19 June 2025
EMA/193903/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rezdiffra

resmetirom

On 19 June 2025, 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 Rezdiffra, intended for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH). The applicant for this medicinal product is Madrigal Pharmaceuticals EU Limited.

Rezdiffra will be available as 60 mg, 80 mg and 100 mg film-coated tablets. The active substance of Rezdiffra is resmetirom, a liver therapy (ATC code: A05BA11). Resmetirom stimulates the thyroid hormone receptor beta (THR-β) in the liver, thus reducing lipotoxic liver fat, inflammation and liver fibrosis.

The benefits of Rezdiffra are the resolution of MASH as well as improvement in fibrosis compared with placebo, as observed in a multicentre, randomised, double-blind, placebo-controlled clinical trial in patients with MASH and liver fibrosis. The most common side effects with Rezdiffra include diarrhoea, nausea, and pruritus.

The full indication is:

> Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (fibrosis stages F2 to F3).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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

[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.

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