MITSUBISHI TANABE PHARMA CANADA ANNOUNCES ORAL TREATMENT FORMULATION FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) NOW ELIGIBLE FOR COVERAGE THROUGH VETERAN AFFAIRS CANADA AND INDIGENOUS SERVICES CANADA

TORONTO, ON, December 13, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA) a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), announced today that RADICAVA® Oral Suspension (edaravone) for the treatment of amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease[1], is now reimbursed by Veterans Affairs Canada (VAC) (Standard Benefit) and Indigenous Services Canada via the Non-Insured Health Benefits (NIHB) Program (Limited Use).

"We would like to thank Veterans Affairs Canada and Indigenous Services Canada for providing eligible people in Canada with access to this new ALS treatment formulation," said Andrew Zylak, President, MTP-CA. "Including RADICAVA® Oral Suspension on these formularies is an important step to support those living with ALS who are eligible under the federal programs."

According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS[2], an incurable disease that affects the nerve cells in the brain and spinal cord.[3] The majority of people with ALS die within two to five years of diagnosis.[4] 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.[5, 6]

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%.[7,8]

In addition to VAC and NIHB, RADICAVA® Oral Suspension is also covered under the Correctional Service of Canada federal drug plan, as well as the provincial drug plans in British Columbia, Alberta, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland and Labrador. To date, it is estimated that the majority 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). 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] Benchmarking Survey, Federation of ALS Societies of Canada, 2016.
[3] 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.
[4] 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.
[5] Richards D, Morren JA, Pioro EP. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. J Neurol Sci. 2020;417:117054.
[6] 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.
[7] RADICAVA® Product Monograph. Mitsubishi Tanabe Pharma America, Inc.; 2022.
[8] 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.