MITSUBISHI TANABE PHARMA CANADA ANNOUNCES COLLABORATION WITH THE CNDR ON FIRST CANADIAN REAL-WORLD EVIDENCE STUDY OF RADICAVA® IV (EDARAVONE) SURVIVAL BENEFITS IN ALS

TORONTO, ON, August 9, 2023 – Mitsubishi Tanabe Pharma Canada (MTP-CA) publicly announced its collaboration today with the Canadian Neuromuscular Disease Registry (CNDR), an independent, academic registry based out of the University of Calgary, on the first Canadian real-world evidence generation study[1] of RADICAVA® IV (edaravone) for the treatment of people with amyotrophic lateral sclerosis (ALS).

ALS, also known as Lou Gehrig's disease, is a neurodegenerative disease that currently has no cure and can progress rapidly.[2] Until recently, there were limited treatment options for people living with the disease. In 2018, RADICAVA® IV became the first new therapy to be approved in Canada in almost 20 years.[3]

“Edaravone has previously been shown to slow disease progression in people with ALS over six months; however, further real-world effectiveness evidence is needed,” said CNDR’s Co-Principal Investigator, Dr. Agessandro Abrahao, neurologist and associate scientist, Sunnybrook Health Sciences Centre in Toronto who presented the study poster at the 2023 Canadian Neurological Sciences Federation (CNSF) Congress in June. “The objective of this study is to describe real-world survival effectiveness over a longer timeframe.”

According to the ALS Society of Canada, an estimated 3,000 Canadians currently are 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. 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.[6,7]

“Real-world data provides additional insight into treatment for rare diseases like ALS, which can sometimes be challenging to research and evaluate in clinical trials,” said Dung Pham, Medical Affairs Director, Mitsubishi Tanabe Pharma Canada. “Through our collaboration with the CNDR, we hope to gain important real-life insights into the role of RADICAVA® IV in the treatment of ALS – insights that will ultimately benefit people living with this progressive, life-threatening disease and their families.”

ALS Canada welcomed news of today’s collaboration. “Access to innovative therapies is an urgent issue for people living with ALS,” said Tammy Moore, President, ALS Canada. “Understanding how innovative treatments perform in a real-world setting can assist stakeholders from across the healthcare system with decision-making and potentially lead to faster access for patients and improved patient outcomes.”

The retrospective cohort study includes patients with ALS across Canada with a minimum six-month RADICAVA® IV exposure between 2017 and 2022. Subjects were enrolled in the interventional arm or in the control arm. The primary outcome of tracheostomy-free survival was compared between the two groups, accounting for age, sex, ALS-disease progression rate, disease duration, pulmonary vital capacity, bulbar ALS-onset, and presence of frontotemporal dementia or C9ORF72 mutation using inverse propensity treatment weights.

“In 2018, RADICAVA® IV became the first treatment to be approved in Canada in almost 20 years, followed by RADICAVA® Oral Suspension in 2022,” said Andy Zylak, President, Mitsubishi Tanabe Pharma Canada. “This collaboration with the CNDR is part of our legacy in Canada and ongoing commitment to benefit patients, caregivers and loved ones touched by rare diseases, including ALS.”

The impact of edaravone on survival in patients with ALS has not been established and is the subject of the real-world evidence collaboration with CNDR.

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.

Media Inquiries:
Media_MTPA@mt-pharma-us.com

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