Mitsubishi Tanabe Pharma

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Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation Presents Edaravone Clinical Trial Data in ALS at 2016 American Academy of Neurology Annual Meeting

Mitsubishi Tanabe Pharma Corporation (President & Representative Director: Dr. Masayuki Mitsuka) has presented results from a Phase 3 study of edaravone (MCI-186) in amyotrophic lateral sclerosis (ALS) at the 68th Annual Meeting of the American Academy of Neurology in Vancouver, British Columbia. The MCI-186 19 study met its primary efficacy endpoint of mean change in the ALS Functional Rating Scale-Revised (ALSFRS-R) at 24 weeks with a frequency of adverse events similar to placebo.

"Helping patients enjoy healthier lives is what inspires and motivates us. We recognize the challenges patients and their families face with rare medical conditions such ALS and are encouraged by these results." said Joseph M. Palumbo, MD, Vice President, Head of Clinical Research, Mitsubishi Tanabe Pharma Development America, Inc.

Mitsubishi Tanabe Pharma Corporation was awarded Orphan Drug Designation for edaravone by the U.S. Food and Drug Administration in May 2015 and the European Medicines Agency in June 2015. It is not currently approved for use in either region.

ABOUT EDARAVONE

Edaravone (MCI-186) has been studied in Japan for the treatment of ALS. It has not been investigated in the U.S. It is believed to relieve effects of oxidative stress – a likely key factor in the onset and progression of ALS. [i, ii] 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.[iii] In patients with ALS, there are consistent increases in oxidative stress biomarkers.[iii]

ABOUT ALS

ALS, also known as Lou Gehrig's disease, is a rapidly progressive neurological disease in which patients die, on average, within 3 to 5 years from onset of symptoms.[iv] ALS attacks the nerve cells responsible for controlling voluntary muscles, such as those in the arms, legs and respiratory tract.[i] It is one of the most well-known neuromuscular diseases, affecting approximately two in 100,000 people worldwide.[i,v] While a hereditary form of the disease, familial ALS, accounts for 5%–10% of cases, the majority of ALS cases do not have a definitive cause.[vi]

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. Based on our philosophy "We contribute to the healthier lives of people around the world through the creation of pharmaceuticals", we formulated the "Medium-Term Management Plan 16-20: Open Up the Future." We are taking on the challenge of discovering drugs that address unmet medical needs in fields of priority disease areas, including autoimmune disorders, diabetes and kidney diseases, central nervous system diseases and vaccines. To those ends, we contribute to the healthier lives of people around the world. www.mt-pharma.co.jp/e

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

[i] 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

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

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

[iv] National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. Available at: http://www.ninds.nih.gov/disorders/amyotrophiclateralsclerosis/detail_ALS.htm. Accessed April 7, 2016.

[v] 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.

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