15 October 2020
EMA/CHMP/520993/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Leqvio

inclisiran

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Leqvio, intended for the treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

The applicant for this medicinal product is Novartis Europharm Limited.

Leqvio will be available as a 284-mg solution for injection. The active substance of Leqvio is inclisiran, a lipid-modifying agent (ATC code: C10AX16). Inclisiran reduces the intrahepatic PCSK9 enzyme and increases recycling of LDL-C receptor and its expression on the hepatocyte cell surface, thereby increasing LDL-C uptake and lowering LDL-C levels in the circulation.

The benefits of Leqvio are lowering of LDL-C levels to a significantly greater extent compared to placebo. The most common side effects are reactions at the injection site. These adverse events were localised, predominantly mild or occasionally moderate, transient, and resolved without sequelae.

The full indication is:

> Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
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> - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
> - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

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 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

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