25 July 2024
EMA/CHMP/327112/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Iqirvo

elafibranor

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Iqirvo[3], intended for the treatment of primary biliary cholangitis (PBC).

The applicant for this medicinal product is Ipsen Pharma.

Iqirvo will be available as 80 mg film-coated tablets. The active substance of Iqirvo is elafibranor, a bile therapy (ATC code: A05AX06). Elafibranor and its main active metabolite, GFT1007, are dual peroxisome proliferator-activated receptor (PPAR) α/δ agonists. PPAR α/δ are thought to be key regulators of bile acid homeostasis, inflammation and fibrosis. Activation of PPARα and PPARδ decreases bile toxicity and improve cholestasis by modulating bile acid synthesis, detoxification and transporters. Activation of PPARα and PPARδ also has anti-inflammatory effects by acting on different pathways.

The benefits of Iqirvo are its ability to reduce alkaline phosphatase and bilirubin levels in adults with PBC. Iqirvo is therefore expected to have clinical benefits such as delayed development of liver fibrosis, cirrhosis, liver transplant and death. After authorisation, the company that markets Iqirvo must submit data on its efficacy in terms of clinically relevant events and safety. The most common side effects were abdominal pain, diarrhoea, nausea and vomiting.

The full indication is:

> Iqirvo is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

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

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage
[3] 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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.