Mitsubishi Tanabe Pharma

News Release

January 16, 2018

Reinforcing Our Pharmaceutical Development and Sales in China, the World's Second Largest Pharmaceutical Market

Approval in China Received for Additional Novastan® Indication for Acute Cerebral Infarction

Mitsubishi Tanabe Pharma Corporation (hereafter "MTPC"; Head Office: Osaka; President & Representative Director: Masayuki Mitsuka) announced today that MTPC received approval on December 20, 2017 from the China Food and Drug Administration (hereafter "CFDA") for injectable argatroban (Product Name: Novastan®) for the indication of "Improvement of neurological abnormalities (motor paralysis) and activities of daily living (ADL) disabilities (ADL includes walking, standing, sustaining the sitting position, and eating) associated with the following disease Acute cerebral infarction within 48 hours after the onset of symptoms".

In Japan in 1990, MTPC received approval for Novastan® for the indication of "Improvement of ulcers of extremities, pain while resting, and cold extremities associated with chronic arterial occlusion (Burger's disease and arteriosclerosis obliterans)" and the indication of "Improvement of neurological abnormalities (motor paralysis) and activities of daily living (ADL) disabilities (ADL includes walking, standing, sustaining the sitting position, and eating) " associated with the following disease "Acute cerebral thrombosis within 48 hours after the onset of symptoms (Excluding type of lacunar)" in 1996.

In China, MTPC submitted an application for an import drug license for Novastan® to the CFDA and received approval for the indication of "Improvement of ulcers of extremities, pain while resting, and cold extremities associated with chronic arterial occlusion (Burger's disease and arteriosclerosis obliterans)" in May 1999.
After fully examining related drug management systems in China, we submitted an application for approval of Novastan® for an additional indication of "Acute cerebral infarction" to the CFDA on February 23, 2017. The CFDA reviewed the efficacy of Novastan® via an ordinary technical review and a review by specialists in this field. This led to the approval of our application for the additional indication of Acute cerebral infarction without requiring clinical trials in China.

In collaboration with MTPC group companies, including Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd. in charge of self-promoted clinical development aimed at receiving marketing approval of pharmaceuticals in China, the world's second largest pharmaceutical market, and Tianjin Tanabe Seiyaku Co., Ltd., engaging in the manufacture and sale of pharmaceuticals in China.
MTPC will strive to contribute to the acceleration of its pharmaceutical business in China, a market with a high potential for future growth.

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About Mitsubishi Tanabe Pharma Corporation

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 2016-2020. 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. MTPC is the parent company of MTPA and the license holder of RADICAVA.
https://www.mt-pharma.co.jp/

About Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd.

Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd. is a wholly-owned subsidiary founded by MTPC in Beijing, China, in 2006. The company is engaged in self-promoted clinical development aimed at receiving marketing approval of pharmaceuticals in China. As a key base of the MTPC group in China, it promotes business in China by developing new drugs and receiving their approval in the country, thereby seeking to enhance MTPC's corporate value.

About Tianjin Tanabe Seiyaku Co., Ltd.

Tianjin Tanabe Seiyaku Co., Ltd. was founded in Tianjin, China, in 1993 through joint financing from Tianjin Lisheng Pharmaceutical Co., Ltd. and MTPC. The company is engaged in the manufacture and sales of pharmaceuticals in China. As a core company of the MTPC group in China, the company seeks to contribute to medical needs in China through the manufacture and sales of high quality pharmaceuticals with the MTPC brand, particularly cardiovascular drugs, gastrointestinal drugs, and anti-allergic agents for patients in China.