Regeneron and Sanofi Announce Phase 3 Results Showing LDL-C Reductions of More Than 60 Percent in Japanese Patients Treated with Praluent® (alirocumab) Injection

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TARRYTOWN, N.Y. and PARIS, July 8, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the Phase 3 ODYSSEY JAPAN trial of the investigational therapy Praluent® (alirocumab) Injection met its primary endpoint. At week 24, patients in the Praluent group experienced an average 64 percent greater reduction from baseline in their bad cholesterol, known as low-density lipoprotein cholesterol (LDL-C), when added to current standard of care including statins, compared to standard of care alone (p less than 0.0001). Patients were started on the lower dose of 75 mg, with the option to adjust their dose to 150 mg if they had not achieved their LDL-C goal (as defined by the Japan Atherosclerosis Society guidelines) at week 8. At week 24, 97 percent of patients in the Praluent group reached their LDL-C treatment goal, compared to 10 percent for placebo (p less than 0.0001). Ninety-nine percent of patients treated with Praluent remained on the lower dose; two patients required adjustment to the higher dose.

The trial involved 216 Japanese patients with hypercholesterolemia at high cardiovascular (CV) risk and/or with an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH). Results were presented today for the first time at the Annual Scientific Meeting of the Japan Atherosclerosis Society (JAS) in Sendai, Japan. Praluent is an investigational fully human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

"These results demonstrate the significant cholesterol-lowering ability of Praluent among patients with some of the greatest unmet needs in Japan. This includes those with an inherited form of high cholesterol or pre-existing cardiovascular disease, such as a history of heart attack," said lead investigator Tamio Teramoto, MD, PhD, Director of Teikyo Academic Research Center. "Despite current treatment options, many Japanese patients with hypercholesterolemia are still unable to reach their LDL-C goals, highlighting the need for additional treatment options. Notably, almost all patients reached their LDL-C target levels while remaining on the 75 mg dose, avoiding the need for overtreatment."

ODYSSEY JAPAN evaluated Praluent (n=144) compared to placebo (n=72), both on top of standard care, in Japanese patients with hypercholesterolemia, with either HeFH or at high CV risk, and who could not reach their LDL-C treatment goal as defined by the JAS guidelines despite lipid-lowering treatments that included statins. The mean LDL-C value at baseline was 141.2 mg/dL. Patients were initially randomized to receive either Praluent 75 mg every two weeks administered as a single 1 milliliter (mL) injection, or placebo. Patients in both groups received statins, with or without other lipid-lowering therapies.

Ninety-nine percent of patients who received Praluent at week 8 remained on the initial 75 mg dose, while one percent of patients had their dose adjusted to receive 150 mg every two weeks, also as a single 1 mL injection. The most common adverse events (occurring in at least 5 percent of patients in the Praluent group) were nasopharyngitis, injection site reaction, and back pain.

On June 9, the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. Food and Drug Administration (FDA) recommended the approval of Praluent. The FDA has a target action date of July 24; and while the FDA takes the Committee's advice into consideration, the FDA is not bound by its recommendation. In addition, the Marketing Authorization Application for Praluent in the European Union is currently under review by the European Medicines Agency (EMA). The safety and efficacy of Praluent have not been fully evaluated by any regulatory authority.

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 eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

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

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"), 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); unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation Praluent, and the impact of the recommendation of the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration discussed in the news release on the possible regulatory approval of Praluent; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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; 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; 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 quarter ended March 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.

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