14 September 2017
EMA/CHMP/556833/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tremfya

guselkumab

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tremfya, intended for the treatment of plaque psoriasis. The applicant for this medicinal product is Janssen-Cilag International N.V.

Tremfya will be available as a 100-mg solution for injection. The active substance of Tremfya is guselkumab, a human IgG1λ monoclonal antibody that binds selectively to interleukin 23 (IL-23) with high specificity and affinity. IL-23 is a key driver of Th17 cell differentiation and survival, and an upstream regulator of IL-17A, which is implicated in the pathogenesis of psoriasis.

The benefits with Tremfya are its ability to inhibit the inflammation and clinical symptoms associated with psoriasis. Tremfya showed superiority to placebo at week 16, and to adalimumab at weeks 16, 24 and 48 with respect to the co-primary endpoints Investigator Global Assessment score of cleared or minimal (IGA 0/1) and Psoriasis Area and Severity Index (PASI) 90 response.

The most common side effect is upper respiratory infection.

The full indication is:

“Tremfya is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy”.

The medicine is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque 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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