TAKEDA PRESENTS ANALYSES FROM VEDOLIZUMAB DATA IN ULCERATIVE COLITIS AT 2016 DIGESTIVE DISEASE WEEK (DDW) ANNUAL MEETING

OSAKA, JAPAN – Takeda Pharmaceutical Company Limited [TSE: 4502], ("Takeda") announced the oral presentations of two data analyses: one evaluating the optimal position of vedolizumab in the ulcerative colitis (UC) treatment paradigm, and a second separate analysis assessing whether early vedolizumab trough levels were associated with subsequent drug efficacy. Findings were presented during the 2016 Digestive Disease Week (DDW) Annual Meeting in San Diego, California, and were included in a total of 13 Takeda-sponsored vedolizumab or inflammatory bowel disease (IBD)-focused abstracts, including four oral presentations and nine posters.

"The treatment paradigm for ulcerative colitis is evolving, and further investigation into how to integrate various treatment options may be beneficial for physicians," said Karen Lasch, M.D., U.S. medical director, Gastroenterology, Takeda. "We believe vedolizumab is an important treatment for patients with ulcerative colitis and these findings help expand our understanding of its use in the clinical setting."

Vedolizumab is a humanized monoclonal antibody approved in May 2014 in the European Union and the United States under the trade name Entyvio® (vedolizumab). Entyvio is now approved in 49 countries, across five continents. Entyvio is the first and only biologic therapy to be approved simultaneously for the treatment of adults with moderately to severely active UC or CD who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF antagonist.

Vedolizumab oral presentations at DDW 2016 included:

Association of Vedolizumab Drug Concentrations at or Before Week 6 with Remission at Week 14 in Patients with Moderately to Severely Active Ulcerative Colitis from GEMINI 1 (Osterman, Roblin, Glover, et al.); presentation #512

- A post hoc analysis of GEMINI 1 data was completed to assess whether early vedolizumabtrough levels were associated with subsequent drug efficacy for the treatment of adults with moderately to severely active UC. In GEMINI 1, patients received either placebo or vedolizumab at weeks 0 and 2. Vedolizumab-treated patients who achieved clinical response at week 6 were randomized to placebo or vedolizumab every 8 or 4 weeks, in this 52 week study. This post hoc analysis focused on the every 8-week dosing group. Clinical remission was determined at week 14, and vedolizumab trough concentrations were summarized by remission status. Percentages of patients in clinical remission were summarized for patients stratified into quartiles based on their vedolizumab trough levels at week 2, 4, or 6.
- Vedolizumab trough concentrations at week 6 correlated with clinical remission rates at week 14. Patients who achieved clinical remission at week 14 had higher median vedolizumab trough concentrations at weeks 2, 4, and 6 than those not in clinical remission. Further evaluation is needed to help identify if there is an optimal vedolizumab concentration range at an early time point predictive of clinical remission in UC patients.

Determining the Optimal Position for Vedolizumab in the Current Treatment Paradigm for Ulcerative Colitis: A Markov Model (Scott, Shah, Lasch, Luo, Lewis); presentation #511

- A Markov model was constructed to assess where in the current treatment paradigm vedolizumab use would yield the greatest benefit when measured in clinical outcomes and quality adjusted life years (QALYs).
- This model suggested that incorporating vedolizumab early in the treatment paradigm may result in the greatest potential benefit for individuals with moderate to severe UC who require steroid-sparing therapy.

About Ulcerative Colitis and Crohn's disease

Ulcerative colitis (UC) and Crohn's disease (CD) are marked by inflammation in the GI tract. 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. CD can impact any part of the digestive tract and common symptoms may include abdominal pain, diarrhea, rectal bleeding, weight loss, and fever. 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 play a role. 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.

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