EMA/269186/2023 Rev.1
Committee for Medicinal Products for Human Use (CHMP)

Update as of 20 July 2023:

The applicant withdrew the marketing authorisation application for Jesduvroq on 12 July 2023.

The application was withdrawn after CHMP had adopted a positive opinion recommending the granting of a marketing authorisation. At the time of withdrawal, the European Commission had not yet granted marketing authorisation for this product.

22 June 2023

Summary of opinion[1] (initial authorisation)

Jesduvroq

daprodustat

On 22 June 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 Jesduvroq, intended for the treatment of symptomatic anaemia in adults with chronic kidney disease who are on chronic dialysis. The applicant for this medicinal product is Glaxosmithkline Trading Services Limited.

Jesduvroq will be available as film-coated tablets. The active substance of Jesduvroq is daprodustat, an orally administered antianaemic (ATC code: B03XA07). Daprodustat inhibits hypoxia-inducible factor (HIF)-prolyl hydroxylase, thereby stimulating erythropoietin production. This increases iron mobilisation and the production of haemoglobin and red blood cells.

The benefit of Jesduvroq is its ability to correct haemoglobin levels in dialysis-dependent patients, with effects comparable to those seen with erythropoiesis-stimulating agents. The most common side effects are hypertension, thromboembolic events and diarrhoea.

The full indication is:

> Jesduvroq is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

Jesduvroq should be prescribed by physicians experienced in the treatment of anaemia.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.