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Press release

Mitsubishi Tanabe Pharma Corporation

Approval for Additional Indication for selective β_1 antagonist, MAINTATE® Tablets 0.625, 2.5, and 5 and Launch of MAINTATE ® Tablets 0.625

Osaka, Japan, May 20, 2011---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that the Company obtained approval for additional indication for selective β1 antagonist, MAINTATE® Tablets 0.625, 2.5, and 5, (generic name: JP bisoprolol fumarate tablets) for chronic heart failure resulting from ischemic heart disease or dilated cardiomyopathy. Moreover, MAINTATE® 0.625, a tablet for exclusive use of chronic heart failure that is listed on the List of Standard Drug Prices, will be launched on June 3, 2011.

Chronic heart failure is caused by a decline in the pumping function of the heart. Since the heart is unable to pump out sufficient blood to satisfy the oxygen needs of the major peripheral organs, the lungs or the venous system become congested with blood, and various symptoms appear throughout the body such as shortness of breath and a sense of exhaustion, causing difficulty in leading a normal daily life.

MAINTATE® has been referred to in the Guideline for Treatment of Chronic Heart Failure (Revised Version 2010) as a recommended chemotherapy choice based on many reports of heart protection evidence. It has its greatest sales share in Europe and is gaining a strong presence as a β antagonist. In Japan, as part of an initiative by the Ministry of Health, Labor and Welfare to eliminate drug lag, the First Committee on Pharmaceutical Products of the Pharmaceutical Affairs and Food Sanitation Council issued a pre-assessment report in October 2010 that an “application for approval of additional indication for a publicly known prescription” may be filed for additional indication of chronic heart failure. Based on this pre-assessment report, the Company filed an application for approval of additional indication for a publicly known prescription in fall 2010, and the approval was obtained for the additional indication of chronic heart failure.
In treating chronic heart failure, since it is necessary to start the administration with a low dosage (0.625 mg per day, once a day) and increase the dosage gradually, we acquired the approval for the additional formulation “MAINTATE® Tablet 0.625” in March 2011. The Company will start providing this tablet, exclusively intended for the treatment of chronic heart failure soon.

Mitsubishi Tanabe Pharma will strive to contribute to the treatment of as many patients as possible and improve their QOL by continuing to establish evidence relating to MAINTATE®, actively communicating information on its correct use, and promoting the widespread of β antagonists.

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