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Beerse, Belgium, October 10, 2014 - Janssen-Cilag International NV (Janssen) announced today that a Type II Variation has been filed with the European Medicines Agency seeking approval of STELARA® (ustekinumab) for the treatment of moderate to severe plaque psoriasis in pediatric patients ages 12 to 17 years old who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

There currently are limited options for this population in the European Union. In general, children living with moderate to severe psoriasis must contend with a potentially disfiguring and lifelong disease that can permanently impair psychological development.[1]

"Janssen is committed to the continued development of STELARA, especially in this underserved pediatric population," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We look forward to collaborating with the European Medicines Agency in working towards providing a new treatment option for dermatologists and pediatric patients 12 years and older who may benefit from STELARA."

The application is supported by data from the Phase 3 CADMUS registration study, which evaluated the efficacy and safety, as well as improvements in quality of life, among adolescents (pediatric patients ages 12 to 17) receiving STELARA compared with patients receiving placebo.

About CADMUS

CADMUS, a Phase 3, randomized, double-blind, placebo-controlled, parallel, multicenter trial, evaluated the efficacy and safety of STELARA in pediatric patients ages 12 to 17 years with moderate to severe plaque psoriasis. Patients (N=110) had been diagnosed more than six months prior to first study agent administration with 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 randomized 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 Psoriasis

Psoriasis, a chronic, immune-mediated disease that results from the overproduction of skin cells, affects 125 million people worldwide, including 14 million Europeans.[2-6] 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.7 It is estimated that nearly 3 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.[2] Although the disease can present at any age, approximately one-third of people who develop psoriasis are under the age of 20 when the disease first surfaces.[8] Prevalence in childhood and adolescence varies by region, ranging from 0.5 to 2 percent of the general population.[1]

About STELARA® (ustekinumab)

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, is currently approved in 79 countries for the treatment of moderate to severe plaque psoriasis. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in immune-mediated inflammatory diseases, including psoriasis and psoriatic arthritis.

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 (MTX) or PUVA (psoralen plus UVA). 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.

Janssen Biotech, Inc. discovered and developed STELARA, and the Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA.

Important Safety Information (EU)[9]

STELARA is a selective immunosuppressant and may have the potential to increase the risk of infections and reactivate latent infections. Serious infections have been observed in patients receiving STELARA in clinical trials. Do not start STELARA during an active infection. If a serious infection develops, monitor patients carefully and stop STELARA until the infection resolves. Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with STELARA.

STELARA is a selective immunosuppressant. Immunosuppressive agents have the potential to increase the risk of malignancy. Malignancies have been observed in patients receiving STELARA in clinical trials. Caution should be exercised when considering the use of STELARA in patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy.

Serious allergic reactions have been reported in the post-marketing setting, in some cases several days after treatment. Anaphylaxis and angioedema have occurred. If an anaphylactic or other serious allergic reaction occurs, administration of STELARA should be discontinued immediately and appropriate treatment instituted.

It is recommended that live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin [BCG]) should not be given concurrently with STELARA.

No overall differences in efficacy or safety in patients aged 65 and older who received STELARA were observed compared to younger patients. Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly.

Special Warnings and Precautions for Use[9]
Concomitant immunosuppressive therapy: Caution should be exercised when considering concomitant use of other immunosuppressants and ustekinumab or when transitioning from other immunosuppressive biologics.

For complete EU prescribing information, please visit www.ema.europa.eu.

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 healthcare 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 www.janssen-emea.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 199 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, Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges 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 regulations and domestic and foreign health care reforms; and general industry conditions including 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 29, 2013, 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 nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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