MT Pharma America

Press Release

# MT Pharma America Enrolls More Than 700 Sites of Care in Newly Created National Infusion Center Directory for ALS Patients

**JERSEY CITY, N.J., June 30, 2017 –** MT Pharma America, Inc. today announced the enrollment of more than 700 sites of care in its National Infusion Center Directory, to help physicians identify local infusion centers for patients with amyotrophic lateral sclerosis (ALS) who are prescribed RADICAVA™ (edaravone), an intravenous infusion treatment for any patient with ALS, which was approved by the U.S. Food and Drug Administration (FDA) in May. RADICAVA is on schedule to be available to patients in the U.S. in August 2017.

"Our teams have been working diligently to enroll as many infusion center sites as possible in advance of RADICAVA becoming available in the U.S. to ensure the treatment process is as smooth and convenient as possible for physicians and their patients," said Atsushi Fujimoto, President, MT Pharma America. "These efforts are part of our ongoing commitment to help people with ALS and caregivers access the support they need and deserve."

RADICAVA is given to patients through an IV and can be administered at an outpatient center, in the patient's home or in a healthcare provider's (HCP) office, depending on the individual's health plan.

Patients are encouraged to schedule an appointment with their HCP prior to RADICAVA becoming available in August to determine if the treatment is right for them and if so, to identify the appropriate site of infusion based on their needs. The National Infusion Center Directory is only available by calling Searchlight Support™, which will assist HCPs by identifying a listing of local sites of care most convenient for their patients based on geography, insurance and location hours. For more information including directory details, contact 1-844-SRCHLGT (1-844-772-4548).

Healthcare providers may enroll their infusion center by visiting www.mtsiteofcaredirectory.com. Once enrolled, an MT Pharma America representative at Searchlight Support will call to confirm information before adding the infusion center to the directory. The National Infusion Center Directory is not a referral service.

To register to receive the latest updates on product availability, visit www.RADICAVA.com.

**About RADICAVA™ (Edaravone)**

On May 5, the U.S. Food and Drug Administration (FDA) approved RADICAVA™ (edaravone) as a treatment for any patient diagnosed with amyotrophic lateral sclerosis (ALS).[1] Patients given RADICAVA for six months experienced a significantly lower rate of decline in loss of physical function, by 33 percent or 2.49 points 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.[1,2,3]

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 will be commercialized in the U.S. by MT Pharma America. MTPC group companies began researching ALS in 2001 through a comprehensive 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 MT 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 MT Pharma America, Inc.**

Based in Jersey City, N.J., MT Pharma America 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. MT Pharma America 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.[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 16-20. 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 MT Pharma America 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. May 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.

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

[4] Research by TOKYO SHOKO RESEARCH, LTD.