



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%).

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

Please click [here](#) for the full prescribing information.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: [REGN](#)) is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron Forward-Looking Statements and Use of Digital Media

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation Praluent® (alirocumab) Injection; unforeseen safety issues and possible liability resulting from the administration of products (including without limitation Praluent) and product candidates in patients; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials, such as the ODYSSEY OUTCOMES trial evaluating Praluent; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Praluent), research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2014 and its Form 10-Q for the quarterly period ended September 30, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

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