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 ONTARIO

TORONTO, ON, August 1, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced that RADICAVA® Oral Suspension (edaravone) is now covered under the Ontario Drug Benefit Formulary (Exceptional Access Program) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.[1] Ontario becomes the first province to confirm public drug plan listing for RADICAVA® Oral Suspension following the successful conclusion of negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA). RADICAVA® Oral Suspension was authorized by Health Canada on November 8, 2022.

*"*We are extremely grateful to the Government of Ontario for becoming the first province to make RADICAVA® Oral Suspension available to those who are eligible for coverage under the Ontario Drug Benefit program," said Andy Zylak, President, MTP-CA. "This is excellent news for the province's ALS community and we will continue to collaborate with decision makers 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 significantly 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 affects the motor neurons, the nerve cells in the brain and spinal cord that are needed for activities like talking, walking, eating, swallowing and breathing," said Lorne Zinman, M.D., M.Sc., FRCPC, Director of the ALS and Neuromuscular Clinic at the Sunnybrook Health Sciences Centre. "Today's news is important for people and families impacted by ALS in Ontario, and their treating physicians, because it gives them 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 ALS[4], 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]

"We thank the Ontario government for taking a leadership role in prioritizing the needs of people living with ALS in this province by making this new treatment formulation available through the public drug plan," said Tammy Moore, CEO, ALS Society of Canada. "Timely access to treatments is crucial. We urge other provinces to move quickly and give people living with ALS across the country the same opportunity."

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.

The reimbursement criteria for RADICAVA® Oral Suspension are the same as for RADICAVA® IV, which can be found on the Ontario Ministry of Health's Exceptional Access Program webpage.

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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). MTPC is the pharma arm of Mitsubishi Chemical Group (MCG). It was established by MTPC to 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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