Mitsubishi Tanabe Pharma Corporation

Applications filed for REMICADE[®] for I.V. Infusion 100, an anti-human TNFα monoclonal antibody, for additional indications for entero-Behcet's disease, neuro-Behcet's disease, and vasculo-Behcet's disease

Osaka, Japan, October 30 , 2014---Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka) announced today that it has filed applications for a partial change of approved information for REMICADE[®] for I.V. Infusion 100 (generic name: infliximab, hereafter REMICADE[®]), an anti-human TNF α monoclonal antibody. The partial changes are related to additional indications for neuro-Behcet's disease, entero-Behcet's disease, and vasculo-Behcet's disease.

Behcet's disease is a systemic inflammatory autoimmune disease characterized by cyclical relapse and remission. It is an intractable disease for which there are no effective treatments. Major symptoms include aphthous ulcers in the oral mucosa, genital ulcers, skin manifestations, and eye manifestations. In addition, enteric, neurological, and vascular symptoms are also seen. Mitsubishi Tanabe Pharma has implemented clinical trials in Japan involving patients with neuro-Behcet's disease, entero-Behcet's disease, and vasculo-Behcet's disease, which confirmed the efficacy and safety of REMICADE[®]. Accordingly, the Company filed the applications for additional indications.

REMICADE[®] has been designated as an orphan drug for the treatment of Behcet's disease with special lesions (entero-Behcet's disease, neuro-Behcet's disease, and vasculo-Behcet's disease).

Moving forward, Mitsubishi Tanabe Pharma will continue working to establish evidence for REMICADE[®], to thoroughly promote correct usage, and to contribute to quality-of-life improvements for a large number of patients.

End

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