



## Sanofi and Regeneron To Present Alirocumab Clinical Data at the American College of Cardiology's 63rd Annual Scientific Session

March 27, 2014

PARIS and TARRYTOWN, N.Y., March 27, 2014 /PRNewswire/ -- Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that data from alirocumab clinical studies will be presented at the American College of Cardiology's (ACC) 63rd Annual Scientific Session in Washington, D.C. March 29-31. Alirocumab is an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) currently in Phase 3 studies.

"ACC marks the beginning of the presentation of our Phase 3 ODYSSEY data in 2014, with the first full data results from the Phase 3 ODYSSEY MONO study," said Jay Edelberg M.D., Ph.D., Head of the PCSK9 Development and Launch Unit, Sanofi Group. "We are presenting new data with our 150 mg four-week dosing regimen in individuals not receiving statins and long-term data in heterozygous familial hypercholesterolemia patients."

"Despite the availability of lipid-lowering therapies, millions of people worldwide are unable to satisfactorily control their levels of low-density lipoprotein-cholesterol," said George D. Yancopoulos, M.D., Ph. D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "We have designed a robust Phase 3 ODYSSEY program that consists of 14 studies in more than 23,500 patients and we look forward to reporting Phase 3 data from the majority of the ODYSSEY clinical studies later this year."

Sanofi and Regeneron are developing alirocumab as a potential new treatment for patients with moderate and high cardiovascular risk who face challenges in achieving control of their low-density lipoprotein-cholesterol (LDL-C) levels. Sanofi and Regeneron plan to submit applications for global regulatory approval of alirocumab based on the Phase 3 ODYSSEY program.

The following data will be presented at ACC on March 30 at 9:30 AM EDT:

### PHASE 3 ODYSSEY MONO FULL RESULTS:

- Abstract #1183-125: *A 24-Week Study of Alirocumab as Monotherapy versus Ezetimibe: The First Phase 3 Data of a Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitor*

24-Week Phase 3 ODYSSEY MONO study comparing the LDLc -lowering efficacy and safety of alirocumab vs. ezetimibe in patients not receiving statin or other lipid-lowering therapies<sup>1</sup>

*Eli M. Roth - Sterling Research Group, Cincinnati, OH, USA*

### OTHER ALIROCUMAB CLINICAL DATA:

- Abstract #1183-126: *One Year Open-Label Treatment with Alirocumab 150 mg Every Two Weeks in Heterozygous Familial Hypercholesterolemic Patients*

Phase 2 study assessing initial 52-week safety and efficacy data (as part of a longer term four-year open label treatment extension) in patients taking alirocumab 150 mg every two weeks<sup>2</sup>

*Evan A. Stein - Metabolic and Atherosclerosis Research Center, Cincinnati, OH, USA*

- Abstract #1183-131: *Randomized, Partial Blind Study of the Pharmacodynamics, Pharmacokinetics and Safety of Multiple Subcutaneous Doses of Alirocumab, a Fully Human Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9, Administered Every 4 Weeks Alone or In Combination with Ezetimibe or Fenofibrate in Healthy Subjects*

Partial blind study in three parallel groups of healthy subjects not on lipid-lowering therapy, comparing the efficacy of alirocumab 150 mg Q4W as monotherapy or with ezetimibe or fenofibrate over a four week dosing interval<sup>3</sup>

*Jacques Rey - Sanofi, Paris, France*

- Abstract # 1183-128: *Effects of Alirocumab, a Fully Human Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9, on Lipoprotein Particle Concentrations Determined by Nuclear Magnetic Resonance: Substudy of a Randomized Double-Blind Phase 2 Clinical Trial*

Study determining alirocumab's effect on LDL particle and other lipid particle concentrations versus placebo<sup>4</sup>

*Michael J. Koren - Jacksonville Center for Clinical Research, Jacksonville, FL, USA*

- Abstract #1183-133: *A Randomized Study of the Relative Bioavailability, Pharmacodynamics, and Safety of Alirocumab, a Fully Human Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9, after Single Subcutaneous*

## Administration at Three Different Injection Sites in Healthy Subjects

Single-center, open-label, randomized Phase 1 study comparing the bioavailability and adverse events of a single dose of alirocumab in different injection sites (arm, leg, abdomen)<sup>5</sup>

