

February 28, 2013

Press Release

Mitsubishi Tanabe Pharma Corporation
Kyowa Hakko Kirin Co., Ltd.

**Approval 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, February 28, 2013—Mitsubishi Tanabe Pharma Corporation (President & Representative Director, Chief Executive Officer: Michihiro Tsuchiya) and Kyowa Hakko Kirin Co., Ltd. (Executive Director of the Board, President & Chief Executive Officer: Nobuo Hanai) today acquired approval of a partial change in the approved items for GRTPA[®] Injection and ACTIVACIN[®] Injection, thrombolytic agents manufactured and marketed in Japan by the two companies, respectively, to extend their time window from 3 hours after the onset of symptoms to 4.5 hours for amelioration of functional impairment in the acute ischemic cerebrovascular disease.

Ischemic cerebrovascular disease, typically characterized by cerebral infarction, is known to cause functional impairment as a sequela in many sufferers, often leading to a bedridden state. Although the use of GRTPA[®] and ACTIVACIN[®] has been limited to the 3-hour time window, the treatment guidelines in Europe and the United States have recently been revised to recommend administration within 4.5 hours after the onset of symptoms.

With this overseas situation, the Japan Stroke Society requested Japan's Ministry of Health, Labor and Welfare to extend the time window from 3 hours after the onset of symptoms to 4.5 hours. Thereafter, based on the assessment at a meeting of the Study Group on Unapproved and Off-labeled Drugs of High Medical Need^{*1}, the First Committee on Drugs in the Pharmaceutical Affairs and Food Sanitation Council decided at its meeting in August 2012 to permit a public-knowledge-based application^{*2}. Accordingly, Mitsubishi Tanabe Pharma and Kyowa Hakko Kirin filed a supplementary application for approval of a partial change in the approved items for each drug in September 2012, and obtained approval today.

Mitsubishi Tanabe Pharma and Kyowa Hakko Kirin believe that by holding the approval for the time-window extension they will contribute to improving the treatment and QOL for more patients.

Note 1: The Study Group on Unapproved and Off-labeled Drugs of High Medical Need

The Study Group was established to help advance the development by pharmaceutical companies of unapproved drugs and drugs used off-label by evaluating the medical necessity of

pharmaceutical indications that are approved in Europe and U.S. but not yet approved in Japan, and confirming the applicability of a public-knowledge-based application and the suitability of additional studies that need to be implemented for the application.

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.

Contact for Inquiries	
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