



NEW BIOLOGIC STELARA™ RECEIVES APPROVAL IN EUROPE FOR TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

First and Only Biologic Approved with Infrequent, Every Twelve-Week Maintenance Dosing

BEERSE, BELGIUM, 22 January, Janssen-Cilag announced today that STELARA™ (ustekinumab), the first in a new class of biologics, has been approved by the European Commission for use across Europe. The approved indication of ustekinumab is 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 and PUVA (psoralen plus ultraviolet A light). With the approval by the European Commission, ustekinumab is approved in 27 countries in the EU. Psoriasis, a chronic skin disease that affects between two and three percent of the European population,¹ is associated with substantial physical and emotional burdens and potentially serious co-morbidities.^{2,3}

In clinical studies, treatment with ustekinumab demonstrated significant improvements in patients' psoriasis, and quality of life, which were sustained with as few as four injections a year (every twelve weeks) following two starter doses at weeks 0 and 4. The approval of ustekinumab offers adults living with moderate-to-severe plaque psoriasis a new therapy which has the potential to make a considerable impact on their daily lives.

The approval is based on data from two large, pivotal Phase III, multi-centre, randomised, double-blind, placebo controlled trials (PHOENIX 1 & 2) involving nearly 2,000 patients in whom the efficacy and safety of ustekinumab in the treatment of moderate-to-severe plaque psoriasis were evaluated.^{4,5} Two-thirds or more of patients achieved the primary endpoint of each trial, at least 75% improvement in psoriasis using the Psoriasis Area and Severity Index (PASI 75) at week 12, after receiving just two doses of ustekinumab 45 mg or 90 mg, respectively, at weeks 0 and 4. At week 12, 66 percent to 76 percent of patients receiving ustekinumab 45 mg or 90 mg doses, respectively, achieved PASI 75 compared with 3 to 4 per cent of patients receiving placebo (p<0.001). The majority of responders receiving injections every 12 weeks maintained PASI 75 response through up to 18 months.

Rates of serious adverse events, including serious infections, malignancies and cardiovascular events, were low and consistent with the expected background rates. The most common adverse reactions in Phase III clinical trials were arthralgia, cough, headache, injection site erythema, nasopharyngitis and upper respiratory tract infection. Most were considered to be mild and did not necessitate discontinuation of therapy.

About Psoriasis

Psoriasis is a chronic, immune-mediated inflammatory disease, which results from the over-production of skin cells resulting in their accumulation on the surface of the skin, which causes red, scaly plaques that may itch and bleed. It is estimated that between two and three percent of the European population have psoriasis.¹ Twenty to thirty percent of people with psoriasis have cases that are considered severe.⁶

About STELARA (ustekinumab)

Ustekinumab is a new, human monoclonal antibody with a novel mechanism of action that targets the p40 sub-unit of cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23), naturally occurring proteins that are important in regulating immune responses and that are thought to be associated with some immune-mediated inflammatory disorders, including plaque psoriasis. In the United States, the Biologics License Application (BLA) for ustekinumab is under regulatory review by the U.S. Food and Drug Administration (FDA).

Centocor Ortho Biotech Inc. discovered STELARA and has exclusive marketing rights to the product in the United States. Janssen-Cilag companies have exclusive marketing rights in all countries outside of the United States.

Important Safety Information

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.

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References

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