Regeneron and Sanofi to Present New Analyses from the Praluent® (alirocumab) Injection ODYSSEY Clinical Trial Program at the AHA Scientific Sessions 2017

November 7, 2017

TARRYTOWN, N.Y. and BRIDGEWATER, N.J., Nov. 7, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced new data analyses from the Praluent® (alirocumab) Injection ODYSSEY clinical trial program will be presented at the American Heart Association (AHA) Scientific Sessions 2017, November 11-15, in Anaheim, CA.

New analyses from the ODYSSEY ESCAPE trial evaluating treatment of Praluent in high-risk patients with heterozygous familial hypercholesterolemia (HeFH) undergoing apheresis therapy will be presented. Additional ODYSSEY clinical trial program data include a post-hoc analysis of three pooled ODYSSEY Phase 3 studies evaluating efficacy and safety data by race and ethnicity, and results of the ODYSSEY Open-Label Extension study observing long-term adherence to Praluent.

Key poster presentations at AHA Scientific Sessions 2017 from the ODYSSEY clinical trial program and other studies include:

Praluent Data

- ***Characteristics of Patients with &< 15% Reduction in Low-Density Lipoprotein Cholesterol with Alirocumab (Bays)***
  - Abstract # S2114
  - Sunday, November 12, 3:15 PM - 4:30 PM PT
- ***Effect of Apheresis on Alirocumab and PCSK9 Concentrations in the ODYSSEY ESCAPE Study (Moriarty)***
  - Abstract # M5005
  - Monday, November 13, 3:00 PM - 4:15 PM PT
- ***Impact of Age on the Efficacy and Safety of Alirocumab in Patients With Heterozygous Familial Hypercholesterolemia (Santos)***
  - Abstract # T2064
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT
- ***High Level of Adherence to Alirocumab and Concomitant Background Treatments for Patients with Heterozygous Familial Hypercholesterolemia in the ODYSSEY Open-Label Extension Study (Farnier)***
  - Abstract # T2144
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT
- ***Alirocumab Efficacy and Safety by Race and Ethnicity: Analysis From Three ODYSSEY Phase 3 Trials (Ferdinand)***
  - Abstract # T2063
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT
- ***Predictive Factors of the Magnitude of Response to Alirocumab Dose Increase in Patients with Dyslipidemia (Ray)***
  - Abstract # T2138
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT

Other Data of Interest

- ***PCSK9 Inhibitors: Patient-Reported Barriers to Medication Initiation & Persistence (Navar)***
  - Abstract # S2112
  - Sunday, November 12, 3:15 PM - 4:30 PM PT
- ***Statin Utilization and Side Effects Among Adults Over Age 75: Insights From the PALM Registry (Nanna)***
  - Abstract # M2198
  - Monday, November 13, 3:00 PM - 4:15 PM PT
- ***Associations of Provider Knowledge and Beliefs Regarding Lipid Management With Statin Therapy Use and Lipid Outcomes (Lowenstern)***
  - Abstract # T2113
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT
- ***Statin Decision-Making Since the 2013 AHA/ACC Cholesterol Guidelines: Do Clinicians Do What They Say? (Lowenstern)***
  - Abstract # T2109
  - Tuesday, November 14, 10:30 AM - 11:45 AM PT

Additional information on the AHA Scientific Sessions 2017 is available on the meeting website.

About Praluent

Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells, which results in lower LDL-C levels in the blood.

Praluent is approved in more than 50 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as the European Union (EU). In the U.S., Praluent is approved for use as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. In the EU, 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-C 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 been determined. ODYSSEY OUTCOMES is prospectively evaluating the effect of Praluent on the occurrence of CV events in approximately 18,000 patients who have experienced an acute coronary syndrome.

Important Safety Information for the 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 is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, and provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led by physician-scientists for nearly 30 years, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*® technologies, including *VelocImmune*® to yield optimized fully-human antibodies, and ambitious initiatives such as the Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

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, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, including the patent litigation relating to Praluent, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, unexpected safety, quality or manufacturing issues, 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 or Praluent, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, trends in exchange rates and prevailing interest rates, volatile economic conditions, 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, 2016. 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, risks associated with intellectual property of other parties and pending or future litigation relating thereto, including the patent litigation proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; 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; 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; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be canceled or terminated without any further product success. 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, 2016 and its Form 10-Q for the quarterly period ended June 30, 2017. 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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