## Mitsubishi Tanabe Pharma Corporation

## Remicade<sup>®</sup> for I.V. Infusion 100, Anti-Human TNF α Monoclonal Antibody Lifting of Condition on Approval for Psoriasis

**Osaka, Japan, May 8, 2012---**Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that the condition on approval for psoriasis of the anti-human TNF  $\alpha$  monoclonal antibody, Remicade<sup>®</sup> for I.V. Infusion 100 (generic name: infliximab) has been lifted.

Psoriasis is an intractable chronic skin disease. In addition to plaque psoriasis, there are several other types of psoriasis, such as psoriatic arthritis which, in addition to skin symptoms, causes progressive destruction of the joints as in rheumatoid arthritis; pustular psoriasis, marked by pus-filled blisters on the skin; erythrodermic psoriasis, with red inflammatory skin symptoms all over the body. In particular, generalized pustular psoriasis, with appearance of pus-filled blisters over the entire body, is designated as an intractable disease by the government; and psoriasis is well-known for deteriorating the patients' quality of life (QOL) by significant levels, the reason being severe emotional distress and the difficulty in making complete recovery.

In January 2010, Mitsubishi Tanabe Pharma Corporation received approval for the additional indication of Remicade<sup>®</sup> for psoriasis (plaque psoriasis, psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis). The Company has since collected data on the safety and efficacy of the drug by conducting post-marketing surveillance on all patients. The surveillance results were recently examined by the Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council of the Ministry of Health, Labor and Welfare, and the condition imposed on approval was lifted.

Throughout the surveillance, no specific adverse reactions in psoriasis cases were observed, and the safety profile of the drug was confirmed to be similar to that of other indications. The results of efficacy at the final evaluation were confirmed to be similar to the domestic clinical trial results.

May 2012 will mark the 10th anniversary of Remicade<sup>®</sup> launch in Japan. During that decade, a total of 80,000 patients of all indications, including over 2,000 psoriasis patients, have been treated with this drug.

Mitsubishi Tanabe Pharma Corporation will promote the proper use of Remicade<sup>®</sup> by providing these accumulated data on efficacy, safety and usage, and contribute to improve the QOL of patients with intractable autoimmune diseases such as psoriasis.

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