December 23, 2022

For Treatment of ALS, Edaravone RADICUT® Oral Suspension 2.1% Approved in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Group, announced today, that MTPC obtained the regulatory approval of RADICUT® Oral Suspension 2.1% (generic name: edaravone) for the treatment of patients with amyotrophic lateral sclerosis (ALS) from the Ministry of Health, Labour and Welfare on December 23, 2022.

RADICUT® Oral Suspension 2.1% 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 the treatment of ALS.
RADICUT® Oral Suspension 2.1% is specifically formulated for patients with ALS and provides 5 mL dose, an oral dosing syringe once a day*.

Prior to this approval, edaravone is solely administered via intravenous infusion in Japan. MTPC Group continues 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.
In the U.S., where the same oral suspension formulation of edaravone (U.S. product name: RADICAVA ORS®) was approved on May 12, 2022, RADICAVA ORS® has been highly evaluated for its benefits of reducing burdens associated with conventional injections and enabling oral and tube administration.

MTPC Group is providing edaravone oral suspension as a new treatment option that has reduced the burden on ALS patients.

*RADICUT® Oral Suspension 2.1% is taken daily for 14 consecutive days followed by a 14-day drug-free period for the initial treatment cycle. For subsequent treatment cycles, RADICUT® Oral Suspension 2.1% is taken for 10 days within a 14-day period followed by a 14-day drug-free period.

Mitsubishi Chemical Group
Corporate Communications Division
Osaka Corporate Communications Department
Media contacts: [+81] (0)6-6205-5119

■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.

■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 8 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 treatment of ALS was approved in the U.S. in May 2022 and in Canada in November 2022.