

## News Release

May 28th, 2018

# For the ALS patients in the world, we hope to deliver Japan-originated ALS treatment EMA accepts our filing for Edaravone to treat ALS

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that the European Medicines Agency (EMA) has accepted MTPC's filing through Mitsubishi Tanabe Pharma Europe Ltd. that is MTPC's R&D subsidiary in EU for edaravone (Japan name: RADICUT® BAG for I.V. Infusion 30mg. US name: RADICAVA®) an intravenous treatment for amyotrophic lateral sclerosis (ALS), a rapidly progressive neurological disease on May 24th.

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. As many as 29,000 people are estimated to be affected by ALS in EU.

Edaravone is a free-radical scavenger that was discovered by MTPC. 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.

MTPC accomplished the clinical research program in patients diagnosed with ALS in Japan. Edaravone was approved for use as a treatment for ALS in Japan, June 2015, South Korea, December 2015 and the U.S., May 2017.

MTPC will strive to deliver edaravone to patients fighting against ALS all over the world.

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#### <Reference>

#### About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Japanese Ministry of Health, Labor 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.

#### ■ About Mitsubishi Tanabe Pharma Europe Ltd.

Based in London, UK, Mitsubishi Tanabe Pharma Europe Ltd. is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). Mitsubishi Tanabe Pharma Europe Ltd. is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs of patients in EU.

http://www.mt-pharma-eu.com/