Sanofi and Regeneron Announce Collaboration with American College of Cardiology for PCSK9 Inhibitor Clinical Program

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PARIS and TARRYTOWN, N.Y., Dec. 19, 2013 /PRNewswire/ -- Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced an innovative collaboration with the American College of Cardiology (ACC) focused on enhancing clinical research with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9). PCSK9 is known to contribute to circulating low-density lipoprotein cholesterol (LDL-C) levels. Alirocumab is being co-developed by Sanofi and Regeneron.

Under the terms of the agreement, the ACC will apply its expertise in clinical research and utilize its extensive registries to identify patients who might be appropriate candidates for the Phase 3 ODYSSEY OUTCOMES clinical trial. This Data Driven Trial Recruitment Program is a new approach to identification and recruitment of patients for the clinical trial. Additional activities under the collaboration include a comprehensive educational program for both physicians and patients with the goal to broaden knowledge and understanding of the value of clinical trial research.

"This project represents another example of how medical registries can help transform medicine," said Ralph Brindis, past-President of the ACC and Senior Medical Officer of External Affairs for the National Cardiovascular Data Registries (NCDR). "The ACC's registries and related provider networks support quality improvement programs for practitioners. For the first time, through our PINNACLE ambulatory office-based registry of the NCDR, we will be helping to solve the difficult problem of identifying physicians with patients who may be eligible for a clinical trial."

"Through this collaboration, we hope to provide better access to our Phase 3 ODYSSEY OUTCOMES Trial," said Jay Edelberg, M.D., Ph.D. Vice President, PCSK9 Development and Launch Unit, Sanofi. This is the first time that ACC's PINNACLE Registry will be used for clinical trial recruitment, and we believe this novel approach will help trial sites meet and hopefully exceed their recruitment goals."

About ODYSSEY
ODYSSEY is the global Phase 3 trial program for investigational compound alirocumab. ODYSSEY currently comprises at least 12 clinical trials enrolling more than 23,000 patients with hypercholesterolemia in 2,000 study centers across North and South America, Europe, Australia, South Africa and Asia.

The trials will evaluate alirocumab in combination with other lipid-lowering agents or as monotherapy across a broad patient population, including high cardiovascular risk patients with primary hypercholesterolemia, patients with primary hypercholesterolemia unable to tolerate statins, and patients with heterozygous familial hypercholesterolemia (HeFH) who are inadequately controlled by current lipid-modifying therapy.

The primary study endpoint in the ODYSSEY trials (except ODYSSEY OUTCOMES) is mean percentage LDL-C reduction at 24 weeks. Several other lipid markers will be evaluated, and trials will continue up to 24 months. In ODYSSEY OUTCOMES, the primary endpoint is a composite of coronary heart disease (CHD) death, non-fatal MI, fatal and non-fatal ischemic stroke, and unstable angina requiring hospitalization.

The ODYSSEY Phase 3 trials are designed to create options to help meet the needs of individual patients. Patients in the majority of ODYSSEY trials will receive a 75mg Q2w (once every two weeks) dose of alirocumab, and will only be up-titrated to 150mg Q2w if they do not show sufficient low-density lipoprotein cholesterol (LDL-C) lowering (to their target level based on risk) after 8 weeks. In addition, ODYSSEY CHOICE I is evaluating alirocumab dosed once every four weeks.

All of the ODYSSEY trials, with the exception of ODYSSEY CHOICE I and ODYSSEY CHOICE II and ODYSSEY OUTCOMES, are fully enrolled. For more information on the ODYSSEY clinical trials, please visit http://www.odysseytrials.com or http://www.clinicaltrials.gov.

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-cholesterol from the blood. Moreover, traditional LDL-lowering therapies such as statins actually stimulate the production of PCSK9, which limits their own ability to lower LDL-cholesterol. Blocking the PCSK9 pathway is therefore a potentially novel mechanism for lowering LDL-cholesterol.

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, a global and diversified 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, 2012. 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 and the planned collaboration with the American College of Cardiology; 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; on-going regulatory obligations and oversight impacting Regeneron's 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, 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, 2012 and its Form 10-Q for the quarterly period ended September 30, 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.

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