CHMP Recommends Approval of Praluent® (alirocumab) Injection to Reduce Cardiovascular Risk in People with Established Atherosclerotic Cardiovascular Disease

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TARRYTOWN, N.Y. and PARIS, Feb. 4, 2019 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Praluent® (alirocumab) Injection, recommending a new indication to reduce cardiovascular risk by lowering low-density lipoprotein cholesterol (LDL-C) levels as an adjunct to correction of other risk factors in adults with established atherosclerotic cardiovascular disease (ASCVD). Praluent should be used in addition to maximally-tolerated statins or can be used alone in patients intolerant to or inappropriate for statin therapy.

ASCVD is an umbrella term, defined as a build-up of plaque in the arteries that can lead to reduced blood flow and a number of serious conditions such as stroke, peripheral artery disease and acute coronary syndrome (ACS), which includes heart attack and unstable angina.

The CHMP opinion is based on data from ODYSSEY OUTCOMES, a Phase 3 cardiovascular outcomes trial that assessed the effect of Praluent in 18,924 patients who had an ACS between 1-12 months (median 2.6 months) before enrolling in the trial. Results from the ODYSSEY OUTCOMES trial were published in *The New England Journal of Medicine* in 2018.

The European Commission is expected to make a final decision in the coming months. Data from ODYSSEY OUTCOMES have also been submitted to the U.S. Food and Drug Administration (FDA), with a target action date of April 28, 2019.

About ODYSSEY OUTCOMES
ODYSSEY OUTCOMES assessed the effect of Praluent on the occurrence of major adverse cardiovascular events (MACE) in patients who had experienced an ACS before enrolling in the trial, and who were already on intensive or maximally-tolerated statin treatment. Patients were randomized to receive Praluent (n=9,462) or placebo (n=9,462) and were assessed for a median of 2.8 years, with some patients being treated for up to 5 years. Approximately 90% of patients were on a high-intensity statin.

The trial was designed to maintain patients' LDL-C levels between 25-50 mg/dL (0.65-1.29 mmol/L), using two different doses of Praluent (75 mg and 150 mg). Praluent-treated patients started the trial on 75 mg every 2 weeks and switched to 150 mg every 2 weeks if their LDL-C levels remained above 50 mg/dL (1.29 mmol/L) (n=2,615). Some patients who switched to 150 mg switched back to 75 mg if their LDL-C fell below 25 mg/dL (0.65 mmol/L) (n=805), and patients who experienced two consecutive LDL-C measurements below 15 mg/dL (0.39 mmol/L) while on the 75 mg dose (n=730) stopped active Praluent therapy for the remainder of the trial.

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 to clear LDL, which lowers LDL-C levels in the blood. Praluent was developed by Regeneron and Sanofi under a global collaboration agreement and invented by Regeneron using the company's proprietary *VelocImmune*® technology that yields optimized fully-human monoclonal antibodies.

Praluent is approved in more than 60 countries worldwide, including the EU, U.S., Japan, Canada, Switzerland, Mexico and Brazil. 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 ASCVD who require additional lowering of LDL-C.

The results of ODYSSEY OUTCOMES, which evaluated the effect of Praluent on cardiovascular morbidity and mortality, are currently under evaluation by a number of regulatory authorities worldwide. To date, only the CHMP has completed its assessment.

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

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting 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.

About Sanofi
Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Regeneron Forward-Looking Statements and Use of Digital Media
This press 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; the impact of the opinion adopted by the European Medicines Agency'sCommittee for Medicinal Products for Human Use discussed in this press release on the European Commission's decision regarding the Marketing Authorization Application for Praluent toreduce cardiovascular risk by lowering low-density lipoprotein cholesterol levels in adults with established atherosclerotic cardiovascular disease; 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 possible new regulatory approvals of Praluent in the European Union and by the the U.S. Food and Drug Administration (the "FDA") discussed in this press release; the impact of the recent and any potential future U.S. government shutdowns on the anticipated timing of the FDA regulatory action relating to Praluent referenced in this press release; 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; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Praluent), research and clinical programs, and business, including those relating to patient privacy; 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, including without limitation Praluent; 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; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product

candidates; the availability and extent of reimbursement of the Company's products (such as Praluent) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation and other proceedings relating to Praluent, the ultimate outcome of any such proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, 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 U.S. Securities and Exchange Commission. 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).

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, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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