Mitsubishi Tanabe Pharma Canada

Press Release

MITSUBISHI TANABE PHARMA CANADA ANNOUNCES CANADIAN AUTHORIZATION OF prRADICAVA® (EDARAVONE) ORAL SUSPENSION FOR THE TREATMENT OF PATIENTS WITH ALS

- *Comprehensive clinical development program for edaravone in ALS has spanned over a decade and included multiple clinical trials for IV and oral formulations*[1]

TORONTO, Canada – November 8, 2022 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that Health Canada has granted market authorization for RADICAVA® Oral Suspension, the oral formulation of RADICAVA® IV (edaravone), for the treatment of patients with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, a neurodegenerative disease that currently has no cure and can progress rapidly.[1,2] MTP-CA is working to make RADICAVA® Oral Suspension commercially available in Canada as soon as possible.

Granted a Notice of Compliance (NOC) following Priority Review, RADICAVA® Oral Suspension was developed to have similar efficacy to RADICAVA® IV Infusion, which was authorized by Health Canada for the treatment of ALS in October 2018[3] and has shown in a pivotal trial to help slow the loss of physical function in ALS.[1,4]

"A diagnosis of ALS is life altering, but recent medical advances can help to slow the loss of function," says Dr. Angela Genge, Neurologist and Director, Clinical Research Unit at The Neuro (Montreal Neurological Institute-Hospital). "The availability of new treatment options is good news for patients and families impacted by ALS."

RADICAVA® Oral Suspension has been formulated with the challenges of ALS patients in mind to ensure edaravone can be delivered orally.[1]

"In 2018, we were pleased to bring to market RADICAVA® IV Infusion, the first new treatment option for patients with ALS in 20 years. Today, we are excited to be able to provide patients and physicians with RADICAVA® Oral Suspension, an oral formulation of edaravone," says Atsushi Fujimoto, President, MTP-CA. "Mitsubishi Tanabe Pharma Canada is committed to addressing the unmet needs of those living with ALS, and we are proud to be leading the discovery and development of important treatment options that benefit the ALS community."

According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS,[5] an incurable 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.[1,2] 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]

"Time is of the essence for Canadians living with ALS, and Health Canada's approval of oral edaravone under a priority review pathway underscores the importance of equitable and expedited access to effective treatments," said Tammy Moore, CEO, ALS Society of Canada.

“We are hopeful this approval will continue to build momentum for ongoing investment in innovative research to address the urgent unmet needs of Canadians affected by ALS.”

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. The Health Canada authorization of RADICAVA® Oral Suspension is supported by several studies, including data from the pivotal Phase 3 clinical trial (MCI186-19) evaluating 137 ALS patients.

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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[1] RADICAVA® Product Monograph. Mitsubishi Tanabe Pharma America, Inc.; 2022.
[2] Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. National Institute of Neurological Disorders and Stroke, National Institutes of Health, June 2013, https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet
[3] Health Canada. Notice of Compliance Database. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/database.html
[4] 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.
[5] Benchmarking Survey, Federation of ALS Societies of Canada, 2016.
[6] 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.
[7] 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.