

News Release

April 10, 2018

To ALS patients in the world, we hope to deliver Japan-originated ALS treatment Health Canada accepts our filing for Edaravone to treat ALS and we established commercializing company in Canada

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that the Health Canada has accepted MTPC's filing 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 April 6, 2018. And Mitsubishi Tanabe Pharma America Inc. (MTPA) has established Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA) on March 27, with a view to commercializing approved pharmaceutical products in Canada as a wholly-owned subsidiary of MTPA.

Health Canada granted Priority Review are subject to a regulatory review target of 180 days from the date Health Canada accepts MTPC's filing for edaravone.

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 3,000 people are estimated to be affected by ALS in Canada.

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.

< Mitsubishi Tanabe Pharma Canada, Inc. >

Name : Mitsubishi Tanabe Pharma Canada Inc.

Address: Ontario, Canada
Managing Director: Atsushi Fujimoto
Establishment: 27 March, 2018

Share Capital: 4 million Canada Dollar

Shareholder: Mitsubishi Tanabe Pharma America Inc. (100%)
 Main Activities: Marketing of pharmaceutical products in Canada

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About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the 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 America Inc. (MTPA)

Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America (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. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in North America. It was established by MTPC to commercialize approved pharmaceutical products in North America with plans to expand its product line through collaborations with partners. Mitsubishi Tanabe Pharma Canada (MTP-CA) is a wholly-owned subsidiary of MTPA. For more information, please visit www.mt-pharma-america.com or follow us on Twitter at https://twitter.com/MTPharmaUS.