



21 May 2015  
EMA/CHMP/291871/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Repatha evolocumab

On 21 May 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Repatha, intended for the treatment of adult patients with hypercholesterolaemia or mixed dyslipidaemia, and adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia.

The applicant for this medicinal product is Amgen Europe B.V.

Repatha will be available as 140 mg/ml solution for injection in pre-filled syringe or in pre-filled pen. The active substance of Repatha is evolocumab, a lipid modifying agent (ATC code: C10AX13).

Evolocumab, a human monoclonal antibody, binds selectively to proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that regulates the recycling of LDL-receptors on the surface of liver cells and decreases the ability of the liver to clear LDL from the blood. By binding to PCSK9 evolocumab increases liver levels of LDL receptor thereby reducing serum LDL-cholesterol levels.

The benefits with Repatha are its ability to reduce the level of serum LDL-cholesterol in patients who are unable to control their cholesterol despite taking maximum tolerated dose of statins or who cannot take statins.

The most common side effects are: nasopharyngitis, upper respiratory tract infection, and back pain. The use of Repatha may lead to very low cholesterol levels where long-term safety has not yet been established.

The full indication is:

#### “Hypercholesterolaemia and mixed dyslipidaemia

Repatha is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- 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,

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated.

#### Homozygous familial hypercholesterolaemia

Repatha is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

The effect of Repatha on cardiovascular morbidity and mortality has not yet been determined.”

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.