September 28, 2012

Application for time-window extension of the thrombolytic agents GRTPA® and ACTIVACIN® up to 4.5 hours after the onset of symptoms of ischemic cerebrovascular disease

Osaka and Tokyo, Japan, September 28, 2012---Mitsubishi Tanabe Pharma Corporation (President and Representative Director, Chief Executive Officer: Michihiro Tsuchiya) and Kyowa Hakko Kirin Co., Ltd. (Executive Director of the Board President & Chief Executive Officer: Nobuo Hanai) filed a two-company joint application with the Ministry of Health, Labour and Welfare on September 27, 2012. The public knowledge-based application is for a time-window extension of the thrombolytic agents that are marketed in Japan by the two companies with indication to improve functional disability in the acute ischemic cerebrovascular disease. Specifically, the application is for an extension from 3 hours after the onset of symptoms to 4.5 hours for GRTPA® and ACTIVACIN® for injection.

For cerebral infarction, which is the principal ischemic cerebrovascular disease, GRTPA® and ACTIVACIN® are already in use for the improvement of functional disability in the acute stage patients. However their use is currently limited to the 3-hour time-window after the onset of symptoms. In recent years, a research team in Europe announced and reported clinical benefits from the use of these drugs within 4.5 hours after the onset of symptoms. Based on that data, the treatment guidelines in Europe and the United States have been revised, and administration to patients within 4.5 hours of the onset of symptoms is now recommended.

Therefore, the Ministry of Health, Labour and Welfare asked for public opinion regarding the development of unapproved and Off-label drugs of High Medical need. The Japan Stroke Society requested the time-window extension of these drugs from 3 hours after the onset of symptoms to 4.5 hours. Subsequently, at an April 2011 meeting of the Study Group on Unapproved and Off-label Drugs of High Medical Need[*1] held in April 2011, the time-window extension of these drugs, as requested by the Japan Stroke Society, was determined to have a high medical necessity, and Mitsubishi Tanabe Pharma and Kyowa Hakko Kirin were asked to conduct the development. The two companies presented documentation and other materials that comprised the foundation for public knowledge, and in August 2012, a decision was made that it would be appropriate to file a publicknowledge-based application[*2] in accordance with the evaluation of the Study Group. As a result of this decision, Mitsubishi Tanabe Pharma and Kyowa Hakko Kirin filed a partial change application for these drugs.

Mitsubishi Tanabe Pharma and Kyowa Hakko Kirin believe that by obtaining approval for the time-window extension of these drugs, they will be able to contribute to improving the treatment and QOL for more patients.

Note 1. The Study Group on Unapproved and Off-label Drugs of High Medical Need

The Study Group evaluates the medical necessity of pharmaceutical indications that are approved in Europe and the U.S. but not yet approved in Japan; confirms the applicability of a public-knowledge-based application and confirms the suitability of additional tests that need to be implemented for the application. In this way, the Study Group was established to help advance the development by pharmaceutical companies of unapproved drugs / drugs used off label.

Note 2. Public knowledge-based application

For pharmaceuticals whose efficacy and safety are widely recognized, such as through the public knowledge of medical societies, this system enables applications (additional indications, etc.), to be filed without the implementation of all or a portion of clinical trials.

For further information:

Mitsubishi Tanabe Pharma Corporation,
Corporate Communications Department
TEL: +81-6-6205-5211

Kyowa Hakko Kirin Co., Ltd.,
Corporate Communications Department
TEL: +81-3-3282-1903