Regeneron and Sanofi Announce UnitedHealth Group Selects Praluent® (alirocumab) Injection for Preferred Access

December 11, 2015

TARRYTOWN, N.Y. and BRIDGEWATER, N.J, Dec. 11, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that UnitedHealth Group will provide preferred access to Praluent® (alirocumab) Injection through OptumRx and UnitedHealthcare for Commercial, Medicare, and Managed Medicaid patients. Praluent is the only PCSK9 inhibitor preferred across UnitedHealth Group formularies. This decision, when combined with prior favorable coverage decisions at Express Scripts, Aetna and other insurers, provides for access to flexible dosing with Praluent on formularies covering more than 100 million patients in the United States. Praluent is the only PCSK9 inhibitor currently available in two doses, that allows a healthcare provider to adjust the dose based on their patient's LDL cholesterol lowering needs.

Praluent, the first PCSK9 inhibitor available in the U.S., 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 low-density lipoprotein (LDL) cholesterol. ASCVD is 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. The effect of Praluent on cardiovascular morbidity and mortality has not yet been determined.

"We are pleased that the appropriate patients in the U.S. now have preferred access to Praluent through UnitedHealth Group," said Jez Moulding, President, North America Pharmaceuticals, Sanofi US. "Praluent is a significant innovation for patients with the highest unmet need who may benefit from further reduction of their LDL cholesterol, and we look forward to continued collaboration with other insurers to help ensure appropriate patient access to Praluent."

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 either ASCVD or the inherited form of high LDL cholesterol known as HeFH.

"Both the Praluent 75 mg and 150 mg doses will be preferred on UnitedHealth formularies, providing physicians with the flexibility to individualize dosing for their patients," said Robert Terifay, Senior Vice President, Commercial, Regeneron. "Our comprehensive support program, MyPraluent™ also provides important services to help patients such as disease management, and financial assistance for patients with or without insurance."

Sanofi and Regeneron are committed to ensuring that patients in the U.S. who are prescribed Praluent® (alirocumab) Injection are able to access the medicine and receive the support they may need. MyPraluent is a comprehensive program that offers support, training and follow up for patients at every step of the process. The program provides insurance eligibility support; financial assistance to uninsured or underinsured patients including providing free medicine to eligible patients; free medicine for up to 90 days if your insurance denies coverage; and with the MyPraluent Copay Card, patients may qualify to receive Praluent at no cost for 6 months and no more than $10 thereafter. Additional services include access to educational information and clinical support for physicians, nurses and pharmacists, and help navigating specialty pharmacies. For more information, please visit www.praluent.com or call 1-844-PRALUENT (1-844-772-5836).

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, 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 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 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 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 prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit); 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; 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 September 30, 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.

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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