EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Praluent recommended for approval to lower cholesterol

Medicine to offer therapy for patients unable to control high cholesterol with currently available treatment

The European Medicines Agency (EMA) has recommended the granting of a marketing authorisation for Praluent (alirocumab) to lower high levels of cholesterol in the blood of people who are unable to control their cholesterol despite taking optimal doses of statins or who cannot take statins. The medicine should be used in addition to a healthy diet. Other lipid-lowering therapies (statins and others) should also be used if tolerated.

High levels of cholesterol in the blood are common risk factors for heart disease, which is the leading cause of death globally.

Praluent belongs to a new class of medicines called PCSK9 inhibitors, which provide new options for the treatment of high cholesterol, an area where only few effective therapies have emerged since the introduction of statins. It is the second representative of this new type of monoclonal antibody (a type of protein) to be recommended for approval in the European Union (EU). Praluent blocks the PCSK9 protein, which would otherwise lower the number of LDL-receptors in the liver and through this, diminish the liver's ability to remove LDL-cholesterol ('bad cholesterol') from the blood.

The efficacy of Praluent was assessed in 10 phase III (late-stage) studies, involving close to 5,300 patients with hypercholesterolaemia (high blood cholesterol levels) and mixed dyslipidaemia (abnormal levels of fat in the blood, including high levels of LDL-cholesterol). Praluent reduced LDL-cholesterol for these patient groups. Available evidence does not yet allow the longer term benefits of Praluent for patients in reducing heart disease or death from heart disease to be determined.

The Committee for Medicinal Products for Human Use (CHMP) also looked at safety information from over 3,300 patients treated with Praluent. The Committee considered that the safety profile of Praluent is acceptable, with few patients discontinuing treatment or showing serious adverse events.

The full indication of Praluent as recommended by the CHMP is as follows:

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

The company received scientific advice on quality, non-clinical and clinical aspects of the application from the CHMP. This is one of the Agency's main tools to facilitate and stimulate research and development within the EU.

The opinion adopted by the CHMP at its July 2015 meeting is an intermediary step on Praluent's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing-authorisation applicant for Praluent is sanofi-aventis groupe.
3. In May 2015, the CHMP recommended authorising another medicine from the same class, Repatha. More information is available here.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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