26 January 2023
EMA/CHMP/898000/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sotyktu

deucravacitinib

On 26 January 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 Sotyktu, intended for the treatment of moderate to severe psoriasis. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Sotyktu will be available as a 6 mg film-coated tablet. The active substance of Sotyktu is deucravacitinib, a selective immunosuppressant (ATC code: L04AA56) that inhibits the tyrosine kinase 2 (TYK2) enzyme (TYK2 belongs to the JAK family). TYK2 mediates signalling of interleukin-23 (IL-23), interleukin-12 (IL-12), and type I interferons (IFNs), which are naturally occurring cytokines involved in inflammatory and immune responses. By binding to TYK2, Sotyktu inhibits receptor-mediated activation of TYK2 and its downstream functions in cells, which controls the inflammation caused by plaque psoriasis.

The benefits of Sotyktu are its ability to improve the skin condition, measured by the proportion of patients achieving a PASI 75 response (at least a 75% reduction in the Psoriasis Area and Severity Index) and a static Physician's Global Assessment (sPGA) of clear or almost clear (0 or 1) in two phase 3 multicentre, randomised, double-blind, placebo- and apremilast-controlled clinical studies. The most common side effects are upper respiratory infections, most frequently nasopharyngitis.

The full indication is:

> SOTYKTU is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Sotyktu should be prescribed by physicians experienced in the treatment 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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