12 December 2024
EMA/CHMP/548691/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Seladelpar Gilead

seladelpar

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[3] marketing authorisation for the medicinal product Seladelpar Gilead[2], intended for the treatment of Primary Biliary Cholangitis (PBC).

The applicant for this medicinal product is Gilead Sciences Ireland UC.

Seladelpar Gilead will be available as 10 mg hard capsules. The active substance of Seladelpar Gilead is seladelpar lysine dihydrate, a drug for bile therapy (ATC code: A05AX07). Seladelpar Gilead is a peroxisome proliferator-activated receptor (PPAR)-delta agonist. Seladelpar Gilead reduces the production of bile acid in the liver, preventing liver damage and reducing circulating bile acid levels.

The benefit of Seladelpar Gilead is its ability to reduce alkaline phosphatase and bilirubin levels in adults with PBC. Seladelpar Gilead 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 Seladelpar Gilead must submit further data on its efficacy in terms of clinically relevant events and safety. The most common side effects were abdominal pain, headache, nausea and abdominal distension.

The full indication is:

> Seladelpar Gilead is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in those 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 made available in all official European Union languages after the marketing authorisation has been

[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
[3] 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.

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