Mitsubishi Tanabe Pharma Press Release

May 13, 2016

Press release

Mitsubishi Tanabe Pharma Corporation

Approval of REMICADE® for I.V. Infusion 100, an Anti-Human TNFα Monoclonal Antibody, for a Partial Change in Dosage and Usage in Psoriasis

Osaka, Japan, May 13, 2016 - Mitsubishi Tanabe Pharma Corporation (President & Representative Director: Masayuki Mitsuka) announced today that it has received approval of REMICADE® for I.V. Infusion 100 (generic name: infliximab, hereinafter REMICADE®), an anti-human TNFα monoclonal antibody, for a partial change in dosage and usage in psoriasis.

Psoriasis is an intractable immunologic skin disease of unknown cause with such inflammatory symptoms as swelling skin rashes, and dried, silvery scurf-like scales exfoliating from the skin. Psoriasis is a disease well-known for seriously impairing the patients' quality of life due to severe emotional distress.

In January 2010, Mitsubishi Tanabe Pharma Corporation received approval for REMICADE® as treatment for four types of psoriasis (plaque psoriasis, psoriatic arthritis, pustular psoriasis and erythrodermic psoriasis). The Company has since contributed to the improvement of quality of life of many patients with psoriasis. However, in some patients on this drug, inability to sustain sufficient effects remained an issue, and increased dosage as well as shorter dosing intervals had been requested.

In response to such needs, Mitsubishi Tanabe Pharma Corporation conducted clinical trials in Japan, and became one of the first to receive approval for increased dosage and shorter dosing intervals in psoriasis.

To address unmet medical needs, Mitsubishi Tanabe Pharma is striving to develop REMICADE® for various incurable diseases including rare diseases, to expand its indications. Moving forward, Mitsubishi Tanabe Pharma will continue working to establish an adequate sales organization so products can be used by patients with peace of mind through promoting appropriate usage of REMICADE® and obtaining thorough efficacy and safety data on post-marketing surveillance.

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