MITSUBISHI TANABE PHARMA CANADA ANNOUNCES CANADIAN AUTHORIZATION OF RADICAVA™ (EDARAVONE) TO TREAT ALS

TORONTO, October 4, 2018 -- Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA) today announced that Health Canada has granted market authorization of RADICAVA™ (edaravone) as an intravenous infusion treatment for amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease.[1,2]

Granted under the Priority Review process, the Notice of Compliance (NOC) authorization was based on a clinical trial in which the primary endpoint was a measurement utilizing the ALS Functional Rating Scale-Revised (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in patients with ALS.[3]

“ALS is one of the most serious neurodegenerative diseases due to the crippling loss of function,” said Dr. Angela Genge, Director, Clinical Research Unit and ALS Clinic, Montreal Neurological Institute and Hospital. “New therapies are most welcomed for patients and their families dealing with ALS.”

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.[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 12 to 14 months to be accurately diagnosed.[5]

“We are extremely pleased to receive the authorization to bring RADICAVA to the Canadian ALS community,” said Atsushi Fujimoto, President, Mitsubishi Tanabe Pharma Canada (MTP-CA). “We are committed to providing new treatments for people facing serious diseases and working closely with government bodies to make our medicines accessible to Canadians.”

In March of 2018, MTPA established the subsidiary MTP-CA to facilitate the distribution of RADICAVA in Canada.

“For nearly 20 years, Canadians living with ALS have had only one treatment option – making the Canadian approval of RADICAVA an important and hopeful milestone for a community that still faces a challenging diagnosis,” said Tammy Moore, CEO, ALS Society of Canada. “It is our hope that the approval of RADICAVA will build momentum for the development of additional therapies, underscoring the importance of research investment and the need for Canadians living with ALS to have timely and equitable access to treatments within the healthcare system.”

About RADICAVA® (edaravone)

RADICAVA® (edaravone) is indicated for the treatment of 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 in May of 2017. In Canada, edaravone will be marketed as RADICAVA™ (edaravone).

IMPORTANT SAFETY INFORMATION

Before you receive RADICAVA, tell your healthcare provider about all of your medical conditions, including if you:

- have asthma.
- are allergic to other medicines.
- are pregnant or plan to become pregnant. It is not known if RADICAVA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RADICAVA passes into your breast milk. You and your healthcare provider should decide if you will receive RADICAVA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of RADICAVA?

- RADICAVA may cause serious side effects including hypersensitivity (allergic) reactions and sulfite allergic reactions.

- Hypersensitivity reactions have happened in people receiving RADICAVA and can happen after your infusion is finished.

- RADICAVA contains sodium bisulfite, a sulfite that may cause a type of allergic reaction that can be serious and life-threatening. Sodium bisulfite can also cause less severe asthma episodes in certain people. Sulfite sensitivity can happen more often in people who have asthma than in people who do not have asthma.

- Tell your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms: hives; swelling of the lips, tongue, or face; fainting; breathing problems; wheezing; trouble swallowing; dizziness; itching; or an asthma attack (in people with asthma).

- Your healthcare provider will monitor you during treatment to watch for signs and symptoms of all the serious side effects.

The most common side effects of RADICAVA include bruising (contusion), problems walking (gait disturbance), and headache.

These are not all the possible side effects of RADICAVA. Call your healthcare provider for medical advice about side effects. You may report side effects to Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, including full Prescribing Information and Patient Information, please visit **www.RADICAVA.com**.

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. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in North America. It was established by MTPC to commercialize approved pharmaceutical products in North America with plans to expand its product line through collaborations with partners. For more information, please visit www.mt-pharma-america.com.

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[1] National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Information Page. https://www.ninds.nih.gov/disorders/all-disorders/amyotrophic-lateral-sclerosis-als-information-page. Accessed March 2018.

[2] Mehta P, Kaye W, Bryan L, et al. (2016). Prevalence of Amyotrophic Lateral Sclerosis — United States, 2012–2013. *MMWR Surveill Summ*, 65(8), 1-12. http://dx.doi.org/10.15585/mmwr.ss6508a1.

[3] 2017 Full Issue PDF, Volume 18, Issue S1, Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, 18: sup1, 1-103.

[4] Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

[5] Brooks BR. (2000). Risk factors in the early diagnosis of ALS: North American epidemiological studies. *Amyotrophic Lateral Sclerosis and Other Motor Neuron Disorders*, 1(1), S19-S26. http://dx.doi.org/10.1080/14660820052415871.