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STELARA® INDUCED CLINICAL RESPONSE AND REMISSION IN PHASE 3 STUDY FOR THE TREATMENT OF PATIENTS WITH MODERATE TO SEVERE CROHN'S DISEASE WHO HAD PREVIOUSLY FAILED OR WERE INTOLERANT TO ANTI-TNF-ALPHA THERAPY

Efficacy and Safety Results from Second STELARA® Phase 3 Induction Study (UNITI-1) in Patients Refractory to TNF Inhibitors, Presented at the 11th Congress of ECCO

Amsterdam, March 18, 2016 — Phase 3 data presented at the 11th Congress of the European Crohn's and Colitis Organisation (ECCO) showed that treatment with STELARA® (ustekinumab) induced clinical response and clinical remission in adult patients with moderate to severe Crohn's disease who had previously failed or were intolerant to one or more anti-tumour necrosis factor (TNF)-alpha therapies (anti-TNF failure population). The Janssen Phase 3 UNITI-1 study, which included 741 people with Crohn's disease, achieved its primary endpoint with ustekinumab treatment groups demonstrating significantly higher rates of clinical response at week 6 when compared with the placebo group (p=0.003, p=0.002, respectively).[1] Major secondary endpoints of clinical response at week 8 ($p \leq 0.001$) and clinical remission at week 8 ($p<0.001$, p=0.003, respectively) were also significantly higher among patients receiving ustekinumab compared with patients receiving placebo.[1]

These latest findings follow Phase 3 results from the UNITI-2 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.[2] Regulatory applications seeking approval of ustekinumab for the treatment of moderately to severely active Crohn's disease are currently under review in Europe and the United States. Ustekinumab, which is approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in many countries, is a monoclonal antibody that targets interleukin (IL)-12 and IL-23 cytokines, which are believed to play a role in immune-mediated diseases, including Crohn's disease.[3]

"Results from the UNITI-1 study show that ustekinumab therapy induced clinical response and remission in patients with moderate to severe Crohn's disease who had previously failed treatment with TNF inhibitors," said Professor Paul Rutgeerts, Professor Emeritus of Medicine and Former Director of the Multidisciplinary Department of Endoscopy, Catholic University of Leuven, Belgium, and ustekinumab Crohn's disease steering committee member. "With two Phase 3 induction studies demonstrating the efficacy and safety of ustekinumab in anti-TNF-alpha naïve, exposed and failure patient populations, we look forward to the forthcoming maintenance study findings. The need to induce and maintain control of disease symptoms is paramount in the treatment of Crohn's disease."

Patients participating in the Phase 3 UNITI-1 study received a single intravenous (IV) infusion of placebo, ustekinumab 130 mg or ustekinumab ~6 mg/kg (weight-tiered dosing: patients weighing less than or equal to 55 kg received 260 mg; patients weighing more than 55 kg and less than or equal to 85 kg received 390 mg; and patients weighing more than 85 kg received 520 mg) at week 0. All enrolled patients had previously failed or were intolerant to treatment with at least one anti-TNF-alpha therapy, and half of the enrolled patients had failed two or more anti-TNF-alpha therapies.[1]

At week 6, 34 percent of patients receiving ustekinumab 130 mg and 34 percent of patients receiving ustekinumab ~6 mg/kg achieved clinical response, as defined by a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of at least 100 points, compared with 22 percent of patients receiving placebo ($P = 0.002$ for ustekinumab 130 mg; $P = 0.003$ for ustekinumab ~6 mg/kg).[1] CDAI is a symptom-based disease assessment tool commonly used in clinical trials to quantify Crohn's disease activity.

At week 8, 34 percent and 38 percent of patients receiving ustekinumab 130 mg and ustekinumab ~6 mg/kg, respectively, achieved clinical response, compared with 20 percent of patients receiving placebo ($P \leq 0.001$). In addition, 16 percent of patients receiving ustekinumab 130 mg and 21 percent of patients receiving ustekinumab ~6 mg/kg achieved clinical remission at week 8, as defined by a CDAI score of less than 150 points, compared with 7 percent of patients receiving placebo ($P = 0.003$ for ustekinumab 130 mg; $P < 0.001$ for ustekinumab ~6 mg/kg).[1]

In addition to significant improvements in signs and symptoms as measured by CDAI, both doses of ustekinumab resulted in significant improvements in the Inflammatory Bowel Disease Questionnaire (IBDQ), a health-related quality of life measure for patients with IBD, as well as significant reduction in markers of inflammation, including faecal lactoferrin, calprotectin and C-reactive protein (CRP) ($P < 0.001$ for ustekinumab ~6 mg/kg; $P = 0.012$ for ustekinumab 130 mg).[4]

Through week 8 (placebo-controlled period), adverse events (AEs), serious AEs and infections were reported in similar proportions across ustekinumab and placebo treatment groups. One case of Listeria meningitis infection was reported in the ustekinumab ~6 mg/kg group. No malignancies, deaths, cases of tuberculosis or major adverse cardiovascular events (MACE) were observed in patients treated with ustekinumab.[1]

"We are pleased to share these important results from the Phase 3 UNITI-1 induction study, which complement Phase 3 results from the UNITI-2 study and further support regulatory applications submitted seeking approval 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. "Janssen Immunology remains committed to the continued development of ustekinumab and the discovery of innovative medicines for the treatment of immune-mediated diseases."

About the UNITI-1 Trial

UNITI-1, a Phase 3, multicentre, randomised, double-blind, placebo-controlled, parallel group study, evaluated the efficacy and safety of ustekinumab induction therapy in adult patients with moderate to severe Crohn's disease. Patients (n=741) were randomised equally to receive a single IV infusion of placebo, ustekinumab 130 mg or ustekinumab ~6 mg/kg (weight-tiered dosing: patients weighing less than or equal to 55 kg received 260 mg; patients weighing more than 55 kg and less than or equal to 85 kg received 390 mg; and patients weighing more than 85 kg received 520 mg) at week 0. All participating patients had previously failed or were intolerant to treatment with at least one anti-TNF-alpha therapy. The primary endpoint was clinical response at week 6, measured by the proportion of patients who achieved at least a 100-point reduction from baseline CDAI scores. Major secondary endpoints at week 8 included clinical response and clinical remission (defined by CDAI scores less than 150 points). At week 8, patients either transitioned to the IM-UNITI maintenance study or were to complete a safety follow-up period through week 20.[1]

UNITI-1 is part of a comprehensive Phase 3 clinical development program investigating ustekinumab for the treatment of moderate to severe Crohn's disease.

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 people in Europe.[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, 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**.**

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 materialise, 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 and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; 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 December 28, 2014, 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. The Janssen Pharmaceutical Companies of Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

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