Mitsubishi Tanabe Pharma Canada

Press Release

prRADICAVA® (EDARAVONE) ORAL SUSPENSION RECEIVES POSITIVE RECOMMENDATION FROM INESSS FOR THE TREATMENT OF PATIENTS WITH ALS

TORONTO, Canada – December 19, 2022 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) is pleased to announce a positive recommendation from the Institut national d'excellence en santé et en services sociaux (INESSS) for RADICAVA® Oral Suspension, the oral formulation of RADICAVA® IV (edaravone), for the treatment of patients with Amyotrophic Lateral Sclerosis (ALS). Full details on the recommendation by INESSS, including recommended criteria for reimbursement, are available on the INESSS website.

"Today's announcement marks an important milestone in our efforts to secure coverage for RADICAVA® Oral Suspension under publicly funded drug plans across Canada," said Atsushi Fujimoto, President, MTP-CA. "With this positive recommendation from INESSS, eligible patients living in Quebec are one step closer to being able to access RADICAVA® Oral Suspension."

RADICAVA® Oral Suspension, the oral form of edaravone is authorized by Health Canada for the treatment of patients with ALS. RADICAVA® Oral Suspension was developed to have similar efficacy to RADICAVA® IV Infusion, which was authorized by Health Canada for the treatment of patients with ALS in October 2018 and has shown in a pivotal trial to slow the loss of physical function in ALS.[1,2]

MTP-CA is continuing to work closely with stakeholders to make RADICAVA® Oral Suspension accessible to patients through private insurance and public formularies.

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. It is important ALS patients begin the most appropriate treatment available to them as soon as possible, regardless of mode of delivery.[3]

About ALS

ALS, also known as Lou Gehrig's disease, is a neurodegenerative disease that currently has no cure and can progress rapidly.[4] According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS,[5] a disease that affects the nerve cells in the brain and spinal cord.[1] The majority of patients 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]

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), China (July 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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