

## FREQUENTLY ASKED QUESTIONS ABOUT RADICAVA™ (EDARAVONE)

### What is RADICAVA?

RADICAVA™ (edaravone) is a prescription medicine approved by the U.S. Food and Drug Administration (FDA) to treat people with amyotrophic lateral sclerosis (ALS).<sup>1</sup>

In clinical trials, people given RADICAVA showed significantly less decline in 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 patients with ALS.<sup>1,2</sup>

### What will RADICAVA do for people with ALS? How meaningful of a treatment is it?

Although RADICAVA is not a cure, it may be an important advance in helping people live with the disease. While people with ALS experience varying rates of progression, the loss of physical abilities can be fast and cruel. Slowing the decline of that loss of function in ALS is incredibly important. Depending on people's level of function when they begin treatment, the impact RADICAVA demonstrated in clinical trials could translate into potentially helping people preserve function longer, assisting their ability to get out of bed, feed themselves, or even hug their loved ones.<sup>1</sup>

### What is the recommended dose of RADICAVA?

According to the Prescribing Information, RADICAVA is administered by intravenous infusion. It takes 60 minutes to receive each 60 mg dose.<sup>1</sup>

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.<sup>1</sup>

### What data formed the basis for the FDA approval?

Study MCI186-19 was the pivotal Phase 3 study that evaluated the efficacy and safety of RADICAVA compared with placebo in 137 people with ALS. In the study, 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 primary endpoint for the study was change in the ALSFRS-R score from baseline to six months.<sup>1</sup>

### What were the safety results?

The most common adverse reactions that occurred in greater than 10 percent of patients and greater than placebo were bruising (contusion), problems walking (gait disturbance) and headache.<sup>1</sup>

Hypersensitivity (allergic) reactions<sup>1</sup>



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- Hypersensitivity reactions have happened in people receiving RADICAVA and can happen after your infusion is finished. Tell your healthcare provider right away or go to the emergency room if you have any of the following symptoms: hives, breathing problems, itching, dizziness, wheezing, fainting or swelling of the lips, tongue or face.
- Your healthcare provider will monitor you during treatment to watch for signs and symptoms of all the serious side effects.

## Accessing RADICAVA Treatment

### How do I get RADICAVA?

We anticipate RADICAVA will be available in the U.S. by August 2017; however, there are several steps you can take now to be able to access RADICAVA when it becomes available:

- Like other FDA-approved medications, RADICAVA requires a prescription from your health care professional. Talk to him/her to determine if RADICAVA is right for you. If so, they will provide you a prescription.
- Go to [www.RADICAVA.com](http://www.RADICAVA.com) to provide your email address, which will enable you to receive updates on availability.
- As soon as you receive a prescription, contact Searchlight Support by calling 844-SRCHLGT (844-772-4548). Searchlight Support can assist you with personal case management, reimbursement support, and once you start treatment, 24/7 product support. Some people with ALS who have received prescriptions for RADICAVA may be eligible to receive additional assistance from MTPA.

### Why is RADICAVA not available immediately after FDA approval?

Although MTPA is taking multiple steps to accelerate getting RADICAVA to the U.S., there are certain portions of the complex supply chain that could not be done prior to approval. For example, FDA approval of the manufacturing facility and certain required customs clearances.

We know time is critical for people with ALS. We are working to get the medicine into the U.S. as quickly as possible. In addition to manufacturing hundreds of thousands of IV bags ahead of FDA approval and taking steps to prepare logistics ahead of time, we will be air-shipping RADICAVA to further accelerate supply of the medicine from Japan where it is manufactured to the U.S.

### How does the Searchlight Support program work?

Searchlight Support is a program designed to help people with ALS prescribed RADICAVA access the medicine and to support people once they are taking the medicine. As soon as a patient receives a RADICAVA prescription and then opts in to participate in the program, Searchlight Support will initiate:



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- **Case Manager:** Every person who opts in will have access to a dedicated, personal case manager who will help them investigate and secure coverage through their insurance. The Case Manager will assist the person with ALS through the process.
- **Bridge Program:** We know every day matters for people with ALS. So, we created a program in which eligible patients may receive RADICAVA at no charge from MTPA for up to two months while their insurance is making a coverage determination.
- **Clinical Educator Support:** The challenges of living with ALS or caring for a loved one with the disease are immense. Under Searchlight Support, patients who sign up can ask a clinical educator questions about ALS, RADICAVA, or our support programs. These clinical educators are available to answer product or insurance-related questions day or night.

For more information, call 844-SRCHLGT or 844-772-4548. Patients prescribed RADICAVA should check eligibility requirements for each aspect of our patient assistance program as restrictions apply.

### How much will RADICAVA cost me?

MT Pharma America wants people with ALS who have been prescribed RADICAVA to have affordable access to the medicine. Knowing that people with ALS have more complex needs, we carefully thought through how we can help. Your affordability questions can be answered by contacting a specialist at Searchlight Support, 844-SRCHLGT (844-772-4548). Patients prescribed RADICAVA should check eligibility requirements for each aspect of our patient assistance program as restrictions apply.

### What do I do if I don't have insurance?

MTPA has created a program that provides RADICAVA at no charge if you do not have insurance and meet income and certain other requirements. The program is available to eligible patients without insurance.

### What happens while I'm waiting for Searchlight Support to confirm my insurance?

We have a program in which eligible patients may receive RADICAVA at no charge from MTPA for up to two months while insurance is making a coverage determination.

### Can I get RADICAVA before August?

There is currently no RADICAVA available in the U.S. As soon as it arrives in the U.S. and is delivered to treatment centers and/or health care provider offices, patients will have immediate access. We expect RADICAVA to be available in August.

### Do I need to travel to an ALS Center?



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RADICAVA is given to patients through an IV, and your insurance coverage may determine whether it is administered at an outpatient center, in your home or someplace else. MTPA will ship RADICAVA to ALS Centers, and to specialty pharmacies that can deliver it to patients who will receive treatments in their homes.

### **Can Searchlight Support help with my transportation?**

We understand that traveling can be difficult for people with ALS. When you are first prescribed RADICAVA and opt in to Searchlight Support, your case manager can help you identify transportation options in your area.

### **What if I have clinical questions about RADICAVA?**

The challenges of living with ALS or caring for a loved one with the disease are immense. Under Searchlight Support, patients who sign up can ask a clinical educator questions about ALS, RADICAVA, or our support programs. These clinical educators are available to answer product or insurance-related questions day or night.

### **Consumer Important Safety Information for RADICAVA (edaravone injection)**

#### **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.



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- 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](http://www.fda.gov/medwatch).

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<sup>1</sup> RADICAVA™ U.S. Prescribing Information. May 2017.

<sup>2</sup> 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.



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