



## **MITSUBISHI TANABE PHARMA AMERICA TO HIGHLIGHT ALS RESEARCH INITIATIVES AT 2019 MDA CLINICAL & SCIENTIFIC CONFERENCE**

***Poster Presentations Include Real-World Data Regarding Patient Experience with RADICAVA® (edaravone) and Underscore Company's Commitment to Continued Research***

**JERSEY CITY, N.J., April 11, 2019** – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced poster presentations of amyotrophic lateral sclerosis (ALS) research at the 2019 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference being held April 13-17 in Orlando, Fla. Abstracts include the protocol and design of a study evaluating the potential role of [biomarkers](#) in ALS treatment, real-world postmarketing safety data and insights on patient experience with RADICAVA® (edaravone) in the U.S., and an update on the development plan for an [investigational oral formulation](#) of edaravone.

“We look forward to sharing research updates with the community that may help to increase our understanding of treatment with RADICAVA,” said Stephen Apple, M.D., Senior Director of Medical Affairs, MTPA. “We are focused on seeking new information about treating ALS, and each clinical trial or opportunity to gather additional real-world insight helps bring us closer to achieving that goal.”

### **Poster presentations include:**

*Monday, April 15 from 6:00 PM – 8:30 PM EDT*

- **RADICAVA® (edaravone) for Amyotrophic Lateral Sclerosis: U.S. Experience at 1 Year After Launch**  
Abstract 241, Exhibit Hall

*Tuesday, April 16 from 6:00 PM – 8:30 PM EDT*

- **Protocol and Design of the RADICAVA® (edaravone) Biomarker Study for ALS Patients in the United States**  
Abstract 4, Exhibit Hall
- **Edaravone for Amyotrophic Lateral Sclerosis: Oral Formulation and Its Development Plan**  
Abstract 216, Exhibit Hall
- **Summary of the U.S. Safety Data for RADICAVA® (edaravone): Findings From Postmarketing Pharmacovigilance**  
Abstract 218, Exhibit Hall

### **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](http://www.mt-pharma-america.com) or follow us on [Twitter](#) and [Facebook](#).

### **Overview of Mitsubishi Tanabe Pharma Corporation**

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.<sup>1</sup> 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<sup>®</sup> (edaravone) IV**

The U.S. Food and Drug Administration (FDA) approved RADICAVA<sup>®</sup> (edaravone) on May 5, 2017 as a treatment for amyotrophic lateral sclerosis (ALS).<sup>2</sup> In a pivotal clinical trial, people given RADICAVA experienced on average a 33 percent slower 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.<sup>2,3,4</sup>

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 February 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](http://www.fda.gov/medwatch).

For more information, including full Prescribing Information and Patient Information, please visit [www.RADICAVA.com](http://www.RADICAVA.com).

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<sup>1</sup> Research by TOKYO SHOKO RESEARCH, LTD.

<sup>2</sup> RADICAVA® U.S. Prescribing Information. August 2018.

<sup>3</sup> Simon N, Turner, M, Vucic S, et al.(2014). Quantifying Disease Progression in Amyotrophic Lateral Sclerosis. *Annals of Neurology*, 76(5), 643–657. <http://dx.doi.org/10.1002/ana.24273>.

<sup>4</sup> 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. [http://dx.doi.org/10.1016/S1474-4422\(17\)30115-1](http://dx.doi.org/10.1016/S1474-4422(17)30115-1).