



## Regeneron and Sanofi Present Positive Phase 3 Investigational Data for Praluent® (alirocumab) Injection in Patients Undergoing LDL Apheresis Therapy at ESC Congress 2016

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TARRYTOWN, N.Y. and PARIS, Aug. 29, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and [Sanofi](#) today announced detailed positive results from ODYSSEY ESCAPE, a Phase 3 trial which evaluated Praluent® (alirocumab) Injection in patients with an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH) who require regular weekly or bi-weekly apheresis treatment. The trial demonstrated that adding Praluent to existing therapy reduced LDL cholesterol by approximately 50 percent from baseline (compared to 2 percent increase for placebo). Praluent significantly reduced the need for apheresis treatment by 75 percent compared to placebo (p less than 0.0001), the primary endpoint of the study. Results will be presented today at a Hot Line session at the ESC Congress 2016 in Rome, Italy.

Apheresis is a procedure similar to kidney dialysis where bad (LDL) cholesterol is removed from the blood, and is usually reserved for high-risk patients with very high cholesterol unable to achieve their cholesterol-lowering goals on any other therapy. Despite being treated with apheresis and entering ODYSSEY ESCAPE with very high LDL cholesterol levels (4.7 millimoles/liter [mmol/L] or 181 milligrams/deciliter [mg/dL]), nearly two-thirds (63 percent) of patients treated with Praluent no longer required apheresis therapy after six weeks of receiving Praluent. At this same time point, the average LDL cholesterol level among the Praluent-treated group was 2.3 mmol/L (90 mg/dL), compared to 4.8 mmol/L (185 mg/dL) in the placebo group. European guidelines recommend LDL cholesterol target levels between 1.8-3.0 mmol/L (70-115 mg/dL), depending on cardiovascular risk.

"Findings from ODYSSEY ESCAPE suggest a role for Praluent in the overall management of patients with HeFH undergoing regular apheresis therapy, with the potential to reduce the need for burdensome apheresis treatments," said Patrick M Moriarty, MD, Professor, Department of Internal Medicine; Director, Atherosclerosis and Lipoprotein Apheresis Center, University of Kansas Medical Center, United States. "This is a significant development in the continued investigation of this drug in HeFH patients, because it is the first clinical trial to demonstrate that Praluent reduced the frequency of apheresis therapy."

Apheresis therapy is an invasive, time-consuming and expensive treatment for some of the most difficult-to-treat patients. Treatment may cost up to \$100,000 for each patient per year in the U.S. or up to €60,000 in Germany, where there are 200 centers and LDL apheresis is more frequently used. In the U.S. there are only approximately 60 apheresis centers and many patients must travel significant distances for the procedure.

Other key results from ODYSSEY ESCAPE, which will be concurrently published in the *European Heart Journal*, include:

- Ninety-three percent of patients treated with Praluent experienced at least a 50 percent reduction in their apheresis procedures (p greater than 0.0001).
- Throughout the trial, patients treated with Praluent experienced significant reductions in their LDL cholesterol starting at week 6 (55 percent greater reduction compared to placebo), and lasting until the trial ended, at week 18 (46 percent greater reduction compared to placebo) (p less than 0.0001).
- A similar proportion of patients experienced adverse events (AEs) in both the Praluent and placebo groups (76 percent both groups). The most common AEs (occurring in at least 5 percent of the Praluent group) were: fatigue (15 percent Praluent; 10 percent placebo), nasopharyngitis (10 percent Praluent; 10 percent placebo), diarrhea (10 percent Praluent; 0 percent placebo), myalgia (10 percent Praluent; 5 percent placebo), upper respiratory infection (7 percent Praluent; 19 percent placebo), headache (7 percent Praluent; 5 percent placebo), arthralgia (7 percent Praluent; 10 percent placebo), and back pain (5 percent Praluent; 10 percent placebo).

### About ODYSSEY ESCAPE

The completed Phase 3 placebo-controlled ODYSSEY ESCAPE trial involved 62 patients from 14 treatment centers in the U.S. and Germany. These patients were receiving regular baseline apheresis therapy at fixed intervals of every week or every 2 weeks prior to randomization. Average LDL cholesterol at baseline was 4.7 mmol/L (181 mg/dL). Eighty-six percent (placebo group) and 90 percent (Praluent group) of patients had a history of coronary heart disease.

Patients were randomized to receive Praluent 150 mg (n=41) subcutaneously every 2 weeks or placebo (n=21), in addition to their existing treatment regimen. The double-blind treatment period comprised two intervals: for the first 6 weeks, patients remained on their established apheresis schedule at baseline, and for the following 12 weeks, apheresis frequency was adjusted based on the patient's LDL cholesterol response to treatment. ODYSSEY ESCAPE is part of the overarching Phase 3 ODYSSEY program, which includes more than 25,000 patients.

### About Praluent

Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells, which results in lower LDL cholesterol levels in the blood. Praluent is the only PCSK9 inhibitor available in two dosages with two levels of efficacy (75 mg and 150 mg), allowing physicians to select the dose based on a patient's LDL cholesterol lowering needs.

Praluent is approved in approximately 40 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico, Brazil and the European Union (EU). In the U.S., Praluent is approved for use as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic CV disease, who require additional lowering of LDL cholesterol. 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. ODYSSEY OUTCOMES is prospectively evaluating the effect of Praluent on the occurrence of CV events in approximately 18,000 patients who have experienced an acute coronary syndrome.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

#### **Important Safety Information for U.S.**

Do not use PRALUENT if you are allergic to alirocumab or to any of the ingredients in PRALUENT.

Before you start using PRALUENT, tell your healthcare provider about all your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face, or trouble breathing.

The most common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site, symptoms of the common cold, and flu or flu-like symptoms. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Talk to your doctor about the right way to prepare and give yourself a PRALUENT injection and follow the "Instructions for Use" that comes with Praluent.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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 eye diseases, high LDL-cholesterol, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, atopic dermatitis, pain, cancer 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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, 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; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; 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; 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 (or their respective affiliated companies, as applicable), 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 and its Form 10-Q for the quarterly period ended June 30, 2016. 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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