13 October 2022
EMA/CHMP/804058/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Spevigo

spesolimab

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Spevigo, intended for the treatment of flares in adult patients with generalised pustular psoriasis. The applicant for this medicinal product is Boehringer Ingelheim International GmbH.

Spevigo will be available as a 450 mg concentrate for solution for infusion. The active substance of Spevigo is spesolimab, an immunosuppressant and interleukin inhibitor (ATC code: L04AC22). Spesolimab is a humanised antagonistic monoclonal immunoglobulin G1 (IgG1) antibody which blocks human IL-36 receptor(IL36R) signalling. Binding of spesolimab to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL-36 α, β and γ) and downstream activation of pro-inflammatory pathways.

The benefits of Spevigo are increases in the proportion of patients achieving a Generalised Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 0 (indicating no visible pustules) and GPPGA total score of 0 or 1 (clear or almost clear skin) in the spesolimab arm compared with placebo at week 1 in a phase II, randomised, double-blind, placebo-controlled trial. The most common side effects are infections. The most serious adverse reaction was urinary tract infection.

The full indication is:

> Spevigo is indicated for the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.

Spevigo should be initiated and supervised by physicians experienced in the management of patients with inflammatory skin diseases.

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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