Sanofi and Regeneron Announce FDA Approval of Praluent® (alirocumab) Injection, the First PCSK9 Inhibitor in the U.S., for the Treatment of High LDL Cholesterol in Adult Patients

- Praluent available early next week to U.S. patients -

- Companies to host Investor Conference Call on Praluent today at 15:30 EDT/21:30 CET -

Paris and Tarrytown, New York - July 24, 2015 - Sanofi and Regeneron Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) approved Praluent® (alirocumab) Injection, the first FDA-approved treatment in a new class of drugs known as PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitors. Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein (LDL) cholesterol. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Praluent is the first and only PCSK9 inhibitor approved in the U.S. and is available in two different doses (75 mg and 150 mg). Both doses of Praluent are available in a single 1 milliliter (mL) injection delivered in a single-dose prefilled pen or syringe that patients self-administer every two weeks.

"*For patients with high LDL, or bad, cholesterol the primary focus of treatment is to lower their levels, but many patients today do not achieve recommended levels despite lifestyle modifications and treatment with statins*," said Christopher Cannon, M.D., Professor of Medicine at Harvard Medical School, Cardiovascular Division at Brigham and Women's Hospital, and a member of the Steering Committee for the Phase 3 ODYSSEY clinical trial program. *"In the ODYSSEY clinical trial program, two doses of alirocumab showed significant LDL cholesterol lowering in a variety of patients who were not able to adequately lower their LDL cholesterol with current standard of care alone. The majority of patients achieved their LDL-lowering goals with the 75 mg dose, when added to maximally tolerated dose of a statin, with a generally acceptable safety profile."*

Many patients in the U.S. face the challenge of achieving LDL cholesterol levels recommended by healthcare providers, despite treatment with standard of care including statins. These include approximately 8-10 million patients with an inherited form of high LDL cholesterol known as heterozygous familial hypercholesterolemia and those with clinical ASCVD, defined as a build-up of plaque in the arteries which can lead to reduced blood flow and a number of conditions including heart attack, stroke, chest pain (stable or unstable angina), transient ischemic attack, revascularization and peripheral artery disease.

"*Despite significant progress over the last decades, high cholesterol remains a leading concern in the U.S. and globally*," said Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi. "*Praluent demonstrates the power of the Sanofi and Regeneron alliance to deliver a first-in-*

class therapy in the U.S. for patients in need. Sanofi has a strong cardiovascular heritage and dedication to these patients, and we look forward to working with other regulatory authorities to make Praluent available to patients worldwide."

"*We are grateful to the thousands of patients and investigators worldwide who participated in the ODYSSEY clinical trial program*," said Leonard S. Schleifer, M.D., Ph.D., Founder, President, and Chief Executive Officer, Regeneron. "*Praluent represents the culmination of more than a decade of tireless work to translate the genetic-based discovery of PCSK9 into an innovative medicine that brings meaningful value to patients.*"

The approval of Praluent was based on data from the pivotal Phase 3 ODYSSEY program, which showed consistent, positive results compared to placebo and included current standard of care therapy (statins). In the ODYSSEY LONG TERM trial which evaluated Praluent 150 mg every two weeks, Praluent reduced LDL cholesterol by 58 percent versus placebo at week 24 when added to current standard of care, including maximally tolerated statins. In ODYSSEY COMBO I, Praluent 75 mg every two weeks as an adjunct to statins reduced LDL cholesterol by an additional 45 percent compared to placebo at week 12. At week 24 in the same trial, Praluent reduced LDL cholesterol by an additional 44 percent compared to placebo. In this study, if additional LDL cholesterol lowering was required based on pre-specified criteria at week 8, Praluent was up-titrated to 150 mg at week 12 for the remainder of the trial. Eighty-three percent of patients remained on their initial 75 mg dose.

Praluent is generally well-tolerated with an acceptable safety profile. Local injection site reactions including redness, itching, swelling, or pain/tenderness, where the injection is given were the most common events (7.2 percent with Praluent vs. 5.1 percent with placebo) and resulted in a low discontinuation rate that was comparable to placebo (0.2 percent with Praluent vs. 0.4 percent with placebo). Patients receiving Praluent had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo. Other common adverse events occurring more frequently in patients with Praluent than placebo included symptoms of the common cold and flu or flu-like symptoms.

