



## 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 MANITOBA

# - RADICAVA® Oral Suspension (edaravone) has been listed on all public drug plans in Canada-

**TORONTO, ON, December 15, 2023** – Mitsubishi Tanabe Pharma Canada (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced that effective December 21, 2023, the Manitoba Pharmacare Program (Exceptional Drug Status) will cover RADICAVA® Oral Suspension (edaravone) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.<sup>1</sup>

"We would like to thank the Government of Manitoba for supporting eligible patients living with ALS to have publicly funded access to RADICAVA® Oral Suspension," said Andy Zylak, President, MTP-CA. "We're also pleased to confirm that RADICAVA® Oral Suspension is now available through all provincial, territorial and federal public drug plans."

The efficacy of RADICAVA<sup>®</sup> Oral Suspension, is based on a bioavailability/bioequivalence study comparing it to RADICAVA<sup>®</sup> 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%.<sup>2</sup>, <sup>3</sup> RADICAVA<sup>®</sup> 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 is a rapidly progressive neurodegenerative disease which can lead to disabling loss of physical function," said Dr. Davood Fathi, Neurologist, Director ALS/MND Clinic in Winnipeg, Assistant Professor, University of Manitoba. "The progression of ALS can vary greatly from person to person and having access to all approved treatment options that can help slow the progression of the disease is critical."

According to the ALS Society of Canada, an estimated 3,000 Canadians are currently living with ALS<sup>4</sup>, an incurable disease that affects the nerve cells in the brain and spinal cord.<sup>5</sup> The majority of people with ALS die within two to five years of diagnosis.<sup>6</sup> 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.<sup>7,8</sup>

RADICAVA<sup>®</sup> Oral Suspension is covered under all provincial drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, as well as the Veteran Affairs Canada, Correctional Service of Canada and Indigenous Services Canada, via the Non-Insured Health Benefits (NIHB) Program, federal drug plans. To date, it is estimated that the majority of private insurance plans in the country cover RADICAVA<sup>®</sup> 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<sup>®</sup> ORS (edaravone) was approved by the U.S. FDA in May 2022. RADICAVA<sup>®</sup> 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 <u>www.mt-pharma-ca.com</u>.

## 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:

<sup>8</sup> 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.

<sup>&</sup>lt;sup>1</sup> Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health. Available at: <u>https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet</u>. Accessed on June 6, 2023.

<sup>&</sup>lt;sup>2</sup> RADICAVA® Product Monograph. Mitsubishi Tanabe Pharma America, Inc.; 2022.

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

<sup>&</sup>lt;sup>5</sup> Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health. Available at: <u>https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet</u>. Accessed on June 6, 2023.

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> Richards D, Morren JA, Pioro EP. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. J Neurol Sci. 2020;417:117054.