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New Japan-originated ALS treatment option available to patients in the U.S.

FDA approval of RADICAVA ORS® 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 U.S. Food and Drug Administration (FDA) has approved RADICAVA ORS® (edaravone) for the treatment of amyotrophic lateral sclerosis (ALS) on May 12, 2022.

RADICAVA ORS® is an oral suspension formulation that contains the same active ingredient as edaravone for intravenous infusion (Japanese product name: Radicut® Injection 30 mg and Radicut® Bag for I.V. Infusion 30 mg) for ALS treatment and being developed globally, primarily by Mitsubishi Tanabe Pharma Development America, Inc.
The route of administration of edaravone is limited to intravenous infusion so far. With the approval of RADICAVA ORS®, ALS patients have flexibility in how they take their medicine.

RADICAVA ORS® is specifically formulated for patients with ALS and provides a flexible administration option with a small, 5 mL dose (taken orally or via feeding tube), a portable bottle, an oral dosing syringe and no need for refrigeration or reconstitution.

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 has already filed this drug in Japan and Switzerland.

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■ About RADICAVA ORS® (edaravone)

RADICAVA ORS® is an investigational oral suspension of edaravone being studied in patients with amyotrophic lateral sclerosis (ALS) by Mitsubishi Tanabe Pharma Corporation (MTPC). RADICAVA ORS® received Fast Track designation from the FDA in October 2019. 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® 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®. One cycle of administration of RADICAVA® is a total of 28 days, including both the dosing period and the drug-free period, and that cycle is repeated. Adults receive 60 mg of RADICAVA® intravenously for 60 minutes once per day. 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 infusions for 10 days within a 14-day dosing period, followed by a 14-day drug-free period. 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.

■ About Mitsubishi Tanabe Pharma Development America, Inc.

The headquarter of Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) is located in Jersey City, New Jersey. MTDA is a wholly-owned subsidiary of MTPC's 100 percent-owned US holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MTDA achieved the approval of Radicava for the first time in more than 20 years in the U.S in the ALS treatment.

MTDA is dedicated to researching and developing innovative pharmaceutical products that address the unmet medical needs of patients.

For more information, go to https://mt-pharma-development-america.com/