16 December 2021
EMA/CHMP/683625/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Saphnelo

anifrolumab

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Saphnelo, intended for the treatment of moderate to severe systemic lupus erythematosus (SLE).

The applicant for this medicinal product is AstraZeneca AB.

Saphnelo will be available as a 300 mg concentrate for solution for infusion. The active substance of Saphnelo is anifrolumab, a selective immunosuppressant (ATC code: L04AA51). Anifrolumab is a monoclonal antibody which binds to subunit 1 of the type I interferon receptor blocking the biologic activity of type I interferons.

The benefit of Saphnelo is an increase in proportion of patients with BICLA response at week 52 (defined as improvement in all organ domains with moderate or severe SLE activity at baseline) compared with placebo. The most common side effects are upper respiratory tract infection, bronchitis, infusion-related reaction and herpes zoster. The most common serious adverse reaction was herpes zoster.

The full indication is:

> Saphnelo is indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

Treatment should be initiated and supervised by a physician experienced in the treatment of SLE.

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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