



REGENERON

Sanofi and Regeneron Announce Positive Topline Results from First Phase 3 Trials Evaluating Monthly Dosing of Alirocumab in Patients with Hypercholesterolemia

- Primary efficacy endpoints met in two trials of alirocumab administered every four weeks -

Tarrytown, New York and Paris - January 9, 2015 - [Sanofi](#) and [Regeneron Pharmaceuticals, Inc.](#) today announced that two new ODYSSEY trials, which are the first Phase 3 trials to assess alirocumab administered every four weeks, met their primary efficacy endpoints. The trials compared the reduction from baseline in low-density lipoprotein cholesterol (LDL-C, or “bad” cholesterol) at 24 weeks with alirocumab versus placebo in patients with hypercholesterolemia. Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9).

“In the new monthly dosing trials, ODYSSEY CHOICE I and CHOICE II, the mean percent reduction in LDL-C from baseline was consistent with that seen in previous phase 3 trials evaluating alirocumab every other week dosing,” said Bill Sasiela, Ph.D., Vice President, Program Direction, Cardiovascular and Metabolic, Regeneron. *“These results continue to validate our clinical development approach, which is designed to investigate various alirocumab doses and intervals to address patients’ lipid-lowering needs.”*

ODYSSEY CHOICE I evaluated the efficacy and safety of alirocumab in 803 patients with hypercholesterolemia at moderate to high cardiovascular (CV) risk. It compared alirocumab 300 mg every four weeks with placebo. More than two-thirds (68 percent) of patients also received statin therapy.

ODYSSEY CHOICE II evaluated the efficacy and safety of alirocumab in 233 patients with hypercholesterolemia with high CV risk and/or a history of intolerance to two or more statins. It compared alirocumab 150 mg every four weeks with placebo. No patients received statin therapy.

The most common adverse events in the trials (occurring in at least 5 percent of alirocumab-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the alirocumab groups compared to placebo.

In both trials, alirocumab-treated patients who did not achieve their pre-specified LDL-C goals, or who did not achieve at least a 30 percent reduction in their LDL-C levels from baseline, were switched to receive alirocumab 150 mg every two weeks at 12 weeks.

“Despite current lipid-lowering therapies, many patients at high CV risk struggle to reach optimal LDL-C levels,” said Jay Edelberg, M.D., Ph.D., Head of the PCSK9 Development & Launch Unit, Sanofi. *“The ODYSSEY clinical trial program has provided key insights and allowed us to investigate alirocumab administered every four weeks in different patient populations, including those who cannot get control of their high LDL-C because of difficulty tolerating statin therapy.”*

Detailed data will be presented at future medical congresses. Alirocumab is currently under clinical development and its safety and efficacy have not been evaluated by any regulatory authority.

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 eye diseases, colorectal cancer, 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. Several Regeneron programs are based on human genetics findings. 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, 2013. 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 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, such as the ODYSSEY global trial program evaluating alirocumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation alirocumab; ongoing regulatory obligations and oversight impacting Regeneron's 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, 2013 and its Form 10-Q for the quarter ended September 30, 2014. 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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