Better Health, Brighter Future

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News Release

ENTYVIO™ (vedolizumab) Now Available in the United States for the Treatment of Adults with Moderately to Severely Active Ulcerative Colitis and Crohn's Disease

Deerfield, Ill., June 16th, 2014, and Osaka, Japan, June 17th, 2014 – Takeda Pharmaceutical Company Limited ("Takeda") and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc., today announced the United States (U.S.) commercial availability of a new biologic therapy, ENTYVIO™ (vedolizumab), for the treatment of adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD).[i]

"We understand how a great need still exists for additional treatment options for ulcerative colitis and Crohn's disease patients," said Nicole Mowad-Nassar, vice president, marketing, Takeda Pharmaceuticals, U.S.A., Inc. "We're pleased that we were able to make Entyvio available for appropriate patients so quickly after receiving FDA approval."

In May, the U.S. Food and Drug Administration (FDA) simultaneously approved Entyvio for the treatment of adults with moderately to severely active UC and CD. That same month, Entyvio was also granted Marketing Authorisation in the European Union from the European Commission (EC) for the treatment of adults with moderately to severely active UC and CD.i[ii]

Entyvio is now available to U.S. healthcare providers for inducing and maintaining clinical response and remission, improving endoscopic appearance of the mucosa, and achieving corticosteroid-free remission in adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids. Entyvio is also indicated for achieving clinical response and remission, and achieving corticosteroid-free remission in adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.i

In order to connect patients in need with access and services for Entyvio, Takeda has launched EntyvioConnect, with dedicated case managers available to answer questions. For more information, visit www.ENTYVIO.com/hub/.

About ENTYVIO® (vedolizumab)

Entyvio, an integrin receptor antagonist, is a humanized monoclonal antibody that specifically binds to the alpha4beta7 integrin and blocks the interaction of alpha4beta7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. Entyvio does not bind to or inhibit function of the alpha4beta1 and alpha E beta 7 integrins and does not antagonize the interaction of alpha4 integrins with vascular cell adhesion molecule-1 (VCAM-1). The alpha4beta7 integrin is expressed on the surface of a discrete subset of memory T-lymphocytes that preferentially migrate into the gastrointestinal tract. MAdCAM-1 is mainly expressed on gut endothelial cells and plays a critical role in the homing of T-lymphocytes to gut lymph tissue. The interaction of the alpha4beta7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis and Crohn's disease.[i]

INDICATIONS: ENTYVIO® (vedolizumab)

Adult Ulcerative Colitis (UC)

Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- inducing and maintaining clinical response
- inducing and maintaining clinical remission
- improving endoscopic appearance of the mucosa
- achieving corticosteroid-free remission

Adult Crohn's Disease (CD)

Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- achieving clinical response
- achieving clinical remission
- achieving corticosteroid-free remission

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

- Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections.

- Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.

- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

- Most common adverse reactions (incidence greater than or equal to 3% and greater than or equal to 1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please see the accompanying full Prescribing Information including Medication Guide for ENTYVIO.

More information is also available at www.ENTYVIO.com and www.ENTYVIOHCP.com.

About Ulcerative Colitis and Crohn's Disease

Ulcerative colitis (UC) and Crohn's disease (CD) are marked by inflammation in the lining of the gastrointestinal tract.[iii] UC impacts the large intestine only, which includes the colon and the rectum, while CD can impact any part of the digestive tract, and predominantly affects the ileum.[iv,v] There is no known cause for UC and CD, although many researchers believe that the interaction between genes, the body's immune system, and environmental factors may play a role.[vi]

About Takeda Pharmaceuticals U.S.A., Inc.

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.

The company has a commercial presence covering around 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China. Takeda is ranked 15th globally. Areas of focus include cardiovascular and metabolic, oncology, respiratory and immunology, central nervous system, general medicine, and vaccines.

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

Takeda Pharmaceuticals U.S.A., Inc. is located in Deerfield, Ill., and is the U.S. marketing and sales organization of Takeda Pharmaceutical Company Limited.

Additional information about Takeda is available through its corporate website, www.takeda.com**, and additional information about Takeda Pharmaceuticals U.S.A., Inc. is available through its website,** www.takeda.us**.**

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.

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking

words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

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[i] ENTYVIO Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.

[ii] Entyvio Summary of Product Characteristics. May 2014.

[iii] Knigge KL. Inflammatory bowel disease. *Clin Cornerstone*. 2002;4(4):49-60.

[iv] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, National Digestive Diseases Information Clearinghouse. Ulcerative colitis. http://digestive.niddk.nih.gov/ddiseases/pubs/colitis/index.aspx. Published October 2011. Accessed March 1, 2013

[v] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, National Digestive Diseases Information Clearinghouse. Crohn's disease. http://digestive.niddk.nih.gov/ddiseases/pubs/crohns/index.aspx. Published December 2011. Accessed March 1, 2013.

[vi] Crohn's and Colitis Foundation of America. The facts about inflammatory bowel diseases. http://www.ccfa.org/assets/pdfs/ibdfactbook.pdf. Published June, 2011. Accessed January 4, 2013.