

May 15, 2015

Press Release

Mitsubishi Tanabe Pharma Corporation

**Application filed for REMICADE<sup>®</sup> for I.V. Infusion 100, an anti-human TNF $\alpha$  monoclonal antibody, for an additional indication for Kawasaki disease**

**Osaka, Japan, May 15, 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 for REMICADE<sup>®</sup> for I.V. Infusion 100 (generic name: infliximab, hereafter REMICADE<sup>®</sup>), an anti-human TNF $\alpha$  monoclonal antibody. The partial change is related to an additional indication for Kawasaki disease.

Kawasaki disease is an acute febrile illness of unknown cause that usually occurs in infants and children younger than four years of age. The main pathology is vasculitic syndromes primarily of small and medium-sized arteries. Major symptoms include fever lasting at least five days, bilateral bulbar conjunctival congestion, and labial flushing, and may be followed by complications/sequelae including coronary arterial dilatation and aneurysm.

Mitsubishi Tanabe Pharma conducted clinical trials in Japan involving Kawasaki disease patients who had responded inadequately to conventional treatment, and confirmed the efficacy and safety of REMICADE<sup>®</sup>. Accordingly, the Company filed an application for an additional indication.

REMICADE<sup>®</sup> has been designated as an orphan drug for the treatment of intractable Kawasaki disease.

To address unmet medical needs, Mitsubishi Tanabe Pharma is striving to develop REMICADE<sup>®</sup> 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<sup>®</sup>, to thoroughly obtain efficacy and safety data through post-marketing surveillance.

End

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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	