25 April 2024
EMA/CHMP/148449/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

JERAYGO

aprocitentan

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product JERAYGO, intended for the treatment of resistant hypertension in adult patients. The applicant for this medicinal product is Idorsia Pharmaceuticals Deutschland GmbH.

JERAYGO will be available as 12.5 mg and 25 mg film-coated tablets. The active substance of JERAYGO is aprocitentan, an antihypertensive (ATC code: C02KN01). Aprocitentan is a dual endothelin (ET) receptor antagonist that inhibits the effects mediated by ET_A and ET_B receptors, such as vasoconstriction, fibrosis, cell proliferation and inflammation.

The benefit of JERAYGO is its ability to lower blood pressure in patients with uncontrolled high blood pressure despite the use of at least three blood pressure-lowering medicinal products, as observed in a phase 3 randomised, double-blind, placebo-controlled multicentre study. The most common side effects are oedema/fluid retention and decreased haemoglobin.

The full indication is:

> JERAYGO is indicated for the treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products (see section 5.1).

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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