

April 25, 2022

**Swissmedic has accepted the filling for
a New Oral Edaravone Formulation for the treatment of ALS**

Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Holdings Group, announced that the Swissmedic has accepted the filling for an investigational oral suspension formulation of edaravone (MT-1186) for the treatment of amyotrophic lateral sclerosis (ALS) by Mitsubishi Tanabe Pharma GmbH which is MTPC's consolidated subsidiary on April 19, 2022.

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

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. As many as 500 people are estimated to be affected by ALS in Switzerland.

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 Switzerland but also in other countries with earliest timing and will continue to approach promptly for regulatory authorities in each country.

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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 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.

■ **Mitsubishi Tanabe Pharma GmbH (MTPD)**

Headquartered in Dusseldorf, Germany, Mitsubishi Tanabe Pharma GmbH has been founded in 2003 as a subsidiary of Mitsubishi Pharma Europe Ltd. (London/UK). The company in Switzerland, based in Zurich, focuses not only on Radicava®, but also on marketing the direct thrombin inhibitor, Argatra® (argatroban monohydrate).