24 July 2025
EMA/CHMP/225521/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tryngolza

olezarsen

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tryngolza[2], intended for the treatment of adults with familial chylomicronemia syndrome (FCS).

The applicant for this medicinal product is Ionis Ireland Limited.

Tryngolza will be available as an 80 mg solution for injection in pre-filled pens. The active substance of Tryngolza is olezarsen, a lipid modifying agent (ATC code: not yet assigned). Olezarsen is an antisense oligonucleotide which inhibits the formation of apolipoprotein C3 (apoC-III), a protein that regulates both triglyceride metabolism and hepatic clearance of chylomicrons and other triglyceride-rich lipoproteins. By reducing serum apoC-III, olezarsen increases clearance of plasma triglycerides.

The benefit of Tryngolza is its ability to reduce levels of fasting triglycerides in adults with FCS after 6 months of treatment compared with placebo, as observed in a randomised, multicentre, double-blind, placebo-controlled phase 3 study. The most common side effects with Tryngolza include injection site erythema, headache, arthralgia and vomiting.

The full indication is:

> Tryngolza is indicated as an adjunct to diet in adult patients for the treatment of genetically confirmed familial chylomicronemia syndrome (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 will now review the information available to date to determine if the orphan designation can be maintained

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