May 8, 2017

New Japan-originated ALS treatment option available to patients in the U.S.

U.S. FDA approves RADICAVA™ (edaravone) for the treatment of ALS

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director: Masayuki Mitsuka) announced today that RADICAVA™ (generic name: edaravone; Japan names: RADICUT® BAG for I.V. Infusion 30mg) was approved by the U.S. Food and Drug Administration (FDA) for an indication of amyotrophic lateral sclerosis (ALS). Promoting RADICAVA™ in the United States will be handled by MT Pharma America (MTPA), a sales subsidiary of Mitsubishi Tanabe Pharma.

ALS is an idiopathic neurodegenerative disease in which motor neurons selectively degenerate and vanish. Muscle strength declines throughout the entire body, including the extremity, facial, and respiratory muscles, and muscular atrophy progresses. In the U.S., 5,000 to 6,000 people are diagnosed with ALS each year. Initial symptoms can be subtle, and accordingly it can take 12 to 14 months to be accurately diagnosed.

The FDA approval of this drug was based on the evaluation of the results of the clinical trials that led to the approval of an additional indication in Japan for ALS (June 2015). The data from one Phase 3 study demonstrated that, in comparison with placebo, the administration of RADICUT® over six months for patients with comparatively moderate ALS slowed the decline of physical function by approximately 33% based on the ALS Functional Rating Scale-Revised (ALSFRS-R)*.

* Refer to the package insert (clinical trial results) for RADICUT® inj. 30mg ampule and RADICUT® BAG for I.V. Infusion 30mg

The approval of RADICAVA™ by the FDA represents another step forward in accelerating U.S. Business Development, which is one of the strategic issues in Mitsubishi Tanabe Pharma's Medium-Term Management Plan 16-20: Open Up the Future.

Mitsubishi Tanabe Pharma will strive to deliver RADICAVA™ to all U.S. patients that need it and will also continue working to contribute to patients health by discovering innovative drugs that address unmet medical needs.

⟨⟨For Details, Contact the Following Section⟩⟩
Corporate Communications Department
Tel +81-6-6205-5211

<Reference Materials>

■ **MTPA press release (English)**
https://www.mt-pharma-america.com/wp-content/uploads/2017/05/MTPA-Edaravone-FDA-Decision-Press-Release_50517-FINAL-Updated.pdf

■ **About RADICAVA™ (edaravone)**
Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Ministry of Health, Labor and Welfare in April 2001 as a treatment agent for the acute stage of cerebral infarction. In Japan, it is being marketed under the product name RADICUT®. Edaravone has the effect of scavenging free radicals that arise accompanying cerebral ischemia, controlling the lipid peroxidation reaction, and protecting neurons in the region of the ischemia and the surrounding region. Accordingly, it is thought that edaravone has the effect of scavenging free radicals, which increase in ALS, protecting motor neurons from oxidative stress, and delaying the decline in muscle strength and the progress of muscular atrophy.

One cycle of administration of RADICAVA™ is a total of 28 days, including both the dosing period and the drug-free period, and that cycle is repeated. Adults receive 60 mg of RADICAVA™ intravenously for 60 minutes once per day. The first cycle has a dosing period of 14 consecutive days of administration followed by a drug-free period of 14 days. In subsequent cycles, patients receive daily infusions for 10 days within a 14-day dosing period, followed by a 14-day drug-free period.

RADICAVA™ will be marketed in the U.S. by MTPA, a sales subsidiary of Mitsubishi Tanabe Pharma. In addition to the U.S., approvals for an indication of ALS have been received in Japan in June 2015 and in South Korea in December 2015.

Further information about RADICAVA™ is available at the following site: www.RADICAVA.com (English-language website provided by MTPA)

■ **About MT Pharma America (MTPA)**
MTPA is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation's 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MTPA was established by Mitsubishi Tanabe Pharma to commercialize approved pharmaceutical products in the U.S. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in the U.S.

With the approval of RADICAVA™ in the U.S., MTPA will establish Searchlight Support to provide support for patients who are prescribed RADICAVA™. In line with the needs of each patient who has been prescribed RADICAVA™, programs provided through Searchlight Support will include personal case management, insurance reimbursement support, and 24/7 clinical nursing hotline support.

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