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STELARA® (USTEKINUMAB) DATA DEMONSTRATE LONG-TERM EFFICACY AND SAFETY RESULTS IN ADULTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS IN PHASE 3 EXTENSION TRIAL

Two-year UNIFI data presented for the first time as a late breaking oral presentation at United European Gastroenterology Week (UEGW) congress

BARCELONA, SPAIN, 21 October, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new two-year data from the long-term extension of the Phase 3 UNIFI study, demonstrating the efficacy and safety of ustekinumab through two years of treatment in adults with moderately to severely active ulcerative colitis (UC). These data are being presented today as a late-breaking data presentation (LB01) at the 27th UEGW congress.[1]

These data include 399 participants who were in clinical response eight weeks after receiving a single intravenous (IV) induction dose of ustekinumab and who were then randomised to receive ustekinumab subcutaneous (SC) 90 mg injections every 12 weeks (q12w), ustekinumab SC 90 mg injections every 8 weeks (q8w), or placebo, and who were treated in the long-term extension.[1]

Results showed that the majority of patients were able to sustain remission through to week 92 as assessed by symptomatic remission. The percentage of patients receiving ustekinumab SC who were in symptomatic remission between weeks 44 and 92 ranged from 83 to 90 percent.[1] Among patients who had achieved clinical remission at maintenance baseline, 69 percent of patients receiving ustekinumab q8w and 80 percent of patients receiving ustekinumab q12w maintained symptomatic remission at both weeks 44 and 92. Additional analyses demonstrated that approximately 60 percent of patients receiving ustekinumab q8w and q12w achieved corticosteroid-free symptomatic remission at week 92 (64.3 percent and 63.8 percent, respectively).[1]

"*Ulcerative colitis is a life-long and debilitating inflammatory bowel disease, interrupting the daily lives of millions of people around the world who may still be searching for an effective treatment option*," said lead study investigator Bruce E. Sands, M.D., Icahn School of Medicine, Mt. Sinai, New York, who will be delivering the oral presentation. "*It's encouraging to see data from long-term extension trials that can offer symptom relief and remission over time to those struggling with UC*."*

Through two years, the proportions of patients with adverse events (AEs), serious AEs, and serious infections in the ustekinumab groups were generally comparable to the placebo group. No new safety signals were observed.[1] Ustekinumab has demonstrated a consistent safety profile in UC where trials show the treatment is well tolerated. In the primary randomised population of the Induction and Maintenance studies, a similar proportion of patients in the ustekinumab and placebo groups experienced AEs, serious AEs, infections and serious infections through to week 44. During the Induction phase, one death from an oesophageal varices haemorrhage was reported, and no malignancies, opportunistic infections or tuberculosis were reported. During the Maintenance phase, no deaths and two malignancies other than non-melanoma skin

cancer (NMSC) were reported (90 mg ustekinumab q8w: colon cancer [n=1]; 90 mg ustekinumab q12w: papillary renal cell carcinoma [n=1]). There was one patient-reported NMSC in the 90 mg ustekinumab q12w group (2 squamous cell carcinoma events).[2,3]

"The Phase 3 UNIFI two-year data builds upon the growing body of evidence of ustekinumab as a promising treatment option for UC, further underscoring our commitment to advancing research and development in inflammatory bowel diseases," said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. *"We are proud to present these results for the first time at UEGW because we recognise the significant unmet needs that continue to persist in treating the life-altering symptoms of moderately to severely active UC."*

Janssen is presenting a total of 17 abstracts at this year's UEGW congress, of which seven are oral presentations, including additional data from the UNIFI UC clinical trials programme. Another late-breaker on UNIFI data reports results from the maintenance study by individual ustekinumab IV induction dose and suggests an optimal regimen of IV induction and SC maintenance for the treatment of moderately to severely active UC (LB07).[4] These data will also be delivered in an oral presentation today. Results from the UNITI Crohn's disease (CD) clinical trial programme are also being presented at the congress.

Ustekinumab is currently approved for the treatment of adults with moderately to severely active ulcerative colitis in the European Union (EU) and the United States.[5]

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*Prof Bruce Sands is a paid consultant for Janssen. He has not been compensated for any media work.

Key definitions

- Partial Mayo remission was defined as a partial Mayo score ≤2 points[1]
- Clinical remission was defined as a Mayo score ≤2 points, with no individual subscore >1[1]
- Partial Mayo score includes stool frequency, rectal bleeding, and physician's global assessment subscores and ranges from 0 to 9[6]
- Symptomatic remission is defined as a stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0[1]

About Ulcerative Colitis (UC)

UC affects up to 2.6 million people in Europe.[7] It is a chronic disease of the large intestine, also known as the colon, in which the lining becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucous. UC 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 stools, loss of appetite, weight loss and fatigue.[8,9]

About the UNIFI Programme

UNIFI is a Phase 3 study, designed to evaluate the safety and efficacy of ustekinumab induction and maintenance dosing for the treatment of moderately to severely active 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 tumour necrosis factor [TNF]-alpha antagonists 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 continues to follow two groups of eligible participants. The randomised population includes those participants who were in clinical response eight weeks after receiving

single IV ustekinumab infusion and who were then randomised to receive ustekinumab 90 mg every 12 weeks (q12w) or ustekinumab 90 mg every 8 weeks (q8w) or placebo. Non-randomised patients include patients in clinical response following an IV and 90 mg SC ustekinumab dose who received SC ustekinumab 90 mg q8w and placebo responders who received SC placebo.[2,3]

About STELARA® (ustekinumab)[5]

In the EU, ustekinumab is approved for the treatment of adults with moderately to severely active UC who have had an inadequate response with, or lost response to, or were intolerant to either conventional therapy or a biologic, or have medical contraindications to such therapies. Ustekinumab is also approved for the treatment of adult patients with moderately to severely active 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. 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.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

Important safety information

Please refer to the full Summary of Product Characteristics for full prescribing information for ustekinumab:
https://www.ema.europa.eu/en/medicines/human/EPAR/stelara

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 at www.twitter.com/JanssenEMEA.

Janssen-Cilag International NV, the marketing authorisation holder for STELARA® in the EU, and Janssen Research & Development, LLC, are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development and potential availability in the EU of STELARA® (ustekinumab). 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-Cilag International NV, and any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 30 December, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, 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 nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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References

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