Regeneron and Sanofi Announce Positive Topline Results from Phase 3 Praluent® (alirocumab) Study in Patients Undergoing LDL Apheresis Therapy

March 23, 2016

TARRYTOWN, N.Y. and PARIS, March 23, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced positive results from the Phase 3 ODYSSEY ESCAPE trial evaluating Praluent® (alirocumab) Injection in patients with an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH), whose cholesterol levels required chronic, weekly or bi-weekly apheresis therapy. The trial met its primary endpoint, demonstrating that patients who added Praluent to their existing treatment regimen significantly reduced the frequency of their apheresis therapy by 75 percent, compared to placebo (p less than 0.0001). Sixty-three percent of patients treated with Praluent no longer required apheresis, compared to zero percent of placebo patients. Apheresis is a procedure where bad (LDL) cholesterol is removed from the blood, in a process similar to kidney dialysis.

"This is the first time a PCSK9 inhibitor has shown in a clinical study that it reduced the frequency of apheresis therapy, an invasive, difficult to access, time-consuming and expensive treatment for some of the most difficult-to-treat patients," said Bill Sasiela, Ph.D, VP, Program Direction, Regeneron. "The ODYSSEY clinical trial program was designed to understand the effect of Praluent on many different patient populations with a high degree of unmet need who required further reduction of their LDL cholesterol."

Apheresis therapy is invasive and burdensome to patients, given that it can take more than three hours. Treatment may also be inconvenient and cost up to $100,000 for each patient per year in the U.S. or up to €60,000 in Germany, where there are 200 centers and LDL apheresis is more frequently used. In the U.S. there are only approximately 60 apheresis centers and many patients must travel significant distances for the procedure.

"Despite statins, a subset of patients with heterozygous familial hypercholesterolemia are unable to sufficiently reduce their LDL cholesterol, and require regular apheresis treatment," said Jay Edelberg, MD., Ph.D, Head of Cardiovascular Development, Sanofi. "The results demonstrate that treatment with Praluent may help these patients decrease the frequency or even eliminate the need for apheresis."

The most common adverse events in the trial were fatigue (15 percent Praluent; 10 percent placebo), nasopharyngitis (10 percent Praluent; 10 percent placebo), diarrhea (10 percent Praluent; 0 percent placebo), myalgia (10 percent Praluent; 5 percent placebo), upper respiratory infection (7 percent Praluent; 19 percent placebo), headache (7 percent Praluent; 5 percent placebo), arthralgia (7 percent Praluent; 10 percent placebo), and back pain (5 percent Praluent; 10 percent placebo).

Detailed data will be presented at future medical congresses.

About ODYSSEY ESCAPE
The completed Phase 3 placebo-controlled ODYSSEY ESCAPE trial involved 62 patients from 14 treatment centers in the U.S. and Germany. These patients were receiving regular baseline apheresis therapy at fixed intervals of every week or every 2 weeks prior to randomization. Patients were randomized to receive Praluent 150 mg (n=41) subcutaneously every 2 weeks or placebo (n=21), in addition to their existing treatment regimen. The double-blind treatment period comprised two intervals: for the first 6 weeks, patients remained on their established apheresis schedule at baseline, and for the following 12 weeks, apheresis frequency was adjusted based on the patient's LDL cholesterol response to treatment. ODYSSEY ESCAPE is part of the overarching Phase 3 ODYSSEY program, which includes more than 25,000 patients.

About Praluent
In July 2015, 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 CVD, who require additional lowering of LDL cholesterol. The effect of Praluent on CV morbidity and mortality has not been determined.

In September 2015, 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.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Important Safety Information for U.S.
Do not use PRALUENT if you are allergic to alirocumab or to any of the ingredients in PRALUENT. Before you start using PRALUENT, tell your healthcare provider about all your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face, or trouble breathing.

The most common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site, symptoms of the common cold, and flu or flu-like symptoms. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Talk to your doctor about the right way to prepare and give yourself a PRALUENT injection and follow the "Instructions for Use" that comes with Praluent.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 initiatives 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, 2015. 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 prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit; 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); 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, 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).

Contacts Sanofi:

Media Relations	**Investor Relations**
Jack Cox	**Sébastien Martel**
Tel: +33 (0)1 53 77 46 46	Tel: +33 (0)1 53 77 45 45
mr@sanofi.com	ir@sanofi.com

Contacts Regeneron:

Media Relations	
Arleen Goldenberg	**Investor Relations**
Tel: +1 (914) 847-3456	**Manisha Narasimhan, Ph.D.**
Mobile: +1 (914) 260-8788	Tel: +1 (914) 847-5126
arleen.goldenberg@regeneron.com	manisha.narasimhan@regeneron.com