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Strengthen the Lineup of ALS Treatments in the U.S.
EXSERVAN™ (RILUZOLE) IS NOW AVAILABLE IN THE U.S. FOR THE TREATMENT OF ALS

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Hiroaki Ueno), announced today that Mitsubishi Tanabe Pharma America, Inc. (MTPA) (Head Office: NJ, U.S.; President: Atsushi Fujimoto) launched EXSERVAN™ (riluzole), an oral film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS) in the U.S.

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.
EXSERVAN™, which quickly dissolves on top of the tongue, was developed to meet the needs of people with ALS, including those who have difficulty swallowing some medications and is taken twice a day.

The U.S. Food and Drug Administration (FDA) approved EXSERVAN™ in November 2019 for the treatment of ALS.

Following RADICAVA® (edaravone) for the treatment of ALS, MTPC are currently conducting global development of MT-1186 (oral suspension formulation of Radicava).
In addition to EXSERVAN™ lineup, MTPC group aims to contribute to the treatment of ALS disease while increasing treatment options for as many patients as possible around the world who are fighting ALS.

Press release from Mitsubishi Tanabe Pharma America, Inc.
Mitsubishi Tanabe Pharma America announces EXSERVAN™ (RILUZOLE) is now available in the U.S. for the Treatment of ALS

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<Reference>

■ About Exservan™ (riluzole oral film)


<how to take Exservan /image>

Exservan, an oral film formulation of riluzole, was developed by Aquestive using its PharmFilm® innovative drug delivery technology. The oral film is placed on the patient's tongue and quickly dissolves without the need for liquids or food. RILUTEK® (riluzole) tablets were the reference product during the oral film development. Oral film riluzole was approved by the U.S. Food and Drug Administration (FDA) in November 2019.

■ About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Japanese Ministry of Health, Labour and Welfare in April 2001 as a treatment agent for the acute stage of cerebral infarction. In Japan, it is being marketed under the product name 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.

For use as a treatment for ALS, edaravone was approved in Japan in June 2015, South Korea in December 2015, US in May 2017, Canada in October 2018, Switzerland in January 2019, China in July 2019 and Indonesia in July 2020.

MTPC are conducting a global Phase 3 clinical trial of MT-1186 (A01), an oral suspension formulation of edaravone. MTPC received the Fast Track designation* regarding MT-1186 in October 2019.

■ 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's (MTPC) 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. It was established by MTPC to commercialize approved pharmaceutical products in North America.