Mitsubishi Tanabe Pharma

12-month Edaravone Clinical Study Data in ALS
Presented at the 27th International Symposium on ALS/MND

Osaka, Japan, December 9, 2016 -- Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director, CEO: Dr. Masayuki Mitsuka) has presented data that show patients with amyotrophic lateral sclerosis (ALS) given edaravone intravenously in 10-14 day cycles for 48 weeks experienced significantly less functional loss as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R). The data were presented at the 27th International Symposium on ALS/MND in Dublin, Ireland.

In the 48-week study, a 24-week double blind placebo controlled phase was followed by a 24-week open label active treatment phase. Data previously presented at the 2016 Annual Meeting of the American Academy of Neurology, showed edaravone met the primary efficacy endpoint of mean change in the ALSFRS-R at 24 weeks. The frequency of serious adverse events was similar to placebo.

“These findings suggest that intervention with edaravone may provide a treatment option to people living with ALS when therapy is promptly initiated,” said Joseph M. Palumbo, MD, Vice President, Medical Sciences and Translational Research, Mitsubishi Tanabe Pharma Development America, Inc.

About ALS
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.[1,2] It is one of the most well-known neuromuscular diseases, affecting approximately two in 100,000 people worldwide.[3,4] 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.[5,6] There is currently no cure.[6]

About Edaravone
Discovered by Mitsubishi Tanabe Pharma Corporation (MTPC), 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.[3,7] Oxidative stress is thought to be an imbalance between the production of free radicals and the ability of the body to counteract or detoxify their harmful effects.[8] In patients with ALS, there are consistent increases in oxidative stress biomarkers.[7]

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.

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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. It was established by MTPC to commercialize approved pharmaceutical products in the U.S. with plans to expand its product line through collaborations with partners. For more information, go to www.mt-pharma-america.com.

Overview of Mitsubishi Tanabe Pharma

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.[9] 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 16-20. 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. For more information, go to http://www.mt-pharma.co.jp/.

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1 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.

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4 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.

5 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.

6 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.

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

9 Research by TOKYO SHOKO RESEARCH, LTD.