April 1, 2014

Sanofi and Regeneron Report Positive Results With Alirocumab From Phase 2 Japanese Study

New investigational PCSK9 inhibitor shown to significantly reduce LDL-C among Japanese patients

BRIDGEWATER, N.J. and TARRYTOWN, N.Y., April 1, 2014 /PRNewswire/ -- Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the first Phase 2 study with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), in Japanese patients met its primary endpoint. The results demonstrated that the mean low-density lipoprotein-cholesterol (LDL-C, or "bad" cholesterol) percentage reduction from baseline to week 12, the primary efficacy endpoint of the study, was significantly greater in patients randomized to receive one of three doses of alirocumab administered every other week (Q2W) -- 150 milligrams (mg), 75 mg, and 50 mg, in combination with statin therapy, compared to patients receiving placebo.

At Week 12, the mean percentage reduction in LDL-C from baseline in patients receiving alirocumab 50 mg Q2W was 55 percent, alirocumab 75 mg Q2W was 62 percent and alirocumab 150 mg Q2W was 72 percent, compared to 3 percent in the placebo group ($p < 0.0001$ vs. placebo for all treatment arms). All patients in each of the alirocumab groups achieved LDL-C levels of < 100 mg/dL, compared to 8 percent of patients in the placebo group.

Treatment emergent adverse events (TEAEs) in this study were reported by 52 percent of patients in the alirocumab 50 mg group, 48 percent of patients in the 75 mg group, 64 percent of patients in the 150 mg group, compared to 32 percent in the placebo group. The most frequently reported TEAEs were nasopharyngitis, injection site reaction, back pain, cystitis and ligament sprain.

"We are delighted with the findings from the first Phase 2 trial with alirocumab in Japanese patients. Not only was alirocumab shown, in this study, to significantly reduce LDL-C in this patient population, the results of this study also demonstrate the potential efficacy of alirocumab at a range of doses," said Jay Edelberg M.D., Ph.D., Head of the PCSK9 Development and Launch Unit, Sanofi Group.

"Hypercholesterolemia is a growing problem in Japan and many patients are poorly-controlled on statins," commented George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "The results from this trial support the efficacy and safety of alirocumab at a range of doses in Japanese patients."

About the Alirocumab Phase 2 Japanese Study
This multicenter, placebo-controlled Phase 2 study randomized approximately 100 patients with LDL-C greater than or equal to 100 mg/dL receiving lipid-modifying therapy. 25 patients per group were randomized to receive one of three doses of alirocumab dosed subcutaneously every other week (Q2W) -- 150 milligrams (mg), 75 mg or 50 mg, or placebo, all in combination with statin therapy.

The primary study endpoint was the percentage change in calculated LDL-C from baseline to Week 12. The secondary study endpoints included absolute change in calculated LDL-C from baseline to Week 12 and percent and absolute changes in other lipid parameters at Week 12.

About PCSK9
PCSK9 is known to be a determinant of circulating LDL levels, as it binds to LDL receptors resulting in their degradation so that fewer are available on liver cells to remove excess LDL-C from the blood. Moreover, statins increase the level of circulating PCSK9, which in turn may reduce the density of LDL-C receptors available to clear LDL-C from the circulation. Blocking the PCSK9 pathway is therefore a potentially novel mechanism for lowering LDL-C.

About alirocumab
Alirocumab is an investigational, fully-human monoclonal antibody that targets and blocks PCSK9. It is administered via subcutaneous injection. By inhibiting PCSK9, a determinant of circulating LDL-C levels in the blood, alirocumab has been shown in pre-clinical studies to increase the number of LDL receptors on hepatocytes, thereby lowering LDL-C.

The investigational agent described above is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority.

About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

About Regeneron Pharmaceuticals, Inc.
Regeneron 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 markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, 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, 2013. 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, 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 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, including without limitation the Phase 2 trial of alirocumab in Japanese patients and the ODYSSEY global Phase 3 trial program; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; 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, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property 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, 2013. 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.

Sanofi Contacts:

US Media Relations

MK Steel
Tel: 908.981.6031
E-mail: marykathryn.steel@sanofi.com

Investor Relations
George Grofik
Tel: 908.981.3779
george.grofik@sanofi.com

Elizabeth Baxter
PCSK9 Communications
Tel: 1 (908) 981-5360
Mobile: 1 (908) 340-7811
E-mail: Elizabeth.Baxter@sanofi.com

Regeneron Contacts:

Media Relations
Sandy Sexton
Tel: +1 914- 847-3358
sandra.sexton@regeneron.com

Investor Relations
Manisha Narasimhan, Ph.D.
Tel: +1 914-847-5126
manisha.narasimhan@regeneron.com

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media