REGENERON

March 10, 2018

Praluent® (alirocumab) Injection Significantly Reduced Risk of Cardiovascular Events in High-Risk Patients, and was Associated with Lower Death Rate

- ODYSSEY OUTCOMES trial met its primary endpoint, demonstrating that high-risk patients who added Praluent® (alirocumab) Injection to maximally-tolerated statins experienced significantly fewer major adverse cardiovascular events compared to those on maximally-tolerated statins alone
- For the first time, adding a lipid-lowering therapy to maximally-tolerated statins was associated with reduced death from any cause
- More pronounced effect observed in patients with baseline LDL-cholesterol (LDL-C) levels at or above 100 mg/dL despite maximally-tolerated statins, who are at high risk of suffering a future event; in this group, Praluent reduced risk of major adverse cardiovascular events by 24% and was associated with a 29% lower risk of death overall
- In this 18,924-patient, long-term trial, the safety profile of Praluent was consistent with previous trials and no new safety issues were observed

TARRYTOWN, N.Y. and PARIS, March 10, 2018 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the ODYSSEY OUTCOMES trial met its primary endpoint, showing Praluent® (alirocumab) Injection significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who had suffered a recent acute coronary syndrome (ACS) event, such as a heart attack. Results from the trial will be presented today during a late-breaker session at the American College of Cardiology's 67th Annual Scientific Session (ACC.18) in Orlando, Florida and are available here.

Key findings include:

- On the primary endpoint, Praluent reduced the overall risk of MACE by 15% (HR=0.85, CI: 0.78-0.93, p=0.0003). The MACE composite endpoint includes patients who experienced a heart attack, ischemic stroke, death from coronary heart disease (CHD), or unstable angina requiring hospitalization.
- Praluent was also associated with a lower risk of death overall, known as "all-cause mortality" (HR=0.85; CI: 0.73-0.98, nominal p=0.026), and there were also numerically fewer CHD deaths (HR=0.92; CI: 0.76-1.11, p=0.38).
- In a pre-specified analysis, the patients with baseline LDL-C levels at or above 100 mg/dL experienced a more pronounced effect from Praluent, reducing their risk of MACE by 24% (HR=0.76, CI: 0.65-0.87). In a post-hoc analysis of this group, Praluent was associated with a lower risk of death from any cause by 29% (HR=0.71, CI: 0.56-0.90).
- The analyses described above include the results from 730 patients (8%) in the Praluent group who continued to be assessed in the Praluent arm despite stopping active Praluent therapy, as specified in the protocol for patients with persistent LDL-C readings below 15 mg/dL.
- For those in the Praluent treatment arm, approximately 75% of patient time was on the 75 mg dose.
- There were no new safety signals in the trial, with injection site reactions experienced more commonly in the Praluent group compared to patients on maximally-tolerated statins alone (3.8% Praluent; 2.1% placebo). There was no difference in neurocognitive events (1.5% Praluent; 1.8% placebo) or new-onset diabetes (9.6% Praluent; 10.1% placebo).

"This trial was consistent with earlier statin trials, showing the greatest benefit in patients with higher cholesterol levels at baseline," said George D. Yancopoulos, MD, PhD, President and Chief Scientific Officer, Regeneron. "Many patients who have survived a recent heart attack or other coronary event are unable to reach an LDL cholesterol goal of less than 100 mg/dL, and have an urgent need for new therapeutic options because of their increased risk of another event. In this trial, such patients who received Praluent on top of maximally-tolerated statins had important reductions in their risk."

"Not all patients with heart disease are the same. Through this trial, we have been able to identify high-risk patients treated with optimal statins who still have an urgent need for additional treatment options," said Elias Zerhouni, MD, President, Global R&D, Sanofi. "With nearly 90 percent of the patients in this trial on high-intensity statins, the data demonstrate that a precision-medicine approach in the field of cardiovascular disease may further advance how we better treat high-risk patients."

Investor Relations Conference Call on ODYSSEY OUTCOMES
Sanofi and Regeneron will be hosting a conference call for the financial community on ODYSSEY OUTCOMES. The

conference call will take place on Saturday, March 10, 2018 (18:00 CET / 12:00 EST / 09:00 PST).

The call will be available on www.sanofi.com and www.regeneron.com through a webcast.

Conference call numbers are as follows:
United States: +1 (1) 631 570 5613
France: +33 (0)1 7091 8706
United Kingdom: +44 (0) 207 107 0613
Europe: +41 (0) 58 310 50 00
Other international numbers available **here**.

About ODYSSEY OUTCOMES
ODYSSEY OUTCOMES (n=18,924) assessed the effect of Praluent on the occurrence of MACE in patients who had experienced an ACS between 1-12 months (median 2.6 months) before enrolling in the trial, and who were already on maximally-tolerated statins. All patients were randomized to receive Praluent (n=9,462) or a placebo (n=9,462) and were treated for an average (median) of 2.8 years, with some patients being treated for up to five years. Approximately 90% of patients were on a high-intensity statin.

The trial was designed to maintain patients' LDL-C levels between 25-50 mg/dL, using two different doses of Praluent (75 mg and 150 mg). Praluent-treated patients started the trial on 75 mg every 2 weeks, and switched to 150 mg every 2 weeks if their LDL-C levels remained above 50 mg/dL (n=2,615). Some patients who switched to 150 mg switched back to 75 mg if their LDL-C fell below 25 mg/dL (n=805), and patients who experienced two consecutive LDL-C measurements below 15 mg/dL while on the 75 mg dose (n=730) stopped active Praluent therapy for the remainder of the trial.

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 lowers LDL-C levels in the blood. The use of Praluent to reduce the risk of MACE is investigational and has not been evaluated by any regulatory agency.

Praluent is approved in more than 60 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as in the European Union (EU). In the U.S., Praluent is approved for use as an 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-C. In the EU, 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-C 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.

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.

The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Important Safety Information for the 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 or call 1-800-FDA-1088.

Please click here for the full Prescribing Information

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led by physician-scientists for 30 years, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*® technologies, including *VelocImmune*® to yield optimized fully-human antibodies, and ambitious initiatives such as the Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About Sanofi
Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, and provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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; 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), including the ODYSSEY OUTCOMES trial discussed in this news release, on the commercial success of Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; 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; 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; 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; 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, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be canceled or terminated without any further product success risks; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including the patent litigation proceedings relating to Praluent, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. 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, 2017. 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)

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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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