MORE THAN 4,000 U.S. PATIENTS WITH ALS TREATED WITH RADICAVA® (EDARAVONE) IN TWO YEARS SINCE AVAILABILITY, MITSUBISHI TANABE PHARMA AMERICA REPORTS

JERSEY CITY, N.J., August 8, 2019 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that more than 4,000 people with amyotrophic lateral sclerosis (ALS) in the United States have received treatment with RADICAVA® (edaravone) and over 1,100 healthcare providers have prescribed the therapy to one or more of their ALS patients since it became available in August 2017.[1]

"Our focus continues to be on how we can make a meaningful difference in the lives of people with ALS and their families," said Atsushi Fujimoto, President, MTPA. "We are pursuing research into biomarkers in ALS and development of an oral formulation of edaravone. Whether it's through our clinical research or providing resources to help families understand the disease and navigate care, we remain as dedicated as ever to continuing that mission."

RADICAVA, the only treatment approved by the U.S. Food and Drug Administration to slow the loss of physical function in people with ALS, is an infusion therapy that can be given to patients in the home or in a variety of clinical settings such as an ALS center or physician's office. In ALS, lost physical function cannot be recovered.

MTPA reports several updates related to the company's efforts to help people with ALS and their families. As of June 2019, our internal data shows that approximately 92 percent of patients who have sought health plan coverage for treatment with RADICAVA received insurance coverage approval for their treatment.*[1,2] According to recent analysis, approximately 70 percent of patients have been on treatment for six months or more.[1]

"RADICAVA offers my ALS patients a much-needed treatment option," said Tomas Holmlund, M.D., Medical Director of the DENT Neurologic Institute's Neuromuscular Center in Buffalo, N.Y., whose patient was one of the first in the United States to receive the treatment when it became available. "One day we hope there will be a cure, but we are not there yet."

An estimated 5,000-6,000 Americans are diagnosed each year with ALS, a rapidly progressive neurodegenerative disease that affects the nerve cells in the brain and the spinal cord.[3,4,5] The majority of ALS patients die within two to five years of receiving a diagnosis, but progression of the disease can vary significantly.[6]

** Based on total number of commercial and government cases submitted through Searchlight Support® from 6/01/2019 through 6/30/2019. Of the 92 percent, the rate for commercial payers was more than 83 percent and government was more than 95 percent. These approval rates include cases that were initially denied and subsequently approved through filing of exception requests or*

through appeals processes. Coverage determinations are based on individual health plan policies, and approval rate could be dependent on insurance plans, appeal processes and severity of disease. Insurance approval does not directly equate to patients receiving RADICAVA. After insurance approval, site of care may still need to be finalized.

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.[7] 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 approved RADICAVA® (edaravone) on May 5, 2017, as a treatment for amyotrophic lateral sclerosis (ALS).[8] 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.[9,10]

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] Mitsubishi Tanabe Pharma America Inc., Data on File as of August 2019.

[2] Searchlight Support® (a hub from which RADICAVA® prescriptions are processed), is operated by McKesson Specialty Health on behalf of Mitsubishi Tanabe Pharma America, Inc. (MTPA), and is the source of this data. Data excludes providers that buy direct. This data has not been independently verified, and should not be considered a guarantee of coverage. MTPA, as well as its employees or agents, shall not be held liable for any damages or harm resulting from any use or reliance on data contained herein.

[3] Centers for Disease Control and Prevention – National Amyotrophic Lateral Sclerosis (ALS) Registry (April 25, 2017). Frequently Asked Questions – Questions About ALS. Retrieved from https://www.cdc.gov/als/ALSFAQ.html.

[4] Marin B, Boumediene F, Logroscino G, et al. (2016). Variation in worldwide incidence of amyotrophic lateral sclerosis: a meta-analysis. Int J Epidemiol, 00:1-18.

[5] National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Information Page. https://www.ninds.nih.gov/disorders/all-disorders/amyotrophic-lateral-sclerosis-als-information-page. Accessed January 2019.

[6] Mehta P, Kaye W, Bryan L, et al. (2016). Prevalence of Amyotrophic Lateral Sclerosis — United States, 2012–2013. MMWR Surveill Summ; 65(No. SS-8):1–12.

[7] Research by TOKYO SHOKO RESEARCH, LTD.

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

[9] 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.

[10] 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.