



31 January 2019  
EMA/CHMP/44606/2019  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Praluent alirocumab

On 31 January 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Praluent. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted a new indication as follows:

#### "Established atherosclerotic cardiovascular disease"

Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1."

For information, the full indications for Praluent will be as follows:<sup>2</sup>

#### "Primary hypercholesterolaemia and mixed dyslipidaemia"

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

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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

<sup>2</sup> **New text in bold, removed text strikethrough**



~~The effect of Praluent on cardiovascular morbidity and mortality has not yet been determined.~~

**Established atherosclerotic cardiovascular disease**

**Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:**

- **in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,**
- **alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.**

**For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1."**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.