Zurich, Switzerland, May 19, 2015 – Takeda Pharmaceuticals International GmbH (“Takeda”) today announced that data highlighting the efficacy and safety of vedolizumab for the treatment of adults with moderately to severely active ulcerative colitis (UC) and Crohn’s disease (CD) were presented at the 2015 Digestive Disease Week (DDW) Annual Meeting in Washington, D.C. Twelve Takeda-sponsored presentations, including one oral presentation, were featured during the meeting May 16-19, 2015. The presentations included data from the Phase 3 pivotal studies GEMINI 1 (UC) and GEMINI 2 (CD), as well as interim data from the ongoing, open-label extension study GEMINI LTS (long-term safety).1,2,3,4,5,6,7,8,9,10,11,12

“Continued research and investigation is critical to the successful management of ulcerative colitis and Crohn’s disease, two chronic diseases that can oftentimes be complex for physicians to treat,” said Dr. Jean-Frederic Colombel, MD, Director of the Mount Sinai Inflammatory Bowel Disease Center. “The set of data presented at DDW supports the potential of vedolizumab in serving the unmet needs of the patient population, while adding to the important scientific exchange surrounding inflammatory bowel disease.”

The GEMINI 1 and 2 studies are two randomized double-blind, placebo-controlled studies examining the efficacy and safety of vedolizumab for induction and maintenance in adult patients with moderately to severely active UC and CD, respectively.13 GEMINI LTS is a Phase 3, ongoing, open-label extension study examining the long-term safety and efficacy of vedolizumab for the treatment of adults with moderately to severely active UC and CD.5
Findings from an analysis of cost per clinical outcome for the treatment of moderately to severely active UC with biologic therapy were highlighted during an oral presentation on Saturday, May 16, 2015, as part of a larger session titled “Bending the Cost Curve in Gastroenterology”:

- Abstract #2160225: Cost per clinical outcomes with biologics for the treatment of moderately to severely active ulcerative colitis (Jansen, Mody, Patel, et al)\(^{10}\)

In addition, the following Takeda-sponsored abstracts highlighting safety, efficacy, and cost-effectiveness information for vedolizumab were also presented as poster sessions on Saturday, May 16, 2015:

- Abstract #2164226: Efficacy of vedolizumab with concomitant corticosteroid or immunomodulator use in patients with ulcerative colitis from GEMINI 1 (Colombel, Loftus, Siegel, et al)\(^{3}\)
- Abstract #2164076: Efficacy of vedolizumab with concomitant corticosteroid or immunomodulator use in patients with Crohn’s disease from GEMINI 2 (Colombel, Loftus, Siegel, et al)\(^{4}\)
- Abstract #2166427: Efficacy and safety of vedolizumab with advancing age in patients with ulcerative colitis: Results from the GEMINI 1 study (Yajnik, Khan, Dubinsky, et al)\(^{8}\)
- Abstract #2164450: Efficacy and safety of retreatment with vedolizumab in patients with ulcerative colitis (Sands, Shafran, Farraye, et al)\(^{5}\)
- Abstract #2164356: Efficacy and safety of retreatment with vedolizumab in patients with Crohn’s disease (Sands, Shafran, Farraye, et al)\(^{6}\)
- Abstract #2167413: Vedolizumab for the Treatment of Fistulizing Crohn’s Disease: An Exploratory Analysis of Data From GEMINI 2 (Feagan, Schwartz, Danese, et al)\(^{7}\)
- Abstract #2167535: Deep remission as a predictor of clinical outcomes in vedolizumab-treated patients with ulcerative colitis (Sandborn, Colombel, Panaccione, et al)\(^{9}\)
- Abstract #2157221: Comparative efficacy of biologics in the treatment of moderately to severely active ulcerative colitis (UC): A systematic review and network meta-analysis (Vickers, Mody, Bergman, et al)\(^{12}\)
- Abstract #2163857: Infusion-related reactions with vedolizumab treatment in patients with UC or CD during the GEMINI 1 and GEMINI 2 clinical trials (Sands, Cohen, Isaacs, et al)\(^{2}\)
- Abstract #2166626: Cost-effectiveness of vedolizumab compared with conventional therapy and biologics for treatment of moderately to severely active ulcerative colitis in the United States (Wilson, Mody, Ursan, et al)\(^{11}\)
The following Takeda-sponsored abstract was also presented as a poster session on Tuesday, May 19, 2015:

- Abstract # 2163900: Effect of vedolizumab on health-related quality of life in patients with Crohn’s disease (Sandborn, Reinisch, Loftus, et al)¹

“At Takeda, we are committed to the patient first and foremost, working to provide support for those living with ulcerative colitis and Crohn’s disease,” said Dr. Michael Smyth, Global Brand Medical Director, General Medicine, Takeda Pharmaceuticals. “As a global company, we are pleased to highlight vedolizumab as an effective and well tolerated treatment option at the world’s largest digestive health conference. These presentations further demonstrate our dedication to the research and development of innovative medicines for communities in need.”

Vedolizumab is a gut-selective humanized monoclonal antibody available in the European Union, under the trade name Entyvio® (vedolizumab). Entyvio is also available in the United States (U.S.). It is the first and only biologic therapy to be approved in the European Union, as well as in the U.S., 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 tumor necrosis factor-alpha antagonist.¹³

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.¹⁴ CD can impact any part of the digestive tract and common symptoms may include abdominal pain, diarrhea, rectal bleeding, weight loss, and fever.¹⁵ 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.¹⁶ 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.¹⁴,¹⁵

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 integrin, inhibiting the binding of alpha4beta7 to intestinal mucosal addressin cell adhesion molecule 1 (MAdCAM-1) and fibronectin, but not vascular cell adhesion molecule 1 (VCAM-1).¹⁷ MAdCAM-1 is preferentially expressed on blood vessels and lymph
nodes of the gastrointestinal tract.\textsuperscript{18} The alpha4beta7 integrin is expressed on a subset of circulating white blood cells.\textsuperscript{17} These cells have been shown to play a role in mediating the inflammatory process in UC and CD.\textsuperscript{17,19} By inhibiting alpha4beta7, vedolizumab may limit the ability of certain white blood cells to infiltrate gut tissues.\textsuperscript{17}

Refer to Summary of Product Characteristics (SmPC) before prescribing.

**About Takeda Pharmaceuticals International GmbH**

Headquartered in Zurich as a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, Osaka, Japan, the Company has a commercial presence covering more than 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China. Areas of focus include cardiovascular and metabolic, oncology, respiratory and immunology, central nervous system, general medicine, and vaccines.

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. Through the integration of Millennium Pharmaceuticals and Nycomed, Takeda has been transforming itself, broadening its therapeutic expertise and geographic outreach.

Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

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