Sanofi and Regeneron Announce Positive Results from First Dedicated Studies Evaluating Praluent® (alirocumab) in Individuals with Diabetes and Hypercholesterolemia

- Data presented at the 77th Scientific Sessions of the American Diabetes Association (ADA) -

Paris, France and Tarrytown, N.Y., June 11, 2017 – Sanofi and Regeneron Pharmaceuticals, Inc. today announced positive results from two Phase 3b/4 ODYSSEY-DM trials in patients with diabetes. In the studies, Praluent® (alirocumab), when administered on top of maximally tolerated doses (MTD) of statins, significantly reduced low-density lipoprotein cholesterol (LDL-C), the primary endpoint of the ODYSSEY DM-INSULIN study, and was superior to usual care in reducing non-high-density lipoprotein cholesterol (non-HDL-C), the primary endpoint of the ODYSSEY DM-DYSLIPIDEMIA study. Both studies also found that a majority of patients reached their lipid goals with Praluent 75 mg every two weeks, with an overall safety profile comparable to the ODYSSEY Phase 3 program.

The results were unveiled today as part of the official symposium of the 77th Scientific Sessions of the American Diabetes Association (ADA) in San Diego, CA, titled, "Inhibition of PCSK9 in Dyslipidemia Patients with Diabetes." The data were also featured in the official ADA Scientific Sessions Advance program.

"Patients with long-standing diabetes, including insulin-treated patients, are at high risk of cardiovascular disease," said Lawrence Leiter, M.D., chair of the ODYSSEY DM Steering Committee and director of the Lipid Clinic at the Li Ka Shing Knowledge Institute at St. Michael's Hospital, University of Toronto, Canada. "The positive results from ODYSSEY DM-INSULIN provide valuable information on the efficacy and safety of Praluent in this high cardiovascular risk group."

Most people with diabetes will develop atherosclerotic cardiovascular disease (ASCVD). Despite current standard of care, nearly 70 percent of people age 65 or older with diabetes die from some form of heart disease, and 16 percent die of stroke.[1]

"Mixed dyslipidemia is common in people with type 2 diabetes and further increases CV risk, and yet it is difficult to treat with available therapies," said Robert Henry, M.D., member of the ODYSSEY DM Steering Committee and Director of the Center for Metabolic Research at the VA San Diego Healthcare System. "The results of ODYSSEY DM-DYSLIPIDEMIA showed that in a real-world setting, Praluent, on top of maximally tolerated doses of statins, significantly reduced non-HDL-C, another measure of bad cholesterol, and was superior to usual care. Praluent may be another option for physicians who need to further help their diabetes patients with clinical ASCVD manage their lipid profiles."

In ODYSSEY DM-INSULIN, patients were randomized to Praluent 75 mg every two weeks or placebo in addition to MTD statins. Praluent dose was adjusted at week 12 to 150 mg every two weeks if their LDL-C was greater than or equal to 70 mg/dL at week 8. Approximately 80 percent of patients reached their LDL-C goals with Praluent 75 mg every two weeks in this study. In

ODYSSEY DM-DYSLIPIDEMIA, patients were randomized to Praluent 75 mg every two weeks or usual care in addition to MTD statins. Praluent dose was adjusted at week 12 to 150 mg every two weeks if their non-HDL-C was greater than or equal to 100 mg/dL at week 8. Approximately 64 percent of patients reached their lipid goals with the Praluent 75 mg dose.

ODYSSEY DM-INSULIN was a randomized, double-blind, placebo-controlled, parallel-group multicenter study that evaluated Praluent in 517 people with type 1 and type 2 diabetes on insulin with high CV risk and hypercholesterolemia who took MTD statins.[2] The primary endpoint was percent change in calculated LDL-C from baseline to week 24. Results in the type 2 diabetes study population (n=441) were presented at ADA and showed:

- Praluent in combination with MTD statins reduced LDL-C by 48.2 percent from baseline compared to a 0.8 percent increase for placebo. The mean difference between the two treatment arms was 49 percent (*p<0.0001*).
- Treatment with Praluent also improved the overall lipid profile.
- Overall, Praluent was generally well tolerated. Treatment emergent adverse events (TEAEs) were similar between the two groups and no emerging safety findings were identified from the study. The most frequent TEAEs included nasopharyngitis, myalgia, arthralgia and cough. There was no new safety signal with the concomitant use of Praluent and insulin.
- There was no impact on glycemic control as assessed by fasting plasma glucose (FPG), A1C and glucose lowering treatments remained stable over time in both treatment groups.

ODYSSEY DM-DYSLIPIDEMIA was a randomized, open-label, parallel-group, multicenter, multinational study designed to evaluate the superiority of Praluent versus usual care in 413 people with type 2 diabetes and mixed dyslipidemia at high CV risk, not adequately controlled with MTD statins.[3] The primary endpoint was percent change in non-HDL-C from baseline to week 24. Non-HDL-C is calculated as total cholesterol minus high-density lipoprotein cholesterol, and provides a single index of all the potentially atherogenic, apolipoprotein (apo) B-containing lipoproteins, including LDL, very-low-density lipoprotein (VLDL), intermediate-density lipoprotein (IDL), and lipoprotein(a).

- Praluent was superior to usual care in lowering non-HDL cholesterol (37.3 percent and 4.7 percent for the usual care arm). The mean difference between the two treatment arms was 32.5 percent (*p<0.0001*).
- Praluent in combination with MTD reduced measured LDL-C by 43.3 percent from baseline compared to a 0.3 percent increase for usual care (*p<0.0001*).
- Treatment with Praluent also improved the overall lipid profile.
- Praluent was generally well-tolerated. The most frequent TEAEs included urinary tract infection, diarrhea, and nasopharyngitis.
- There was no impact on glycemic control observed as assessed by fasting plasma glucose (FPG), A1C and glucose lowering treatments remained stable over time in both treatment groups.

In the previously reported results from the ODYSSEY LONG TERM study in which all patients were treated with Praluent 150 mg on top of MTD statins, Praluent reduced LDL-C by 60 percent from baseline in patients with diabetes (n=545) at week 24.[4]

The recommended starting dose of Praluent is 75 mg administered subcutaneously every 2 weeks, or alternatively 300 mg every 4 weeks (monthly) for patients who prefer less frequent dosing. The majority of patients taking Praluent achieve sufficient LDL-C reduction with the 75 mg dose. If the LDL-C response is inadequate, the dosage may be adjusted to the maximum dosage of 150 mg administered every 2 weeks.

About Praluent

Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells, which results in lower LDL-C levels in the blood.

Praluent is approved in more than 50 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as the European Union (EU). In the U.S., Praluent is approved for use as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical ASCVD who require additional lowering of LDL-C. In the EU, 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-C 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. The effect of Praluent on CV morbidity and mortality has not yet been determined. ODYSSEY OUTCOMES is prospectively evaluating the effect of Praluent on the occurrence of CV events in approximately 18,000 patients who have experienced an acute coronary syndrome.

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 Safety Information for the 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 Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led by physician-scientists for the past 30 years, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, and infectious and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its

unique VelociSuite® technologies and ambitious initiatives such as The Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2016. 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, risks associated with intellectual property of other parties and pending or future litigation relating thereto, including the patent litigation relating to Praluent® (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or commercially manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; 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; 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; 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; 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; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success. 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, 2016 and its Form 10-Q for the quarterly period ended March 31, 2017. 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).

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