



Phase I Clinical Trial study protocol for MT-3921 in Patients with Spinal Cord Injury submitted to the US IND

Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka; Head Office: Chuo-ku, Osaka; hereinafter “Mitsubishi Tanabe Pharma” or “the Company”) and Osaka University (President: Shojiro Nishio; Location: Suita, Osaka) Graduate School of Medicine, Department of Molecular Neuroscience, Pr. Toshihide Yamashita today announced that the Company has submitted a study protocol to its investigational new drug application (IND) for MT-3921 to initiate a phase I clinical trial in patients with spinal cord injury.

MT-3921 is a novel investigational drug developed jointly with Osaka University that will contribute to expanding Mitsubishi Tanabe Pharma’s pipeline in neurological disorders, which is one of the focus areas for the Company. RGMA (repulsive guidance molecule A) was discovered in the 1990’s; however, until recently its role has not been fully understood. Current nonclinical research determined that RGMA is associated with inhibition of protection and regeneration of neurons and progression of inflammation. Additionally, it has revealed that RGMA plays a role in neurological diseases (spinal cord injury, stroke, multiple sclerosis etc.).

MT-3921 is a humanized anti-RGMA antibody that has been developed jointly by Mitsubishi Tanabe Pharma and Pr. Yamashita’s research group since 2005, and is based on initial research by Pr. Yamashita. Pre-clinical studies were conducted by his research group and the Company. Previous research was supported by a grant from the Japan Agency for Medical Research and Development (AMED) and showed that MT-3921 improves locomotor function and promotes neuroregeneration in rat and monkey spinal cord injury models.

Spinal cord injury has been a primary treatment target for regenerative medicine in recent years; however, an effective treatment has yet to be identified.

A phase I clinical trial has been underway in healthy adults in Japan. Now, Mitsubishi Tanabe Pharma Development America, Inc. will initiate a phase I clinical trial in patients with spinal cord injury in the US.

We will accelerate the research and development of MT-3921 with the goal to contribute to delivering the first pharmaceutical treatment option as quickly as possible to patients fighting against severe diseases all over the world.

◆ Contact Information

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◆ Terminology

Spinal cord injury: A disorder caused by damage to the spinal cord due to automobile accidents, falls, sports-related accidents, violence, etc. The injuries vary in severity and can cause motor paralysis, loss of sensation, and disturbance of bladder and rectal function. In addition, spinal cord injuries not only affect the health of the patients themselves but also place a major burden on their families. In the U.S., the annual incidence of spinal cord injury is estimated to be 18,000. To date, there are no FDA-approved drugs for the treatment of spinal cord injury. The current treatment of spinal cord injury mainly focuses on surgical stabilization of the spine, intensive neurological rehabilitation, and prevention and treatment of acute and chronic complications. No effective treatment for traumatic paraplegia or quadriplegia is available

◆ About 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. 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 — immuno-inflammation, diabetes and kidney, central nervous system, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world.

For more information, go to <https://www.mt-pharma.co.jp/>

◆ **About Mitsubishi Tanabe Pharma Development America, Inc. (MTDA)**

The U.S. headquarters of MTDA is located in Jersey City, New Jersey. MTDA is a wholly-owned subsidiary of MTPC's 100 percent-owned U.S. holding company, Mitsubishi Tanabe Holdings America, Inc. MTDA has obtained the approval of Radicava® the new treatment option for ALS in more than 20 years in the ALS therapeutic area in the U.S..MTDA is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs.

For more information, go to <https://mt-pharma-development-america.com/>

◆ **About Osaka University**

Originating from Kaitokudo and Tekijuku, two places of learning established in Osaka during the Edo period, Osaka University was founded in 1931 as Japan's sixth imperial university through strong demand from Osaka citizens and the government and business sectors of Osaka.

Currently comprising 11 faculties, 16 graduate schools, and 6 research institutes, Osaka University continues to develop as a leading comprehensive research university.

In line with its key concept, "Co-creation" with society, Osaka University conducts creative activities in cooperation with society with the goal of becoming a "World-Leading Innovative University Contributing to Social Change" by 2031, when it is to celebrate the 100th anniversary of its founding.

For more information, go to <http://www.osaka-u.ac.jp/en/>