



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 ALBERTA

TORONTO, ON, August 3, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced that RADICAVA® Oral Suspension (edaravone) is covered, as of August 1, 2023, under the Alberta Drug Benefit List (ADBL) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.¹ In addition to ADBL, RADICAVA® Oral Suspension is also listed on the public drug plan in Ontario.

"We are grateful to the Government of Alberta for making RADICAVA® Oral Suspension available to those who are eligible for coverage under the Alberta Drug Benefit List (ADBL) program," said Andy Zylak, President, MTP-CA. "It's wonderful news for the province's ALS community and we will continue to collaborate with decision makers in other jurisdictions 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.^{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.

"ALS touches almost every aspect of the motor functions we depend on for everyday life – like the ability to walk, talk and eat," said Lawrence Korngut, MD, Neuromuscular Neurologist and Associate Professor, at the Hotchkiss Brain Institute, University of Calgary. "The listing in Alberta is welcome news for eligible people and families impacted by ALS in Alberta, and their treating physicians, who will now have publicly funded access to a new oral treatment formulation."

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}

"Time is of the essence for ALS patients and their families. We thank the Albertan government for prioritizing the needs of people living with ALS in this province by making this new treatment formulation accessible through the public drug plan," said Leslie Ring-Adams, Executive Director, ALS Society of Alberta.

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:

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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, 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, 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.