Praluent™ (alirocumab) — New Drug Approval

- On July 24, 2015, the FDA announced the approval of Sanofi and Regeneron's Praluent (alirocumab) as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
  - The effect of Praluent on cardiovascular morbidity and mortality has not been determined.
- HeFH is an inherited condition that causes high levels of LDL-C. A high level of LDL-C in the blood is linked to cardiovascular disease.
  - Heart disease is the number one cause of death for Americans, both men and women. According to the Centers for Disease Control and Prevention, about 610,000 people die of heart disease in the United States every year.
- Praluent is the first cholesterol-lowering treatment in a new class of drugs known as proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. PCSK9 is a protein that reduces the number of LDL receptors on the liver. By blocking PCSK9's ability to work, more receptors are available to remove LDL-C from the blood and thus, lower LDL-C levels.
- The efficacy and safety of Praluent were evaluated in 5 placebo-controlled trials involving 2,476 patients with HeFH or at high risk for heart attack or stroke. Patients were on maximally tolerated doses of a statin, with or without other lipid-modifying therapies.
  - Patients taking Praluent achieved an average reduction in LDL from 36 – 59%, compared to placebo.
  - A trial evaluating the effect of adding Praluent to statins on reducing cardiovascular risk is ongoing.
- Praluent is contraindicated in patients with a history of a serious hypersensitivity reaction to Praluent. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization.
- Warnings and precautions for Praluent include allergic reactions.
- The most common adverse reactions (≥ 5% and occurring more frequently than placebo) with Praluent use were nasopharyngitis, injection site reactions, and influenza.
- The recommended starting dose of Praluent is 75 mg administered subcutaneously once every 2 weeks. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks.
  - LDL-C levels should be measured within 4 to 8 weeks of initiating or titrating Praluent to assess response and adjust the dose, if needed.
  - Administer Praluent by subcutaneous injection into the thigh, abdomen, or upper arm.

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  - Praluent should be stored in a refrigerator at 36ºF to 46ºF. Allow Praluent to warm to room temperature for 30 to 40 minutes prior to use.
- Sanofi and Regeneron plan to launch Praluent early next week. Praluent will be available as 75 mg/mL and 150 mg/mL single-dose, pre-filled pens and syringes.
- The Wholesale Acquisition Cost (WAC) price of Praluent is $40 per day ($1,120 every 28 days) for both the 75 mg and 150 mg doses.
- Sanofi and Regeneron will launch a comprehensive program that offers patient assistance to uninsured or underinsured patients, clinical support for healthcare practitioners, as well as reimbursement services. For more information, call 1-844-PRALUENT (1-844-772-5836).

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