April 17, 2023

For the Treatment of ALS, Edaravone RADICUT® Oral Suspension 2.1% Now Available in Japan

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 MTPC has launched RADICUT® Oral Suspension 2.1% (generic name: edaravone, RADICUT Oral Suspension) for the treatment of patients with amyotrophic lateral sclerosis (ALS) in Japan, following the NHI price listing on March 15,2023.

RADICUT Oral Suspension 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 is formulated for patients with ALS, and a dosage is 5mL, which is administered once a day using an oral dosing syringe.

Formerly, edaravone could only be administered via intravenous infusion in Japan. MTPC Group has developed the oral suspension formulation as a new treatment option for ALS patients to reduce burdens on people living with ALS 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 the burdens related to injections and enabling administration via a feeding tube*.

MTPC Group is pleased to provide RADICUT Oral Suspension as a new treatment option that has reduced the burdens on ALS patients in Japan.

*https://www.mt-pharma.co.jp/news/2023/info230317.html

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Product Summary

Product Name: RADICUT® Oral Suspension 2.1%

Nonproprietary Name: edaravone

Indications: Inhibition on progression of functional disorders in amyotrophic lateral sclerosis (ALS)

Dosage and Administration:

The usual adult dosage is 5 mL (105 mg of edaravone), which is administered orally once a day in the fasted state.

Usually, the duration of administration and cessation of this drug are combined in 1 cycle of treatment for 28 days and the cycle should be re-peated. This drug is consecutively administered for 14 days in the duration of administration followed by cessation for 14 days in the 1st cycle, and from the 2nd cycle, this drug is administered for 10 of 14 days in the duration of administration followed by cessation for 14 days.

Package: bottle: 35mL (orange), 50mL (green)

Drug price: 35mL 96,316.50 yen
50mL 137,595.00 yen

Date of regulatory approval: December 23, 2022

Date of NHI price listing: March 15, 2023

Date of launch: April 17,2023

Manufacturer and distributor: Mitsubishi Tanabe Pharma Corporation

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

■RADICUT® Oral Suspension 2.1%

The two major clinical studies conducted to obtain the approval of RADICUT Oral Suspension 2.1% as follows:

MT-1186-J03

A Phase 1 study, comparing pharmacokinetics of edaravone oral suspension 2.1% and edaravone injection in healthy adult subjects

Hidetoshi Shimizu, Yukiko Nishimura, Youichi Shiide, et al.
Bioequivalence Study of Oral Suspension and Intravenous Formulation of Edaravone in Healthy Adult Subjects
Clinical Pharmacology in Drug Development 2021;10(10):1188-1197

MT-1186-A01

A Phase 3 study, multicenter, open-label, safety study of oral edaravone administered over 48 weeks in subjects with ALS.

Angela Genge, Gary L. Pattee, Gen Sobue, et al.
Oral edaravone demonstrated a favorable safety profile in patients with amyotrophic lateral sclerosis after 48 weeks of treatment
Muscle & Nerve.2023;67:124-129