23 February 2023
EMA/CHMP/27927/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Opzelura

ruxolitinib

On 23 February 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Opzelura, intended for the treatment of non-segmental vitiligo. The applicant for this medicinal product is Incyte Biosciences Distribution B.V.

Opzelura will be available as a 15 mg/g cream. The active substance of Opzelura is ruxolitinib, a Janus Kinase (JAK) inhibitor with selectivity for the JAK1 and JAK2 isoforms (ATC code: D11AH09). JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor receptor interactions on the cellular membrane, influencing cellular processes of haematopoiesis and immune-cell function.

The benefits of Opzelura are its ability to improve the skin condition in non-segmental vitiligo as measured by improvement in the facial and total body depigmentation from baseline on the Vitiligo Area Scoring Index (F-VASI75 and T-VASI50) compared to vehicle group, as demonstrated in two pivotal phase 3 randomised, double-blind, vehicle-controlled studies. The most common side effect is application site acne.

The full indication is:

> Opzelura is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Opzelura should be initiated and supervised by physicians with experience in the diagnosis and treatment of non-segmental vitiligo.

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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