Praluent® (alirocumab) – New and expanded indications

- On April 26, 2019, Regeneron and Sanofi announced the FDA approval of Praluent (alirocumab), 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.