Regeneron and Sanofi Announce New Praluent® (alirocumab) Injection Analyses Presented at AHA Scientific Sessions 2015

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TARRYTOWN, N.Y. and BRIDGEWATER, N.J., Nov. 10, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced a new post-hoc analysis of six Phase 3 clinical trials showing that approximately three quarters (74 percent) of patients reached their pre-specified LDL cholesterol targets within 8 weeks of adding Praluent® (alirocumab) Injection 75 mg to their standard-of-care, which included statins. In the 26 percent of patients whose dose was increased to 150 mg, most were able to achieve their pre-specified LDL cholesterol target, with an average additional 14 percent reduction in LDL cholesterol. The results from this and other analyses, which evaluated Praluent every two weeks, were presented at the American Heart Association (AHA) Scientific Sessions in Orlando, FL.

"In this analysis of patients who required further improvement of their LDL cholesterol levels, adding Praluent 75 mg to their standard-of-care allowed the majority of patients to achieve their LDL cholesterol goals. For those who required further LDL cholesterol lowering, increasing Praluent to 150 mg provided additional efficacy," said Harold Bays, M.D., from the Louisville Metabolic & Atherosclerosis Research Center, Kentucky, U.S. "Data such as these provide clinicians practical insight as to how the two Praluent doses may better allow patients to achieve their LDL cholesterol goals."

These results are based on a pooled post-hoc analysis of 1,291 patients with high cardiovascular (CV) risk or an inherited form of high cholesterol (heterozygous familial hypercholesterolemia, or HeFH) which found 74 percent of patients who added Praluent 75 mg achieved their LDL cholesterol-lowering goals at week 8, and the remaining 26 percent had their dose adjusted to 150 mg at week 12. In other results:

- By week 24, 61 percent of patients who switched to 150 mg achieved their goal, with a mean additional LDL cholesterol reduction of 14 percent.
- Comparable adverse event (AE) rates were observed in patients whose Praluent dose was increased, versus those whose dose was not (66 percent in both arms in placebo-controlled trials; and 55 percent versus 56 percent respectively in ezetimibe-controlled trials).
- *About the data:* The pooled analysis included results from six Phase 3 ODYSSEY trials where patients added Praluent 75 mg to standard-of-care, and had their dose adjusted at week 12 to 150 mg if they did not reach their LDL cholesterol goals by week 8. Cholesterol goals were either less than 70 mg/dL or less than 100 mg/dL, dependent on CV risk. All patients across the six trials received background statin therapy. In three trials Praluent was compared to placebo (ODYSSEY FH I, FH II, COMBO I), and in three it was compared to ezetimibe (ODYSSEY COMBO II, OPTIONS I, OPTIONS II).

In a separate pooled post-hoc analysis of 3,499 patients, individuals with diabetes (n=1,051) who initially received Praluent 75 mg or 150 mg every two weeks had a mean percent difference in LDL cholesterol of 44 percent and 58 percent, respectively, versus placebo at week 24 (p less than 0.0001). In other results:

- Praluent was generally well tolerated, with the most common adverse events among people with diabetes being nasopharyngitis (11 percent Praluent, 10 percent placebo) and upper respiratory tract infection (8 percent Praluent, 9 percent placebo).
- *About the data:* The pooled analysis included results from five placebo-controlled trials of individuals with diabetes (1,051), and without diabetes (2,448) with inadequately controlled hypercholesterolemia receiving standard-of-care, which included maximally-tolerated statins. In two of the trials, patients initially received Praluent 150 mg (ODYSSEY LONG TERM, HIGH FH). In three of the trials, patients initially received Praluent 75 mg and had their dose adjusted to 150 mg at week 12 if they required additional lipid-lowering to meet their LDL cholesterol goals (ODYSSEY COMBO I, FH I, FH II).

A third post-hoc analysis of 4,974 patients did not find an increased risk of diabetes-related AEs among those who didn't have diabetes when they entered the trials, regardless of whether they were taking Praluent or were in a control group (placebo or ezetimibe). There was also no evidence that Praluent affected the incidence of new-onset diabetes or pre-diabetes. The ongoing ODYSSEY OUTCOMES trial will provide further data on the impact of Praluent on glycemic measures.

- *About the data:* The pooled analysis included results from 10 Phase 3 ODYSSEY trials of patients with inadequately controlled hypercholesterolemia, ranging from 24 to 78 weeks (ODYSSEY LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, MONO, ALTERNATIVE). In total, 1,526 (31 percent) had a medical history of diabetes upon entering the trials, 1,969 (40 percent) were identified as having pre-diabetes, and 1,479 (30 percent) did not have diabetes (e.g., had a normal concentration of glucose in the blood).

About Praluent

In July, the companies announced that Praluent was approved for use in the U.S. Praluent is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic CV disease, who require additional lowering of LDL cholesterol. The effect of Praluent on CV morbidity and mortality has not been determined.

In September, the European Commission approved the marketing authorization for Praluent. In the E.U., Praluent is approved for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin or b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on CV morbidity and mortality has not yet been determined.

IMPORTANT SAFETY INFORMATION FOR U.S.

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 (&> 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.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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 (such as the ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit); 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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