PARIS and TARRYTOWN, N.Y., Oct. 16, 2013 /PRNewswire/ -- Sanofi (EURONEXT: **SAN** and NYSE:
SNY
) and Regeneron Pharmaceuticals, Inc. (NASDAQ:
REGN
) today announced that the Phase 3 ODYSSEY MONO trial with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), met its primary efficacy endpoint. The mean low-density lipoprotein-cholesterol (LDL-C, or "bad" cholesterol) reduction from baseline to week 24, the primary efficacy endpoint of the study, was significantly greater in patients randomized to alirocumab, as compared to patients randomized to ezetimibe (47.2% vs. 15.6%, $p<0.0001$). In the trial, which employed a dose increase (up-titration) for patients who did not achieve an LDL-C level of 70 milligrams/deciliter (mg/dL), the majority of patients remained on the initial low dose of alirocumab of 75 milligrams (mg).

"We are excited with the findings from the first Phase 3 trial with alirocumab. While the majority of our clinical program is investigating alirocumab in combination with lipid-lowering therapies, these monotherapy results are encouraging," said Jay Edelberg M.D., Ph.D., Head of the PCSK9 Development and Launch Unit, Sanofi Group. "As in this trial, several of our Phase 3 studies will utilize an up-titration approach, the aim of which is to bring patients to goal with the lowest effective dose of anti-PCSK9 antibody. We look forward to results from the remaining Phase 3 trials, which are investigating alirocumab in a variety of patient populations, combinations with different background therapies, and dosing regimens."

The percentage of patients who reported treatment emergent adverse events was 78.4% in the

ezetimibe group and 69.2% in the alirocumab group. The most common class of adverse events was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related adverse events occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab.

ODYSSEY MONO is the first study to report data from the 12 Phase 3 trials that have been initiated so far as part of the more than 23,000 patient ODYSSEY clinical trial program.

"There are still millions of people around the globe who have poorly controlled LDL-C," said Ge orge D. Yancopoulos
, M.D., Ph. D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "Three years ago, our Phase 1 trials generated the first clinical evidence that blocking PCSK9 could markedly lower cholesterol levels in humans. Today, it is very gratifying to be able to report the first Phase 3 data for this promising potential new class of lipid-lowering agents. It is important to point out that these are just the first of a large amount of data yet to come from our extensive ODYSSEY Phase 3 program."

ODYSSEY MONO (N=103) was a randomized, double-blind, active-controlled, parallel-group study to evaluate the efficacy and safety of alirocumab over 24 weeks in patients with primary hypercholesterolemia and moderate cardiovascular risk. Patients in the trial were randomized to receive monotherapy with either ezetimibe 10 mg, an alternative to statin therapy, or alirocumab. Alirocumab was self-administered initially at its low dose of 75 mg every two weeks, and was up-titrated at week 12 to 150 mg if the LDL-C measurement at week 8 was above 70 mg/dL. The majority of alirocumab patients in the trial remained on the initial low dose of alirocumab because they achieved LDL-C below 70 mg/dL at week 8. Alirocumab was self-administered subcutaneously using a single 1 milliliter (mL) auto-injector.

Detailed results from the ODYSSEY MONO study will be presented at an upcoming medical conference in 2014.

About ODYSSEY The global Phase 3 ODYSSEY program is expected to enroll more than 23,000 patients and currently includes 12 clinical trials of alirocumab both in combination with other lipid-lowering agents and as monotherapy. The primary Phase 3 study endpoint is the percent mean reduction in LDL-C at 24 weeks, giving a robust measure of efficacy and safety. In addition, several other lipid markers will also be assessed.

The ODYSSEY Phase 3 trials are designed to create different options to help meet the needs of individual patients. In addition to the up-titration option explored in this study in which patients received a 75 mg Q2W (once every two weeks) dose of alirocumab, and were only be up-titrated to 150 mg Q2W if they were unable to reach prespecified target LDL-C levels, the other ODYSSEY trials are also exploring initiating patients with a 150 mg every two week regimen (intended for patients needing a larger reduction in LDL-C), as well as regimens evaluating alirocumab dosed once every four weeks.

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

About PCSK9PCSK9 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, 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, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com
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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 "antici pate," "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; 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, 2012 and its Form 10-Q for the quarter ended June 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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