The companies carefully considered the potential medical value that Praluent offers patients in determining the Wholesale Acquisition Cost (WAC). The U.S. WAC price of Praluent is $40 per day ($1,120 every 28 days) for both the 75 mg and 150 mg doses, making Praluent the lowest priced patient-administered monoclonal antibody therapy on an annualized basis. Actual costs to patients, payers and health systems are anticipated to be lower as WAC pricing does not reflect discounts or rebates. Out-of-pocket costs to patients will vary depending on insurance status and eligibility for patient assistance.

Sanofi and Regeneron are committed to ensuring that patients in the U.S. who are prescribed Praluent are able to access the medicine and receive the support they may need. The companies will offer a comprehensive program that provides support, training, and follow up for patients at every step of the process. The program will provide patient assistance to uninsured or underinsured patients, including providing free medicine to eligible patients, and can help identify coverage options for out-of-pocket costs. Additional services include educational information, clinical support for physicians, nurses and pharmacists, as well as reimbursement services, including co-pay support for eligible patients and information about insurance eligibility support. .

Earlier today, the companies announced that the European Medicine Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the marketing authorization of Praluent, recommending its approval for use in certain adult patients with hypercholesterolemia. The European Commission (EC) is expected to make a final decision on the Marketing Authorization Application for Praluent in the European Union in September 2015.

Investor Relations Conference Call on Praluent

Sanofi and Regeneron will be hosting a conference call for the financial community on Praluent® (alirocumab) Injection for the treatment of high LDL cholesterol in adult patients. The conference call will take place on Friday, July 24, 2015 (21:30 CET / 20:30 BST/ 15:30 EDT / 12:30 PDT).

The call will be available through audio webcast at www.sanofi.com and www.regeneron.com and also via the following telephone numbers:

France: +33 (0) 1 70 80 71 53

UK: +44 (0) 203 107 0289

U.S.: +1 888 660 6127

ODYSSEY Program

The ODYSSEY Phase 3 program is one of the most comprehensive clinical trial programs ever conducted for an investigational LDL cholesterol lowering therapy. The program includes 14 global Phase 3 trials evaluating more than 23,500 patients. The primary efficacy end point in all of the studies was the mean percent reduction from baseline in LDL cholesterol at week 24 compared to placebo (maximally tolerated statin therapy); all of the completed studies met their primary endpoint. A significantly higher proportion of patients achieved an LDL cholesterol of less than 70 mg/dL in the Praluent group as compared to placebo at both week 12 and week 24. The ongoing ODYSSEY OUTCOMES trial will prospectively evaluate the cardiovascular benefits of Praluent in approximately 18,000 patients.

Important Safety Information

Do not use PRALUENT if you are allergic to alirocumab or to any of the ingredients in PRALUENT.

Before you start using PRALUENT, tell your healthcare provider about all your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.

The most common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site, symptoms of the common cold, and flu or flu-like symptoms. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Talk to your doctor about the right way to prepare and give yourself a PRALUENT injection and follow the “Instructions for Use” that comes with Praluent.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for the full Prescribing Information

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 (NASDAQ: REGN) 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 commercializes medicines for high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, 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, 2014. 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 Pharmaceuticals, Inc. ("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 Praluent® (alirocumab) Injection; unforeseen safety issues and possible liability resulting from the administration of products (including without limitation Praluent) and product candidates in patients; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials, such as the ODYSSEY OUTCOMES trial evaluating Praluent; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Praluent), research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies such as the ODYSSEY OUTCOMES trial evaluating Praluent; 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; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation Praluent; the impact of the opinion adopted by the European Medicine Agency's Committee for Medicinal Products for Human Use discussed in this news release on the European Commission's decision regarding the Marketing Authorization Application for Praluent in the European Union; 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 and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the 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, 2014 and its Form 10-Q for the quarterly period ended March 31, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and 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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