January 13, 2022

FDA Acceptance of New Drug Application for Oral Edaravone Formulation for the Treatment of ALS

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) announced the U.S. Food and Drug Administration (FDA) has accepted the new drug application (NDA) for an investigational oral formulation of edaravone (MT-1186) for the treatment of amyotrophic lateral sclerosis (ALS) by Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) which is MTPC's research and development subsidiary in the US on January 11th.

The FDA has accepted the application for priority review with a Prescription Drug User Fee Act (PDUFA) action date of May 12, 2022.

MT-1186 is an oral suspension formulation that contains the same active ingredient as edaravone for intravenous infusion (US product name: Radicava®, Japanese product name: Radicut® Injection 30 mg and Radicut® Bag for I.V. Infusion 30 mg) for ALS treatment.

This NDA was submitted based on both the 24-week results from the global Phase 3 study evaluating the safety and tolerability of investigational MT-1186 in the ALS (MT-1186 A01) and the clinical pharmacology study comparing the pharmacokinetics of MT-1186 and the injectable formulation (MT-1186 J03).

At this time, the route of administration of edaravone is limited to intravenous infusion. MTPC Group will continue working tirelessly to develop the oral suspension formulation as a new treatment option for ALS patients in order to reduce the burden on ALS patients such as injection pain and outpatient visits.
MTPC Group aims to obtain approval of MT-1186 not only in the U.S. but also in other countries with earliest timing and will continue to approach promptly for regulatory authorities in each country.

Mitsubishi Tanabe Pharma Corporation
Communication Crossroads Department
Media contacts: TEL: +81 6 6205 5119

<Reference>

About Oral Edaravone (MT-1186)

MT-1186 is an investigational oral suspension of edaravone being studied in patients with amyotrophic lateral sclerosis (ALS) by Mitsubishi Tanabe Pharma Development America, Inc., a subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). MT-1186 received Fast Track designation from the FDA in October 2019. The ongoing MT-1186 A03 study is an extension study of up to 96 weeks of treatment in patients who have completed MT-1186 A01. MT-1186-A01 and MT-1186 A03 studies provide data for up to 144 weeks.

About Edaravone

Edaravone is a free radical scavenger discovered by MTPC. It was approved by the Ministry of Health, Labour and Welfare in April 2001 for the treatment of patients with acute cerebral infarction and is marketed in Japan under the product name of Radicut®. The indication of ALS has been approved in 9 countries including Japan in June, South Korea in December 2015, the United States in May 2017, Canada in October 2018, and Switzerland in January 2019.

About Mitsubishi Tanabe Pharma Development America, Inc.

The headquarter of Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) is located in Jersey City, New Jersey. MTDA is a wholly-owned subsidiary of MTPC's 100 percent-owned US holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MTDA achieved the approval of Radicava for the first time in more than 20 years in the U.S in the ALS treatment.

MTDA is dedicated to researching and developing innovative pharmaceutical products that address the unmet medical needs of patients.

For more information, go to https://mt-pharma-development-america.com/