May 30, 2019

Withdrawal of Marketing Authorization Application of edaravone for ALS in the European Union

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka, Japan; President & Representative Director, CEO: Masayuki Mitsuka), announced today the withdrawal of the Marketing Authorization Application (MAA) of edaravone for the treatment of amyotrophic lateral sclerosis (ALS) in the European Union (EU). The MAA of edaravone was submitted on 30 Apr 2018 by Mitsubishi Tanabe Pharma Europe Ltd. who are the MTPC R&D subsidiary in the EU. Edaravone (Japan name: RADICUT® BAG for I.V. Infusion 30mg.) is an intravenous treatment for ALS, a rapidly progressive neurological disease.

Edaravone has been approved for treatment of ALS in Japan, South Korea, United States, Canada and Switzerland, based on the results from a six-month placebo-controlled study in Japanese ALS patients, in which the primary endpoint was the ALS functional rating scale (ALSFRS-R), a measurement of functional loss in daily living activities in ALS patients. The study demonstrated that edaravone significantly slowed functional loss compared to placebo with 2.49 points difference in ALSFRS-R total score (equivalent to 33% difference) after six months treatment*.

*Reference: Package Inserts of RADICUT®

However, in accord with the European Medicine Agency's (EMA) development guideline for ALS, the EMA's Committee for Medicinal Products for Human Use (CHMP) maintains the position that an additional, long-term, placebo-controlled study of survival (time to death or permanent ventilation support/tracheostomy) of at least 12 months duration would be required to obtain the data necessary for regulatory approval in the EU. MTPC believes that the efficacy and safety of edaravone has been demonstrated and an additional long-term placebo-controlled study is unwarranted. Therefore, MTPC has made the difficult decision to withdraw the MAA for edaravone. MTPC will now carefully consider the future options for edaravone in the EU.

Mitsubishi Tanabe Pharma Group will continue to make every effort to deliver edaravone to patients suffering from ALS worldwide by increasing, as far as possible, the number of countries with regulatory approvals based on the current data. MTPC

is fully committed to providing treatment for ALS patients, including the rapid development of an oral formulation of edaravone as an option to supplement the existing IV formulation.

Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department
Media contacts: TEL:+81 6 6205 5119
Investor contacts: TEL:+81 6 6205 5110

<Reference>

■ About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Japanese 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.

■ About Mitsubishi Tanabe Pharma Europe Ltd.(MTPE)

Based in London, UK, Mitsubishi Tanabe Pharma Europe Ltd. is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). Mitsubishi Tanabe Pharma Europe Ltd. is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs of patients in EU.
http://www.mt-pharma-eu.com/