Regeneron and Sanofi Announce FDA Approval of a New Once-Monthly Dosing Option for Praluent® (alirocumab) Injection

April 25, 2017

TARRYTOWN, N.Y. and BRIDGEWATER, N.J., April 25, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the U.S. Food and Drug Administration (FDA) approved the companies' new supplemental Biologics License Application (sBLA) for a once-monthly (every four weeks), 300 mg dose of Praluent® (alirocumab) Injection for the treatment of adults with high low-density lipoprotein (LDL) cholesterol.

Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL cholesterol. The effect of Praluent on cardiovascular (CV) morbidity and mortality has not been determined.

"The FDA approval of once-monthly Praluent is encouraging news for patients with clinical ASCVD or HeFH because it enables physicians to further tailor their treatment to lower LDL cholesterol," said Robert Pordy, M.D., Vice President of Cardiovascular & Metabolism Therapeutics, Regeneron. "Selecting the most appropriate therapy based on individual patient preference is an important consideration for healthcare professionals as high cholesterol treatment often requires long-term management."

"Many patients in the U.S. continue to struggle with high levels of bad cholesterol, or LDL cholesterol, despite diet, exercise and other lipid-lowering therapies, so new dosing options are welcome additions to the treatment landscape," said Corinne Hanotin, M.D., Global Project Head, Cardiovascular Clinical Development, Sanofi. "Praluent is now the only PCSK9 inhibitor to offer two dosage strengths with two levels of efficacy, as well as a monthly dosing option."

The 300 mg dose is administered via two 150 mg injections at two different injection sites. Each 1 mL pre-filled pen delivers 150 mg of Praluent in 20 seconds or less. The European Commission (EC) also approved the monthly 300 mg dose of Praluent in November 2016.

The once-monthly dose of Praluent was approved by the FDA and the EC based on results from the Phase 3 ODYSSEY CHOICE I study, which evaluated the efficacy and safety of Praluent 300 mg every four weeks compared to placebo in patients with hypercholesterolemia who were also taking concomitant statin. In the U.S., the recommended starting dose for Praluent is 75 mg once every two weeks administered subcutaneously, or alternatively, 300 mg once every four weeks (monthly) for patients who prefer less frequent dosing. These doses can be adjusted to a maximum dose of 150 mg every two weeks for patients requiring greater LDL cholesterol reductions.

Praluent is contraindicated in patients with a history of a serious hypersensitivity reaction to Praluent. Allergic reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization. In the ODYSSEY CHOICE I study in which all patients received an injection of Praluent or placebo every two weeks to maintain the blind, local injection site reactions were reported more frequently in patients treated with Praluent 300 mg every four weeks as compared to those receiving Praluent 75 mg every two weeks or placebo (16.6%, 9.6%, and 7.9%, respectively).

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 cholesterol levels in the blood. Praluent is the only PCSK9 inhibitor available in two dosages with two levels of efficacy (75 mg and 150 mg) and now also available as a monthly dosing option (300 mg), allowing physicians to select the dose based on a patient's LDL cholesterol lowering needs.

Praluent is approved in more than 50 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico, Brazil and 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 HeFH or clinical atherosclerotic CV disease, who require additional lowering of LDL cholesterol. 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 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. 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 science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL cholesterol, atopic dermatitis and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, pain, cancer 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 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 future 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 and 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. 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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