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News Release

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NEW PHASE 3 STUDY FINDINGS SHOW STELARA® MAINTAINED CLINICAL REMISSION AFTER ONE YEAR OF TREATMENT IN PATIENTS WITH MODERATE TO SEVERE CROHN'S DISEASE

Approximately 50 Percent of STELARA®-treated Patients Achieved Clinical Remission According to Pivotal Phase 3 IM-UNITI Study Results Presented for the First Time at Digestive Disease Week® 2016

SAN DIEGO, May 23, 2016 — Janssen Research & Development, LLC (Janssen) Phase 3 data presented for the first time at Digestive Disease Week® 2016 showed that a significantly greater proportion of adult patients with moderate to severe Crohn's disease receiving STELARA® (ustekinumab) subcutaneous (SC) maintenance therapy were in clinical remission at one year. The Phase 3 IM-UNITI maintenance study, which evaluated 388 patients who achieved clinical response eight weeks after a single intravenous infusion of ustekinumab in the UNITI-1 and UNITI-2 Phase 3 induction studies, showed that 53 percent of patients receiving a ustekinumab 90 mg SC injection every eight weeks (Q8W) and 49 percent of patients receiving a ustekinumab 90 mg SC injection every 12 weeks (Q12W) were in clinical remission at week 44, the study's primary endpoint, compared with 36 percent of patients receiving placebo ($P = 0.005$ and $P = 0.040$, respectively).[1] Clinical remission was defined by a Crohn's Disease Activity Index (CDAI) score of less than 150 points; CDAI is a symptom-based disease assessment tool commonly used in clinical trials to quantify Crohn's disease activity.[1]

Applications seeking approval of ustekinumab for the treatment of moderately to severely active Crohn's disease are currently under review in the United States and Europe. Ustekinumab, approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in many countries, is a novel biologic therapy that targets interleukin (IL)-12 and IL-23 cytokines, which are believed to play a role in immune-mediated diseases, including Crohn's disease.[2]

"The totality of the induction and maintenance data over the course of one year show the potential of this biologic therapy in inducing and maintaining a clinically relevant therapeutic effect in patients with moderate to severe Crohn's disease," said William Sandborn, M.D., Chief, Division of Gastroenterology, and Professor of Medicine, University of California, San Diego, and study investigator. "The results of this comprehensive Phase 3 programme—which included anti-tumor necrosis factor (TNF)-alpha naïve, exposed and failure patients—demonstrate the potential of ustekinumab to provide significant benefit for patients in need of an effective therapy."

The IM-UNITI maintenance study represents the third pivotal study in the year-long, comprehensive Phase 3 clinical development programme investigating ustekinumab for the treatment of moderate to severe Crohn's disease. The

findings, presented as part of the Distinguished Abstract Plenary at Digestive Disease Week 2016, follow Phase 3 results from the UNITI-1 induction study, which demonstrated the efficacy and safety of ustekinumab in patients who had previously failed or were intolerant to treatment with one or more anti-TNF-alpha therapies (anti-TNF failure population),[3] and the Phase 3 UNITI-2 induction study, which demonstrated the efficacy and safety of ustekinumab in patients who had previously failed conventional therapy, the majority of whom were naïve to treatment with anti-TNF-alpha therapy.[4] Patients responding to a single intravenous dose of ustekinumab in the induction studies were re-randomised in the IM-UNITI maintenance study to receive ustekinumab 90 mg SC Q8W, ustekinumab 90 mg SC Q12W or placebo (withdrawal from therapy) and were followed for a combined one year of treatment.[1] All patients randomised in the IM-UNITI maintenance study had achieved clinical response to ustekinumab at week 8,[1] and approximately 60 percent of patients were in clinical remission at entry into the IM-UNITI study.[4]

Major secondary endpoints of the IM-UNITI study included clinical response, clinical remission among patients in remission after induction, corticosteroid-free remission, and clinical remission in patients refractory or intolerant to anti-TNF-alpha therapies (UNITI-1 subpopulation), all at week 44.[1]

- Clinical response (an improvement in a CDAI score of at least 100 points after ustekinumab induction) was maintained in a significantly greater proportion of patients receiving ustekinumab 90 mg SC Q8W (59 percent) and ustekinumab 90 mg SC Q12W (58 percent) compared with patients receiving placebo (44 percent) (P = 0.018 and P = 0.033, respectively)[1]
- Of those patients who were in clinical remission at the start of the IM-UNITI study, 67 percent receiving ustekinumab 90 mg SC Q8W and 56 percent of patients receiving ustekinumab 90 mg SC Q12W were in clinical remission at week 44 compared with 46 percent of patients receiving placebo (P < 0.01; P = not significant, respectively)[1]
- A significantly higher percentage of patients receiving ustekinumab 90 mg SC Q8W (47 percent) and a higher percentage of patients receiving ustekinumab 90 mg SC Q12W (43 percent) who were not receiving concomitant corticosteroids were in clinical remission at week 44 compared with 30 percent of patients receiving placebo (P = 0.004*; nominal* P = 0.035, respectively)[1]
- Numerically higher proportions within the subgroup of patients who had previously failed or were intolerant to treatment with one or more anti-TNF-alpha therapies (UNITI-1 subpopulation) achieved clinical remission while receiving ustekinumab maintenance therapy at week 44, with similar treatment effects to the overall population, (41 percent for ustekinumab 90 mg SC Q8W and 39 percent for ustekinumab 90 mg SC Q12W) compared with 26 percent of patients receiving placebo (P = not significant for both)[1]

