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NEW PHASE 3 STELARA® (USTEKINUMAB) DATA SHOW POSITIVE RESULTS AS MAINTENANCE THERAPY IN ADULTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

44-week UNIFI data presented for the first time during plenary session at 14th Congress of the European Crohn's and Colitis Organisation (Abstract OP37)

New data evaluating STELARA® (ustekinumab) therapy on endoscopic and histologic healing featured as digital oral presentation (Abstract DOP71)

COPENHAGEN, DENMARK, 11th March, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 3 UNIFI maintenance study. The data showed that a significantly greater proportion of adults with moderate to severe ulcerative colitis (UC) receiving ustekinumab subcutaneous (SC) maintenance therapy were in clinical remission* at Week 44, compared to patients receiving placebo – the study's primary endpoint.[1]

*Remission was defined as a Mayo score ≤2 points, with no individual sub-score >1. The Mayo score is designed to measure the severity of UC, giving a score from 0–12 points; a higher score indicates more severe disease activity

Patients receiving ustekinumab SC maintenance therapy had a clinical response 8 weeks after receiving a single intravenous (IV) dose of ustekinumab.[1]

These data were presented as part of a plenary session (Abstract OP37) at the 14th Congress of the European Crohn's and Colitis Organisation (ECCO) in Copenhagen, Denmark. At the Congress, Janssen also shared a digital oral presentation with additional data from the UNIFI induction study evaluating the effects of ustekinumab on histo-endoscopic mucosal healing (HEMH), a novel, pre-specified endpoint in this programme.

Results from the maintenance phase of the Phase 3 study demonstrated that 44 percent (90 mg every 8 weeks [q8w]) and 38 percent (90 mg every 12 weeks [q12w]) of patients with moderate to severe UC receiving ustekinumab SC injections achieved clinical remission, as defined by the Mayo score, at week 44 (52 weeks after IV induction) compared to 24 percent of patients who received placebo ($p<0.001$ and $p=0.002$, respectively).[1] These data were included in submissions to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) seeking approval of ustekinumab as a treatment for UC.

"Ulcerative colitis is a disruptive, lifelong and potentially debilitating inflammatory bowel disease; however, it is a condition where remission is possible," said lead study investigator William Sandborn, MD, Chief, Division of Gastroenterology and Professor of Medicine, University of California, San Diego. "The data suggest the potential of ustekinumab as an effective therapy for helping people living with ulcerative colitis achieve remission, as well as providing other meaningful outcomes, including clinical response, histo-endoscopic improvement and corticosteroid-free remission."

Major secondary endpoints, including maintenance of clinical response, endoscopic improvement, corticosteroid-free remission and maintenance of clinical remission from baseline, were also achieved in greater proportions of patients receiving ustekinumab q8w and q12w injections versus patients receiving placebo. At week 44:

- 71 percent of patients receiving ustekinumab q8w and 68 percent of patients receiving ustekinumab q12w maintained clinical response, compared with 44 percent of patients receiving placebo (both $p<0.001$).[1] Clinical response was defined as a decrease from

baseline in the Mayo score by ≥30 percent and ≥3 points, with a rectal bleeding sub-score of 0 or 1 or a decrease in the rectal bleeding sub-score ≥1

- 51 percent of patients receiving ustekinumab q8w and 44 percent of patients receiving ustekinumab q12w achieved endoscopic improvement, compared with 29 percent of patients receiving placebo ($p<0.001$ and $p=0.002$, respectively).[1] Endoscopic improvement was defined as a Mayo endoscopy sub-score of 0 (normal mucosa or inactive disease) or 1 (mild disease activity)
- 42 percent of patients receiving ustekinumab q8w and 38 percent of patients receiving ustekinumab q12w were in clinical remission and were corticosteroid-free, compared with 23 percent of patients receiving placebo ($p<0.001$ and $p=0.002$, respectively).[1] The global remission definition was a Mayo score ≤2 points, with no individual sub-score >1

Through to week 44, the proportions of patients with adverse events (AEs), serious AEs, infections and serious infections in the ustekinumab groups were generally comparable to the placebo group. The proportions of patients who discontinued the study agent were lower with ustekinumab q8w and q12w versus placebo. Among the primary population in the maintenance study, no deaths occurred. Two malignancies other than non-melanoma skin cancer (NMSC) (one colon cancer, q8w; one papillary renal cell carcinoma, q12w) were reported. One patient reported NMSC (two squamous cell carcinoma events, q12w).[1] Overall, the safety for ustekinumab in UC patients was consistent with the known safety profile of ustekinumab in Crohn's disease (CD).[2]

"The UNIFI maintenance data further build the case for ustekinumab as a potential new treatment option for ulcerative colitis and illustrate our ongoing commitment to researching and developing meaningful therapies for people living with inflammatory bowel diseases," said Scott E. Plevy, M.D., Gastroenterology Disease Area and IL-23 Pathway Leader, Janssen Research & Development, LLC†. "Furthermore, we are proud that UNIFI is the first Phase 3 study to report a combined histo-endoscopic endpoint in patients with ulcerative colitis."

In the abstract (DOP71) presenting the induction study colonic mucosal healing results, patients achieved higher rates of endoscopic improvement, histologic improvement and the combined endpoint of histo-endoscopic mucosal healing (HEMH), versus placebo, 8 weeks after receiving a single IV induction dose of ustekinumab.[3] Histo-endoscopic mucosal healing assesses how the

colon is responding both histologically and endoscopically to therapy and both have been associated with improved long-term clinical outcomes, such as reduced risk of relapse and need for surgery/hospitalisation, and reduced risk of developing cancer.[4]

#ENDS#

About the UNIFI trial

UNIFI is a Phase 3 protocol, designed to evaluate the safety and efficacy of ustekinumab induction and maintenance dosing for the treatment of moderate to severe UC in adults who demonstrated an inadequate response to, or were unable to tolerate, conventional (i.e., corticosteroids, immunomodulators) or biologic (i.e., one or more TNF blockers and/or vedolizumab) therapies. Both the induction and maintenance studies are randomised, double-blind, placebo-controlled, parallel group, multicentre studies. The induction study was conducted over a duration of at least 8 weeks for each participant. Participants achieving clinical response in the induction study were eligible for the maintenance study. The maintenance study was 44 weeks in duration. The primary endpoint of the induction study was clinical remission at week 8, and the primary endpoint for the maintenance study was clinical remission at week 44 among responders to a single IV ustekinumab infusion. After completion of the maintenance study, a long-term extension study will follow eligible participants for an additional three years.

About ulcerative colitis

Ulcerative colitis affects up to 2.6 million people in Europe.[5] It is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucous. Ulcerative colitis is the result of an abnormal response by the body's immune system. Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[6]

About STELARA® (ustekinumab)[2]

In the European Union, ustekinumab is approved 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, and is also indicated for the treatment of moderate to severe plaque psoriasis in adolescent

patients aged 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 therapy has been inadequate. In November 2016, the European Commission approved ustekinumab for the treatment of adult patients with moderate to severe CD who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha antagonist or have medical contraindications to such therapies.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to ustekinumab. In December 2018, a Group Type II Variation Application to the EMA was submitted, which seeks approval of ustekinumab for the treatment of adults with moderate to severe UC.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/EMEA. Follow us on Twitter: @JanssenEMEA. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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