Mitsubishi Tanabe Pharma Press Release

December 21, 2015

Press release

Mitsubishi Tanabe Pharma Corporation

Remicade® for I.V. Infusion 100
Approval of Additional Indication for Kawasaki Disease
World First Biologic Treatment

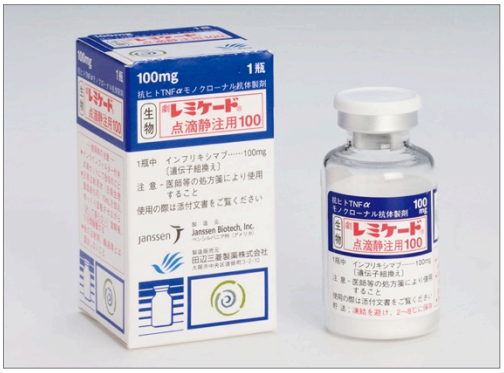
Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director: Masayuki Mitsuka) announced today that it has received approval for an additional indication for Remicade® for I.V. Infusion 100 (generic name: infliximab), an anti-human TNFα monoclonal antibody. The additional indication is for acute-stage Kawasaki disease for which existing treatments are not sufficiently effective.

Key Points

- Remicade® has become the world's first biologic to receive an indication for Kawasaki disease.
- Development of a new treatment agent was needed for acute-stage Kawasaki disease for which existing treatments are not sufficiently effective.
- Through this approval, the treatment options have been expanded for patients with Kawasaki disease for which existing treatments are not sufficiently effective.

Overview

Acute-stage Kawasaki disease can result in the development of coronary lesions (coronary artery expansion or aneurysm formation). Consequently, a therapeutic goal is to rapidly address acute-stage symptoms, such as fever. However, there are patients for which existing treatments are not sufficiently effective and additional treatment is needed, and there are reports that one in four of these patients has coronary lesions. Accordingly, the development of new treatment agents has been needed.



In response to these strong medical needs, Mitsubishi Tanabe Pharma implemented domestic clinical trials for patients with Kawasaki disease for which existing treatments are not sufficiently effective. As a result, the efficacy and safety of Remicade® were confirmed, and following accelerated examination by the Ministry of Health, Labour and Welfare, the Company was able to rapidly obtain approval for this indication.

In 2012, Remicade® was designated as an orphan drug with a planned indication of refractory Kawasaki disease.

Moving forward, the Company will take thorough steps to promote appropriate usage, including for use by children, and to collect safety and efficacy information through post-marketing surveillance. In these ways, Mitsubishi Tanabe Pharma will work to support even-greater peace of mind in the use of Remicade®.

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What is Kawasaki disease?
In 1967, Dr. Tomisaku Kawasaki first described the disease as “acute febrile Muco-Cutaneous Lymph-node Syndrome” in children. Currently, the disease has been named “Kawasaki disease” after Dr. Kawasaki.

Kawasaki disease, which is most commonly seen in children aged four years or younger, is an ideopathic vasculitic syndrome. The principal symptoms are described in 1 to 6 below.

1. Fever that lasts for five days or more (38 C or higher).
2. Rash.
3. Red eyes (red bulbar conjunctiva in both eyes).
4. Red lips, and strawberry-like spots on the top of the tongue (strawberry tongue)
5. In the first phase of the disease, the skin on the palms of the hands and the soles of the feet swells and become red. In addition, after the fever declines, the skin on the tips of the fingers and toes and the hand in general may peel off.
6. Swollen lymph nodes in the neck.

Kawasaki disease has been reported in all areas of the world, but the prevalence reported in East Asia, especially in Japan and South Korea, is high in comparison with Europe and North America. In Japan, about 16,000 people contracted the disease in 2014.
In some cases, this disease has sequelae, such coronary aneurysms, and in the event of these complications, limited mobility and long-term drug therapy may be necessary. Accordingly, Kawasaki disease is considered to lower patient quality of life into the future.

Indications for Remicade®
*****The bold/underlined section shows the recent additional indication.
To address unmet medical needs, Mitsubishi Tanabe Pharma has worked to develop Remicade® and expand its indications for refractory diseases, including orphan diseases. Remicade® has 13 indications in Japan, including Kawasaki disease, and to this point more than 90,000 patients in Japan have used Remicade®. As a result, this biologic has accumulated evidence of efficacy and safety.

Indications	Timing of approval
Crohn’s disease	Approved January 2002
Rheumatoid arthritis	Approved July 2003
Behcet’s disease with refractory uveoretinitis	Approved January 2007
Plaque psoriasis	Approved January 2010
Psoriatic arthritis	
Pustular psoriasis	
Psoriatic erythroderma	
Ankylosing spondylitis	Approved April 2010
Ulcerative colitis	Approved June 2010
Intestinal-Behcet’s disease	Approved August 2015
Neuro-Behcet’s disease	
Vasculo-Behcet’s disease	
Acute stage Kawasaki disease	**Approved December 2015**