



Regeneron and Sanofi to Present Results from Phase 3 Praluent® (alirocumab) Injection Clinical Trials at AHA Scientific Sessions 2015

November 5, 2015

Tarrytown, New York and Bridgewater, New Jersey - November 5, 2015 - Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that new data from the Praluent clinical trial program will be presented at the American Heart Association's (AHA's) Scientific Sessions 2015 in Orlando, FL, from November 7-11, 2015. Data includes two oral presentations on the safety and efficacy of LDL cholesterol lowering with Praluent in people with diabetes and its effect on glycemic measures, and a poster on an analysis which assessed the LDL cholesterol reduction achieved when Praluent was increased from a 75 mg to 150 mg dose.

Praluent is a fully-human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

Regeneron and Sanofi data will be presented throughout AHA Scientific Sessions 2015 during the following events:

ORAL PRESENTATIONS

- **Cardiometabolic Therapies: Lipids and Diabetes**

- Alirocumab Effect on Glycemic Measures in Patients Without Diabetes at Baseline (Colhoun)
 - Tuesday, November 10, 5:30-6:45 p.m. ET (*Presentation from 5:45-6:00 p.m. ET*)
- Efficacy and Safety of Alirocumab: Pooled Analyses of 1048 Individuals With Diabetes Mellitus From Five Placebo-controlled Phase 3 Studies of at Least 52 Weeks Duration (Ginsberg)
 - Tuesday, November 10, 5:30-6:45 p.m. ET (*Presentation from 6:00-6:15 p.m. ET*)

POSTER PRESENTATIONS

- **Risk Factors**

- Additional LDL-C Reduction Achieved With Alirocumab Dose Increase on Background Statin (Kastelein)
 - Sunday, November 8, 9:00-10:15 a.m. ET
- Alirocumab LDL-C-Lowering Efficacy in Patients With Moderate CKD (Toth)
 - Sunday, November 8, 9:00-10:15 a.m. ET

- **New Insights into Treatment of Cardiovascular Diseases**

- Effects of a Proprotein Convertase Subtilisin/kexin Type 9 (PCSK9) Inhibitor, Alirocumab, on Lipid and Lipoprotein Metabolism in Healthy Subjects (Reyes-Soffer)
 - Sunday, November 8, 5:30-6:45 p.m. ET

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

Important Safety Information

PRALUENT® (alirocumab) 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 (?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%).

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