March 30, 2017

Press release

Notice regarding approval of indication of ulcerative colitis and additional formulation for SIMPONI® subcutaneous injection 50 mg syringe (generic name: golimumab), a human monoclonal antibody specific for human TNF α

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director: Masayuki Mitsuka) announced today that Janssen Pharmaceutical K.K (Head Office: Chiyoda-ku, Tokyo; President: Chris Hourigan) had received approval of a partial change in manufacturing and marketing approval items for SIMPONI® subcutaneous injection 50 mg syringe (generic name: golimumab), a human monoclonal antibody specific for human TNF α. The approval was for an indication of improvement and maintenance therapy for moderate to severe ulcerative colitis for which existing treatments are not sufficiently effective, and for an additional formulation, a 100 mg syringe.

Ulcerative colitis is an inflammatory bowel disease that causes erosions (mucosal infections) and ulcers in the colonic mucosa. It causes frequent diarrhea, bloody stool, and abdominal pain. Very serious cases require surgery to remove the large intestine. The cause of the disease is unknown, and no fundamental treatment has yet been established. Ulcerative colitis is designated as an intractable disease, and is studied in the Specified Disease Treatment Research Program of the Ministry of Health, Labour and Welfare. Many patients have anxiety regarding surgery and difficulty in daily life due to stool-related symptoms. Their quality of life (QOL) is significantly reduced.

To date, SIMPONI® has been used by many rheumatoid arthritis patients, and with the approval of this additional indication, it can now contribute to the treatment of patients with ulcerative colitis. Mitsubishi Tanabe Pharma and Janssen Pharmaceutical are implementing strategic co-promotion of SIMPONI® so that it can quickly be used to meet the needs of health care professionals and patients.

Moving forward, Mitsubishi Tanabe Pharma will continue to advance the appropriate usage of SIMPONI®, to accumulate information regarding its safety and usage methods, and to build an inhouse system that will enable it to be used with a high sense of security. At the same time, Mitsubishi Tanabe Pharma will also continue to aggressively develop and market pharmaceuticals that address unmet medical needs.

In addition, at the same time as the SIMPONI® approval, Janssen Pharmaceutical's STELARA® received approval for an indication of Crohn's disease. Mitsubishi Tanabe Pharma will also implement information provision activities for STELARA® for this indication.

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