

## Praluent® (alirocumab) - New and expanded indications

- On April 26, 2019, <u>Regeneron</u> and <u>Sanofi</u> announced the FDA approval of <u>Praluent (alirocumab)</u>, to reduce the risk of myocardial infarction (MI), stroke, and unstable angina requiring hospitalization in adults with established cardiovascular (CV) disease.
- The FDA also approved Praluent as an adjunct to diet, alone or in combination with other lipid-lowering therapies (eg, statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).
  - Previously, Praluent was only approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic CV disease.
- The new indication for Praluent was based on data from ODYSSEY OUTCOMES, a double-blind study in 18,924 adult patients with an acute coronary syndrome event 4 to 52 weeks prior to randomization. Patients were randomized to receive either Praluent or placebo. Primary composite endpoint defined as: time to first occurrence of coronary heart disease death, non-fatal MI, fatal and non-fatal ischemic stroke, or unstable angina requiring hospitalization.
  - The median follow-up duration was 33 months.
  - The incidence rate of the primary composite endpoint per 100 patient years was 3.5 (95% CI: 3.3 to 3.8) and 4.2 (95% CI: 3.9 to 4.4) for Praluent and placebo, respectively (Hazard Ratio [HR] 0.85; 95% CI: 0.78, 0.93; p = 0.0003).
- The recommended starting dose of Praluent is 75 mg once every 2 weeks administered subcutaneously (SC), since the majority of patients achieve sufficient LDL-C reduction with this dosage. An alternative starting dosage for patients who prefer less frequent dosing is 300 mg once every 4 weeks (monthly).
  - If the LDL-C response is inadequate, the dosage may be adjusted to the maximum dosage of 150 mg administered every 2 weeks.
  - The recommended dose of Praluent in patients with HeFH undergoing LDL apheresis is 150 mg once every 2 weeks. Praluent can be administered without regard to timing of apheresis.
  - Refer to the Praluent drug label for additional dosing recommendations.



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