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STELARA® RECEIVES EUROPEAN COMMISSION APPROVAL FOR TREATMENT OF ADOLESCENTS WITH MODERATE-TO-SEVERE PSORIASIS IN EUROPE

Approval provides new therapeutic option for plaque psoriasis patients aged 12 and older for whom limited approved treatment options are available

Beerse, Belgium, 29 June 2015 – Janssen-Cilag International NV ("Janssen") announced today that the European Commission (EC) has approved 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 EC approval follows a positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in May 2015 recommending the use of STELARA for this indication.

"In addition to the very significant emotional and psychological effects of psoriasis, young patients may also face a lifetime of managing a challenging chronic disease. The availability of STELARA as a new treatment for adolescents with moderate-to-severe plaque psoriasis is an important addition to the currently limited range of approved therapeutic options available to this population," said Newman Yeilding, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC.

Plaque psoriasis is a chronic autoimmune disease that affects from 0.5 to 2 percent of the general population during childhood and adolescence.[1] Plaque psoriasis is the most common type of psoriasis and often results in patches of thick, red or inflamed skin covered with silvery scales known as plaques.[1]

The EC provided approval based on data from the CADMUS study, a Phase 3, randomised, double-blind, placebo-controlled, multicentre trial.[2] Patients aged 12–17 with moderate-to-severe plaque psoriasis were randomised 1:1:1 to receive subcutaneous placebo, STELARA standard dosing (intended to achieve exposures comparable to adults) or STELARA half standard dosing (intended to achieve exposures half of those seen in adults) at weeks 0 and 4 followed by every 12 week dosing. STELARA dosing tiers were determined by body weight. Patients receiving placebo crossed over to receive the STELARA standard dose or half standard dose at weeks 12 and 16; all patients continued with maintenance dosing every 12 weeks through week 40.[3]

The primary endpoint was the proportion of patients who achieved a Physician Global Assessment (PGA) score of cleared (0) or minimal (1) at week 12. Secondary endpoints included Psoriasis Area Severity Index (PASI) 75, PASI 90, change from baseline in Children's Dermatology Life Quality Index (CDLQI), and change from baseline in the total scale score of PedsQL (Paediatric Quality of Life Inventory) at week 12. Final efficacy and safety evaluations were made at weeks 52 and 60, respectively.[3]

At week 12, patients treated with STELARA showed significantly greater improvement in their psoriasis and health-related quality of life compared with placebo. 69.4 percent in the STELARA standard dose group achieved a PGA score of 0 or 1, compared with 5.4 percent of patients who received placebo. Beyond week 12, efficacy was generally higher and better sustained in the standard dose group compared with half standard dose group. Improvements in PGA, PASI, CDLQI and PedsQL were maintained through week 52 in the standard dose group.[3]

Through week 12, the proportion of patients with at least one adverse event was comparable between the treatment arms: 47.9 percent in the combined STELARA cohort vs 56.8 percent for placebo-treated patients. In the STELARA-treated patients, one patient in the half standard dose group reported a serious adverse event through week 12. The safety profiles of the standard dose and half standard dose groups were comparable.[4]

Adverse events occurred in 81.8 percent of the patients treated with STELARA through week 60, with 5.5 percent reporting a serious adverse event. Malignancies, opportunistic infections and anaphylactic reactions did not occur. The adverse events reported were similar to those seen in previous studies in adults with plaque psoriasis.[4]

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.[5,6,7,8,9] 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.[10] 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 18.[11]

About STELARA in paediatric patients (CADMUS study)[3]

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 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. Approximately 60% of the patients had prior exposure to conventional systemic therapy or phototherapy. Approximately 11% of the patients had prior exposure to biologics.

About STELARA (ustekinumab)[3]

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 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. The safety and efficacy of STELARA in children less than 12 years have not yet been established.

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)[3]

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 immunology, oncology, 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.

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