



HEALTH CANADA ACCEPTS MITSUBISHI TANABE PHARMA CORPORATION'S NDS FILING FOR EDARAVONE TO TREAT ALS, GRANTS PRIORITY REVIEW

Mitsubishi Tanabe Pharma Canada Launched in Toronto to Prepare Business Operations

JERSEY CITY, N.J., April 6, 2018 -- Mitsubishi Tanabe Pharma Corporation (MTPC) and Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced that Health Canada has accepted MTPC's New Drug Submission (NDS) for edaravone, an intravenous treatment option for amyotrophic lateral sclerosis (ALS), a rapidly progressive neurological disease.ⁱ Health Canada also informed the company that the NDS has been granted Priority Review.

In March of 2018, MTPA established the subsidiary Mitsubishi Tanabe Pharma Canada (MTP-CA) to prepare the required infrastructure and business operations to facilitate the distribution of the drug in Canada, if and when approved by Health Canada.

"We are dedicated to delivering innovative products that address the unmet medical needs of patients facing serious and life-threatening diseases," Atsushi Fujimoto, President, Mitsubishi Tanabe Pharma America. "The clinical development effort for edaravone in ALS spanned 13 years and included the pivotal Phase 3 study MCI186-19, which forms the basis for the company's NDS submission."

The NDS filing was submitted to Health Canada on March 9, 2018. NDS submissions granted Priority Review are subject to a regulatory review target of 180 days from the date Health Canada accepts the NDS filing.ⁱⁱ Edaravone currently is approved as a treatment for ALS in Japan, South Korea and the United States.

ALS is a neurodegenerative disease in which the majority of patients die within two to five years of diagnosis.^{iii,iv} According to the ALS Society of Canada, an estimated 3,000 Canadians currently are living with ALS,^v an incurable disease that affects the nerve cells in the brain and spinal cord.ⁱ Symptoms of the condition can be subtle at first, and it can take 12 to 14 months to be accurately diagnosed.^{vi}

About Mitsubishi Tanabe Pharma America, Inc.

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>.

Overview of Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan.^{vii} In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 2016-2020. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. MTPC is the parent company of MTPA and the license holder of RADICAVA. For more information, go to <http://www.mt-pharma.co.jp/>

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ⁱ National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Information Page. <https://www.ninds.nih.gov/disorders/all-disorders/amyotrophic-lateral-sclerosis-als-information-page>. Accessed March 2018.

ⁱⁱ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/priority-review/drug-submissions.html#a1.5>. Accessed March 2018.

ⁱⁱⁱ National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Information Page. <https://www.ninds.nih.gov/disorders/all-disorders/amyotrophic-lateral-sclerosis-als-information-page>. Accessed March 2018.

^{iv} Mehta P, Kaye W, Bryan L, et al. (2016). Prevalence of Amyotrophic Lateral Sclerosis — United States, 2012–2013. *MMWR Surveill Summ*, 65(8), 1-12. <http://dx.doi.org/10.15585/mmwr.ss6508a1>.

^v Benchmarking Survey, Federation of ALS Societies of Canada, 2016.

^{vi} Brooks BR. (2000). Risk factors in the early diagnosis of ALS: North American epidemiological studies. *Amyotrophic Lateral Sclerosis and Other Motor Neuron Disorders*, 1(1), S19-S26. <http://dx.doi.org/10.1080/14660820052415871>.

^{vii} Research by TOKYO SHOKO RESEARCH, LTD.