23 April 2026
EMA/CHMP/94677/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Redemplo

plozasiran

On 23 April 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Redemplo[2], intended for the treatment of adults with familial chylomicronaemia syndrome (FCS).

The applicant for this medicinal product is Arrowhead Pharmaceuticals Ireland Limited.

Redemplo will be available as a 25 mg solution for injection in pre-filled syringes. The active substance of Redemplo is plozasiran, a small interfering RNA conjugated with N-acetylgalactosamine (ATC code: not yet assigned). Plozasiran selectively degrades the mRNA for apolipoprotein C3 (APOC3) in hepatocytes, resulting in reduced levels of hepatic and serum APOC3 protein. This, in turn, enhances the activity of lipoprotein lipase and hepatocyte uptake of triglyceride-rich lipoprotein remnants, leading to decreases in serum triglycerides.

The benefit of Redemplo is a reduction in the levels of fasting triglycerides compared with placebo, as observed in a phase 3, randomised, double-blind, placebo-controlled clinical study involving adults with FCS. The most common side effects with Redemplo are hyperglycaemia, headache, nausea and injection site reactions.

The full indication is:

> Redemplo is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with familial chylomicronaemia syndrome (FCS) (See section 4.2 for patient selection criteria).

Treatment with Redemplo should be initiated and supervised by a physician experienced in the treatment of patients with FCS.

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] This product was designated as an orphan medicine during its development. EMA has reviewed the information available to date and determined that the orphan designation should be maintained

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