MITSUBISHI TANABE PHARMA AMERICA TO SHOWCASE ALS RESEARCH AT 29TH INTERNATIONAL SYMPOSIUM ON ALS/MND IN GLASGOW

Presentations Highlight Commitment to Further ALS Research and Treatment

JERSEY CITY, N.J., November 28, 2018 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced presentations on amyotrophic lateral sclerosis (ALS) at the 29th International Symposium on ALS/MND in Glasgow, Scotland, December 7-9. The data will provide deeper insight into ALS, the U.S. experience with RADICAVA® (edaravone) since its launch in 2017 and the Company's plans for future research and development.

"We look forward to sharing research updates that reinforce our ongoing dedication to the ALS community, including the design of a biomarker study that may advance our understanding of diagnosis and treatment of ALS," said Jean Hubble, M.D., Vice President of Medical Affairs, MTPA. "As part of our commitment to helping those affected by ALS, we continue to explore ways to improve the patient journey, from our research on the use of big data to findings on edaravone's use beyond clinical trials."

ALS Patient Journey

MTPA will present findings from an analysis of patient health claims data from more than 170 million individuals that identified features captured in the database, differentiating people with ALS from the general population up to five years prior to diagnosis. These findings may help to shed light on how to identify ALS sooner, an important goal given it can take 12 to 14 months for patients to be accurately diagnosed.[1]

- **Big Data Analytics for Early Diagnosis of Amyotrophic Lateral Sclerosis**
  Abstract 21, Poster Session B, Saturday, December 8 from 6:00 PM – 6:50 PM GMT

Development Program

MTPA will present details on two research initiatives. Through a biomarker study, MTPA aims to research the use of biomarkers as quantifiable, biological, non-clinical measures for disease progression and treatment effect in people with ALS. Representatives of Mitsubishi Tanabe Pharma group companies also will provide an overview of the development program for a new formulation of edaravone, including Phase 1 pharmacokinetic (PK) results showing oral edaravone is expected to have similar PK parameters to the current intravenous infusion.

- **Protocol and Design of the RADICAVA® (edaravone) Biomarker Study for ALS Patients in the United States**
  Abstract 15, Poster Session A, Friday, December 7 from 6:50 PM – 7:40 PM GMT

- **Edaravone for Amyotrophic Lateral Sclerosis: New formulation and its development plan**
  Abstract 13, Poster Session A, Friday, December 7 from 6:00 PM – 6:50 PM GMT

RADICAVA Treatment Experience

MTPA will share a summary of real-world safety data from RADICAVA use in the U.S. and provide an update on the U.S. Food and Drug Administration's (FDA) required post-marketing studies for the treatment. The company will present insights from a survey of RADICAVA utilization one year post-launch, including key learnings regarding logistics and support services.

- **Summary of the U.S. Safety Data for RADICAVA® (edaravone): Findings from the Postmarketing Pharmacovigilance**
  Abstract 11, Poster Session B, Saturday, December 8 from 6:50 PM – 7:40 PM GMT

- **RADICAVA® (edaravone) for Amyotrophic Lateral Sclerosis: Progress on Postmarketing Requirements and Commitments**
  Abstract 14, Poster Session A, Friday, December 7 from 6:00 PM – 6:50 PM GMT

- **RADICAVA® (edaravone) for Amyotrophic Lateral Sclerosis: U.S. Experience at 1 Year After Launch**
  Abstract 17, Poster Session B, Saturday, December 8 from 6:50 PM – 7:40 PM GMT

Additionally, preliminary patient background and safety data from the SUNRISE Japan Registry will be presented by Mitsubishi Tanabe Pharma Corporation. The study aims to assess long-term safety and efficacy of edaravone in the postmarketing surveillance of people with ALS in Japan, for up to five years.

- **Surveillance of using free radical scavenger, edaravone to investigate survival effect for ALS patients in Japan (SUNRISE Japan): Report for intermediate summary**
  Abstract 14, Poster Session A, Friday, December 7 from 6:50 PM – 7:40 PM GMT

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 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 (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in people with ALS.[1,3,4]

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. MTP 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, and in 2018, the treatment was approved in Canada.

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 (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 the U.S. It was established by MTPC to commercialize approved pharmaceutical products in the U.S. 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

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.[5] 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/.

Media inquiries:

Debbie Etchison
908-340-8578
Media_MTPA@mt-pharma-us.com

---

[1] 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.

[2] RADICAVA® U.S. Prescribing Information. August 2017.

[3] 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.

[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. http://dx.doi.org/10.1016/S1474-4422(17)30115-1.

[5] Research by TOKYO SHOKO RESEARCH, LTD.