22 April 2021
EMA/CHMP/164775/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Evkeeza

evinacumab

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Evkeeza, intended for the treatment of adult and adolescent patients aged 12 years and older with homozygous familial hypercholesterolaemia (HoFH).

The applicant for this medicinal product is Regeneron Ireland Designated Activity Company (DAC).

Evkeeza will be available as concentrate for solution for infusion (150 mg/ml). The active substance of Evkeeza is evinacumab, a monoclonal antibody belonging to the therapeutic class of lipid modifying agents (ATC code: C10AX). It reduces LDL-C cholesterol (LDL-C) level independent of the presence of the LDL receptor by promoting very low-density lipoprotein (VLDL) processing and VLDL remnants clearance upstream of LDL formation.

The benefits of Evkeeza are its ability to reduce LDL-C. The most common side effects are nasopharyngitis, influenza like illness, dizziness, back pain and nausea.

The full indication is:

> Evkeeza is indicated as an adjunct to diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and adolescent patients aged 12 years and older with homozygous familial hypercholesterolaemia (HoFH).

Evkeeza should be initiated and monitored by physicians experienced in the treatment of lipid disorders.

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] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.