April 9th, 2024

RADICAVA ORS® as Orphan drug designation and approval in US

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Holdings Group, announced that on March 28, 2024, the United States Food and Drug Administration (FDA) has recognized seven years of orphan-drug exclusive approval for RADICAVA ORS® (edaravone) for treatment of amyotrophic lateral sclerosis (ALS). The period of exclusive approval is seven years from May 12, 2022, the date of approval of New Drug Application (NDA).

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, affecting approximately two in 100,000 people worldwide.

RADICAVA ORS® is an oral suspension formulation that contains the same active ingredient as RADICAVA® for intravenous infusion. MTPC Group has been developing RADICAVA ORS® as a new treatment option for ALS patients in order to address unmet needs of people living with ALS. Promoting RADICAVA ORS® in the U.S. is handled by Mitsubishi Tanabe Pharma America, Inc.

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 ORS® and RADICAVA®.

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■About amyotrophic lateral sclerosis: ALS

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■About RADICAVA ORS®

RADICAVA ORS® 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 ORS® 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 ORS® are available in bottles and do not require water or solution to administer. RADICAVA ORS® 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 ischemic stroke and is marketed in Japan under the product name of Radicut®. Edaravone has the effect of scavenging free radicals that arise accompanying cerebral ischemia, controlling the lipid peroxidation reaction, and protecting neurons in the region of the ischemia and the surrounding region. Accordingly, it is thought that edaravone has the effect of scavenging free radicals, which increase in ALS, protecting motor neurons from oxidative stress, and delaying the decline in muscle strength and the progress of muscular atrophy.

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).

■About Mitsubishi Tanabe Pharma America, Inc.

Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America, Inc. (MTPA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). It was established by MTPC in 2015 to develop and advance our pipeline as well as commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com