



October 5th, 2018

**For the ALS patients in Canada,
we hope to deliver Japan-originated ALS treatment
Health Canada approves RADICAVA™ (edaravone)
for the treatment of ALS**

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that Edaravone (US name: RADICAVA®; Japan names: RADICUT® BAG for I.V. Infusion 30mg) was approved by the Health Canada for an indication of amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease on October 3rd.

Granted under the Priority Review process, the Notice of Compliance (NOC) authorization was based on a clinical trial which the primary endpoint was a measurement utilizing the ALS Functional Rating Scale-Revised (ALSFRRS-R), a validated rating instrument for monitoring the progression of disability in patients with ALS.

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. According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS, an incurable disease that affects the nerve cells in the brain and spin cord.

Promoting RADICAVA™ in Canada will be handled by Mitsubishi Tanabe Pharma Canada that was established by a sales subsidiary of Mitsubishi Tanabe Pharma on March 2018.

Mitsubishi Tanabe Pharma 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 Canada Ltd. (MTP-CA)

Based in Toronto, Ontario., MTP-CA was born in March 2018 as a subsidiary of Mitsubishi Tanabe Pharma America Inc. that was established by Mitsubishi Tanabe Pharma Corporation (MTPC) to commercialize approved pharmaceutical products in the U.S. MTP-CA will promote RADICAVA[™] in the ALS new treatment option for nearly 20 years in Canada. MTP-CA is dedicated to delivering innovative products that address the unmet medical needs of patients in Canada.

<https://www.mt-pharma-ca.com/en>