March 25, 2020

STELARA® (ustekinumab) Now Approved for the Treatment of Adults with Moderate-to-Severe Ulcerative Colitis in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President and Representative Director: Masayuki Mitsuka; hereafter, Mitsubishi Tanabe Pharma) announced today that Janssen Pharmaceutical K.K. (Headquarters: Chiyoda-ku, Tokyo; President: Chris Hourigan; hereafter, Janssen) has acquired approval for a partial change in manufacturing and marketing approval items for STELARA® (generic name: ustekinumab; (genetically modified)), which is a monoclonal antibody that binds to the p40 subunit of human anti-interleukin (IL)-12 and IL-23. The approval covers an intravenous infusion form (induction therapy in adults with moderate to severe UC, who previously experienced an inadequate response or were intolerant to conventional or biologic therapies) and a subcutaneous injection form (maintenance therapy in adults with moderate to severe UC, who previously experienced an inadequate response or were intolerant to conventional or biologic therapies).

Mitsubishi Tanabe Pharma has the co-promotion agreement with Janssen for STELARA® in Japan. Under the terms of this agreement, Janssen holds the marketing authorization for STELARA® and licenses distribution rights to Mitsubishi Tanabe Pharma Corporation in Japan. Under the terms of this agreement, promotion of STELARA® to healthcare professionals in Japan is undertaken by both companies.

STELARA® controls inflammation in the gastrointestinal tract by selectively targeting the IL-12 and IL-23 cytokines, which play a key role in inflammatory and immune responses. In Japan, the intravenous infusion form of this drug has been approved for induction treatment for moderate to severe Crohn's disease (which does not adequately respond to conventional treatments). The subcutaneous injection form has been approved for psoriasis vulgaris and psoriasis arthropathica in which does not adequately respond to conventional treatments and for maintenance therapy for moderate to severe Crohn's disease (which does not adequately respond to conventional treatments).

Going forward, in the field of inflammatory bowel disease (Crohn's disease, ulcerative colitis), Mitsubishi Tanabe Pharma will offer REMICADE® and STELARA® for the indication of Crohn's disease and REMICADE®, SIMPONI® and STELARA® for

the indication of ulcerative colitis. In this way, Mitsubishi Tanabe Pharma will strive to strategically reinforce its foundation in the field of inflammatory bowel disease and contribute to improvements in patients' quality of life and to their medical treatment.

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