25 February 2016
EMA/CHMP/78341/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Taltz

ixekizumab

On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Taltz, intended for the treatment of plaque psoriasis. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Taltz will be available as a 80 mg solution for injection. The active substance of Taltz is ixekizumab, an immunosuppressant (ATC Code: L04AC13). Ixekizumab is a monoclonal antibody that binds with high affinity and specificity to both forms of interleukin 17A (IL-17A and IL-17A/F). Neutralisation of IL-17A by ixekizumab inhibits keratinocyte proliferation and activation which have been implicated in the pathogenesis of psoriasis.

The benefits with Taltz are its statistically significant and clinically relevant effects compared to placebo or etanercept in terms of 'Psoriasis Area and Severity Index' (PASI) score 75 and 'static Physician Global Assessment of 0 or 1 (sPGA (0/1)) at week 12. PASI 90, PASI 100 and sPGA 0 response rates indicating nearly complete/complete clearance were also statistically significantly better with Taltz compared to placebo or etanercept.

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

The full indication is: "Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy". It is proposed that Taltz is prescribed by physicians experienced in the treatment and diagnosis of psoriasis.

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.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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