

# MITSUBISHI TANABE PHARMA GROUP COMPANIES CONDUCTED 13 YEARS OF CLINICAL RESEARCH OF EDARAVONE IN ALS

Company Researchers Applied In-depth Analyses and Perseverance 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



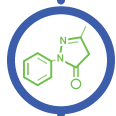
### MCI186-12 (PHASE 2): EXPLORING EFFICACY IN ALS (2001-2002)

Initial small study in ALS to determine a potential clinical effect and appropriate ALS 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 conducted post hoc analyses to define the group of ALS patients in whom edaravone showed an effect.



### MCI186-17 EXTENSION (PHASE 3): SEEKING TO UNDERSTAND MORE ABOUT ALS (2006-2009)

This randomized extension added to the important learnings of study MCI186-16. In this extension study, half of patients who previously received edaravone treatment were randomized to shift to a placebo. In addition, all patients previously on placebo began to receive edaravone treatment.



### 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 study, 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](http://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 Mitsubishi Tanabe 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).

For medical questions, call 888-292-0058 or to find more information, including full Prescribing Information, please visit [www.RADICAVA.com](http://www.RADICAVA.com).

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### MEDIA INQUIRIES:

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### ADDITIONAL INFORMATION:

For further information, visit [www.RADICAVA.com](http://www.RADICAVA.com)



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