

PRALUENT® (alirocumab) Injection: Achieving Further LDL-C Control With Two Different Doses

Guest Speaker

John Osborne, MD, PhD
Dallas Physician Medical Group
Dallas, TX

Wednesday, March 22, 2017

Program Time: 6:30 PM - 8:00 PM
Program Registration Time: 6:00 PM

Stone Forks Restaurant

189 E. Kings Highway
Shreveport, LA 71104

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Please send your completed registration form to Susan Brewster with Regeneron Educational Programs at sbrewster@sphase.com or by fax to (678) 534-3840.

Questions regarding this Program should be directed to Susan Brewster at (770) 984-5181 or your Regeneron Medical Specialist, Kristy Arnold, at (903) 353-3018 or kristy.arnold@regeneron.com.

This Program is being conducted by Regeneron Pharmaceuticals, Inc. No CME credits are available.

IMPORTANT SAFETY INFORMATION

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.

Please see accompanying full Prescribing Information.



SANOFI
Sanofi US
55 Corporate Drive
Bridgewater, NJ 08807

REGENERON
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

October 2015

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

PRALUENT (alirocumab) is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

The effect of PRALUENT on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

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.

Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve.

The most commonly occurring adverse reactions ($\geq 5\%$ of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza.

Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

Neurocognitive events were reported in 0.8% of patients treated with PRALUENT and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2% for each) than in those treated with placebo ($<0.1\%$ for each).

Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with PRALUENT and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with PRALUENT and 1.4% of patients treated with placebo.

The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus $<0.1\%$).

PRALUENT is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT.

Please see accompanying full Prescribing Information


Praluent[®]
(alirocumab) Injection 75mg/mL
150mg/mL

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