Through week 44 (placebo-controlled period), adverse events (AEs) were reported in similar proportions across ustekinumab and placebo treatment groups. Serious AEs occurred in 10 percent, 12 percent and 15 percent of patients receiving a ustekinumab 90 mg SC Q8W, ustekinumab 90 mg SC Q12W and placebo, respectively; 2 percent, 5 percent and 2 percent of patients reported serious infections in these respective groups. In the placebo controlled period, no deaths or major adverse cardiovascular events (MACE) were reported, and two patients reported malignancies (one case of basal cell carcinoma in each of the placebo and ustekinumab 90 mg SC Q8W groups).[1]

“These maintenance data complement the induction data previously presented and provide important insights into the efficacy and safety profile of ustekinumab for the treatment of moderately to severely active Crohn’s disease,” said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “Pending approval, we look forward to bringing ustekinumab to patients who may benefit from this new therapeutic option and providing gastroenterologists with a new alternative to treat Crohn’s disease.”

About the IM-UNITI Trial[1]

IM-UNITI, a Phase 3, multicentre, randomised, double-blind, placebo-controlled, parallel group study, evaluated the efficacy and safety of ustekinumab maintenance therapy in adult patients with moderate to severe Crohn's disease. Patients (n=388) who had responded to a single intravenous dose of ustekinumab in the UNITI-1 or UNITI-2 induction studies were randomised equally to receive maintenance SC injections of ustekinumab 90 mg SC Q8W or Q12W, or placebo. Together, the UNITI-1 and UNITI-2 induction studies and the IM-UNITI maintenance study represent one year of

therapy. The primary endpoint was clinical remission at week 44, defined by CDAI scores less than 150 points. Major secondary endpoints at week 44 included clinical response, measured by the proportion of patients who achieved at least a 100-point reduction from baseline CDAI scores, corticosteroid-free clinical remission, clinical remission among patients in remission at the start of the IM-UNITI study, and clinical remission in the subgroup of patients refractory or intolerant to treatment with one or more anti-TNF-alpha therapies.

About Crohn's Disease

More than five million people worldwide are living with Crohn's disease and ulcerative colitis—collectively known as inflammatory bowel disease (IBD).[5] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects nearly 250,000 Europeans.[6] The cause of Crohn's disease is not known, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition or diet and other environmental factors. Symptoms of Crohn's disease can vary but often include abdominal pain and tenderness, frequent diarrhoea, rectal bleeding, weight loss and fever. There is currently no cure for Crohn's disease.[7]

About ustekinumab[8]

Ustekinumab, a human IL-12 and IL-23 antagonist, is approved in the European Union for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen plus ultraviolet A (PUVA). Ustekinumab is also indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies. In addition, ustekinumab is approved alone or in combination with MTX for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to ustekinumab, which is currently approved for the treatment of moderate to severe plaque psoriasis in 87 countries and psoriatic arthritis in 71 countries.

Important Safety Information (EU)[8]

Special Warnings & Precautions

Infections: Potential to increase risk of infections and reactivate latent infections. Exercise caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis and treated for latent TB prior to initiation of ustekinumab. Also, consider anti-tuberculosis therapy prior to initiation of ustekinumab in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, they should be closely monitored and ustekinumab should not be administered until infection resolves.

Malignancies: Potential to increase the risk of malignancy. No studies have been conducted in patients with a history of malignancy or in those who continue to receive ustekinumab after being diagnosed with a malignancy. Exercise caution when considering ustekinumab in these patients. Monitoring for the appearance of non-melanoma skin cancer recommended, in particular for patients greater than 60 years of age, or with a medical history of prolonged immunosuppressant therapy or a history of PUVA treatment.

Hypersensitivity reactions: Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur, institute appropriate therapy and discontinue use of ustekinumab.

Vaccinations: Patients receiving ustekinumab should not receive concurrent live viral or live bacterial vaccines such as BCG. Before live viral or live bacterial vaccination, treatment with ustekinumab should be withheld for at least 15 weeks

after the last dose and can be resumed at least 2 weeks after vaccination. Patients receiving ustekinumab may receive concurrent inactivated or non-live vaccinations.

Concomitant immunosuppressive therapy: Exercise caution, including when changing immunosuppressive biologic agents. In psoriasis studies, the safety and efficacy of ustekinumab in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of ustekinumab.

Immunotherapy: Not known whether ustekinumab affects allergy immunotherapy.

Serious skin conditions: In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. If these symptoms occur, appropriate therapy should be instituted. Ustekinumab should be discontinued if a drug reaction is suspected.

Latex sensitivity: Needle cover contains natural rubber (latex), may cause allergic reactions.

Elderly Patients > 65years: Use caution when treating elderly patients.

For complete European Union (EU) prescribing information, please visit:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000958/human_med_001065.jsp&mid=WC0b01ac058001d124

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care.

Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. For more information on Janssen in Europe, Middle East and Africa, please visit www.janssen.com/EMEA for more information. Follow us on Twitter @JanssenEMEA**.**

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 21-24, 2016, at the San Diego Convention Center, San Diego, CA. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining

regulatory approvals; uncertainty of commercial success for products; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

European Federation of Pharmaceutical Industries and Associations. Inflammatory Bowel Disease. Available at http://www.efpia.eu/diseases/78/59/Inflammatory-Bowel-Disease. Accessed May 10, 2016

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