MITSUBISHI TANABE PHARMA AMERICA ANNOUNCES MORE THAN 10,000 PEOPLE WITH ALS TREATED WITH RADICAVA ORS® (EDARAVONE) AND/OR RADICAVA® (EDARAVONE)

JERSEY CITY, N.J., March 16, 2023 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that more than 10,000 people with amyotrophic lateral sclerosis (ALS) have received treatment with intravenous (IV) RADICAVA® (edaravone) and/or RADICAVA ORS® (edaravone) since the therapies became available in the U.S. in August 2017 and June 2022, respectively.[1] To date, more than 2,000 U.S. HCPs have prescribed RADICAVA ORS and/or RADICAVA to one or more of their patients, and 79% of people who started treatment in the six-month period between June 1, 2022 and November 30, 2022 have continued treatment for three months or more through February.[2,3] RADICAVA ORS and RADICAVA are widely distributed by specialty pharmacies across the U.S. and in Puerto Rico.

“This product milestone falls on MTPA’s seventh anniversary as a U.S. company committed to helping those with ALS,” said Atsushi Fujimoto, President, MTPA. “Addressing the unmet needs of people living with serious, debilitating diseases like ALS, is of the utmost importance to us, and we remain focused on delivering meaningful treatments to this community."

RADICAVA ORS is an oral formulation that offers the same efficacy as RADICAVA and was shown in a pivotal trial to help slow the loss of physical function in ALS.[4,5] To learn more about RADICAVA ORS, including information about dosing and administration, visit RADICAVA.com.

“As one of the first physicians to prescribe RADICAVA IV in 2017 and the oral formulation in 2022, this milestone holds significant meaning for me,” said Benjamin Rix Brooks, M.D., ALS specialist. “ALS is a devastating disease with no cure, but it’s reassuring to know that many living with the disease have received therapy with a treatment that may slow their disease progression.”

“I started receiving RADICAVA IV in 2017 when the therapy was approved by the FDA, and recently, I switched to the oral formulation before taking an RV trip with my family,” said Juan Reyes, U.S. Air Force Veteran living with ALS. “RADICAVA ORS offers me the flexibility to take my treatment on the road, instead of at an infusion center, and as an advocate and mentor to people living with ALS, I’m encouraged to know others have treatment options that may help them.”

The initial treatment cycle starts with daily dosing of RADICAVA ORS for 14 days followed by a 14-day drug-free period. Subsequent treatment cycles include daily dosing 10 out of 14 days followed by a 14-day drug-free period. People taking RADICAVA ORS should use the provided five milliliter syringe that comes with the product and should not use a household teaspoon to measure the medication. RADICAVA ORS should be stored upright at room temperature between 68°F-77°F and protected from light.[4]

In prior clinical trials for RADICAVA, the most common adverse events (AEs) reported in participants were contusion (15%), gait disturbance (13%) and headache (10%). In the pivotal safety trial for RADICAVA ORS (MT-1186-A01), the most common AEs reported at 24 weeks in participants were muscular weakness (16.2%), fall (15.7%) and fatigue (7.6%). RADICAVA and RADICAVA ORS are contraindicated in people with a history of hypersensitivity to edaravone or any of the inactive ingredients. See Important Safety Information below.

About RADICAVA® (edaravone) and RADICAVA ORS® (edaravone)
The U.S. Food and Drug Administration (FDA) approved RADICAVA® (edaravone) on May 5, 2017, and the oral formulation RADICAVA ORS® (edaravone) on May 12, 2022, for the treatment of amyotrophic lateral sclerosis (ALS). RADICAVA is administered in 28-day cycles by IV 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. RADICAVA ORS is taken daily for 14 consecutive days followed by a 14-day drug-free period for the initial treatment cycle. For subsequent treatment cycles, RADICAVA ORS is taken for 10 days within a 14-day period followed by a 14-day drug-free period. RADICAVA ORS should be taken in the morning after overnight fasting. Patients should not eat or drink (except water) within one hour after taking RADICAVA ORS.[4]

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and Mitsubishi Tanabe Pharma Development America, Inc. (MTDA), commercialized in the U.S. by Mitsubishi Tanabe Pharma America, Inc. (MTPA). The MTPC group companies began researching ALS in 2001 through an iterative clinical platform over a 13-year period. In 2015, edaravone was approved as RADICUT® for the treatment of ALS in Japan and South Korea. Marketing authorizations were subsequently granted in Canada (October 2018), Switzerland (January 2019), Indonesia (July 2020), Thailand (April 2021) and Malaysia (December 2021). Marketing authorization for RADICAVA® Oral Suspension was granted in Canada in November 2022, and RADICUT® Oral Suspension 2.1% was granted regulatory approval in Japan in December 2022. To date, in the U.S., RADICAVA and RADICAVA ORS have been used to treat over 10,000 people with ALS, with over 1.2 million days of therapy, and have been prescribed by nearly 2,000 HCPs. [1,2,6]

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions
RADICAVA (edaravone) and RADICAVA ORS (edaravone) are contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred with RADICAVA.

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA or RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Sulfite Allergic Reactions
RADICAVA and RADICAVA ORS contain sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Adverse Reactions
The most common adverse reactions (≥10%) reported in RADICAVA-treated patients were contusion (15%), gait disturbance (13%), and headache (10%). In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Pregnancy
Based on animal data, RADICAVA and RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact Mitsubishi Tanabe Pharma America, Inc., at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION
RADICAVA and RADICAVA ORS are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

For more information, including full Prescribing 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. It was established by MTPC to commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com or follow us on Twitter, Facebook and LinkedIn.

About Mitsubishi Tanabe Pharma Development America, Inc.
The U.S. headquarters of Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) is located in Jersey City, New Jersey. MTDA is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation's 100 percent-owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. For more information, please visit https://mt-pharma-development-america.com/.

About Mitsubishi Tanabe Pharma Corporation
Mitsubishi Tanabe Pharma Corporation (MTPC), the pharma arm of the Mitsubishi Chemical Group, is one of the oldest pharmaceutical companies in the world, founded in 1678, and focusing on ethical pharmaceuticals. MTPC is headquartered in Doshomachi, Osaka, the birthplace of Japan's pharmaceutical industry. The Mitsubishi Chemical Group has positioned

health care as its strategic focus in its management policy, “Forging the future”. MTPC sets the MISSION of “Creating hope for all facing illness”. To that end, MTPC is prioritizing work on “precision medicine” to provide drugs with high treatment satisfaction by identifying patient populations with high potential for efficacy and safety, focusing on the disease areas of central nervous system and immuno-inflammation. In addition, MTPC is working to develop “around the pill solutions” to address specific patient concerns based on therapeutic medicine, including prevention of diseases, pre-symptomatic disease care, prevention of aggravation and prognosis. For more information, go to https://www.mt-pharma.co.jp/e/.

Media inquiries:
Media_MTPA@mt-pharma-us.com

---

[1] Data on file. Mitsubishi Tanabe Pharma America, Inc.
[2] Data on file. Mitsubishi Tanabe Pharma America, Inc.
[3] Data on file. Mitsubishi Tanabe Pharma America, Inc.
[4] RADICAVA and RADICAVA ORS Prescribing Information. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; 2022.
[5] Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16(7):505-512.
[6] Data on file. Mitsubishi Tanabe Pharma America, Inc.