March 21, 2012

PRESS RELEASE

Mitsubishi Tanabe Pharma Corporation

“IMUSERA® Capsules 0.5mg” Multiple Sclerosis Treatment Agent
Notice regarding revision of “warnings” and “important basic precautions” sections of prescribing information

Osaka, Japan, March 21, 2012 — Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President and Representative Director: Michihiro Tsuchiya) announced today that on March 19 it had received a notice regarding “IMUSERA® Capsules 0.5mg” (generic name: fingolimod hydrochloride) from the Ministry of Health, Labour and Welfare (MHLW). The Company, which manufactures IMUSERA®, launched it in Japan on November 28, 2011, for the treatment of multiple sclerosis. In accordance with the MHLW notice, the Company revises the prescribing information for IMUSERA®.

Overseas, Novartis (Head Office: Basel, Switzerland), which is a licensee for this drug, markets “Gilenya® capsules 0.5mg.” Gilenya® has the same ingredient as IMUSERA®. Although there have not been reports of adverse events during the six-hour observation period following the administration of the first dose of Gilenya®, there have been reports of cardiac arrest or death occurring for unknown reasons within 24 hours of the administration of the first dose. (It is not clear if there is a connection between fingolimod hydrochloride and the reported cases of cardiac arrest or death.) As a result of these reports, the MHLW notice called for the revision of the prescribing information used in Japan. It is not clear if there is a connection between these overseas reports and IMUSERA®. However, the MHLW notice directed the Company to focus on the emergence of symptoms within 24 hours of the administration of IMUSERA® and to add statements regarding the strengthening of monitoring following initial administration of IMUSERA® to the “warnings” and “important basic precautions” sections of the prescribing information.

In accordance with this notice, the Company has made an addition to the “warnings” section of the prescribing information for IMUSERA®, as follows: Heart rate tends to decrease for a few days after initiation of treatment with IMUSERA®. Since significant decrease in heart rate may occur during the initial period of treatment in particular, treatment with IMUSERA® should be started under supervision which can take adequate measures, e.g. cooperating with physician specializing in cardiovascular. In addition, in the “important basic precautions” section, the following statement was added: 12-lead ECG* should be obtained at least prior to dosing and 6 hours after the initial dose. In addition, continuous monitoring of ECG is recommended, as well as measuring heart rate and blood pressure, for 24 hours after the initial dose. (ECG*: electrocardiogram)

In Japan, Mitsubishi Tanabe Pharma and Novartis Pharma K.K. are implementing co-marketing of this product. The two companies are working to conduct appropriate information provision regarding this revision of the prescribing information and to support the appropriate usage of this drug by patients.

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