



November 15th, 2018

**Mitsubishi Tanabe Pharma to present New data on  
Investigational Oral Suspension of Edaravone for ALS  
at 29<sup>th</sup> International Symposium on ALS/MND**

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that MTPC will present pharmacokinetic (PK) data on an investigational oral suspension formulation of edaravone for the treatment of ALS at the 29<sup>th</sup> International Symposium on ALS/MND being held December 7-9 in Glasgow, Scotland.

Edaravone (US name: RADICAVA<sup>®</sup>; Japan names: RADICUT<sup>®</sup> Injection 30mg and RADICUT<sup>®</sup> BAG for I.V. Infusion 30mg) was approved for an indication of amyotrophic lateral sclerosis (ALS) on June 2015, in Japan. Afterwards it was approved in Korea, US and Canada. It has been commercialized in the US by Mitsubishi Tanabe Pharma America, Inc. (MTPA), MTPC's US sales subsidiary since August 2017.

Now the intravenous (IV) formulation of edaravone is a treatment option, therefore MTPC focused on the development of the oral formulation which a burden of the treatment to patients could be largely reduced. MTPC is working hard to go forward the phase I clinical trial of the oral suspension which is easy to take in consideration of the situation that there are not few patients with dysphagia.

The initial Phase I dose-ranging PK study confirmed that a single oral dose of edaravone has a similar PK profile when compared to IV infusion. No new safety findings were observed relative to IV infusion. The latest results will be presented at the upcoming Symposium.

Mitsubishi Tanabe Pharma will strive to deliver a beneficial new therapy option 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<sup>®</sup>. 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. MTPC filed for edaravone to EMA and Swissmedic.

### ■ About International Symposium on ALS/MND

International Symposium on ALS/MND is the conference to foster strong collaboration between leading researchers around the world, and sharing new understanding of ALS and MND as rapidly as possible. Each year, the Symposium attracts the global MND research community. The 29th International Symposium will take place in Glasgow, UK.