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 QUÉBEC

TORONTO, ON, August 16, 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 Régie de l'assurance maladie du Québec (RAMQ) formulary (special authorization) for the treatment of people living with amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.[1]

"Today's announcement is excellent news for the ALS community in Québec," said Andy Zylak, President, MTP-CA. "We'd like to thank the Government of Québec for making RADICAVA® Oral Suspension available to those who are eligible for coverage under the province's public formulary. MTP-CA is continuing to work with other provincial, territorial and federal drug plans to help ensure that RADICAVA® Oral Suspension is listed on all public formularies across the country."

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%.[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 is a rapidly progressive neurodegenerative disease which can lead to a crippling loss of physical function," said Dr. Angela Genge, executive director of the ALS Center of Excellence and phase one unit at The Neuro (Montreal Neurological Institute-Hospital). "Today's announcement is welcome news because it gives Québec patients, and their treating physicians, publicly funded access to a new and less burdensome treatment formulation that has been shown to slow the loss of physical function in ALS."

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]

"The availability of RADICAVA® Oral Suspension on the Régie de l'assurance maladie du Québec formulary is an important milestone for the ALS community in this province," said Claudine Cook, Executive Director, ALS Society of Quebec. "Due to the swift progression of this disease, it's imperative that people living with ALS have publicly funded access to all approved therapies that could help slow the loss of physical function. We call on the other provinces to move quickly and provide access for all ALS patients across the country."

In addition to RAMQ, RADICAVA® Oral Suspension is also listed on the public drug plans in Ontario and 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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