EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/CHMP/392428/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Praluent

alirocumab

On 23 July 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 Praluent, intended for the treatment of adult patients with primary hypercholesterolaemia (heterozygous familial and non-familial) and mixed dyslipidaemia. The applicant for this medicinal product is sanofi-aventis groupe.

Praluent will be available as 75 mg/ml and 150 mg/ml solution for injection in pre-filled syringes and pre-filled pens. The active substance of Praluent is alirocumab, a lipid modifying agent. Alirocumab, a human monoclonal antibody, binds selectively to proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that regulates the recycling of low-density lipoprotein (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, alirocumab increases the levels of LDL receptor on the surface of liver cells thereby reducing serum LDL-cholesterol levels.

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

The most common side effects are upper respiratory tract signs and symptoms, pruritus and injection site reactions. The use of Praluent may lead to very low cholesterol levels, the impact of which on long-term safety has not yet been established.

The full indication is:

"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,

[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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or for whom a statin is contraindicated.

The effect of Praluent 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.