May 16, 2017

Mitsubishi Tanabe Pharma announces The Lancet Neurology publication of the positive clinical results of Edaravone for ALS

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director: Masayuki Mitsuka) announced today that the positive clinical results of RADICAVA™ (generic name: edaravone; Japan names: RADICUT® BAG for I.V. Infusion. 30mg, US name: RADICAVA) for an amyotrophic Lateral sclerosis (ALS) was published in The Lancet Neurology on May 15, 2017 (BST).

Title: Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial
DOI: http://dx.doi.org/10.1016/S1474-4422(17)30115-1

After Edaravone has been marketed for a treatment of acute ischemic stroke in Japan since April 2001, was approved for an additional indication of amyotrophic lateral sclerosis (ALS). As consequence from ALS approval in Japan at June, 2015, eradavone was approved in U.S. at May, 2017 following approval in Korea at December, 2015 based on our evaluation of the results of clinical trials in Japan.

The positive clinical results of Edaravone published by The Lancet Neurology showed the data that, in comparison with placebo, the administration of edaravone over six months for well defined patients with ALS slowed the decline of physical function by approximately 33% based on the ALS Functional Rating Scale-Revised (ALSFRS-R).

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. The number of patients are said to be 10,000 in japan and 20,000 in U.S. approximately.

Mitsubishi Tanabe Pharma will strive to deliver edaravone (RADICUT®, RADICAVA™) to all 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》
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<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. 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.

■ **About The Lancet Neurology**

The Lancet Neurology was launched in May, 2002, and is lively monthly journal of original research, review, opinion, and news covering international issues relevant to neurologists worldwide.

The Lancet Neurology's Impact Factor is 23.468 and ranks first among 193 journals in the clinical neurology category (2013 Journal Citation Reports[®], Thomson Reuters 2014). The journal provides an authoritative and independent forum for the highest quality clinical neurology research, reviews, and news in all areas of global clinical neurology with a particular focus in the research and treatment of stroke, MS, movement disorders, epilepsy, headache, and dementia.

-Quotated from web site

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