Sanofi and Regeneron Announce Patient Enrollment in Cardiovascular Outcomes Trial with Antibody to PCSK9 for Hypercholesterolemia

- 18,000 patient Phase 3 outcomes study will evaluate the impact of antibody to PCSK9 on cardiovascular events -

Paris, France and Tarrytown, N.Y., November 5, 2012 – Sanofi (EURONEXT: SAN and NYSE: **SNY**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the ODYSSEY OUTCOMES trial, a Phase 3 cardiovascular outcomes trial (CVOT) with SAR236553/REGN727 is now recruiting patients. SAR236553/REGN727 is an investigational subcutaneously administered, fully-human antibody that is being evaluated for its impact on lowering low-density lipoprotein cholesterol (LDL-C) by targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

The ODYSSEY OUTCOMES trial will enroll approximately 18,000 patients, who recently suffered an acute coronary syndrome (ACS), from 49 countries across six continents. With the start of this study, eleven trials are now recruiting in the companies' global anti-PCSK9 Phase 3 program.

"Despite widespread use of statin therapy, many patients at risk do not reach recommended targets for LDL. Even among those who do reach targets, further LDL lowering may further reduce the risks of coronary heart disease (CHD) death, myocardial infarction (MI) and stroke," said Ph. Gabriel Steg M.D., Professor of Cardiology at the Hôpital Bichat-Claude Bernard in Paris, France, and co-Chair of the ODYSSEY OUTCOMES Steering Committee. *"The ODYSSEY cardiovascular (CV) outcomes trial will test the efficacy and safety of SAR236553/REGN727 added to maximal doses of statins in reducing cardiovascular morbidity and mortality in patients with recent ACS, a population at high risk of CV events despite best contemporary therapy."*

ODYSSEY OUTCOMES is a double-blind, randomized, placebo-controlled, multi-national study. The primary objective of the study is to evaluate the effect of our anti-PCSK9 on the incidence of cardiovascular events in patients who have experienced an ACS and are not at LDL-C goal. Patients will receive either a 1-milliliter (mL) injection of 75 milligrams (mg) of SAR236553/REGN727 or placebo every two weeks, in addition to individually optimized lipid-lowering therapy. If patients do not reach a predetermined LDL-C goal with the 75 mg dose they will be up-titrated to a dose of 150 mg, also delivered as a 1 mL injection. 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. ODYSSEY OUTCOMES is being conducted under a Special Protocol Assessment (SPA) agreed upon with the U.S. Food and Drug Administration (FDA).

About the Ongoing Phase 3 ODYSSEY Program

The broad Phase 3 ODYSSEY program is underway and will be conducted across more than 2,000 study centers across the United States, Canada, Western and Eastern Europe, South America, Australia and Asia. In addition to ODYSSEY OUTCOMES, the Phase 3 ODYSSEY program includes the following studies:

- ODYSSEY FH I, FH II and HIGH FH, in patients with heFH who are not adequately controlled with their lipid-modifying therapy.
- ODYSSEY COMBO I and COMBO II, in patients with primary hypercholesterolemia at high cardiovascular risk who are not adequately controlled with their lipid-modifying therapy.
- ODYSSEY MONO, in patients with primary hypercholesterolemia.
- ODYSSEY ALTERNATIVE, in patients with primary hypercholesterolemia (heFH and non-familial hypercholesterolemia) who are unable to tolerate statins.
- ODYSSEY OPTIONS I and OPTIONS II, in patients with primary hypercholesterolemia at high cardiovascular risk or with heFH who are not adequately controlled on statins, in comparison to several second-line lipid-lowering strategies.
- ODYSSEY LONG TERM, in patients with hypercholesterolemia at high cardiovascular risk or patients with heFH inadequately controlled with their current lipid-modifying therapy.

Based on the cumulative efficacy and safety data from the SAR236553/REGN727 Phase 1 and Phase 2 clinical studies, 75 mg and 150 mg Q2W doses were chosen to be tested in the Phase 3 program. The selection of these doses was also supported by information from current lipid treatment guidelines and data from large, completed CV event trials that have demonstrated a correlation between the degree of LDL-C lowering and the resultant lowered risk for CV events.

Further information about the initiated Phase 3 studies can be found at www.clinicaltrials.gov.

About PCSK9

PCSK9 is known to be a determinant of circulating LDL-C 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, traditional LDL-lowering therapies such as statins actually stimulate the production of PCSK9, which limits their own ability to lower LDL-C. Blocking the PCSK9 pathway is therefore a potentially novel mechanism for lowering LDL-C.

About SAR236553/REGN727

SAR236553/REGN727, created using Regeneron's VelocImmune® technology, is a fully human monoclonal antibody targeting PCSK9, administered via subcutaneous injection. By inhibiting PCSK9, a determinant of circulating LDL-C levels in the blood, SAR236553/REGN727 has been shown in pre-clinical studies to increase the number of LDL receptors which can clear circulating LDL-C from the bloodstream.

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 fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets three products in the United States, EYLEA® (aflibercept) Injection, ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, and ARCALYST® (rilonacept) Injection for Subcutaneous Use; ZALTRAP is co-commercialized with Sanofi. Phase 3 studies are in progress with EYLEA in two additional indications and with product candidates sarilumab and REGN727. Regeneron has active research and development programs in many disease areas, including

ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at www.regeneron.com.

Media Webcast on the ODYSSEY OUTCOMES Study

Sanofi and Regeneron will host a live media webcast on **Monday, Nov. 5 2012** at **3:00PM Paris CET/ 2:00PM London GMT/ 9:00AM New York EST/ 6:00AM Los Angeles PST**. A Q&A session will take place following the presentation. To register for this event, please click here: http://www.videonewswire.com/event.asp?id=90518.

Investor Relations Conference Call on PCSK9

Sanofi and Regeneron will host a conference call for the financial community during the upcoming American Heart Association Scientific Sessions, focusing on the LDL cholesterol-lowering PCSK9 Antibody (SAR236553/ REGN727) following the launch of ODYSSEY, our comprehensive Phase 3 clinical program. It will take place on **Monday Nov. 5 2012** at **4:15PM Paris CET / 3:15PM London GMT/ 10:15AM New York EST/ 7:15AM Los Angeles PST.** It will be accessible through audio webcast at www.sanofi.com and www.regeneron.com and also via the following telephone numbers.

France:
Participant Toll-Free Dial-In Number: 0800 910 374
Participant Toll Dial-In Number: +33 1 76 74 89 88

USA:
Participant Toll-Free Dial-In Number: (888) 660 6127
Participant International Dial-In Number: +1 (973) 890 8355

UK:
Participant Toll-Free Dial-In Number: 0800 051 3806 or 0800 032 3836
Participant International Dial-In Number: +44 208 602 0818

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, 2011. 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. 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 REGN727/SAR236553, unforeseen safety issues resulting from the administration of products and product candidates in patients, 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 drug candidates, competing drugs that may be superior to Regeneron's products and drug candidates, uncertainty of market acceptance of Regeneron's products and drug candidates, unanticipated expenses, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated, 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, 2011 and its Form 10-Q for the quarter ended June 30, 2012. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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