MITSUBISHI TANABE PHARMA CANADA ANNOUNCES prRADICAVA® (EDARAVONE) ORAL SUSPENSION IS NOW AVAILABLE IN CANADA FOR THE TREATMENT OF PATIENTS WITH ALS

TORONTO, Canada – February 10, 2023 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that RADICAVA® Oral Suspension, the oral formulation of RADICAVA® IV (edaravone), is now commercially available in Canada for the treatment of patients with amyotrophic lateral sclerosis (ALS).

RADICAVA® Oral Suspension is the first and only oral treatment option for ALS, which has been granted a Notice of Compliance (NOC) by Health Canada following Priority Review. RADICAVA® Oral Suspension was developed to have similar efficacy to RADICAVA® IV, which was authorized by Health Canada for the treatment of ALS in October 2018[1] and has shown in a pivotal trial to help slow the loss of physical function in ALS.[1,2]

"We are proud to announce that RADICAVA® Oral Suspension is now available in Canada, providing Canadians impacted by ALS with a new formulation option to fight this devastating disease," says Atsushi Fujimoto, President, MTP-CA. "We know that time is of the essence for people living with ALS, and we are working closely with stakeholders, decision makers and the ALS community to secure swift and equitable access to this treatment."

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

"The availability of oral edaravone in Canada is positive news and can provide a new formulation choice for people living with this debilitating disease," said Tammy Moore, CEO, ALS Society of Canada. "Canadians living with ALS do not have the luxury of time, and 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 option."

The comprehensive clinical development program for edaravone in ALS has spanned over a decade and included multiple clinical trials for the IV and oral formulations.

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), 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] Health Canada. Notice of Compliance Database. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/database.html

[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] Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

[4] 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.

[5] 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 Nov;45(6):652-659.