WHAT IS RADICAVA® (EDARAVONE)?

The only FDA-approved treatment option for ALS to slow the loss of physical function.[1]

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RADICAVA is a U.S. Food and Drug Administration (FDA) approved intravenous infusion treatment option for **amyotrophic lateral sclerosis (ALS)**, a rapidly progressive neurodegenerative disease in which the majority of patients die within two to five years of diagnosis.[1,2,3] Over time, people with ALS lose their ability to perform the basic functions of daily living.[2]

RADICAVA has been demonstrated to **slow the decline in physical function** as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in patients with ALS.[1,4]

Edaravone was discovered and developed by Mitsubishi Tanabe Pharma Corporation and will be commercialized in the U.S. by Mitsubishi Tanabe Pharma America. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. In 2018, edaravone was granted market authorization in Canada.

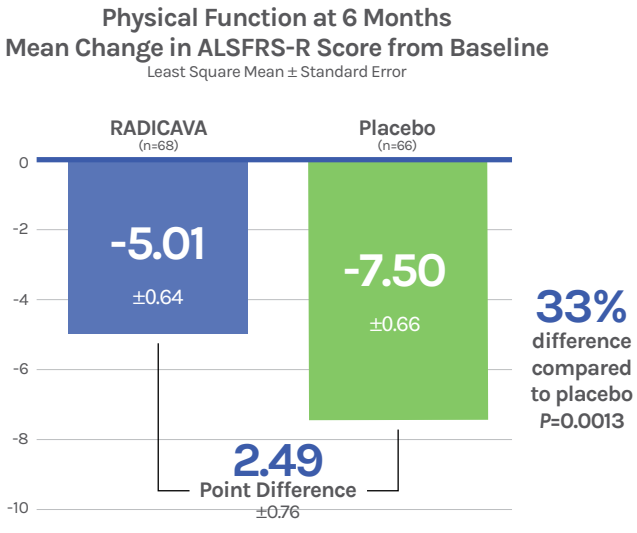
WHAT DO THE DATA SHOW?

The comprehensive clinical development effort for RADICAVA in ALS spanned 13 years and included multiple Phase 3 trials.

PIVOTAL PHASE 3 STUDY OVERVIEW[1]

TRIAL DESIGN: Study MCI186-19 is the Phase 3 study that evaluated the efficacy and safety of RADICAVA in 137 people with ALS, and formed the basis for FDA approval of RADICAVA.

- After a 12-week pre-observation period, eligible patients were randomized 1:1 to receive RADICAVA 60 mg intravenously for 60 minutes or placebo during a six-month double-blind placebo-controlled phase.
- The study was designed to be six months so patients wouldn't receive placebo longer than necessary to effectively evaluate the impact of RADICAVA.
- **Primary endpoint**: Change in ALSFRS-R* score from baseline to six months.



SIX-MONTH STUDY RESULTS: The data demonstrated that patients who received RADICAVA for six months experienced the following, relative to those who received placebo:

- Statistically significant reduction in the rate of decline in physical function by **33 percent or 2.49 ALSFRS-R points** (p=0.0013).

SAFETY RESULTS: The most common adverse reactions that occurred in greater than 10 percent of patients and greater than placebo were bruise (contusion), problems walking (gait disturbance) and headache.[2]

*Although rates of ALS progression can vary significantly, research shows people with ALS lose an average of one point per month on the ALSFRS-R scale.[4,6]

Please see complete Important Safety Information on page 2 and full Prescribing Information at RADICAVA.com.

Mitsubishi Tanabe Pharma America

Radicava® (edaravone) IV infusion 30mg/100mL

For U.S. use only

CP-RC-US-0037 11/18

HOW IS IT USED?[1]

Administered in 28-day cycles by intravenous (IV) infusion. It takes 60 minutes to receive each 60 mg dose (two 30 mg IV bags).

Initial cycle: Daily infusion for 14 consecutive days followed by a two-week drug-free period.

All cycles thereafter: Daily infusion for 10 days within a 14-day period, followed by a two-week drug-free period.

Refer to the full Prescribing Information at RADICAVA.com for additional Dosing and Administration.

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 breastmilk. 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 **fda.gov/medwatch**.

For medical questions, call 888-292-0058 or to find more information, including full Prescribing Information, please visit **RADICAVA.com**.

MEDIA INQUIRIES:
DEBBIE ETCHISON | 908-340-8578 | MEDIA_MTPA@MT-PHARMA-US.COM

ADDITIONAL INFORMATION:
For further information, visit **RADICAVA.com**

1. RADICAVA® U.S. Prescribing Information. May 2017. **2:** 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 April 18, 2017. **3.** 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. **4.** 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. **5.** Rutkove, S. B. (2015). Clinical Measures of Disease Progression in Amyotrophic Lateral Sclerosis. *Neurotherapeutics*, 12(2), 384– 393.

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