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Mitsubishi Tanabe Pharma expands domestic co-promotion framework for STELARA®.

An application for an additional indication has been filed for ulcerative colitis, which will be included in co-promotion activities.

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President and Representative Director: Masayuki Mitsuka; hereafter, Mitsubishi Tanabe Pharma) has agreed to expand the domestic co-promotion agreement with Janssen Pharmaceutical K.K. (Headquarters: Chiyoda-ku, Tokyo; President: Chris Hourigan; hereafter, Janssen) for STELARA®. Up to this point, the co-promotion activities of the two companies have focused on the treatment of Crohn's disease with 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. Going forward, the two companies have agreed to expand the co-promotion framework to include an intravenous infusion form (induction treatment for moderate to severe ulcerative colitis (which does not adequately respond to conventional treatments)) and a subcutaneous injection form (maintenance therapy for moderate to severe ulcerative colitis (which does not adequately respond to conventional treatments)). An application for a partial change in manufacturing and marketing approval items has been submitted for these items.

In accordance with this agreement, Janssen, as the manufacturing distributor of STELARA®, will continue to provide the product to Mitsubishi Tanabe Pharma, which will have sales rights in Japan. In addition, both companies will continue to jointly provide information to health care professionals.

STELARA® controls inflammation in the gastrointestinal tract by selectively targeting the IL-12 and IL-23 pathway, an important therapeutic target in inflammatory bowel disease. 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 cases of psoriasis vulgaris and psoriasis arthropathica in which existing treatments are not sufficiently effective 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[®] and 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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About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed pharmaceutical company in Japan. In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 16-20. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — Immuno-inflammation, Diabetes and kidney, Central nervous system, Vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. For more information, go to <https://www.mt-pharma.co.jp/e/>