



NEWS RELEASE

# Janssen Receives CHMP Positive Opinion for STELARA® (ustekinumab) Recommending Approval for the Treatment of Moderately to Severely Active Crohn's Disease in the European Union

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If Approved, STELARA® Will Be The First Interleukin (IL)-12/23 Inhibitor Licensed For Crohn's Disease

BEERSE, Belgium--(BUSINESS WIRE)-- Janssen-Cilag International NV ("Janssen") announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorisation in the European Union for 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. If approved, ustekinumab will offer people with Crohn's disease a new treatment option to induce and maintain remission of their disease symptoms.<sup>1</sup>

"Crohn's disease is a debilitating chronic condition that has a huge impact on patients' quality of life. Patients experience unpredictable disease flares and many have lost response to currently available treatments, so it is vital that new therapeutic options are made available to help control their symptoms," said Frederic Lavie, EMEA Therapeutic Area Leader Immunology, Cardiovascular and Metabolics, Janssen. "Ustekinumab has shown clinical benefit, is generally well tolerated, and has a convenient dosing regimen for people living with Crohn's disease who are eligible for a biologic therapy."

The CHMP adopted the opinion based on data from three pivotal Phase 3 trials which included approximately 1,400 patients with moderately to severely active Crohn's disease:<sup>2,3,4</sup>

- 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 TNF $\alpha$  antagonist therapies.<sup>2</sup> 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  $\leq$  0.001 for each).<sup>2</sup> Clinical response was defined as a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of  $\geq$ 100 points or being in clinical remission. Clinical remission was defined as the CDAI  $\leq$  150.<sup>2</sup> The CDAI is a symptom-based disease assessment tool that quantifies symptoms of Crohn's disease and measures improvement with treatment.<sup>5</sup>
- UNITI-2 also demonstrated significantly greater clinical response at Week 6 with IV ustekinumab induction compared to IV placebo (p  $\leq$  0.001) in a population of patients who had previously failed conventional therapy, but who had not previously failed TNF $\alpha$  antagonist therapies. The secondary endpoints of clinical remission and response at Week 8 were also each both significantly higher in the ustekinumab groups compared to placebo (p  $\leq$  0.001 in each).<sup>3</sup>
- 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.<sup>4</sup>

Ustekinumab was generally well tolerated as an induction and maintenance therapy in all three studies, and the safety profile of ustekinumab in the Crohn's disease clinical development program remained consistent with the established safety profile of ustekinumab based upon current labelled indications. In the induction studies (UNITI-1 and UNITI-2), through Week 8 (placebo-controlled period), adverse events (AEs), serious AEs (SAEs) and infections were reported in similar proportions across ustekinumab and placebo treatment groups.<sup>2,3</sup> Through Week 44 (placebo-controlled period) in the maintenance study (IM-UNITI), AEs were reported in similar proportions across ustekinumab 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. SAEs occurred in 10 percent, 12 percent and 15 percent of patients receiving ustekinumab 90 mg subcutaneously every 8 weeks, ustekinumab 90 mg subcutaneously every 12 weeks and placebo, respectively; 2 percent, 5 percent and 2 percent of patients reported serious infections in these respective groups. Through the 8-week induction and 44-week maintenance phases (representing 1 year total of therapy), no deaths or major adverse cardiovascular events were reported. Only two randomised patients reported

malignancies (one case of basal cell carcinoma in the subcutaneous placebo group and another in the subcutaneous ustekinumab every 8 weeks group).<sup>4</sup>

Following this positive opinion, a final decision from the European Commission is expected later this year. Janssen is also currently seeking approval for ustekinumab for the treatment of adult patients with moderately to severely active Crohn's disease in the U.S.

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## Information for Editors

### 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).<sup>6</sup> Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects nearly 250,000 Europeans.<sup>7</sup> 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.<sup>8,9</sup>

### About Ustekinumab<sup>10</sup>

Ustekinumab, a human IL-12 and IL-23 antagonist, is approved in the European Union 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. Ustekinumab 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 therapy has been inadequate.

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 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?](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000958/human_med_001065.jsp&mid=WC0b01ac058001d124)

[curl=pages/medicines/human/medicines/000958/human\\_med\\_001065.jsp&mid=WC0b01ac058001d124](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](http://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 potential regulatory approvals and benefits of a new treatment option. 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 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](http://www.sec.gov), [www.jnj.com](http://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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## References

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