Sanofi and Regeneron Present Detailed Positive Results from Four Pivotal Alirocumab Trials at ESC Congress 2014

- Alirocumab, an investigational treatment for hypercholesterolemia, showed a 62 percent reduction in LDL-C compared to placebo at 24 weeks on top of maximally-tolerated lipid-lowering therapy in ODYSSEY LONG TERM trial -

Paris and Tarrytown, New York – August 31, 2014 – Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced detailed positive results from four Phase 3 ODYSSEY trials of alirocumab in people with hypercholesterolemia. Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9). Results from the four ongoing trials, all of which met their primary efficacy endpoint, will be presented today at a Hot Line session at the ESC Congress 2014 in Barcelona, Spain.

"Across these four trials, alirocumab showed significant and sustained reductions in LDL-C over one year on top of standard-of-care statin therapy across different patient types," said Jennifer Robinson, M.D., M.P.H., Director of the Prevention Intervention Center, Professor, Departments of Epidemiology & Medicine, College of Public Health at the University of Iowa. *"We are also encouraged by the consistent safety profile across the trials, including in ODYSSEY LONG TERM, the largest Phase 3 trial of a PCSK9 inhibitor, with the longest follow-up period reported to date."*

ODYSSEY LONG TERM Trial

The ongoing 2,341-patient, double-blind ODYSSEY LONG TERM trial is designed to evaluate the long-term safety and efficacy of 150 milligrams (mg) alirocumab every two weeks versus placebo in patients with hypercholesterolemia who are at high or very-high cardiovascular (CV) risk, including patients with an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH). Both study groups are treated with statins at a maximally-tolerated dose and some patients also receive additional lipid-lowering therapies. A pre-specified interim analysis was performed when all patients reached one year and approximately 25 percent of patients reached 18 months of treatment. Key data presented today include:

- On the primary efficacy endpoint of the trial, at 24 weeks, there was a 61 percent reduction from baseline in LDL-C levels in the alirocumab group as compared to a 1 percent increase in the placebo group (62 percent reduction in alirocumab group compared to placebo), p<0.0001.
- At 52 weeks, there was a 57 percent reduction from baseline in LDL-C levels in the alirocumab group as compared to a 4 percent increase in the placebo group (61 percent reduction in alirocumab group compared to placebo), p<0.0001.
- 81 percent of alirocumab patients achieved their pre-specified LDL-C goal (either 70 milligrams/deciliter [mg/dL] or 100 mg/dL depending on patients' baseline CV risk) compared to 9 percent for placebo (p<0.0001).
- The most common adverse events (≥5 percent of patients) were nasopharyngitis (13 percent alirocumab; 13 percent placebo), upper respiratory tract infection (7 percent alirocumab; 8 percent placebo), and injection site reactions (6 percent alirocumab; 4 percent placebo).
- In a post hoc safety analysis, there was a lower rate of adjudicated major CV events (cardiac death, myocardial infarction, stroke, and unstable angina requiring hospitalization) in the alirocumab group compared to placebo (1.4 percent compared to 3.0 percent, nominal p-value <0.01). These CV events comprise the composite primary endpoint of the ongoing

18,000-patient ODYSSEY OUTCOMES trial, which is prospectively evaluating the potential of alirocumab to demonstrate CV benefit.

Three additional trials (ODYSSEY COMBO II, FH I and FH II) will also be presented today.
In these three trials, alirocumab-treated patients receive an initial dose of alirocumab 75 mg every two weeks, increasing to 150 mg if needed to reach pre-specified LDL-C levels. The 75 mg and 150 mg alirocumab doses were delivered as a single, self-administered 1 milliliter (mL) injection.

"As physicians, we often start patients on a lower dose of a medication and only increase it if needed. In these trials, the majority of patients who were started at a 75 mg dose of alirocumab, were able to achieve their target LDL-C goals while remaining on their initial dose," said Christopher Cannon M.D., Professor of Medicine, Harvard Medical School.

