FDA Accepts Mitsubishi Tanabe Pharma's NDA Filing for Edaravone to Treat ALS

- Edaravone may be the first ALS treatment approved in U.S. in more than 20 years.
- As many as 30,000 Americans are estimated to be affected by ALS and more than 5,600 are diagnosed annually.[1]

Osaka, Japan, August 30, 2016 -- Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for edaravone (MCI-186) an intravenous treatment for amyotrophic lateral sclerosis (ALS), a rapidly progressive neurological disease. A decision on the application is anticipated on June 16, 2017 based on the Prescription Drug User Fee Act. If approved, the medicine will be commercialized, under the brand name RADICAVA™, through the newly-formed MT Pharma America, Inc.

"This is an important milestone for Mitsubishi Tanabe Pharma and for the U.S. ALS community," said Joseph M. Palumbo, MD, Vice President, Head of Clinical Research, Mitsubishi Tanabe Pharma Development America, Inc. "There is an urgent need for new treatment options in ALS and we are now an important step closer to potentially making that a reality. We look forward to working with the FDA as part of the review process."

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.[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.[6]

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.

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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.[3,8] 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.[9] In patients with ALS, there are consistent increases in oxidative stress biomarkers.[7]

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.

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 central nervous system diseases, autoimmune disorders, diabetes, kidney disease 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.

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