Mitsubishi Tanabe Pharma America Announces 1,000 People with ALS Have Received FDA-Approved Treatment Option in First Three Months Available

Searchlight Support™ Staff Expanded to Accelerate Processing of Benefits and Access Requests

JERSEY CITY, N.J., November 16, 2017 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that more than 1,000 people with amyotrophic lateral sclerosis (ALS) have been treated with RADICAVA® (edaravone) since it became available in the U.S. in August as the first FDA-approved treatment option for the disease in more than 20 years.

"Our goal is to help as many people with ALS as possible," said Atsushi Fujimoto, President, Mitsubishi Tanabe Pharma America. "This is an important milestone, and we remain keenly focused on continuing to ensure that patients prescribed RADICAVA are able to access this treatment as quickly as possible."

Since May, more than 14,000 calls have been handled by representatives from MTPA's Searchlight Support™ program, which helps facilitate insurance confirmation and product access requests for those prescribed RADICAVA. The company has hired additional case managers to accelerate benefits investigations, and also has streamlined the form process for healthcare providers and patients.

"After decades of waiting for a treatment option, the ALS community is one step closer to managing this devastating disease," said Tomas H. Holmlund, M.D., Attending Neurologist and Medical Director of the Neuromuscular Center/MDA Clinic at DENT Neurologic Institute, whose patients were among the first in the country to receive treatment with RADICAVA in August. "This is extremely meaningful to me and to the patients I treat."

RADICAVA is given to patients intravenously and can be administered in multiple settings, including an ALS center or through home infusion under the supervision of an HCP. Over the last three months since becoming available in the U.S., more than 300 infusion centers have treated patients, and more than half of patients have received treatment through home infusion providers.

An estimated 5,000-6,000 Americans are diagnosed each year with ALS.[1,2,3] The majority of ALS patients die within two to five years of receiving a diagnosis.[4]

About RADICAVA® (Edaravone)

The U.S. Food and Drug Administration (FDA) approved RADICAVA® (edaravone) on May 5, as a treatment option for all adult patients diagnosed with amyotrophic lateral sclerosis (ALS).[5] In clinical trials, 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.[5,6,7]

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.[5]

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and commercialized in the U.S. by Mitsubishi Tanabe Pharma America. 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 (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 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.[8] 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] ALS Association. Quick Facts about ALS. http://www.alsa.org/news/media/quick-facts.html. Accessed November 2017.

[2] 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.

[3] 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 November 2017.

[4] 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

[5] RADICAVA® U.S. Prescribing Information. May 2017.

[6] 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.

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

[8] Research by TOKYO SHOKO RESEARCH, LTD.