PRESS RELEASE

Sanofi and Regeneron Announce Approval of Praluent® (alirocumab) for the Treatment of Hypercholesterolemia in Japan

Paris, France and Tarrytown, New York - July 5, 2016 - Sanofi and Regeneron Pharmaceuticals, Inc. announced today that the Ministry of Health, Labor and Welfare in Japan has granted marketing and manufacturing authorization for Praluent® (alirocumab) for the treatment of uncontrolled low-density lipoprotein (LDL) cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk.

Praluent is a human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9). In Japan Praluent is indicated for the treatment of patients with hypercholesterolemia and familial hypercholesterolemia (FH) who are at high cardiovascular risk and in whom treatment with statins (HMG-CoA reductase inhibitors) is not sufficient. Praluent 75 mg and 150 mg will be available in Japan as a single-dose pre-filled pen and syringe.

"Hypercholesterolemia is a significant concern in Japan, and many patients are not able to achieve their LDL cholesterol treatment goals despite current lipid-lowering therapy," said Jay Edelberg, MD., Ph.D, Head of Cardiovascular Development, Sanofi. "*For these patients, Praluent could be an important treatment option to help address their needs*."

Data from the global Phase 3 ODYSSEY trials showed consistent, robust reductions in LDL cholesterol for Praluent compared to placebo, when added to current standard-of-care, which included maximally-tolerated statins. The Phase 3 ODYSSEY JAPAN trial evaluated the safety and efficacy of Praluent 75 mg starting dose every two weeks, in comparison with placebo in 216 Japanese patients with primary hypercholesterolemia and LDL cholesterol of at least 100 milligrams/deciliter (mg/dL) (at least 2.59 millimoles per liter [mmol/L]). All study patients were on ongoing statin treatment with or without other lipid-lowering therapies. Average baseline LDL cholesterol levels in the randomized population were similar between the Praluent (141 mg/dL / 3.6 mmol/L) and placebo groups (142 mg/dL / 3.7 mmol/L). Patients in the Praluent group who did not achieve their pre-specified LDL cholesterol goals with Praluent 75 mg at week 8 (2 out of 140 patients who continued treatment beyond week 12) were increased to Praluent 150 mg every two weeks at week 12.

In the ODYSSEY JAPAN trial, Praluent reduced LDL cholesterol by 63 percent at week 24 on top of stable background statin therapy, compared to a 2 percent increase in the placebo group ($p<0.0001$, ITT analysis). Patients treated with Praluent maintained their LDL cholesterol reductions for the duration of the trial. By week 52 patients in the Praluent group achieved an average LDL cholesterol of 53.4 mg/dL (1.38 mmol/L) compared to an average LDL cholesterol of 135.6 mg/dL (3.51 mmol/L) in the placebo group (ITT population).

In the trial, Praluent was generally well-tolerated with an acceptable safety profile. Frequently reported adverse events included nasopharyngitis (46 percent Praluent versus 36 percent placebo); back pain (13 percent Praluent versus 6 percent placebo); and injection site reaction (13 percent Praluent versus 4 percent placebo).

"*Results from the Japanese Phase 3 trial were consistent with the findings from our global ODYSSEY program that evaluated the efficacy and safety of Praluent in patients who required further reduction of their LDL cholesterol,"* said Bill Sasiela, Ph.D, VP, Program Direction, Regeneron. "*Notably, in the ODYSSEY JAPAN trial, 99 percent of patients were able to effectively*

reach their LDL cholesterol goals as defined by the Japan Atherosclerosis Society with Praluent 75 mg Q2W and maintain these reductions for the duration of their therapy, up to 52 weeks."

In ODYSSEY JAPAN, LDL cholesterol goals were defined according to the "Guidelines for Prevention of Atherosclerotic Cardiovascular Diseases 2012" published by the Japan Atherosclerosis Society (JAS) in which goals are set according to patients' risk of cardiovascular events. The JAS guidelines define the risk of cardiovascular events as high when the patient has a history of coronary artery disease, a history of ischemic stroke (other than cardiogenic cerebral infarction), peripheral artery disease, diabetes mellitus, and chronic kidney disease, or in the presence of several risk factors for atherosclerosis.

In Japanese Phase 2 and 3 clinical trials, adverse events were observed in 17 percent (33 of 193) of patients on Praluent 75 mg or 150 mg. The most common adverse event was injection site reactions in 22 cases (11.4 percent).

Praluent is also approved in the United States, European Union, Canada and Mexico. The effect of Praluent on cardiovascular morbidity and mortality has not yet been determined.

About Praluent
Praluent inhibits the binding of PCSK9 to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells, which results in lower LDL cholesterol (so-called "bad" cholesterol) levels in the blood.

In July 2015, the companies announced that Praluent was approved for use in the U.S. as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL cholesterol.

In September 2015, the European Commission approved the marketing authorization for Praluent. In the E.U., Praluent is approved for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: **a)** in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL cholesterol goals with the maximally-tolerated statin or **b)** alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Important Japan Product Information
Praluent is indicated for the treatment of patients with FH or hypercholesterolemia who have high cardiovascular risk with LDL cholesterol not adequately controlled by HMG-CoA reductase inhibitors.

Precautions Related to Indications in Japan
(1) Patients should undergo careful medical examinations, including tests confirming FH or non-FH before using Praluent.
(2) In patients with non-FH, the use of Praluent should be considered for patients with high cardiovascular risk based on confirmed risk factors (e.g., coronary artery disease, non-cardiogenic cerebral infarction, peripheral arterial disease, diabetes mellitus, chronic kidney disease, etc.) See 'Clinical Studies' section.
(3) For homozygous FH, the efficacy and safety of Praluent has not been established. Treatment with Praluent should be carefully determined, and in case of no response, treatment should be discontinued. See 'Important Precautions (2)' section.

Dosage and Administration in Japan

For adults, the usual dosage is 75 mg administered subcutaneously every two weeks. If there is an insufficient response, dosage can be increased to 150 mg.

Precautions Related to Dosage and Administration in Japan

(1) Praluent should be administered in combination with HMG-CoA reductase inhibitor therapy. (The efficacy and safety of Praluent monotherapy in Japanese patients has not been established.)
(2) When used with LDL apheresis treatment concomitantly, Praluent treatment should be scheduled following the LDL apheresis treatment.

Important Safety Information for U.S.

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, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. 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 eye diseases, high LDL-cholesterol, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including cancer, rheumatoid arthritis, asthma, atopic dermatitis, pain and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 initiatives 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, 2015. 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 and Use of Digital Media

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" or the "Company"), 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 prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; 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); 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; 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; 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 (or their respective affiliated companies, as applicable), 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, 2015 and its Form 10-Q for the quarterly period ended March 31, 2016. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

Contacts Sanofi:

Media Relations
Mai Tran
Tel: +33 (0)1 53 77 46 46
mr@sanofi.com

Investor Relations
George Grofik
Tel: +33 (0)1 53 77 45 45
ir@sanofi.com

Contacts Regeneron:

Media Relations
Arleen Goldenberg
Tel: +1 (914) 847-3456
Mobile: +1 (914) 260-8788
arleen.goldenberg@regeneron.com

Investor Relations
Manisha Narasimhan, Ph.D.
Tel: +1 (914) 847-5126
manisha.narasimhan@regeneron.com