Better Health, Brighter Future

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News Release

Takeda Receives European Commission Marketing Authorisation for Entyvio® (vedolizumab) for the Treatment of Ulcerative Colitis and Crohn's Disease

Zurich, Switzerland, May 27th, 2014 and Osaka, Japan, May 28th, 2014 – Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals International GmbH, today announced that the European Commission (EC) has granted Marketing Authorisation for Entyvio® (vedolizumab), a gut-selective humanized monoclonal antibody, and the first and only biologic therapy to be approved simultaneously for the treatment of adults with moderately to severely active ulcerative colitis (UC) and adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumor necrosis factor-alpha (TNFα) antagonist.[1] UC and CD are the two most common types of inflammatory bowel disease (IBD),[2] affecting more than four million people worldwide,[3,4,5,6,7,8] including approximately 2.2 million in Europe.[5]

"Ulcerative colitis and Crohn's disease are serious conditions which can have a devastating impact on patients, many of whom are in early adulthood when they receive a diagnosis. As physicians, our aim is to help patients achieve and maintain remission and disease control. The approval of vedolizumab in Europe is an important step forward in the treatment of ulcerative colitis and Crohn's disease. It is the first gut-selective, biologic agent for this condition to be approved in Europe and provides us with a new therapeutic option to help us to tackle these challenging diseases," said Paul Rutgeerts, M.D., Ph.D., F.R.C.P, Emeritus Professor of Medicine, Catholic University of Leuven, Belgium.

Vedolizumab is now approved for marketing in the 28 member states of the European Union as well as Norway, Iceland and Liechtenstein.

"In clinical trials, vedolizumab demonstrated statistically significant efficacy on a range of endpoints and was well-tolerated in trials for both UC and CD and we are pleased that the European Commission recognizes its clinical benefit," said Trevor Smith, Head of Commercial Operations, Europe and Canada,

Takeda. “Takeda has a long history of research into gastrointestinal diseases, and we are very excited to be moving into inflammatory bowel disease. We are committed to expanding the range of therapeutic options available for this patient community.”

The Marketing Authorisation Application submission is supported by the GEMINI™ Studies, a clinical program investigating vedolizumab in 2,700 patients across nearly 40 countries. It is the largest Phase 3 clinical trial program conducted to date evaluating both UC and CD patient populations in parallel.[9,10,11] Enrolled patients had failed at least one conventional therapy, including corticosteroids, immunomodulators and/or a tumor necrosis factor-alpha (TNFα) antagonist. TNFα antagonist and conventional therapy failure patients included those with inadequate response (primary non-responders), loss of response (secondary non-responders) or those who were intolerant.[12,13,14]

Vedolizumab is also now approved for marketing in the United States, for the treatment of adult patients with moderately to severely active UC or CD.[15]

This approval does not change the outlook for Takeda's consolidated results for fiscal 2014.

About ulcerative colitis and Crohn’s disease

Ulcerative colitis (UC) and Crohn’s disease (CD) are marked by inflammation in the GI tract.[2] UC impacts the large intestine only, which includes the colon and the rectum. The most common symptoms of UC include abdominal discomfort and blood or pus in diarrhea.[16] CD can impact any part of the digestive tract and common symptoms may include abdominal pain, diarrhea, rectal bleeding, weight loss, and fever.[17] There is no known cause for UC or CD, although many researchers believe that the interaction between genes, the body’s immune system, and environmental factors may play a role.[18] The aim of UC and CD treatments is to induce and maintain remission, or achieve extended periods of time when patients do not experience symptoms.[16,17]

About Entyvio® (vedolizumab)

Vedolizumab, developed for the treatment of UC and CD, is a humanized monoclonal antibody that is designed to specifically antagonize the alpha4beta7 (α4β7) integrin, inhibiting the binding of α4β7 to intestinal mucosal addressin cell adhesion molecule 1 (MAdCAM-1) and fibronectin, but not vascular cell adhesion molecule 1 (VCAM-1).[19] MAdCAM-1 is preferentially expressed on blood vessels and lymph nodes of the gastrointestinal tract.[20] The α4β7 integrin is expressed on a subset of circulating white blood cells.[19] These cells have been shown to play a role in mediating the inflammatory process in UC and CD.[19,21] By inhibiting α4β7, vedolizumab may limit the ability of certain white blood cells to infiltrate gut tissues.[19]

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

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