September 6, 2016

Press release

Application for partial change in administration / dosage for Crohn's disease for REMICADE® for I.V. Infusion 100, an anti-human TNFα monoclonal antibody

Osaka, Japan, September 6, 2016—Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka) announced today that it has filed an application for a partial change of administration / dosage for REMICADE® for I.V. Infusion 100 (generic name: infliximab), an anti-human TNFα monoclonal antibody. The application for a partial change in manufacturing and marketing approval items is for the addition to administration/dosage of a shortened administration interval for Crohn's disease. In addition, the Company plans to revise the precautions for use with pediatric patients.

REMICADE® was approved in 2002 with indications of moderate to severely active Crohn's disease and fistulizing Crohn's disease, making it the first biologic sold in Japan. Approvals were received in 2007 for an additional indication of Crohn's disease maintenance therapy, in 2011 for an increased dosage (10mg/kg, 8-week administration interval) for patients for whom effectiveness weakened at the typical dosage (5mg/kg, 8-week administration interval).

Crohn's disease is a chronic, progressive inflammatory disease that is principally seen in younger patients, with symptoms including inflammation and ulcers in the small intestine and large intestine. There are about 40,000 patients with Crohn's disease in Japan, and currently more than 15,000 patients are being treated with REMICADE®, which is contributing to improvements in the quality of life of patients.

On the other hand, for certain patients the effectiveness has not been sustained even when the dosage was increased to 10mg/kg, and there is a strong need for a further change in administration/dosage. In response to this need, the Company applied for a change in administration/dosage based on the results of a re-examination of a 4-week administration interval at 5mg/kg.

In addition, based on clinical trials targeting pediatric Crohn's disease and pediatric ulcerative colitis, the Company plans to revise the package insert precautions for use with pediatric patients.

To address unmet medical needs, Mitsubishi Tanabe Pharma is working to develop REMICADE® and expand its indications for refractory diseases, including orphan diseases. Moving forward, Mitsubishi Tanabe Pharma will continue working to establish evidence for REMICADE®, to thoroughly promote correct usage, and to build a sales system that enables REMICADE® to be used with peace of mind.

⟨⟨For Details, Contact the Following Section⟩⟩
Corporate Communications Department
Tel +81-6-6205-5211