



20 November 2014  
EMA/CHMP/489954/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

---

### Cosentyx secukinumab

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cosentyx powder for solution for injection, solution for injection in pre-filled pen, solution for injection in pre-filled syringe intended for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The applicant for this medicinal product is Novartis Europharm Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Cosentyx is secukinumab, an immunosuppressant (ATC Code: L04AC10). Secukinumab is a fully human IgG1/κ monoclonal antibody that selectively binds to and neutralises the proinflammatory cytokine interleukin (IL)-17A. Secukinumab works by targeting IL-17A and inhibiting its interaction with the IL-17 receptor, which is expressed on various cell types including keratinocytes. As a result, secukinumab inhibits the release of proinflammatory cytokines, chemokines and mediators of tissue damage and reduces IL-17A-mediated contributions to autoimmune and inflammatory diseases such as psoriasis.

The benefits with Cosentyx are its ability to show superiority to placebo with respect to the co-primary endpoints Psoriasis Area and Severity Index score (PASI) 75 and Investigator's Global Assessment (IGA mod 2011) 0/1 response at Week 12. In a pooled analysis, PASI 90, PASI 100 and IGA 0/1 response rates indicating nearly complete/complete clearance were also statistically significantly better with Cosentyx compared to placebo. Cosentyx was statistically significantly superior to etanercept at Week 12 in achieving PASI 75 and IGA 0/1 response. Cosentyx was efficacious in systemic treatment naive, biologic-naive, biologic/anti-tumour necrosis factor (TNF)-exposed and biologic/anti-TNF-failure patients. Improvements in PASI 75 in patients with concurrent psoriatic arthritis at baseline were similar to those in the overall plaque psoriasis population.

The most frequently reported adverse drug reactions were upper respiratory tract infections (most frequently nasopharyngitis, rhinitis). Most of the reactions were mild or moderate in severity.

---

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



A pharmacovigilance plan for Cosentyx will be implemented as part of the marketing authorisation.

The approved indication is: "Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy". The recommended dose is 300 mg. Cosentyx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Cosentyx is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Cosentyx and therefore recommends the granting of the marketing authorisation.