July 10, 2015

Press Release

Mitsubishi Tanabe Pharma Corporation

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

Osaka, Japan, July 10, 2015 - Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka) announced today that it has filed an application for a partial change of approved information regarding dosage and usage for REMICADE® for I.V. Infusion 100 (generic name: infliximab, hereafter REMICADE®), an anti-human TNFα monoclonal antibody. This application comes as a result of verified effectiveness and safety of increased dosage in a clinical trial conducted by the Company in patients with psoriasis whose response to this drug was decreasing.

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 received approval for REMICADE® as treatment for four types of psoriasis (plaque psoriasis, psoriatic arthritis, pustular psoriasis and psoriatic erythroderma). The Company has contributed to the improvement of quality of life of many patients with psoriasis. Meanwhile, wearing-off of effects in some patients on this drug remained an issue, and increased dosage as well as shorter dosing intervals had been requested.

Professor Hidemi Nakagawa, Department of Dermatology, the Jikei University School of Medicine, who served as coordinating investigator of the clinical trial, commented as follows: "Increased dosage of this drug in psoriasis has not yet been approved in other countries. Mitsubishi Tanabe Pharma, in response to the needs of the medical frontlines, conducted clinical trials in Japan and filed an application. When approved, an increased dosage will be additional good news to patients in need of treatment with this drug. Each clinical trial conducted through cooperation among the company, the physicians and academia, clarifies evidence concerning therapeutic effect and adverse reactions, and will definitely lead to improvement of quality of life of patients in need of this drug. In this sense, information about the range of indications as well as effectiveness and safety based on the evidence gained by clinical trial is indispensable in assessing the product value of a drug."

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

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Reference

Indications for REMICADE®

Indications	Approval/Application Date
Crohn's disease	Approved in January 2002
Rheumatoid arthritis	Approved in July 2003
Behcet's disease with refractory uveoretinitis	Approved in January 2007
Plaque psoriasis	Approved in January 2010
Psoriatic arthritis	
Pustular psoriasis	
Psoriatic erythroderma	
Ankylosing spondylitis	Approved in April 2010
Ulcerative colitis	Approved in June 2010
Intestinal-Behcet's disease	Filed in October 2014
Neuro-Behcet's disease	
Vasculo-Behcet's disease	
Kawasaki disease	Filed in May 2015