15 September 2022
EMA/CHMP/723511/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enjaymo

sutimlimab

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Enjaymo[2], intended for the treatment of haemolytic anaemia in adult patients with cold agglutinin disease (CAD).

The applicant for this medicinal product is Genzyme Europe BV.

Enjaymo will be available as a 50 mg/ml solution for infusion. The active substance of Enjaymo is sutimlimab, a selective immunosuppressant (ATC code: L04AA55) that inhibits the classical pathway (CP). It specifically binds to the s subcomponent (C1s) of complement component 1, a serine protease that cleaves C4. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells. This results in the inhibition of haemolysis in patients with CAD and prevents the generation of proinflammatory anaphylatoxins C3a and C5a and the downstream terminal complement complex C5b-9.

The benefits of Enjaymo are an increase over baseline in haemoglobin level of at least 1.5 g/dL at the treatment assessment time point in the absence of blood transfusions or other medicinal treatment, as observed in a phase 3, randomized, double-blind, placebo-controlled trial study in 42 patients and a phase 3, open-label, single-arm study in 24 patients. The most common side effects are headache, hypertension, urinary tract infection, respiratory tract infection, nasopharyngitis, nausea, abdominal pain, infusion-related reactions and acrocyanosis.

The full indication is:

> Enjaymo is indicated for the treatment of haemolytic anaemia in adult patients with cold agglutinin disease (CAD).

Enjaymo should be administered by a healthcare professional and under the supervision of a physician experienced in the management of patients with haematological disorders.

[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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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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.