PRESS RELEASE

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NEW DATA SHOWS STELARA® (USTEKINUMAB) MAINTAINED CLINICAL RESPONSE AND REMISSION AFTER TWO YEARS OF TREATMENT IN PATIENTS WITH MODERATE TO SEVERE CROHN'S DISEASE

Results of the IM-UNITI Study Presented at the 12th Congress of ECCO

Barcelona, Spain, Friday 17 February, 09:50 CEST – Janssen-Cilag International NV ("Janssen") announced today new two-year data from the ongoing IM-UNITI long-term extension (LTE) study evaluating the efficacy and safety of subcutaneous (SC) STELARA® (ustekinumab) in patients with moderate to severe Crohn's disease. The data presented at the 12th Congress of the European Crohn's and Colitis Organisation (ECCO) showed that treatment with ustekinumab maintained clinical response and remission for up to two years with no new safety signals observed.[1]

"Maintaining control of disease symptoms is paramount in the treatment of Crohn's disease. The two-year clinical response and remission rates from the IM-UNITI study provide further evidence that ustekinumab can be an effective therapeutic option for people living with this chronic and often debilitating disease," said Professor William Sandborn, MD, UC San Diego Health System, Gastroenterology Chief.

Of the 1,281 patients enrolled in the maintenance study, 397 patients who achieved a response to ustekinumab at week 8 following an induction phase were randomised to receive SC ustekinumab 90mg every 8 weeks (Q8W) or every 12 weeks (Q12W), or placebo during a

maintenance (0–44 week) period, before entering the LTE (44–252 week) period. A one-time dose adjustment to ustekinumab 90mg Q8W was permitted in patients in the randomised group who met loss of response criteria between weeks 8–32. Clinical efficacy data were collected every 12 weeks and safety data were collected every 4 weeks from the end of the maintenance trial (week 44) until the maintenance study was unblinded and then at Q8W or Q12W dosing visits during the LTE period; data at week 92 are reported here.

Among randomised patients who entered the LTE period and continued to receive ustekinumab through week 96, 79.2% of patients receiving ustekinumab Q12W and 87.1% of patients receiving ustekinumab Q8W were in remission, while 90.9% of patients and 94.3% of patients showed clinical response at week 92, respectively. Among all ustekinumab-treated patients who continued to receive ustekinumab through week 96, remission and response rates at week 92 were 70.7% and 84.7%, respectively (as observed).

Safety event rates per hundred years of follow up were comparable in ustekinumab-treated patients compared to placebo-treated patients from week 44 through to week 96. Among all ustekinumab-treated patients, there were two deaths (sudden death, asphyxia). There were two NMSC (non-melanoma skin cancer) malignancies reported between weeks 44 and 96, a seminoma in a ustekinumab-treated patient and a papillary thyroid cancer in a placebo-only-treated patient.[1]

“The 96 week data from the IM-UNITI study complement data previously presented from the UNITI programme. We look forward to sharing future results from the UNITI programme, and remain committed to improving overall outcomes for people living with Crohn’s disease,“ said Frederic Lavie, EMEA Therapeutic Area Leader Immunology, Cardiovascular and Metabolics, Janssen.

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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).[2] 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.[3] 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.[4,5]

About the IM-UNITI trial

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 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 ustekinumab 90mg Q8W or Q12W, or placebo. The primary endpoint was clinical remission at week 44, defined by Crohn's Disease Activity Index (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. After week 44, all participants who continued to do well were eligible to continue to receive study agent in the second part of the study, a long-term extension where the study agent continues to be administered up to week 252.

About STELARA[6]

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 39 countries, psoriatic arthritis in 79 countries and Crohn's disease in 33 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: @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 materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV. Risks and uncertainties include, but are not limited to: challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new 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.

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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.

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References

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