



March 13, 2025

Mitsubishi Tanabe Pharma Corporation

Filling for a Oral Edaravone Formulation for the treatment of ALS in Korea

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura, “MTPC”), a member of the Mitsubishi Chemical Group, announced that Mitsubishi Tanabe Pharma Korea Co., Ltd., which is a consolidated subsidiary of MTPC, has submitted to the ministry of Food and Drug Safety in Korea 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 February 28, 2025 .

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.

MT-1186 is an oral suspension formulation that contains the same active ingredient as edaravone for intravenous infusion. At this time, in Korea, 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.

We have already obtained approval for MT-1186 in the United States, Canada, Japan and Switzerland, and are bringing the product to patients.

MTPC Group is working to provide patients with new drugs that address unmet medical needs, including rare diseases, through our own development and through partnerships with other companies.

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■ 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 America, Inc., a subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). In April 2024, MT-1186 received orphan-drug exclusive approval from the U.S. Food and Drug Administration as a product with major contribution to patient care for people living with ALS.

- 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®. This product obtained approval for an additional indication of ALS in Japan in 2015 and has since been launched in 9 countries (South Korea, the U.S., Canada, Switzerland, Indonesia, Thailand, Malaysia and Brazil).