMAJ* 2020;192:E1453-68.

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: December 6, 2022.

⁵ Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

⁶ Mehta P., et al. Prevalence of Amyotrophic Lateral Sclerosis - United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2018 Nov 23;67(46):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 Oct 15;417:117054.

⁸ 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 Nov;45(6):652-659.