MT PHARMA AMERICA, INC. BRINGS FIRST FDA-APPROVED TREATMENT OPTION TO ALS PATIENTS IN MORE THAN 20 YEARS

Company Researchers Applied In-depth Analyses and Perseverance Over a 13-Year Period to Demonstrate Clinical Benefit

We know people with amyotrophic lateral sclerosis (ALS) and their families never give up and neither did we. Our determined researchers went to work on a disease that was not well understood. Each clinical trial became an opportunity to learn more about ALS and how edaravone could benefit patients.

RADICAVA™ (EDARAVONE) ROAD TO FDA APPROVAL

MCI186-12 (PHASE 2): EXPLORING EFFICACY IN ALS (2001-2002)

Initial small study in ALS to determine a potential clinical effect and appropriate dosing for edaravone.

MCI186-16 (PHASE 3): FINDING A PATH IN ALS (2006-2009)

While the trial results numerically favored edaravone over placebo, the differences were not statistically significant. Researchers then analyzed a subset of study patients which set the path for future clinical trials.

MCI186-17 EXTENSION (PHASE 3): UNDERSTANDING THE ESSENCE OF ALS (2006-2009)

This randomized extension added to the important learnings of study MCI186-16. Researchers then conducted post hoc analyses to more precisely define the group of ALS patients in whom edaravone showed an effect. This randomized extension validated the hypothesis of the MCI186-16 study.

MCI186-18 (PHASE 3): EXPLORING ADVANCED DISEASE (2006-2008)

It was an exploratory study in a small group of patients with advanced disease. However the results were inconclusive.

MCI186-19 (PHASE 3): PIVOTAL TRIAL (2011-2014)

Applied critical learnings from the MCI186-16 and MCI186-17 studies, and prospectively demonstrated the safety and efficacy of edaravone in ALS patients.

MCI186-19 (PHASE 3): OPEN-LABEL EXTENSION (2011-2014)

Those who had initially received placebo began treatment with edaravone, and those who had been on edaravone continued for another six months.

FDA GRANTED ORPHAN DRUG DESIGNATION FOR EDARAVONE (MAY 2015)

NEW DRUG APPLICATION SUBMITTED IN U.S. (JUNE 2016)

FDA ACCEPTED NEW DRUG APPLICATION FOR EDARAVONE (AUGUST 2016)

FDA APPROVED RADICAVA MAY 2017

The most common adverse reactions associated with RADICAVA treatment include bruising (contusion), problems walking (gait disturbance), and headache. Please see complete Important Safety Information on page 2 and full Prescribing Information at www.RADICAVA.com.

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 MT Pharma America, Inc. at 1-888-292-0058 or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

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

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

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

MT Pharma America

For U.S. use only.

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

CP-RC-US-0038 05/17