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Takeda bags Japan's approval for ulcerative colitis drug

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Japan's Takeda Pharmaceutical Company recently announced that it has obtained a New Drug Application Approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for Entyvio for the treatment of patients with moderately to severely active ulcerative colitis (UC) in Japan.

Takeda submitted a New Drug Application to the MHLW in August 2017 based on the results from Study CCT-101, a Phase 3 clinical study including Japanese patients with moderately to severely active UC alongside data from the global GEMINI 1 pivotal Phase 3 clinical study of vedolizumab induction and maintenance treatment involving 895 patients with moderately to severely UC.

“In recent years, the number of patients with UC in Japan has been on the increase. The quality of medical treatment has improved and more treatment options are available, but many patients continue to experience difficulty in their daily lives,” said Dr. Toshifumi Hibi, Director of the Center for Advanced IBD Research and Treatment, Kitasato University Kitasato Institute Hospital. “I believe that the addition of Entyvio to available treatment options, as a new biologic treatment for UC with a novel mechanism of action that selectively inhibits the migration of inflammatory cells in the digestive tract, represents a major step forward in the treatment of UC by bringing us closer to achieving better long-term treatment goals.”

“Entyvio has been approved in more than 60 countries worldwide and has provided a major step forward in helping patients with UC achieve and maintain clinical remission. I am delighted that we are now able to offer this new treatment option to patients in Japan,” said Naoyoshi Hirota, Head of the Takeda Development Center Japan. “The recent approval of Takeda’s New Drug Application represents a major milestone for Takeda. We aspire to bring better health and a brighter future for

people worldwide through the delivery of innovative and life-changing medicines.”

Entyvio was approved in the European Union and the U.S. in May 2014 for the treatment of adults with moderately to severely active UC or Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF? antagonist. As of May 2018, global post-marketing exposure to Entyvio totals more than 200,000 patient-years