MT Pharma America

MT Pharma America Presents 12-Month RADICAVA™ (Edaravone) and Amyotrophic Lateral Sclerosis Data at the European Network for the Cure of ALS (ENCALS) Annual Meeting

JERSEY CITY, N.J., May 18, 2017– MT Pharma America, Inc. (MTPA) today announced it presented open-label extension data that show patients with amyotrophic lateral sclerosis (ALS) treated with RADICAVA™ (edaravone) for 48 weeks (12 cycles) experienced significantly less decline in physical function, as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), compared with patients given placebo for six months followed by six months of RADICAVA. The findings were featured in an oral presentation at the European Network for the Cure of ALS (ENCALS) annual meeting held May 18 - 20 in Ljubljana, Slovenia.

"The 12-month data presented at ENCALS suggest that early intervention with RADICAVA may lead to a meaningful clinical benefit when promptly initiated in people with ALS, as opposed to being delayed by six months," said Jean Hubble, M.D., Vice President, Medical Affairs, MT Pharma America. "We strongly believe in the potential of RADICAVA to help people with this devastating disease, and are committed to continuing to advance clinical evidence for this treatment option."

RADICAVA was approved by the U.S. Food and Drug Administration on May 5, 2017, as an intravenous infusion treatment for ALS, a rapidly progressive neurodegenerative disease in which the majority of patients die within two to five years of diagnosis.[1,2,3] The approval was based on six-month results from the pivotal Phase 3 MCI186-19 study, which evaluated 137 people with ALS. The primary endpoint for the study was change in ALSFRS-R score – a validated rating instrument for monitoring the progression of disability in patients with ALS – from baseline to 24 weeks, demonstrating a statistically significant reduction in the rate of decline in physical function by 33 percent or 2.49 ALSFRS-R points (p=0.0013).[1,4,5]

In the open-label extension phase of the MCI186-19 study presented at ENCALS, patients received RADICAVA for an additional 24 weeks. Patients who received RADICAVA for the full 48 weeks continued to experience a statistically significant reduction in the rate of decline in physical function, compared to patients given 24 weeks of placebo before switching to 24 weeks of RADICAVA. Additionally, patients initially given RADICAVA had approximately 58 percent relative risk reduction in death or certain disease progression events (e.g., loss of upper limb function) compared to those initially given placebo. There were no notable differences in the incidence of adverse events between groups other than contusion.

An estimated 5,000-6,000 Americans are diagnosed each year with ALS, an incurable disease that affects the nerve cells in the brain and spinal cord.[2,6,7] Over time, people with ALS lose their ability to perform basic functions of daily living.[2]

About the MCI186-19 Study

Study MCI186-19 was a 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 ALS Functional Rating Scale-Revised (ALSFRS-R) score from baseline to six months.[1]

The initial six-month study period was followed by a six-month open-label extension phase in which patients who were previously on placebo began active treatment with RADICAVA, and those who had been on RADICAVA continued for another six months.

About RADICAVA™ (edaravone)

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.[1]

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and will be commercialized in the U.S. by MT Pharma America. MTPC group companies began researching ALS in 2001 through a comprehensive 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 MT 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 MT Pharma America
Based in Jersey City, N.J., MT Pharma America 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.[8] 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] 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 17, 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] 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*. DOI: http://dx.doi.org/10.1016/S1474-4422(17)30115-1.

[6] 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.

[7] ALS Association. Quick Facts about ALS. http://www.alsa.org/news/media/quick-facts.html. Accessed April 17, 2017.

[8] Research by TOKYO SHOKO RESEARCH, LTD.