August 17, 2011

Mitsubishi Tanabe Pharma Corporation

Remicade® for I.V. Infusion 100, Anti-Human TNF α Monoclonal-Antibody Approval for a Partial Change of Dosage and Usage in Crohn's Disease

Osaka, Japan, August 17, 2011---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that the Company has received, as of August 17, 2011, approval for a partial change of dosage and usage in Crohn's disease for an anti-human TNF-α monoclonal-antibody, *Remicade*® for I.V. Infusion 100 (generic name: infliximab).

Remicade® was launched in 2002 as the first biologic in Japan for "moderate to severe active Crohn's disease" and "fistulizing Crohn's disease", followed by the extended indication of "maintenance therapy" in 2007. Crohn's disease is a chronic and progressive inflammatory disease which can cause inflammation and ulcers in any part of gastrointestinal system, especially, in small and large intestines. In Japan, there are about 30,000 Crohn's disease patients, and over 12,000 patients are prescribed *Remicade*®. The Company has been contributing to improve the patients' quality of life (QOL) through providing *Remicade*®.

On the other hand, some patients were unable to sustain sufficient effects with the original dosage and usage, and physicians have requested for changes in the approved dosage (an increase of dosage). In order to respond to this need and to enable more and more patients to feel the maximum effect of this drug, we have conducted clinical trial aimed at changes in dosage and usage for the patients who did not sustain sufficient effects by the original dosage. As a result, the efficacy and the safety of this drug with an increased dosage from the original dosage of 5mg/kg to 10mg/kg were recognized, and a partial change in dosage and usage was approved.

Mitsubishi Tanabe Pharma will promote the proper use of *Remicade*® by steadily providing health care professionals with safety information, and make a greater contribution to improving the QOL of patients suffering from Crohn's disease.

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