

June 14, 2013

Press release:

Mitsubishi Tanabe Pharma Corporation

## **Approval for Additional Indication for Atrial Fibrillation (Tachycardiac ) MAINTATE<sup>®</sup> Tablets: Selective $\beta_1$ Blocker**

**Osaka, Japan, June 14, 2013**--Mitsubishi Tanabe Pharma Corporation (President and Representative Director: Michihiro Tsuchiya) announced today that the Company obtained approval for partial changes relating to an additional indication of atrial fibrillation (tachycardiac) for selective  $\beta_1$  blocker, MAINTATE<sup>®</sup> Tablets (generic name: bisoprolol fumarate tablets) as of June 14, 2013.

With atrial fibrillation, regular signals that control cardiac systole do not reach the atria, and the atria 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.

In atrial fibrillation (tachycardiac) patients have a rapid heart rate. The 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 rate-control therapy through  $\beta_1$  blockers has been attracting attention. MAINTATE inhibits the excitation conduction by acting on atrioventricular node which conducts the atrial activation to ventricle. It leads to suppress tachyarrhythmia, a rapid heart rate, and improve the symptom and QOL in patients.

MAINTATE is a representative  $\beta_1$  blocker that is used in more than 100 countries around the world. With high  $\beta_1$  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, it 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 drugs and indications with high medical needs, in 2011 it received an additional indication for chronic heart failure. Further, upon request from related academic societies, Mitsubishi Tanabe Pharma has pursued the development of MAINTATE for the new additional indication of atrial fibrillation and then achieved this approval.

Mitsubishi Tanabe Pharma will continue to accumulate evidence regarding MAINTATE which covers the widest range of indications among common  $\beta$  blockers, and to provide appropriate usage information. The Company will work to further promote the use of  $\beta$  blockers in Japan and to contribute to improvements in the treatment and QOL of as many patients as possible.

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