28 February 2019
EMA/CHMP/132686/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Skyrizi

risankizumab

On 28 February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Skyrizi, intended for the treatment of moderate to severe psoriasis. The applicant for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

Skyrizi will be available as a 75 mg solution for injection. The active substance of Skyrizi is risankizumab, a monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23), a cytokine involved in inflammatory and immune responses (ATC code: L04AC).

The benefits with Skyrizi are its ability to block IL-23 from binding to its receptor, therefore inhibiting the release of proinflammatory cytokines involved in psoriasis disease. The most common side effects are upper respiratory infections, which occurred in 13% of patients.

The full indication is: “Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy”.

It is proposed that Skyrizi 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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