



## **FDA Advisory Committee Recommends Approval of Regeneron and Sanofi's Praluent® (alirocumab) Injection for Patients with Hypercholesterolemia**

June 9, 2015

TARRYTOWN, N.Y. and PARIS, June 9, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. Food and Drug Administration (FDA) recommended the approval of the investigational therapy Praluent® (alirocumab) Injection.

The Committee voted 13 to three (with no abstentions) that Regeneron and Sanofi had sufficiently established that the low-density lipoprotein cholesterol (LDL-C, or bad cholesterol) lowering benefit of Praluent exceeds its risks to support approval in one or more patient populations.

"We are pleased with the Committee's recommendation to approve Praluent. Our clinical trial program focused on patients with high unmet need in which Praluent delivered significant reductions in LDL-C on top of statins and other lipid-lowering therapies," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "Our Phase 3 Praluent development program investigated both a 75 mg and 150 mg dose, providing flexible dosing regimens that can be tailored to individual patient cholesterol lowering needs."

The Committee's recommendation was based on Praluent's benefit-risk profile, 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. Common adverse events that were more frequently reported in patients treated with Praluent than the control groups included injection site reaction and pruritus (itching).

"The discovery of PCSK9 as a powerful regulator of cholesterol levels and cardiovascular disease was one of the most important human genetic advances of the last decade," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President, Regeneron Laboratories. "Today's outcome brings us one step closer to translating this genetics-based discovery into a treatment that may help the many patients in need of additional cholesterol lowering."

The Advisory Committee's recommendation will be considered by the FDA in its review of the Biologics License Application (BLA) for Praluent. The FDA is not bound by the Committee's recommendation, but takes its advice into consideration when reviewing investigational medicines. The BLA for Praluent was accepted for priority review by the FDA with a target action date of July 24, 2015.

If approved by the FDA, Praluent is expected to be the first fully human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) in the U.S. The Marketing Authorization Application for Praluent in the European Union is currently under review by the European Medicines Agency (EMA). The safety and efficacy of Praluent have not been fully evaluated by any 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](http://www.regeneron.com)) 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](http://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 and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation Praluent, and the impact of the recommendation of the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration discussed in the news release on the possible regulatory approval of Praluent; 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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