May 11, 2023

RADICAVA® Oral Suspension Approved in Switzerland for the Treatment of ALS

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, “MTPC”), a member of the Mitsubishi Chemical Group, announced today that its wholly owned subsidiary, Mitsubishi Tanabe Pharma GmbH (hereinafter, “MTPD”) obtained the approval from Authority of Switzerland (Swissmedic) to RADICAVA® Oral Suspension (generic name: edaravone) for the indication of amyotrophic lateral sclerosis (hereinafter, "ALS") on May 1, 2023, local time. RADICAVA® Oral Suspension will be commercialized by MTPD in Switzerland.

RADICAVA® Oral Suspension is an oral suspension formulation that contains the same active ingredient as edaravone for intravenous infusion (Japanese product name: RADICUT® Injection 30mg and RADICUT® Bag for I.V. Infusion 30mg). RADICAVA® Oral Suspension offers the same efficacy as edaravone for intravenous infusion, a treatment shown in a pivotal trial to help slow the loss of physical function in ALS. MTPC Group has been developing RADICAVA® Oral Suspension formulation as a new treatment option for ALS patients in order to address unmet needs of people living with ALS.

Since 2019, only intravenous infusion of edaravone (RADICAVA®) has been approved and available in Switzerland. The approval of the oral suspension formulation offers an important new oral treatment option for people living with ALS in Switzerland.

MTPC group will continue working to contribute to people living with ALS worldwide as a leading company in the treatment of ALS by delivering RADICAVA® Oral Suspension in Switzerland, in addition to the U.S., Canada, and Japan where edaravone oral suspension has been approved and launched.

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■About amyotrophic lateral sclerosis: ALS

ALS is an idiopathic neurodegenerative disease in which motor neurons selectively degenerate and vanish. Muscle strength declines throughout the entire body, including the extremity, facial, and respiratory muscles, and muscular atrophy progresses. 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. Around 500 to 600 people are estimated to be affected by ALS in Switzerland*.
*https://www.als-schweiz.ch/krankheitsbild/

■About RADICAVA® Oral Suspension

RADICAVA® Oral Suspension is specifically formulated for patients with ALS and provides a flexible administration option with a 5ml dose taken orally or via feeding tube. One cycle of administration of RADICAVA® Oral Suspension is a total of 28 days, including both the dosing period and the drug-free period, and that cycle is repeated. The first cycle has a dosing period of 14 consecutive days of administration followed by a drug-free period of 14 days. In subsequent cycles, patients receive daily dosing for 10 days within a 14-day dosing period, followed by a 14-day drug-free period. RADICAVA® Oral Suspension are available in bottles and do not require water or solution to administer. RADICAVA® Oral Suspension needs to be refrigerated during the distribution process and in pharmacies, but patients can keep it at room temperature.

■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 11 countries including Japan in June 2015, South Korea in December 2015, the U.S. in May 2017, Canada in October 2018, and Switzerland in January 2019.
Edaravone oral suspension for the indication of ALS was approved in the U.S. in May 2022 (RADICAVA ORS®), in Canada in November 2022 (RADICAVA® Oral Suspension), and in Japan in December 2022 (RADICUT® Oral Suspension 2.1%).

■About Mitsubishi Tanabe Pharma GmbH

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