

Mitsubishi Tanabe Pharma America Announces Addition of RADICAVA[®] (edaravone) to U.S. Department of Veterans Affairs National Formulary

JERSEY CITY, N.J., November 30, 2017 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) announced today that the U.S. Department of Veterans Affairs (VA) has added RADICAVA[®] (edaravone) to its National Formulary (VANF), with a national prior authorization process in place, making it possible for veterans with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, to access treatment within VA's comprehensive healthcare system.

"The VA's decision to offer broad coverage is a significant step to help veterans living with ALS," said Tom Larson, MTPA Chief Commercial Officer. "Veterans sacrificed for our country through their service, and we are pleased the VA has taken this important step for the ALS community."

The VANF criteria follow the FDA's approved labeling, and all VA requests will be determined at the national level by a single team of experts, enabling consistency across the system. The Criteria for Use of RADICAVA can be found at the VA website here: <https://www.pbm.va.gov/apps/VANationalFormulary/>

The VANF is a list of products (drugs and some supplies) covered under VA's comprehensive medical care program. VANF products must be made available across the VA system. The purpose of the VANF management process is to provide high quality, best value pharmaceutical products while assuring the portability and standardization of the pharmacy benefit to all eligible veterans accepted by the VA for care.¹

The VA was prepared and many of the processes required were already established and ready to roll-out when the VA was able to purchase the drug in August 2017.

"It is a great source of hope to not only see the FDA approve RADICAVA, but to also have the VA rapidly approve it for use in veterans," said Matt Bellina, a retired U.S. Navy Lt. Commander with ALS. "This signals a great effort to uphold the sacred obligation to care for all of us who served."

An estimated 5,000-6,000 Americans are diagnosed each year with ALS.^{2,3,4} The majority of ALS patients die within two to five years of receiving a diagnosis, but progression of the disease can vary significantly.⁵

About RADICAVA[®] (Edaravone)

The U.S. Food and Drug Administration (FDA) approved RADICAVA[®] (edaravone) on May 5, as a new treatment option indicated for patients diagnosed with amyotrophic lateral sclerosis (ALS).⁶ In clinical trials, people given RADICAVA experienced a 33 percent slower rate of decline in the loss of 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 people with ALS.^{6,7,8}

RADICAVA is administered in 28-day cycles by intravenous 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.⁶

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and commercialized in the U.S. by Mitsubishi Tanabe Pharma America. MTPC group companies began researching ALS in 2001 through an iterative clinical platform over a 13-year period. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea.

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 breast milk. 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.

For more information, including full Prescribing Information and Patient Information, please visit www.RADICAVA.com.

About Mitsubishi Tanabe Pharma America, Inc.

Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America (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. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in the U.S. It was established by MTPC to commercialize approved pharmaceutical products in the U.S. with plans to expand its product line through collaborations with partners. For more information, please visit www.mt-pharma-america.com or follow us on Twitter at <https://twitter.com/MTPharmaUS>.

Overview of Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan.⁹ In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 16-20. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. MTPC is the parent company of MTPA and the license holder of RADICAVA. For more information, go to <http://www.mt-pharma.co.jp/>.

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¹ Veterans Affairs. National Formulary Frequently Asked Questions.

<https://www.pbm.va.gov/PBM/nationalformulary/VANationalFormularyFrequentlyAskedQuestions.pdf>. Accessed October 2017.

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- ² ALS Association. Quick Facts about ALS. <http://www.alsa.org/news/media/quick-facts.html>. Accessed October 2017.
- ³ Marin B, Boumediene F, Logroscino G, et al. (2016). Variation in worldwide incidence of amyotrophic lateral sclerosis: a meta-analysis. *Int J Epidemiol*, 00:1-18.
- ⁴ 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 October 2017.
- ⁵ 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
- ⁶ RADICAVA™ U.S. Prescribing Information. May 2017.
- ⁷ 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. <http://dx.doi.org/10.1002/ana.24273>
- ⁸ Abe K, Aoki M, Tsuji S, et al. (2017). Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurology*. 16(7), 505-512. [http://dx.doi.org/10.1016/S1474-4422\(17\)30115-1](http://dx.doi.org/10.1016/S1474-4422(17)30115-1).
- ⁹ Research by TOKYO SHOKO RESEARCH, LTD.