



**MITSUBISHI TANABE PHARMA AMERICA TO PRESENT DATA ON RADICAVA®
(EDARAVONE) AT THE EUROPEAN NETWORK FOR THE CURE OF ALS (ENCALS)
ANNUAL MEETING**

***Assessments of RADICAVA Clinical Trial Program
Provide Insights on Efficient Clinical Trial Design in ALS***

JERSEY CITY, N.J., June 21, 2018 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced it will present three abstracts on RADICAVA® (edaravone) in amyotrophic lateral sclerosis (ALS) at the European Network for the Cure of ALS (ENCALS) Annual Meeting held June 20-22 in Oxford, England.

“We look forward to sharing post-hoc analyses from the RADICAVA clinical development program at ENCALS, including assessments that demonstrate the importance of efficient clinical trial design in ALS in order to detect a treatment effect,” said Jean Hubble, M.D., Vice President of Medical Affairs, MTPA. “ALS is a heterogeneous disease with wide ranging variability in presentation and progression. By applying learnings from an earlier study to our pivotal trial for RADICAVA, we were able to address this heterogeneity, decrease the number of ‘slow progressing’ patients and enhance the ability to show the effects of RADICAVA treatment on disease progression within a short six-month timeframe.”

Data to be presented at ENCALS include:

RADICAVA® (edaravone) Presentations

- **Towards more efficient clinical trial designs in ALS: Lessons from the edaravone development program**
Abstract D30, Poster Session 2, Thursday, June 21 from 17:45 - 19:15 BST
- **A post-hoc analysis of edaravone study 19: Forced vital capacity (FVC) subgroup analysis**
Abstract D31, Poster Session 2, Thursday, June 21 from 17:45 - 19:15 BST
- **A post-hoc analysis of the edaravone phase III study 19: Regression analyses to examine long-term efficacy**
Abstract D32, Poster Session 2, Thursday, June 21 from 17:45 - 19:15 BST

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).¹ In a clinical 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 (ALSFRRS-R), a validated rating instrument for monitoring the progression of disability in people with ALS.^{1,2,3}

RADICAVA is administered in 28-day cycles by intravenous infusion. It takes 60 minutes to receive each 60-mg dose. For the initial cycle, the treatment is infused daily for 14 consecutive days, followed by a two-week drug-free period. All cycles thereafter are infused daily for 10 days within a 14-day period, followed by a two-week drug-free period.¹

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.

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 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 at <https://twitter.com/MTPharmaUS>.

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.⁴ 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/>.

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¹ RADICAVA® U.S. Prescribing Information. August 2017.

² 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>.

³ Abe K, Aoki M, Tsuji S, et al. (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).

⁴ Research by TOKYO SHOKO RESEARCH, LTD.