



**MITSUBISHI TANABE PHARMA AMERICA PRESENTS AT 2019 NATIONAL
ALS REGISTRY ANNUAL MEETING IN ATLANTA**

JERSEY CITY, N.J., July 23, 2019 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced the company will present an update on its REFINE-ALS biomarker study during the Centers for Disease Control and Prevention (CDC) 2019 National ALS Registry Annual Meeting in Atlanta on July 23-24.

Wendy Agnese, Pharm.D., Director of Medical Affairs, MTPA, will present details regarding REFINE-ALS study design methodology and goals to identify and measure specific biomarkers and clinical assessments in people with amyotrophic lateral sclerosis (ALS). The CDC National ALS Registry Annual Meeting brings together key stakeholders from the ALS scientific and advocacy community to discuss the Registry findings and the Agency for Toxic Substances and Disease Registry Funded Research Update.

“It is an honor to represent the REFINE-ALS study team and share our current plans with this esteemed gathering of individuals, all of whom are contributing to furthering the efforts, understandings, and advancements in ALS research,” said Dr. Agnese, Scientific Affairs lead for the REFINE-ALS study team. “The conceptualization and development of this study has truly been a collaborative effort with brilliantly passionate experts, and we all look forward to sharing our study findings with the ALS community.”

The CDC National ALS Registry is the only population-based database in the U.S. that collects information such as disease prevalence, demographics and risk factors to help scientists learn more about who gets ALS, as well as its causes. People with ALS who are enrolled in the CDC Registry, and opt-in for research alerts, will receive notification of the REFINE-ALS study.

Additional information on the CDC National ALS Registry can be found at www.cdc.gov/als.

The REFINE-ALS biomarker study, sponsored by MTPA and led by Massachusetts General Hospital (MGH) Neurological Clinical Research Institute (NCRI), will evaluate up to 300 adults with ALS who are starting treatment with RADICAVA® (edaravone). Biomarkers will be measured prior to initiating treatment, at the start of treatment, and at pre-specified time points throughout the 24-week study period (six cycles of treatment).

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](#) and [Facebook](#).

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)

The U.S. Food and Drug Administration (FDA) approved RADICAVA[®] (edaravone) on May 5, 2017 as a treatment for amyotrophic lateral sclerosis (ALS).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.

Media inquiries:

Mitsubishi Tanabe Pharma America

Debbie Etchison

908-340-8578

Media_MTPA@mt-pharma-us.com

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., & Kieman, 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.