PRESS RELEASE

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NEW DATA SHOW SYMPTOM IMPROVEMENT WITHIN ONE WEEK FOR PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE TREATED WITH STELARA® (USTEKINUMAB)

- *Late-breaking data demonstrate rapid improvement in patient-reported symptoms in patients intolerant or refractory to anti-TNF treatment*
- *Additional data presented support the use of continued treatment with ustekinumab regardless of clinical response 8 weeks after initiation*

Barcelona, Spain, Monday 30 October, 15:12 CET– Janssen-Cilag International NV ("Janssen") presented new late-breaking data today from UNITI-1 assessing Crohn's disease symptom improvement in patients during the first 2 weeks after an intravenous (IV) infusion dose of STELARA® (ustekinumab).[1] The data presented at the 25th United European Gastroenterology Week (UEGW 2017) showed that patient-reported symptom improvement began as early as day 1 post ustekinumab IV infusion and was observed consistently at day 8 and beyond when compared with placebo.[1]

"The symptoms of Crohn's disease can cause significant distress to many patients, which is why it's important to find a treatment that can act rapidly to reduce the impact of the disease. These new results from the UNITI-1 trial are encouraging because they demonstrate that treatment with ustekinumab may begin to reduce patient reported symptoms of Crohn's disease within just 1–2 weeks for a number of patients," said Professor William Sandborn, University of California San Diego, USA.

This analysis from the UNITI-1 trial involved patients with moderately to severely active Crohn's disease who were intolerant or refractory to anti-TNF treatment. Patients received an IV infusion dose of ustekinumab (130mg or ~6mg/kg) or placebo at Week 0 (baseline). Symptom improvement was assessed using patient-reported outcomes from the Crohn's Disease Activity Index (CDAI), three components were measured: daily frequency of loose stools (SF), abdominal pain (AP) and general wellbeing (GWB). Patients collected CDAI data in diaries from week 0, allowing investigators to identify when patients first experienced symptom improvement.[1]

The analysis demonstrated that 19.6% of patients receiving ~6mg/kg and 17.6% of patients receiving 130mg ustekinumab via IV infusion reported improvements in symptoms (at least 50 point improvement in SF and AP scores) within 7 days. After 14 days 29.3% and 31.4% reported significant symptom improvements from the ~6mg/kg ($p<0.05$) and 130mg ($p<0.01$) ustekinumab treatment arms respectively.[1]

Janssen also presented new data from an analysis of the UNITI programme evaluating the efficacy of ustekinumab at week 16 in patients who either had or had not responded to ustekinumab at week 8.[2] The data showed that of the 219 patients who did not respond after ustekinumab IV induction (~6 mg/kg) in UNITI-1 and UNITI-2, 37.6% and 60.5% respectively had responded at week 16, 8 weeks after their first subcutaneous (SC) ustekinumab 90mg maintenance dose.[2]

For patients receiving an IV induction dose of 6mg/kg in UNITI-1 response and remission rates were 37.8% and 20.9% respectively at week 8 and had increased to 47.4% and 24.1% at week 16 (8 weeks after the first SC ustekinumab 90mg maintenance dose). For patients receiving an IV induction dose of 6mg/kg in patients in UNITI-2 response and remission rates were 57.9% and 40.7% respectively at week 8 and had increased to 73.7% and 55.5% at week 16.[2]

The most common adverse reactions in controlled periods of the adult psoriasis, psoriatic arthritis and Crohn's disease clinical studies with ustekinumab were nasopharyngitis and headache. Most were considered to be mild and did not necessitate discontinuation of study treatment. The most serious adverse reaction that has been reported for ustekinumab is serious hypersensitivity reactions including anaphylaxis. The overall safety profile for

ustekinumab was similar to approved indications that include moderate to severe plaque psoriasis, active psoriatic arthritis and moderately to severely active Crohn's disease.[3]

Janssen is presenting a total of 6 ustekinumab abstracts at UEGW 2017.

