RADICAVA ORS® (EDARAVONE) NOW AVAILABLE IN THE U.S. FOR THE TREATMENT OF ALS

RADICAVA ORS gives people with ALS an oral treatment option that offers the same efficacy as the IV formulation of edaravone[1]

JERSEY CITY, N.J. June 15, 2022 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced RADICAVA ORS® (edaravone) is now available in the United States (U.S.) for the treatment of amyotrophic lateral sclerosis (ALS), a neurodegenerative disease that currently has no cure and can progress rapidly.[1,2] RADICAVA ORS – approved by the U.S. Food and Drug Administration (FDA) on May 12, 2022 – is an oral suspension form of edaravone, the active ingredient in RADICAVA® (edaravone), an FDA-approved intravenous (IV) treatment shown in a pivotal trial to help slow the loss of physical function in ALS.[1,3]

"I am proud to announce the launch of RADICAVA ORS, which is available to eligible people with ALS in the U.S. starting today," said Atsushi Fujimoto, President, MTPA. "RADICAVA ORS represents an important new treatment option that can be critical in slowing the loss of physical function in ALS. I look forward to seeing this orally administered product impact the lives of patients and caregivers."

In clinical trials, 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.

RADICAVA ORS is approved as a 5 mL dose that can be taken orally or via feeding tube, providing a portable and flexible administration option to ALS patients, with no infusion required.[1] With appropriate instruction from a healthcare provider (HCP), RADICAVA ORS may take only a few minutes to administer on treatment days.[1] RADICAVA ORS should be taken in the morning after overnight fasting for eight hours.[1] To learn more about RADICAVA ORS, visit RADICAVA.com/update. In addition, patients and caregivers can click here to register for an **informational webinar** on RADICAVA ORS, hosted by MTPA.

"The availability of RADICAVA ORS is a significant step forward for the ALS community," said Andrea Pauls Backman, CEO, Les Turner ALS Foundation. "The flexibility that RADICAVA ORS offers in treatment administration can help accommodate the unique needs that people living with ALS have throughout their disease journey."

As a part of MTPA's commitment to helping patients with ALS access RADICAVA and RADICAVA ORS, MTPA created the ***JourneyMate Support Program™***, which provides resources to help patients and caregivers on their ALS treatment journey.

The ***JourneyMate Support Program™*** offers educational support and resources for patients who are considering or have already been prescribed an MTPA product. Experienced program

team members are trained to address patient and caregiver educational needs and provide them with personalized answers and resources for living with ALS.

- ALS Resource Specialist: A go-to resource in the ***JourneyMate Support Program™*** for general information about ALS and RADICAVA ORS.
- Insurance & Access Specialist: Once RADICAVA ORS has been prescribed by a doctor and they have submitted a Benefit Investigation and Enrollment Form (BIF), this specialist can help patients and caregivers understand insurance coverage, financial support options, site of care, specialty pharmacy options and the steps to accessing a RADICAVA ORS prescription.
- ALS Clinical Educator: Once RADICAVA ORS is prescribed, an ALS Clinical Educator can provide personalized education to patients and their families about RADICAVA ORS and will also provide resources throughout treatment.

This program is here to supplement the resources that a doctor provides. For more information, call 1-866-684-7737 or visit radicava.com/journeymate.

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.[1]

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, RADICAVA was approved for the treatment of ALS in Japan and South Korea. Marketing authorizations were subsequently granted in Canada (October 2018), Switzerland (January 2019), China (July 2019), Indonesia (July 2020), Thailand (April 2021) and Malaysia (December 2021). To date, in the U.S., RADICAVA has been used to treat over 6,500 patients, with nearly one-million days of therapy, and has been prescribed by more than 1,600 HCPs.[4]

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 JourneyMate Support Program™
The ***JourneyMate Support Program™*** offers educational support and resources for patients who are considering or have already been prescribed an MTPA product. An ALS Clinical Educator is an educational resource for patients who have been prescribed a Mitsubishi Tanabe Pharma America, Inc. (MTPA) product. An ALS Clinical Educator is provided by MTPA and VMS and is not affiliated with or provided by a doctor. An ALS Clinical Educator does not provide medical advice. The program does not provide medical advice and does not take the place of a patient's doctor. All questions about a condition, diagnosis, or treatment should be referred to the patient's doctor. If a patient has a medical emergency, they should call 911. Adverse events or product complaints should be reported by calling 1-888-292-0058.

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 Mitsubishi Chemical Holdings Group (MCHC 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 MCHC 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/.

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[1] RADICAVA and RADICAVA ORS Prescribing Information. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; 2022.
[2] "Amyotrophic Lateral Sclerosis (ALS) Fact Sheet." National Institute of Neurological Disorders and Stroke, National Institutes of Health, June 2013, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet.
[3] 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.
[4] Data on file. Mitsubishi Tanabe Pharma America, Inc.