November 25, 2019

Mitsubishi Tanabe Pharma Announces the Start of a Phase 3 Clinical Trial using Oral Suspension of Edaravone for ALS

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that its research and development subsidiary in U.S., Mitsubishi Tanabe Pharma Development America, Inc. (MTDA), has started a global Phase 3 clinical trial of an oral suspension formulation of edaravone (U.S. name: RADICAVA®; Japan names: RADICUT® Injection 30mg and RADICUT® BAG for I.V. Infusion 30mg) for the treatment of ALS.

This clinical trial will evaluate 150 people with ALS in U.S., Canada, Europe and Japan over the course of 48 weeks. MTPC is planning to submit 24-week data first to relevant authorities.
MTDA received the Fast Track designation* regarding this product in October 2019. MTPC is targeting the product launch in FY 2021 in U.S..

MTPC is focused on the development of the oral suspension formulation to provide an alternative dosing administration option for ALS patients, where there is a significant unmet need.

Edaravone was approved with intravenous formulation for an indication of amyotrophic lateral sclerosis (ALS) on June 2015, in Japan. Afterwards it was approved in Korea, U.S., Canada, Switzerland and China.

Mitsubishi Tanabe Pharma Group will strive to deliver a new therapy option to patients fighting against ALS from locations around the world.

*This designation allows the Oral Suspension of Edaravone Development Team to have increased dialogue with the FDA regarding the development program at key time points.

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■ About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Japanese Ministry of Health, Labour and Welfare in April 2001 as a treatment agent for the acute stage of cerebral infarction. In Japan, it is being marketed under the product name RADICUT®. Edaravone has the effect of scavenging free radicals that arise accompanying cerebral ischemia, controlling the lipid peroxidation reaction, and protecting neurons in the region of the ischemia and the surrounding region. Accordingly, it is thought that edaravone has the effect of scavenging free radicals, which increase in ALS, protecting motor neurons from oxidative stress, and delaying the decline in muscle strength and the progress of muscular atrophy.
For use as a treatment for ALS, edaravone was approved in Japan in June 2015, South Korea in December 2015, US in May 2017, Canada in October 2018, Switzerland in January 2019 and China in July 2019.

■ Mitsubishi Tanabe Pharma Development America, Inc.

The U.S. headquarters of Mitsubishi Tanabe Pharma Development America, Inc. (MTDA) is located in Jersey City, New Jersey. MTDA is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation's 100 percent-owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc.　MTDA obtained the regulatory approval of RADICAVA ® I.V. the only treatment option for ALS in more than 20 years in the United States. MTDA is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs of patients.　http://mt-pharma-development-america.com/