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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).[4] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects nearly 250,000 Europeans, and around 18,000 new cases are diagnosed each year.[5] 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.[6]

About UNITI

- UNITI-1 demonstrated significantly higher rates of clinical response at Week 6 for ustekinumab treatment groups compared with the placebo group ($p=0.003$) in patients who had failed on TNFα antagonist therapies.[7] The major secondary endpoints of clinical remission at Week 8 and clinical response at Week 8 were each also significantly higher with IV ustekinumab induction versus IV placebo ($p<0.001$ for each).[7] Clinical response was defined as a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of ≥100 points or being in clinical remission. Clinical remission was defined as the CDAI <150.[7] The CDAI is a symptom-based disease assessment tool that quantifies symptoms of Crohn's disease and measures improvement with treatment.[8]
- UNITI-2 also demonstrated significantly greater clinical response at Week 6 with IV ustekinumab induction compared to IV placebo ($p<0.001$) in a population of patients who had previously failed conventional therapy, but who had not previously failed TNFα antagonist therapies. The secondary endpoints of clinical remission at Week 8 were also significantly higher in the ustekinumab groups compared to placebo ($p<0.001$ for the ustekinumab ~6 mg/kg treatment group; $p=0.009$ for the ustekinumab 130 mg treatment group).[7]

- IM-UNITI studied maintenance in patients who achieved clinical response 8 weeks after a single IV infusion of ustekinumab in the UNITI-1 and UNITI-2 Phase 3 induction studies. IM-UNITI showed that a significantly greater proportion of patients in the subcutaneous ustekinumab maintenance groups was in clinical remission at Week 44 versus placebo (p=0.005 in every 8 week and p=0.04 in every 12 week groups; primary endpoint). Clinical response at Week 44 was also significantly greater with both regimens versus placebo at Week 44. Other major secondary endpoints of clinical remission at Week 44 among patients in remission after induction and corticosteroid-free remission were significantly greater for every 8 week ustekinumab maintenance versus placebo.[7]

About ustekinumab[3]

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 (PUVA), and 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. In November 2016, the European Commission approved ustekinumab for the treatment of adult patients with moderately to severely active Crohn's disease 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, which is currently approved for the treatment of moderate to severe plaque psoriasis in 89 countries, paediatric psoriasis in 42 countries, psoriatic arthritis in 83 countries and Crohn’s disease in 40 countries.

Important Safety Information

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 the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us on Twitter at https://twitter.com/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-Cilag International NV 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; 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 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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. Neither 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

[1] Talk: LB07; Ustekinumab IV induction Results in Crohn's Disease Symptom Improvement within the First Week in Anti-TNF Refractory Patients. Session: Clinical and observational trials in inflammatory bowel diseases. Session type: late breaking abstracts. Date: Monday, October 30, 2017. Time: 14:00-15:30. Session room: room A3.

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Presenting Author William J. Sanborn. United European Gastroenterology Week (UEGW 2017); 28 October – 1 November, 2017; Barcelona, Spain.

[2] Colombel JF, Sloan S, Gasink C *et al*. Response and Remission after 16 Weeks of Ustekinumab – An All Patients Analysis from the UNITI Crohn's Studies. United European Gastroenterology Week (UEGW 2017); 28 October – 1 November, 2017; Barcelona, Spain: UEGW 2017 ID# 2728.

[3] Summary of Product Characteristics Stelara 45 mg solution. Janssen-Cilag International NV http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000958/WC500058513.pdf (last accessed October 2017).

[4] World IBD Day. Home. Available at http://www.worldibdday.org/index.html (last accessed October 2017).

[5] European Federation of Pharmaceutical Industries and Associations. Inflammatory Bowel Disease. Available at http://www.efpia.eu/disease/78/59/Inflammatory-Bowel-Disease (last accessed October 2017).

[6] Crohn's and Colitis UK. Crohn's disease. Available at http://www.crohnsandcolitis.org.uk/about-inflammatory-bowel-disease/crohns-disease (last accessed October 2017).

[7] Feagan BG, Sandborn WJ, Gasink C *et al.* Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. N Engl J Med 2016; 375:1946-1960.

[8] Best WR, et al. Gastroenterol 1976;70(3):439–44.