NEWS RELEASE

STELARA® Receives CHMP Positive Opinion For Treatment Of Adolescents With Moderate To Severe Psoriasis In Europe

5/22/2015

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Beerse, Belgium, 22 May 2015 - 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 approval for the use of STELARA® (ustekinumab), 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.

The CHMP adopted the opinion based on a review of data from the CADMUS study, which is a Phase 3, randomised, double-blind, placebo-controlled, multicentre trial designed to evaluate the safety and efficacy of STELARA in patients aged 12 to 17 years with moderate to severe plaque psoriasis.[1]

"Today's recommendation of STELARA for the treatment of paediatric psoriasis is an important step forward for adolescents living with this chronic, debilitating autoimmune disease", said Newman Yeilding, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "We look forward to the European Commission's decision and the opportunity to bring STELARA to adolescent patients who could benefit from biologic therapy."

Based on the CHMP's positive opinion, a final decision from the European Commission is expected during the third quarter of 2015. If approved, STELARA will become available for the treatment of adolescents from the age of 12 years and older living with moderate to severe plaque psoriasis, a chronic autoimmune disease that affects from

0.5 to 2 per cent of the general population during childhood and adolescence.[2]

About psoriasis

Psoriasis, a chronic, immune-mediated disease that results from the overproduction of skin cells, affects 125 million people worldwide, including nearly 14 million Europeans.[3,4,5,6,7]Plaque psoriasis often results in patches of thick, red or inflamed skin covered with silvery scales known as plaques. These plaques can crack and bleed, and may occur anywhere on the body. The disease symptoms can range from mild, to moderate, to severe and disabling.[8] It is estimated that nearly three percent of the world's population is living with psoriasis and nearly one-quarter of those people have cases that are considered moderate to severe.[3] Although the disease can present at any age, approximately one-third of people develop psoriasis before the age of 20.[9]

About STELARA in paediatric patients (CADMUS study)[1]

CADMUS, a Phase 3, randomised, double-blind, placebo-controlled, parallel, multicentre trial, evaluated the efficacy and safety of STELARA in pediatric patients aged 12 to 17 years with moderate to severe plaque psoriasis. Patients (N=110) had a diagnosis of plaque-type psoriasis for at least 6 months prior to first study agent administration and had a moderate to severe disease defined by a Psoriasis Area Severity Index (PASI) score greater than or equal to 12, a Physician's Global Assessment (PGA) score greater than or equal to 3 and body surface area (BSA) involvement of at least 10 percent. In addition, patients were inadequately controlled with topical therapy or were candidates for systemic/phototherapy.

Patients were randomised 1:1:1 to receive subcutaneous placebo, STELARA standard dosing (SD) [intended to achieve exposures comparable to adults] or STELARA half standard dosing (HSD) [intended to achieve exposures half of those seen in adults]. STELARA dosing tiers were determined by body weight. Patients receiving placebo crossed over to receive STELARA SD or HSD at weeks 12 and 16; all patients continued with maintenance dosing every 12 weeks through week 40. Final efficacy and safety evaluations were made at weeks 52 and 60, respectively. The primary endpoint of the study was a PGA score of cleared (0) or minimal (1) at week 12. Secondary endpoints at week 12 included at least a 75 or 90 percent improvement in psoriatic skin lesions, as measured by PASI 75 or PASI 90, and improvement in quality of life, as measured by the Children's Dermatology Life Quality Index (CDLQI) [patient-reported outcome].

About STELARA (ustekinumab)[10]

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, 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). STELARA is also 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.

The Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA, which is currently approved for the treatment of moderate to severe plaque psoriasis in 84 countries and psoriatic arthritis in 55 countries.

Important safety information (EU)[10]

SPECIAL WARNINGS & PRECAUTIONS: Infections: Potential to increase risk of infections and reactivate latent infections. Exercise caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis and treated for latent TB prior to initiation of STELARA®. Also, consider anti-tuberculosis therapy prior to initiation of STELARA® in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, they should be closely monitored and STELARA® should not be administered until infection resolves. Malignancies: Potential to increase the risk of malignancy. No studies have been conducted in patients with a history of malignancy or in those who continue to receive STELARA® after being diagnosed with a malignancy. Exercise caution when considering STELARA® in these patients. Monitoring for the appearance of non-melanoma skin cancer recommended, in particular for patients greater than 60 years of age, or with a medical history of prolonged immunosuppressant therapy or a history of PUVA treatment. Hypersensitivity reactions: Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur, institute appropriate therapy and discontinue use of STELARA®. Vaccinations: Patients receiving STELARA® should not receive concurrent live viral or live bacterial vaccines such as BCG. Before live viral or live bacterial vaccination, treatment with STELARA® should be withheld for at least 15 weeks after the last dose and can be resumed at least 2 weeks after vaccination. Patients receiving STELARA® may receive concurrent inactivated or non live vaccinations. Concomitant immunosuppressive therapy: Exercise caution, including when changing immunosuppressive biologic agents. In psoriasis studies, the safety and efficacy of STELARA® in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA®. Immunotherapy: Not known whether STELARA® affects allergy immunotherapy. Serious skin conditions: In patients with psoriasis, exfoliative dermatitis has been reported following STELARA® treatment. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. If these symptoms occur, appropriate therapy should be instituted. STELARA® should be discontinued if a drug reaction is suspected. Latex sensitivity: Needle cover contains natural rubber (latex), may cause allergic reactions. Elderly Patients > 65years: Use caution when treating elderly patients.

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 Janssen-Cilag International NV and Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care.

Janssen Cilag International NV and Janssen Research & Development, LLC are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit **http://www.janssen-emea.com** for more information.

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, Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including obtaining regulatory approvals; 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 December 28, 2014, 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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References

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[9]National Psoriasis Foundation. About Psoriasis in Children. Available at **https://psoriasis.org/about-psoriasis#children** (last accessed May 2015).
[10]Summary of Product Characteristics Stelara 45 mg solution. Janssen-Cilag International NV. Last updated November 2014.

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