September 13, 2012

Press release:

Mitsubishi Tanabe Pharma Corporation

MAINTATE® Tablets: Selective β_1 Antagonist
Notice regarding application for additional indication for chronic atrial fibrillation

Osaka, Japan, September, 2012--Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Michihiro Tsuchiya) has filed an application for partial changes relating to an additional indication of chronic atrial fibrillation for selective β_1 antagonist MAINTATE® Tablets (generic name: bisoprolol fumarate tablets) on September 10, 2012.

With chronic atrial fibrillation, regular signals from the sinus node do not reach the atria. The atria beat irregularly and rapidly, and do not contract and expand normally. As a result, subjective symptoms include palpitations, shortness of breath, and chest discomfort. In addition, the heart pump function can decline and thromboembolic events can occur. In these ways, chronic atrial fibrillation is a disease that hinders daily living. Currently, there are said to be more than one million atrial fibrillation patients in Japan, and because the prevalence rate increases with age, the number of patients is expected to increase further due to the aging of society. Treatments are broadly classified as preventing embolism or improving symptoms/QOL. For the latter, based on the results of large-scale clinical trials in recent years, the method of controlling the heart rate through β_1 antagonists is drawing attention.

Bisoprolol fumarate is a representative β_1 antagonist that is used in more than 100 countries around the world. In Europe, it has established a position as the No. 1 β_1 antagonist. With high β_1 selectivity and superior pharmacokinetics, it provides excellent control of blood pressure and heart rate. There is also abundant evidence that shows a cardioprotective action. In Japan, bisoprolol fumarate has been approved for hypertension, angina pectoris, and arrhythmia. In addition, due to Ministry of Health, Labour and Welfare initiatives regarding the development of unapproved and off-label drugs when there is a high degree of medical necessity, in May 2011 it received an additional indication for chronic heart failure. Further, upon request from related medical associations, since 2011 the Company has moved ahead with development of MAINTATE for an indication of chronic atrial fibrillation; and an application was filed for this indication.

Moving forward, Mitsubishi Tanabe Pharma will continue to accumulate evidence regarding this drug and to provide appropriate usage information. The Company will work to further promote the use of β antagonists in Japan and to contribute to improvements in the treatment and QOL of as many patients as possible.

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