August 24, 2015

Press Release

Mitsubishi Tanabe Pharma Corporation

Approval of 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, August 24, 2015 - Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka) announced today that it has received approval for a partial change of approved information on REMICADE® for I.V. Infusion 100 (generic name: infliximab, hereafter REMICADE®), an anti-human TNFα monoclonal antibody, in relation to additional indications for entero-Behcet's disease, neuro- Behcet's disease, and vasculo-Behcet's disease in cases where existing treatment is inadequate.

Behcet's disease (see Reference 1 below) is a generalized inflammatory disease presenting orogenital aphthous ulcers, skin manifestations, uveoretinitis, and genital ulcers as prominent symptoms, with characteristic recurring acute inflammatory attacks. Effective treatment for patients with the following types of Behcet's disease has long been awaited since their outcomes are particularly poor, as they not only present with prominent symptoms but also develop lesions in the bowels, nerves and blood vessels.

Entero-Behcet's disease: Patients are characterized by having multiple deep ulcers often leading to intestinal perforation, intestinal hemorrhage or perforative peritonitis requiring emergency surgery.
Neuro-Behcet's disease: Patients may develop dementia, psychiatric symptoms, dysarthria or ataxia due to atrophy of the cerebrum, cerebellum and brainstem.
Vasculo-Behcet's disease: Patients may develop thrombosis, aneurysms or varicose veins that could be life-threatening if rupture occurs.

The Ministry of Health, Labour and Welfare (MHLW) classifies the seriousness of Behcet's disease into six stages, from Stage I to Stage VI (see Reference 2 below). While REMICADE® had already been approved in 2007 for the indication of Behcet's disease with refractory uveoretinitis, this added approval will make it possible to cover a wider range of disease conditions and contribute to the treatment of nearly all patients with Behcet's disease of Stage III or higher.

To address unmet medical needs, Mitsubishi Tanabe Pharma is striving to develop REMICADE® for various incurable diseases, including rare diseases, to expand its indications (see Reference 3 below). Moving forward, Mitsubishi Tanabe Pharma will continue working to promote appropriate usage of REMICADE® to obtain thorough efficacy and safety data through post-marketing surveillance and to establish an adequate sales organization so the product can be used by patients with peace of mind.

End

⟨⟨For Details, Contact the Following Section⟩⟩
Corporate Communications Department
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Reference 1

About Behcet's Disease

Behcet's disease was so-named in 1937 after Hulusi Behcet, a Turkish dermatologist and scientist who became the first professor at the department of dermatology, Istanbul University, reported the disease. It is also known as the "Silk Road disease," as it is prevalent in the region spanning from Japan to the Mediterranean coast from 30 to 45 degrees latitude north. The cause of Behcet's disease is unknown, but a combination of genetic and external environmental factors including bacteria and viruses likely causes immunologic abnormalities leading to onset of the disease.

In Japan, Behcet's disease was designated in 1972 as an intractable disease covered by the Specified Disease Treatment Research Program, with approximately 19,000 patients included. Prominent symptoms of Behcet's disease, which have sometimes been featured in films and TV dramas, include serious ocular symptoms often leading to vision loss.

Reference 2

Severity stages of Behcet's Disease (Classification According to the MHLW)

Stage I	Presenting with prominent symptoms other than ocular symptoms (aphthous ulcers on the oral mucosa, skin manifestations, genital ulcers)
Stage II	Presenting with iridocyclitis in addition to Stage I symptoms Presenting with arthritis or epididymitis in addition to Stage I symptoms
Stage III	Presenting with chorioretinopathy
Stage IV	Presenting with chorioretinopathy and other ocular complications with current or possible future vision loss A special type of Behcet's disease (entero-Behcet's disease, vasculo-Behcet's disease, neuro-Behcet's disease) that is active or that may have severe sequelae
Stage V	A special type of Behcet's disease adversely impacting life or prognosis A progressive neuro-Behcet's disease presenting with a greater than moderate decrease in intellectual function
Stage VI	Death

Reference 3

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
Entero-Behcet’s disease	Approved in August 2015
Neuro-Behcet’s disease	
Vasculo-Behcet’s disease	
Kawasaki disease	Filed in May 2015