25 July 2024
EMA/CHMP/239042/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Anzupgo

delgocitinib

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Anzupgo, intended for the treatment of chronic hand eczema (CHE). The applicant for this medicinal product is LEO Pharma A/S.

Anzupgo will be available as a 20 mg/g cream. The active substance of Anzupgo is delgocitinib, a Janus Kinase (JAK) inhibitor that inhibits the JAK1, JAK2, JAK3 and tyrosine kinase 2 (TYK2) enzymes in a concentration dependant manner (ATC code: D11AH11). Inhibition of the JAK-STAT pathway attenuates the signalling of several pro-inflammatory cytokines, downregulating the immune and inflammatory responses in cells of relevance to CHE pathology.

The benefits of Anzupgo are its ability to improve the skin condition of patients with moderate to severe CHE as measured by the Investigator's Global Assessment for CHE treatment success (IGA-CHE TS), defined as an IGA-CHE score of 0 (clear skin) or 1 (almost clear: barely perceptible erythema) with at least a 2-step improvement from baseline, and by an improvement in the Hand Eczema Severity Index (HECSI)-75 score and a reduction in itch and pain, as measured with the Hand Eczema Symptom Diary (HESD). The most common side effects with Anzupgo are application site reactions.

The full indication is:

> Anzupgo is indicated for the treatment of moderate to severe chronic hand eczema (CHE) in adults for whom topical corticosteroids are inadequate or inappropriate (see section 5.1).

Anzupgo should be initiated and supervised by physicians experienced in the diagnosis and treatment of CHE.

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

[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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