

## Press Release

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### Regeneron and Sanofi to Present Phase 3 Praluent® (alirocumab) Injection Clinical Trial Data at ACC.16

**Tarrytown, NY and Bridgewater, NJ (March 30, 2016)** -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced new pooled Phase 3 data from the Praluent® (alirocumab) Injection clinical trial program will be presented at the American College of Cardiology's 65<sup>th</sup> Annual Scientific Session & Expo (ACC.16), being held April 2-4 in Chicago.

Data include an oral presentation of a new pooled safety analysis on major adverse cardiac events (MACE) for a treatment period of up to two years. Other data will be presented on the efficacy and safety of Praluent by age stratification, and treatment response in patients with mutations in up to five familial hypercholesterolemia (FH) genes.

Praluent is a fully-human monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9). In the U.S. Praluent is indicated as 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 LDL cholesterol. The effect of Praluent on cardiovascular (CV) morbidity and mortality has not been determined. The ongoing ODYSSEY OUTCOMES trial will evaluate the effect of Praluent on CV events in approximately 18,000 patients over five years.

Regeneron and Sanofi data will be presented throughout ACC.16 during the following sessions:

#### Praluent data:

##### 1) ORAL PRESENTATION

- **Prevention and the Year in Review**
  - Relationship Between Major Adverse Cardiovascular Events and Achieved LDL-Cholesterol Levels in Phase 3 ODYSSEY Trials of Alirocumab Versus Control (Cannon)
    - Abstract # 913-04
    - Monday, April 4, 9:15-9:27 a.m. ET (Room S404)

##### 2) MODERATED POSTER PRESENTATIONS

- **Lipids, Diabetes Mellitus and Inflammation in Stable Ischemic Heart Disease**
  - Relationship Between Percentage Reduction in LDL-Cholesterol Levels and Major Atherosclerotic Cardiovascular Disease Among Patients Treated with Statins +/- Alirocumab or Ezetimibe in the Phase 3 ODYSSEY Trials (Ray)
    - Abstract # 1124M-05
    - Saturday, April 2, 11:30-11:40 a.m. ET (South Hall A)
- **PCSK9 Inhibitors – New Insights and Evolving Understanding**
  - Impact of Anti-Drug Antibodies to Alirocumab on LDL-Cholesterol Lowering Efficacy and Safety (Roth)
    - Abstract # 1293M-03

- Monday, April 4, 1:45-1:55 p.m. ET (South Hall A)
  - Efficacy of Alirocumab in 1,191 Patients with a Wide Spectrum of Mutations in Genes Causative for Familial Hypercholesterolemia (Kastelein)
    - Abstract # 1293M-05
    - Monday, April 4, 2:00-2:10 p.m. ET (South Hall A)
- 3) POSTER PRESENTATION
- **Preventative Cardiology Potpourri**
    - Efficacy and Safety of Alirocumab Stratified by Age in Phase 3 Trials (Raal)
      - Abstract # 1236-397
      - Sunday, April 3, 4:45-5:30 p.m. ET (South Hall A)

Additional data:

- 1) POSTER PRESENTATION
- **Predicting Outcomes in Acute Coronary Syndromes**
    - One-Year Cardiovascular Event Rates Among Medicare Advantage Patients with Atherosclerotic Cardiovascular Disease or Diabetes (Reynolds)
      - Abstract # 1100-032
      - Saturday, April 2, 11:00-11:45 a.m. ET (South Hall A)

Additional information on ACC.16 is available on the congress [website](#).

### **About Praluent**

In July 2015, Praluent was approved for use in the U.S. Praluent is a PCSK9 inhibitor indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical ASCVD, who require additional lowering of LDL cholesterol. The effect of Praluent on CV morbidity and mortality has not been determined.

In September 2015, the European Commission approved the marketing authorization for Praluent. In the E.U., Praluent is approved for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: **a)** in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL cholesterol goals with the maximally-tolerated statin or **b)** alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on CV morbidity and mortality has not yet been determined.

### **IMPORTANT SAFETY INFORMATION FOR U.S.**

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization.

Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve.

The most commonly occurring adverse reactions (greater than or equal to 5 percent of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza.

Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT (7.2 percent versus 5.1 percent for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2 percent versus 0.4 percent for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

Neurocognitive events were reported in 0.8 percent of patients treated with PRALUENT and 0.7 percent of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2 percent for each) than in those treated with placebo (less than 0.1 percent for each).

Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5 percent of patients treated with PRALUENT and 1.8 percent of patients treated with placebo, leading to treatment discontinuation in 0.4 percent and 0.2 percent of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7 percent of patients treated with PRALUENT and 1.4 percent of patients treated with placebo.

The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6 percent versus 0.2 percent for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3 percent versus less than 0.1 percent).

PRALUENT is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT.

Please click [here](#) for the full Prescribing Information

### **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 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](http://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 initiatives 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, 2015. 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 prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit; 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); 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, 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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