



Regeneron and Sanofi Announce CHMP Recommends European Approval of Praluent® (alirocumab) for the Treatment of Hypercholesterolemia

July 24, 2015

TARRYTOWN, N.Y. and PARIS, July 24, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the European Medicine Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the marketing authorization of Praluent® (alirocumab), recommending its approval for use in certain adult patients with hypercholesterolemia. Praluent is an investigational fully human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

"We are very pleased to receive a positive opinion from the CHMP for Praluent, and look forward to bringing Praluent to those in greatest need across Europe," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "Despite statins and other lipid-lowering therapies, many patients are unable to reach their LDL cholesterol goals, and may benefit from new therapeutic options such as Praluent."

The CHMP recommended Praluent in both a 75 mg and 150 mg dose be approved for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia [HeFH] and non-familial) or mixed dyslipidemia as an adjunct to diet: **a)** in patients unable to reach their low density lipoprotein cholesterol (LDL-C) goals with a maximally-tolerated statin, Praluent would be used in combination with a statin, with or without other lipid-lowering therapies; and **b)** for patients who are statin intolerant, or for whom a statin is contraindicated, Praluent would be used alone or in combination with other lipid-lowering therapies. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. The most common adverse reactions were injection site reactions, upper respiratory tract signs and symptoms, and pruritus.

The European Commission (EC) is expected to make a final decision on the Marketing Authorization Application for Praluent in the European Union in late September. The CHMP opinion was based on the benefit-risk profile of Praluent, following review of efficacy and safety data from more than 5,000 patients across 10 pivotal Phase 3 double-blind trials ranging from six months to two years. Clinical data from the ODYSSEY Phase 3 program show consistent, positive results in reducing LDL-C.

"In our clinical trial program, Praluent significantly reduced LDL cholesterol among patients with high unmet needs, including those with high or very high cardiovascular risk and those with an inherited form of high cholesterol called familial hypercholesterolemia," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President, Regeneron Laboratories. "In these trials, patients received Praluent as a single subcutaneous injection once every two weeks using either a 75 mg or 150 mg dose, providing flexible dosing options that can be tailored to an individual's cholesterol lowering needs."

The U.S. Food and Drug Administration has set a target action date of July 24 for the Biologics License Application (BLA) of Praluent. The safety and efficacy of Praluent have not been fully evaluated by any other regulatory authority.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and 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 eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

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

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"), 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); 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 likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation Praluent; the impact of the opinion adopted by the European Medicine Agency's Committee for Medicinal Products for Human Use discussed in the news release on the European Commission's decision regarding the Marketing Authorization Application for Praluent in the European Union, as well as the previously reported recommendation of the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (the "FDA") on the possible regulatory approval of Praluent by the FDA; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, 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; 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; 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 quarter ended March 31, 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.

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