

# News Release

March 14, 2022

## **Submission of Oral Edaravone Formulation, MT-1186 New Drug Application in Japan for the Treatment of ALS**

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) announced that MTPC has submitted to the Ministry of Health, Labour and Welfare in Japan an application for the manufacturing and marketing approval of an investigational oral formulation of edaravone (MT-1186) for the treatment of amyotrophic lateral sclerosis (ALS) on March 14<sup>th</sup>, 2022.

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

At this time, the route of administration of edaravone is limited to intravenous infusion. To reduce the burden on ALS patients, including injection pain and outpatient visits, MTPC Group has developed an oral suspension formulation that can be offered as a new treatment option for ALS.

ALS is an idiopathic neurodegenerative disease in which motor neurons selectively degenerate and vanish. Muscle strength declines throughout the entire body, including the limb, facial, and respiratory muscles, and muscular atrophy progress. While the cause for the majority of cases is not well understood but may involve genetic and environmental factors. It is one of the most well-known neuromuscular diseases and incidence is approximately two in 100,000 people per year worldwide. Edaravone was approved in Japan in June 2015 for the indication of progress delay of functional disorder in patients with ALS and has been provided to ALS patients since that time.

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.

MTPC Group will continue to work tirelessly to bring prompt access to new treatment options that reduce the burden of ALS patients.

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**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.