PRESS RELEASE

FOR MEDICAL AND TRADE MEDIA ONLY

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EUROPEAN COMMISSION APPROVES STELARA® (USTEKINUMAB) FOR TREATMENT OF ADULTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE

First Interleukin (IL)-12/23 Inhibitor Licensed For Crohn's Disease

Beerse, Belgium, 11 November 2016 – Janssen-Cilag International NV ("Janssen") announced today that the European Commission (EC) has approved the use of STELARA® (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 tumour necrosis factor alpha (TNFα) antagonist or have medical contraindications to such therapies.[1] STELARA is the first biologic therapy for Crohn's disease that targets interleukin (IL)-12 and IL-23 cytokines, known to play a key role in inflammatory and immune responses.

"Today's decision is an important step forward for people living with Crohn's disease. There is a great need for alternative effective therapeutic options to help people control their symptoms, and STELARA offers a strong clinical dataset demonstrating high rates of clinical response and remission for those whom biologic therapy is appropriate," said Frederic Lavie, EMEA Therapeutic Area Leader Immunology, Cardiovascular and Metabolics, Janssen.

The recommended dosing regimen for STELARA is an initial induction dose based on body weight (~6 mg/kg) given via a single intravenous (IV) infusion. The first subcutaneous (SC) administration of 90 mg STELARA should take place at week 8 after the intravenous dose. After this, dosing every 12 weeks is

recommended. Patients who have not shown adequate response at week 8 after the first SC dose may receive a second SC dose at this time. Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks. Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgement.[1]

The EC approval is based on data from three pivotal Phase 3 trials which included approximately 1,400 patients with moderately to severely active Crohn's disease. The Phase 3 studies showed that treatment with STELARA induced clinical response and maintained clinical remission in a significantly greater proportion of adult patients with moderately to severely active Crohn's disease after one year of therapy compared to placebo.[2,3,4]

"We are proud to be bringing a new class of treatment for Crohn's disease to this underserved patient population", said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. "STELARA has already helped many people living with psoriasis and psoriatic arthritis, and we are committed to working with health authorities across Europe to make it available as quickly as possible for those living with Crohn's disease."

STELARA was generally well tolerated as an induction and maintenance therapy in all three studies, and the safety profile of STELARA in the Crohn's disease clinical development programme remained consistent with five years of cumulative data acquired in patients with psoriasis[5,6] (with STELARA subcutaneous injections up to 90 mg) and two years of safety data in patients with psoriatic arthritis who were treated with STELARA.[7]

In the placebo-controlled IM-UNITI maintenance study adverse events were reported in similar proportions across STELARA and placebo treatment groups, the majority of which were related to gastrointestinal disorders, such as abdominal pain and diarrhoea, and infections/infestations, of which, nasopharyngitis and upper respiratory infection were the most common. Reported serious adverse events were similar in the STELARA groups compared to placebo and no deaths or major adverse cardiovascular events were reported.[4]

The marketing authorisation approval follows a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued on 15 September 2016.[8] This approval allows for the marketing of STELARA in all 28 member states of the European Union as well as the European Economic Area countries (Norway, Iceland and Liechtenstein). STELARA also received approval by the U.S. Food and Drug Administration in September 2016 for the treatment of adult patients with moderately to severely active Crohn's disease.[9]

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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).[10] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects nearly 250,000 Europeans, and around 18,000 new cases diagnosed each year.[11] 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.[12,13]

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.[2] 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).[2] 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.[2] The CDAI is a symptom-based disease assessment tool that quantifies symptoms of Crohn's disease and measures improvement with treatment.[14]
- 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).[3]
- 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 $p=0.040$ 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.[4]

About STELARA[15]

In the European Union, STELARA 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 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, STELARA 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 STELARA 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 STELARA, which is currently approved for the treatment of moderate to severe plaque psoriasis in 87 countries, psoriatic arthritis in 71 countries and paediatric psoriasis in 34 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 the approval of a new indication. 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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; 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 behavior and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; manufacturing difficulties and delays; 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. 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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