Mitsubishi Tanabe Pharma America Press Release

MITSUBISHI TANABE PHARMA AMERICA ANNOUNCES INITIATION OF PHASE 3 STUDY EVALUATING INVESTIGATIONAL ORAL FORMULATION OF EDARAVONE FOR ALS

JERSEY CITY, N.J., November 25, 2019 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced the initiation of a global Phase 3 study evaluating the long-term safety and tolerability of an investigational oral suspension formulation of edaravone (MT-1186) in patients with amyotrophic lateral sclerosis (ALS).

The intravenous (IV) formulation of edaravone, known as RADICAVA® (edaravone), is a treatment option previously approved by the U.S. Food and Drug Administration (FDA) that was shown in a prior clinical study to slow the loss of physical function in ALS patients.

"Enrollment of the first patient in this clinical study marks an important milestone for our company as we continue to seek treatment options for the ALS community," said Atsushi Fujimoto, President, MTPA. "There is a great unmet need in the area of ALS, and we believe an oral formulation of edaravone could potentially serve as an alternative treatment option for patients suffering from this progressive condition."

The global, multi-center, open-label study, sponsored by Mitsubishi Tanabe Pharma Development America, Inc. (MTDA), will evaluate 150 people with ALS across an estimated 65 sites in the U.S., Canada, Europe and Japan over the course of 48 weeks of treatment. Approximately half the study sites will be located in the U.S.

After a screening period of up to 21 days, study participants (18 to 75 years of age) will receive oral edaravone following the same dosing regimen currently utilized by patients on the IV formulation.

In the study, the primary safety assessments will include adverse events, physical examination, electrocardiogram parameters, vital signs, laboratory safety assessments, unsteadiness and sensory evaluations. Exploratory endpoints will include change in ALS Functional Rating Scale-Revised (ALSFRS-R) score, change in percentage of forced vital capacity (FVC), and time (days) to tracheostomy, or permanent assisted mechanical ventilation.

"ALS presents a tremendous burden to patients as the disease robs them of physical function," said Carlayne E. Jackson, M.D., a U.S. principal investigator. "As a researcher and provider of care for ALS patients, I'm pleased to be part of a research effort with a goal to provide a new treatment option for those living with this devastating disease."

Further details on the U.S. trial are available at clinicaltrials.gov (NCT04165824).

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 or follow us on Twitter, Facebook and LinkedIn.

About Mitsubishi Tanabe Pharma Development America, Inc.
Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) 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., and an affiliate of MTPA. It was established by MTPC to conduct clinical development in the U.S. and countries outside of Asia. MTDA obtained the regulatory approval of RADICAVA IV in the United States and is the sponsor of the MT-1186 clinical study. MTDA is dedicated to research and developing innovative pharmaceutical products that address the unmet medical needs of patients. http://mt-pharma-development-america.com/.

Overview of Mitsubishi Tanabe Pharma Corporation (MTPC)
Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan.[1] In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 2016-2020. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. MTPC is the parent company of MTPA and the license holder of RADICAVA. For more information, go to http://www.mt-pharma.co.jp/.

About RADICAVA® (edaravone) IV
The U.S. Food and Drug Administration approved RADICAVA® (edaravone) on May 5, 2017 as a treatment for amyotrophic lateral sclerosis.[2] In a pivotal trial, people given RADICAVA experienced a 33 percent slower rate of decline in the loss of physical function, compared to placebo as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in people with ALS.[3,4]

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and commercialized in the U.S. by Mitsubishi Tanabe Pharma America, Inc. MTPC group companies began researching ALS in 2001 through an iterative clinical platform over a 13-year

period. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. Marketing authorization was granted in Canada in October 2018 and Switzerland in January 2019.

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**.

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[1] Research by TOKYO SHOKO RESEARCH, LTD.

[2] RADICAVA® U.S. Prescribing Information. August 2018.

[3] Simon, N. G., Turner, M. R., Vucic, S., Al-Chalabi, A., Shefner, J., Lomen-Hoerth, C., & Kiernan, M. C. (2014). Quantifying Disease Progression in Amyotrophic Lateral Sclerosis. *Annals of Neurology*, 76(5), 643-657. http://dx.doi.org/10.1002/ana.24273.

[4] The Writing Group on behalf of the Edaravone (MCI-186) ALS 19 Study Group (2017). Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurology*. 16(7), 505-512.