Regeneron and Sanofi to Present New Phase 3 Praluent® (alirocumab) Injection Clinical Trial Analyses at ACC.17 Scientific Sessions

March 7, 2017

TARRYTOWN, N.Y. and BRIDGEWATER, N.J., March 7, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced new Phase 3 data from the Praluent® (alirocumab) Injection clinical trial program will be presented at the American College of Cardiology Scientific Sessions (ACC.17), March 17-19, 2017 in Washington, D.C.

Key data include presentations on the effects of Praluent across several patient subsets such as diabetes, heterozygous familial hypercholesterolemia (HeFH), and atherosclerotic cardiovascular disease (ASCVD) and post-hoc analyses on the effect of Praluent on major cardiovascular events (MACE). Additionally, a safety update utilizing real-world data from the Praluent open-label extension trial will be presented.

Praluent is a human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), which is approved in approximately 40 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico, Brazil and the European Union (EU). The effect of Praluent on cardiovascular (CV) morbidity and mortality has not yet been determined.

Sanofi and Regeneron data will be presented throughout ACC.17 during the following sessions of note:

1) MODERATED POSTER PRESENTATIONS

- **The PCSK9 revolution: new insights into evaluation and treatment**
  - Alirocumab efficacy and safety in patients with hypercholesterolemia and with or without clinical atherosclerotic cardiovascular disease: Pooled analysis of 10 ODYSSEY randomized trials (Jones)
    - Abstract #1133M-03
    - Friday, March 17, 10:00 - 10:10 a.m. ET
  - Alirocumab treatment in a real world setting: Safety update from an open-label treatment extension to the ODYSSEY program for patients with heterozygous familial hypercholesterolemia (Guyton)
    - Abstract #1133M-07
    - Friday, March 17, 10:30 - 10:40 a.m. ET
  - Impact of statin intolerance rates on ezetimibe and/or PCSK9 inhibitor use for meeting low-density lipoprotein goals in a real-world cohort with atherosclerotic cardiovascular disease (Cannon)
    - Abstract #1133M-13
    - Friday, March 17, 11:15 - 11:25 a.m. ET
  - A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of alirocumab in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid-modifying therapy in South Korea and Taiwan (Koh)
    - Abstract #1133M-15
    - Friday, March 17, 11:30 - 11:40 a.m. ET
- **The intersection of diabetes and atherosclerotic cardiovascular disease (ASCVD)**
  - Alirocumab safety in individuals with and without diabetes mellitus: Pooled data from 14 ODYSSEY trials (Leiter)
    - Abstract #1222M-07
    - Saturday, March 18, 1:00 - 1:10 p.m. ET

2) POSTER PRESENTATIONS

- **Advances in cholesterol measurement and management**
  - Efficacy and safety of the PCSK9 inhibitor alirocumab 300 mg every 4 weeks in individuals with type 2 diabetes on maximally tolerated statin therapy (Muller-Wieland)
    - Abstract #1106-055
    - Friday, March 17, 10:00 - 10:45 a.m. ET
- **Traditional and novel factors used to assess the risk of, and used for the treatment of, coronary artery disease (CAD)**
  - Lower on-treatment low-density lipoprotein cholesterol is associated with lower cardiovascular risk in very high risk patients with atherosclerotic cardiovascular disease: analyses from the ODYSSEY trials (Ray)
    - Abstract # 1126-316
    - Friday, March 17, 10:00 - 10:45 a.m. ET
- **Advances in lipid management**

- Alirocumab reduces major cardiovascular events in individuals with atherosclerotic cardiovascular disease: a post-hoc analysis of ODYSSEY LONG TERM (Robinson)
    - Abstract #1203-305
    - Saturday, March 18, 9:45 - 10:30 a.m. ET
- Use of high-intensity statin therapy post-acute coronary syndrome in the ongoing ODYSSEY OUTCOMES trial of alirocumab, a proprotein convertase subtilisin/kexin type 9 monoclonal antibody, versus placebo: Interim baseline data (Goodman)
    - Abstract #1203-307
    - Saturday, March 18, 9:45 - 10:30 a.m. ET

- **Cardiac arrest, diabetes, and other high risk features of patients with acute coronary syndrome (ACS)**
    - Lower on-treatment low-density lipoprotein cholesterol is associated with lower cardiovascular risk in women: Analyses from the ODYSSEY trials of alirocumab versus control (Vallejo-Vaz)
        - Abstract #1204-331
        - Saturday, March 18, 9:45 - 10:30 a.m. ET

Additional information on ACC.17 is available on the congress **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 cholesterol levels in the blood. Praluent is the only PCSK9 inhibitor available in two dosages with two levels of efficacy (75 mg and 150 mg), allowing physicians to select the dose based on a patient's LDL cholesterol lowering needs.

Praluent is approved in approximately 40 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico, Brazil and the European Union (EU). In the U.S., Praluent is approved for use 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. 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. 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.

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 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, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. 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 that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL-cholesterol, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, atopic dermatitis, pain, cancer 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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, 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, 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, risks associated with intellectual property of other parties and pending or future litigation relating thereto, including the patent litigation relating to Praluent® (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, 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 and Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled 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. 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
Ashleigh Koss
Tel: +1 (908) 981-8745
ashleigh.koss@sanofi.com

Contacts Regeneron:

Arleen Goldenberg
Tel: + 1 (914) 847-3456
Mobile: +1 (914) 260-8788
arleen.goldenberg@regeneron.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/regeneron-and-sanofi-to-present-new-phase-3-praluent-alirocumab-injection-clinical-trial-analyses-at-acc17-scientific-sessions-300418970.html

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