

HEALTH CANADA ACCEPTS SNDS FILING AND GRANTS PRIORITY REVIEW FOR ORAL EDARAVONE FORMULATION FOR THE TREATMENT OF ALS

TORONTO, Canada – May 13, 2022 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), announced today that Health Canada has accepted the filing of a Supplement to a New Drug Submission (SNDS) for an investigational oral formulation of edaravone (MT-1186) indicated for the treatment of amyotrophic lateral sclerosis (ALS). The SNDS was filed by MTPA's parent company, Mitsubishi Tanabe Pharma Corporation (MTPC). Health Canada has also granted a Priority Review, which is expected to expedite the review timelines.

“Addressing the unmet needs of the ALS community continues to be our top priority,” says Atsushi Fujimoto, President, MTP-CA. “Through our ongoing development program for edaravone, we strive to uphold this commitment by developing formulation options that best suit the specific treatment needs of ALS patients. We are pleased that Health Canada has granted this formulation Priority Review.”

Investigational oral edaravone has been developed to have a similar clinical profile to the intravenous (IV) formulation of RADICAVA® (edaravone). Until a Notice of Compliance (NOC) has been issued by Health Canada, investigational oral edaravone is not authorized for sale in Canada. Currently, RADICAVA IV is available for treatment in Canada, which was authorized by Health Canada for the treatment of ALS in October 2018.¹

“We have seen encouraging medical advances for the treatment of ALS in recent years,” says Dr. Angela Genge, Neurologist and Director, Clinical Research Unit Montreal Neurological Institute and Hospital – The Neuro. “The ultimate goal is to turn ALS into a chronic disease by slowing loss of function. It is critical to continue growing the pool of therapies available to ALS patients in Canada.”

“Pathways that advance the pace at which new therapies are reviewed by Health Canada are necessary to address the urgent unmet need of people living with ALS,” says Tammy Moore, CEO of ALS Canada. “Due to the terminal nature of ALS, and the heterogeneity of the disease, it's encouraging to see investigational ALS therapies, like oral edaravone, granted Priority Review by Health Canada.”

About Oral Edaravone (MT-1186)

Oral edaravone is an investigational oral formulation of edaravone being developed by Mitsubishi Tanabe Pharma Corporation (MTPC) and Mitsubishi Tanabe Pharma Development America, Inc (MTDA).

In 2019, Mitsubishi Tanabe Pharma group companies completed a series of Phase 1 studies comparing the oral formulation and intravenous formulations of edaravone and have started a global, multi-center, open-label, Phase 3 clinical trial evaluating safety and tolerability of oral edaravone in 185 patients with ALS across approximately 50 sites in the U.S., Canada, Europe and Japan. More information on the clinical trials is available at ClinicalTrials.gov (NCT04165824 and NCT04577404).

About RADICAVA® (edaravone) IV

RADICAVA® (edaravone) IV is indicated to slow the loss of function in patients with amyotrophic lateral sclerosis (ALS), as measured by the ALS Functional Rating Scale - Revised (ALSFRRS).ⁱⁱ 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 was granted in Canada in October 2018 and Switzerland in January 2019.

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.

Media inquiries:

Media_MTPA@mt-pharma-us.com

ⁱ Health Canada. Notice of Compliance Database. <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/database.html>

ⁱⁱ RADICAVA® (edaravone) Canada Product Monograph. March 25, 2021. <https://www.mt-pharma-ca.com/our-product/>