ODYSSEY COMBO II trial
ODYSSEY COMBO II is a double-blind, 720-patient trial designed to evaluate the safety and efficacy of alirocumab compared to ezetimibe in patients with hypercholesterolemia who are at high CV risk and at baseline had inadequate LDL-C reduction despite stable maximally-tolerated statin therapy. Key data to be presented today include:

- On the primary endpoint of the trial, at 24 weeks, there was a 51 percent reduction from baseline in LDL-C levels in the alirocumab group compared to a 21 percent reduction in the ezetimibe group (30 percent reduction in alirocumab group compared to ezetimibe group), p<0.0001.
- At 52 weeks, there was a 50 percent reduction from baseline in LDL-C levels in the alirocumab group compared to an 18 percent reduction in the ezetimibe group (32 percent reduction in alirocumab group compared to ezetimibe group), p<0.0001.
- 77 percent of patients in the alirocumab group achieved an LDL-C level of 70 mg/dL at 24 weeks.
- Approximately 80 percent of patients in the alirocumab group remained on the initial 75 mg alirocumab dose.
- The most common adverse events (≥5 percent of patients) were upper respiratory tract infection (6.5 percent alirocumab; 6 percent ezetimibe), accidental overdose (6 percent alirocumab; 7 percent ezetimibe), dizziness (5 percent alirocumab; 5 percent ezetimibe), and myalgia (4 percent alirocumab; 5 percent ezetimibe).

ODYSSEY FH I and FH II trials
The ODYSSEY FH I and FH II trials enrolled a total of 738 HeFH patients and compare alirocumab to placebo. All patients are on maximally-tolerated daily statin therapy and the majority of patients also receive ezetimibe. Despite receiving this high level of background therapy, patients in these studies had mean baseline LDL-C levels of 145 mg/dL (FH I) and 134 mg/dL (FH II). Key data to be presented today for FH I and FH II include:

- On the primary endpoint of the trials, at 24 weeks, there was a 49 percent reduction from baseline in LDL-C levels in both FH I and FH II alirocumab groups compared to an increase of 9 percent in FH I and 3 percent in FH II in the placebo groups, (58 and 51 percent reduction compared to placebo), p<0.0001.
- At 52 weeks, in FH I, there was a 47 percent reduction from baseline and in FH II, a 50 percent reduction from baseline in LDL-C levels in the alirocumab groups compared to an increase of 9 and 8 percent in the placebo groups, respectively (56 and 58 percent reduction compared to placebo), p<0.0001.
- 72 percent of alirocumab-treated patients in FH I and 81 percent of patients alirocumab-treated patients in FH II achieved their pre-specified LDL-C goal (either 70 mg/dL or 100 mg/dL) at 24 weeks compared to 2 and 11 percent in the placebo groups, respectively (p<0.0001).
- Approximately 50 percent of patients in the alirocumab groups remained on the 75 mg dose.

- In pooled data from both trials, the most common adverse events (≥5 percent of patients) were injection site reactions (11.5 percent alirocumab; 9 percent placebo), nasopharyngitis (10 percent alirocumab; 11 percent placebo), influenza (9 percent alirocumab; 6 percent placebo), and headache (5.5 percent alirocumab; 7 percent placebo).

"Heterozygous FH patients often have high LDL-C despite treatment with statins and other options," said Michel Farnier, M.D., Ph.D., Point Medical, Dijon, France. "Although a large majority of patients in ODYSSEY FH I and FH II had high LDL-C at baseline, at least 70 percent of alirocumab-treated patients reached their treatment goals."

The four ODYSSEY trials reported today, along with results from six other Phase 3 studies, encompass more than 5,000 patients studied in double-blind trials for 24-104 weeks. Sanofi and Regeneron anticipate alirocumab regulatory submissions in the U.S. and EU by the end of 2014. In the U.S., the companies intend to use a Priority Review Voucher to obtain priority review status for the alirocumab regulatory submission.

The ODYSSEY clinical trial program remains ongoing. Click here for more information on the ODYSSEY studies presented at ESC Congress 2014. Alirocumab is currently under clinical development and its safety and efficacy have not been evaluated by any regulatory authority.

INVESTOR RELATIONS CONFERENCE CALL ON ALIROCUMAB

The companies will host an IR Thematic Conference Call for the financial community focusing on alirocumab during ESC Congress 2014. The conference call will take place on Tuesday, September 2, 2014 (14:30 CET / 13:30 BST/ 08:30 EDT / 05:30 PDT). The call will be available through audio webcast at www.sanofi.com and www.regeneron.com and also via the following telephone numbers:

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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 biologic 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, such as the ODYSSEY global trial program evaluating alirocumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation alirocumab; 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, 2013 and its Form 10-Q for the quarter ended June 30, 2014. 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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