Press Release

Takeda Receives Positive CHMP Opinion for Entyvio® (vedolizumab) in Europe for the Treatment of Ulcerative Colitis and Crohn's Disease

Osaka, Japan, March 21, 2014 – Takeda Pharmaceutical Company Limited ("Takeda") today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive Opinion for Entyvio® (vedolizumab), a humanized monoclonal antibody, 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 tumour necrosis factor-alpha (TNFα) antagonist.[1,2] UC and CD are the two most common types of inflammatory bowel disease (IBD),[3] affecting more than four million people worldwide,[4,5,6,7,8,9] including approximately 2.2 million Europeans.[6]

"We are very pleased by the positive Opinion issued by the CHMP for vedolizumab for ulcerative colitis and Crohn's disease, as this recognition of the clinical benefit of vedolizumab brings us closer to providing the first gut-selective biologic agent for ulcerative colitis and Crohn's disease to patients across Europe," said Trevor Smith, Head of Commercial Operations, Europe and Canada, Takeda. "Takeda has a rich history of developing treatments for gastrointestinal disorders and has spent many years studying and gaining insight into the complex science of IBD. With the development of vedolizumab, Takeda is building upon this heritage and expanding into innovative therapies with a new biologic treatment."

Takeda submitted a Marketing Authorisation Application (MAA) to the EMA in March 2013 for vedolizumab for the treatment of adults with moderately to severely active UC or CD. The CHMP Opinion for vedolizumab will now be reviewed by the European Commission (EC). If the CHMP recommendation is formally adopted by the EC, vedolizumab would be approved for marketing in the 28 member states of the European Union as well as Norway, Iceland and Liechtenstein.

"People with ulcerative colitis or Crohn's disease are most often diagnosed as young adults and face a lifetime significantly impacted by the debilitating symptoms and complex management of these chronic diseases," said Paul Rutgeerts, M.D., Ph.D., F.R.C.P, Emeritus Professor of Medicine, Catholic University of Leuven, Belgium. "It's critical that research continues to progress and evolve so physicians and patients have additional options available to help manage these diseases."

In addition to the MAA submitted to the EMA, the United States (U.S.) Food and Drug Administration (FDA) is currently reviewing the Biologics License Application (BLA) for vedolizumab.

Vedolizumab received a positive recommendation for the treatment of adults with moderately to severely active UC or CD from a joint panel of members from the Gastrointestinal Drugs and Drug Safety and Risk Management Advisory Committees of the FDA on December 9, 2013.

The MAA 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.[10,11,12] Enrolled patients had failed at least one conventional therapy, including corticosteroids, immunomodulators and/or a tumour 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.[13,14,15]

For further details about the CHMP Opinion, please visit the EMA website www.ema.europa.eu/ema/.

About ulcerative colitis and Crohn's disease

Ulcerative colitis (UC) and Crohn's disease (CD) are marked by inflammation in the GI tract.3 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 lymphocytes 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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