Catherine Lunven - Sanofi, Paris, France

### Investor Relations Conference Call on Alirocumab

The companies will host an IR Thematic Conference Call for the financial community focusing on alirocumab during ACC. The conference call will take place on Monday, March 31, 2014 (3 p.m. CET / 2 p.m. BST / 9 a.m. EDT / 6 a.m. PDT). The call will be available through audio webcast at [www.sanofi.com](http://www.sanofi.com) and [www.regeneron.com](http://www.regeneron.com) and also via the following telephone numbers:

**France** +33 (0) 1 70 77 09 40

**UK** +44 (0) 203 367 9453

**U.S.** +1 866 907 5925

### About alirocumab

Alirocumab is an investigational, fully-human monoclonal antibody that targets and blocks PCSK9. It is administered via subcutaneous injection. By inhibiting PCSK9, a determinant of circulating LDL-C levels in the blood, alirocumab has been shown in pre-clinical studies to increase the number of LDL receptors on hepatocytes, thereby lowering LDL-C.

ODYSSEY is the global Phase 3 trial program for investigational compound alirocumab. ODYSSEY currently comprises 14 clinical trials enrolling more than 23,500 patients with hypercholesterolemia in 2,000 study centers across North and South America, Europe, Australia, South Africa, and Asia. Alirocumab is currently under clinical development, and its safety and efficacy 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 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 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 markets 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, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com).

### References

1. Roth E, Taskinen M-R, Ginsberg HN, et al. A 24-week study of alirocumab as monotherapy versus ezetimibe: the first 6-month Phase 3 data of a proprotein convertase subtilisin/kexin type 9 inhibitor. Poster #125 (session #1183) at the American College of Cardiology's 63<sup>rd</sup> Annual Scientific Session, March 29-31.
2. Stein EA, Bergeron J, Gaudet D, et al. One year open-label treatment with alirocumab 150 mg every two weeks in heterozygous familial hypercholesterolemic patients. Poster #126 (session #1183) at the American College of Cardiology's 63<sup>rd</sup> Annual Scientific Session, March 29-31.
3. Rey J, Poitiers F, Paehler T, et al. Randomized, partial blind study of the pharmacodynamics, pharmacokinetics and safety of multiple subcutaneous doses of alirocumab, a fully human monoclonal antibody to proprotein convertase subtilisin/kexin type 9, administered every 4 weeks alone or in combination with ezetimibe or fenofibrate in healthy subjects. Poster #131 (session #1183) at the American College of Cardiology's 63<sup>rd</sup> Annual Scientific Session, March 29-31.
4. Koren MJ, Kereiakes D, Pourfarzib R, et al. Effects of Alirocumab, a Fully Human Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9, on Lipoprotein Particle Concentrations Determined by Nuclear Magnetic Resonance: Sub-Study of a Randomized Double-Blind Phase II Clinical Trial. Poster #128 (session #1183) at the American College of Cardiology's 63<sup>rd</sup> Annual Scientific Session, March 29-31.
5. Lunven C, Paehler T, Lewanczyk P, et al. Randomized Study of the Relative Bioavailability, Pharmacodynamics, and Safety of Alirocumab, a Fully Human Monoclonal Antibody to Proprotein Convertase Subtilisin/Kexin Type 9, After Single Subcutaneous Administration at Three Different Injection Sites in Healthy Subjects. Poster #133 (session #1183) at the American College of Cardiology's 63<sup>rd</sup> Annual Scientific Session, March 29-31.

### 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, 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, including without limitation the Phase 3 ODYSSEY MONO study and the ODYSSEY global Phase 3 trial program, which may affect the global filing plan for alirocumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; 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, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property 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. 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.*

#### **Sanofi Contacts:**

##### **Media Relations**

Jack Cox  
Tel : +33 (0)1 53 77 94 74  
[jack.cox@sanofi.com](mailto:jack.cox@sanofi.com)

##### **Investor Relations**

Sébastien Martel  
Tel.: +33 (0)1 53 77 45 45  
[ir@sanofi.com](mailto:ir@sanofi.com)

Elizabeth Baxter  
Global Communications for PCSK9  
Tel: +1 908-981-5360  
Mobile: +1 908-340-7811  
[elizabeth.baxter@sanofi.com](mailto:elizabeth.baxter@sanofi.com)

#### **Regeneron Contacts:**

##### **Media Relations**

Sandy Sexton  
Tel: +1 914- 847-3358  
[sandra.sexton@regeneron.com](mailto:sandra.sexton@regeneron.com)

##### **Investor Relations**

Manisha Narasimhan, Ph.D.  
Tel: +1 914-847-5126  
[manisha.narasimhan@regeneron.com](mailto:manisha.narasimhan@regeneron.com)

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