Mitsubishi Tanabe Pharma Submits New Drug Application for Edaravone to Treat ALS in the United States

Osaka, Japan, June 20, 2016 -- Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), today announced that a New Drug Application has been submitted to the U.S. Food and Drug Administration (FDA) for edaravone (MCI-186) for the treatment of amyotrophic lateral sclerosis (ALS), a rapidly progressive neurological disease. As many as 30,000 Americans may be affected by ALS with more than 5,600 diagnosed annually.[1]

This submission is the Company's first step in accelerating its U.S. business development activities as part of its "Medium-Term Management Plan 16-20: Open up the Future." As part of this plan, the Company established MT Pharma America, Inc., to commercialize approved pharmaceutical products in the U.S. with plans to expand its product line through collaborations with partners.

ALS, sometimes called Lou Gehrig's disease, attacks the nerve cells in the brain and the spinal cord responsible for controlling voluntary muscles, such as those needed to move, speak, eat and breathe.[2,3] It is one of the most well-known neuromuscular diseases, affecting approximately two in 100,000 people worldwide.[4,5] While it is inherited in 5%–10% of cases, the cause for the majority of cases is not well understood but may involve genetic and environmental factors.[6,7] There is currently no cure.[7]

"There is an urgent need for new treatment approaches that may affect the course of this devastating disorder," said Lucie Bruijn, PhD, MBA, Chief Scientist, The ALS Association. "The ALS Association is encouraged by the efforts of Mitsubishi Tanabe Pharma to make this drug available to people living with ALS in the U.S."

The edaravone NDA is supported by a clinical research program in patients diagnosed with ALS in Japan. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. In the same year, the FDA and the European Commission granted Orphan Drug Designation for edaravone. It is not currently approved by the FDA for any use in the U.S.

⟨⟨For Details, Contact the Following Section⟩⟩
Corporate Communications Department
Tel +81-6-6205-5211

About Edaravone

Discovered by Mitsubishi Tanabe Pharma Corporation, edaravone is described as a free radical scavenger that is believed to relieve the effects of oxidative stress, a likely factor in the onset and progression of ALS.[4,8] Oxidative stress is thought to be an imbalance between the production of free radicals (unpaired, reactive electrons) and the ability of the body to counteract or detoxify their harmful effects.[9] In patients with ALS, there are consistent increases in oxidative stress biomarkers.[8]

About MT Pharma America, Inc.

Based in Jersey City, NJ, MT Pharma America is a wholly-owned subsidiary of MTPC's 100% owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MT Pharma America is dedicated to delivering innovative solutions that address the unmet medical needs of patients in the United States. For more information, go to www.mt-pharma-america.com.

About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation is a research-driven pharmaceutical company with a Head Office based in Dosho-machi Osaka, the birthplace of Japan's pharmaceutical industry. As part of its "Medium-Term Management Plan 16-20: Open Up the Future," the company is focused on discovering drugs that address unmet medical needs in several priority disease areas, including autoimmune disorders, diabetes, kidney and central nervous system diseases and vaccines. Through this work, the company contributes to the healthier lives of people around the world. For more information, go to www.mt-pharma.co.jp/e.

---

[1] ALS Association. Quick Facts about ALS. http://www.alsa.org/news/media/quick-facts.html Accessed May 26, 2016.

[2] The Mayo Clinic. Diseases and Conditions: Amyotrophic Lateral Sclerosis. http://www.mayoclinic.org/diseases-conditions/amyotrophic-lateral-sclerosis/basics/causes/con-20024397. Accessed May 17, 2016.

[3] National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. http://www.ninds.nih.gov/disorders/amyotrophiclateralsclerosis/detail_ALS.htm. Updated March 14, 2016. Accessed May 17, 2016.

[4] Nagase M, Yamamoto Y, Miyazaki Y, et al. Increased oxidative stress in patients with amyotrophic lateral sclerosis and the effect of edaravone administration. Redox Rep. 2015

[5] Chiò A, Logroscino G, Traynor B, et al. Global Epidemiology of Amyotrophic Lateral Sclerosis: a Systematic Review of the Published Literature. Neuroepidemiology. 2013;41(2):118-130.

[6] ALS Association. Familial Amyotrophic Lateral Sclerosis (FALS) and Genetic Testing. http://www.alsa.org/about-als/genetic-testing-for-als.html Accessed June 8, 2016.

[7] Centers for Disease Control and Prevention. Prevalence of Amyotrophic Lateral Sclerosis — United States, 2010–2011. http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6307a1.htm. Accessed April 14, 2016.

[8] Manning, M.M. and Kelly-Worden, M. (2015) Potential Regulators of Sporadic ALS Development and Alternative Therapeutic Options. Neuroscience & Medicine. 2015; 6, 5-12.

[9] Betteridge, D.J., What is oxidative stress? Metabolism. 2000;49: 3-8.