MT Pharma America

Press Release

MT Pharma America Begins Patient Insurance Benefits Investigation Process in Advance of Availability of RADICAVA™ (Edaravone)

JERSEY CITY, N.J., July 25, 2017 – MT Pharma America, Inc. today announced that healthcare providers (HCPs) now can begin the insurance benefits investigation process for their patients in preparation for availability of RADICAVA™ (edaravone), an intravenous infusion treatment approved in May by the U.S. Food and Drug Administration (FDA). RADICAVA is indicated for all adult patients diagnosed with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, and is on schedule to be available to patients in the U.S. in mid-August 2017.

"We have initiated the benefits investigation process now to allow people diagnosed with ALS access to RADICAVA as soon as it becomes available," said Atsushi Fujimoto, President, MT Pharma America. "We are committed to making the process of accessing RADICAVA as seamless as possible and encourage healthcare providers to begin the process now for their patients."

The benefits investigation and product access process is initiated by the HCP and facilitated through the Searchlight Support™ hub, which provides assistance for people who are prescribed RADICAVA. Key steps in the process include:

1) **TREATMENT DECISION:** Patient visits HCP, who determines whether RADICAVA is an appropriate treatment for him/her.

2) **BENEFITS VERIFICATION:** Before beginning treatment the patient's insurance coverage must be confirmed:
   a. HCP submits Benefits Investigation and Enrollment Form to connect patient to Searchlight Support. Forms (available at www.RADICAVA.com/HCP) can be submitted by the HCP online through a secure HCP portal, faxed or mailed.
   b. Searchlight Support conducts rapid benefits investigation to confirm patient insurance coverage and assigns a patient ID.
   c. A Care Coordinator from Searchlight Support can help the HCP's office identify a location for infusion service based on individual patient's insurance benefits and geographical proximity (ALS center, home infusion, physician's office, free-standing infusion center or hospital outpatient department).
   d. Case manager contacts patient to explain benefits and discuss co-pay support options.

3) **SCHEDULING INFUSIONS:** Patient or HCP office contacts infusion site or home infusion provider to schedule the first cycle of treatment.

4) **RADICAVA ORDERED:** Site of care submits order form with patient ID to Searchlight Support to obtain RADICAVA for scheduled treatment. Searchlight Support facilitates RADICAVA shipment from distributor to infusion site once available in mid-August.

For more information on the benefits investigation process call 1-844-SRCHLGT (1-844-772-4548).

About RADICAVA™ (Edaravone)

The U.S. Food and Drug Administration (FDA) approved RADICAVA™ (edaravone) on May 5, 2017 as a new treatment option indicated for all adult patients diagnosed with amyotrophic lateral sclerosis (ALS).[1] In clinical trials, people given RADICAVA experienced a 33 percent lower rate of decline in 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.[1,2,3]

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 (e.g., Monday through Friday and the following Monday through Friday) 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 all patients diagnosed with 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, click here **www.RADICAVA.com**.

About MT Pharma America, Inc.
Based in Jersey City, N.J., MT 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.[4] 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] 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.

[3] 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.

[4] Research by TOKYO SHOKO RESEARCH, LTD.