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Press Release

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ODYSSEY OUTCOMES investigators highlight at AHA that Praluent® (alirocumab) was associated with fewer deaths from any cause

- Mortality risk reduction greater in patients treated for at least 3 years or those with baseline LDL-C levels of at least 100 mg/dL
- New analyses show reduction in non-fatal cardiovascular events is associated with a subsequent reduction in non-cardiovascular death

PARIS and Tarrytown, N.Y. – November 11, 2018 – New analyses on mortality from the 18,924-patient ODYSSEY OUTCOMES trial were presented at the American Heart Association (AHA) Scientific Sessions 2018.

Praluent® (alirocumab) was associated with fewer deaths from any cause among patients who had previously experienced a heart attack or unstable angina (known as acute coronary syndrome, or ACS), and this was enhanced in patients who were followed for at least 3 years and those who had an LDL-C (low-density lipoprotein cholesterol) of 100 mg/dL or higher at baseline. Moreover, additional new analyses showed an association between reduced non-fatal cardiovascular (CV) events and reduction in non-CV death during the trial period.

> *"Reducing patients' risk of death is one of cardiologists' key priorities. Some of these deaths could potentially be prevented, particularly among patients who have already been identified as high risk because they have a history of acute coronary syndrome,"* said Gregory G. Schwartz, M.D., Ph.D., University of Colorado School of Medicine, Aurora, CO, and co-chair of the trial. *"In this nearly 19,000-patient trial, alirocumab was associated with fewer deaths from any cause, an observation that was more pronounced among patients who were eligible for at least 3 years of treatment, or who started with LDL-C of at least 100 mg/dL."*

In the trial, Praluent added to maximally-tolerated statins was compared to maximally-tolerated statins alone in patients who had experienced an ACS within the last 12 months. Data published in *The New England Journal of Medicine* last week found Praluent significantly reduced the risk of major adverse cardiovascular events (MACE) and was associated with a lower risk of death from any cause.

In pre-specified analyses of 8,242 patients followed for at least 3 years, Praluent was associated with a 22% lower risk of death from any cause (hazard ratio (HR) 0.78; 95% CI, 0.65 to 0.94; nominal p=0.01). Separate post-hoc analyses showed Praluent-treated

patients whose baseline LDL-C levels were at or above 100 mg/dL experienced a 29% lower risk of death from any cause (HR 0.71; 95% CI, 0.56 to 0.90).

In additional post-hoc analyses researchers found Praluent-treated patients experienced fewer non-fatal CV events and were less likely to die from a non-CV event and that these two findings may be associated (association between non-fatal and fatal events = 2.35; 95% CI, 1.98 to 2.73; p<0.0001).

No new safety signals were found in the analyses. In ODYSSEY OUTCOMES, the incidence of adverse events was similar in the two groups, with the exception of local injection-site reactions (3.8% in the Praluent group vs. 2.1% in the placebo group).

The effect of Praluent on CV morbidity and mortality is currently being reviewed by regulatory authorities and has not yet been fully evaluated. Data from the ODYSSEY OUTCOMES trial have been submitted to regulatory authorities in the European Union and in the U.S., where the target action date for the Food and Drug and Administration (FDA) decision is April 28, 2019.

About ODYSSEY OUTCOMES

ODYSSEY OUTCOMES (n=18,924) assessed the effect of Praluent on the occurrence of major adverse cardiovascular events (MACE) in patients who had experienced an acute coronary syndrome (ACS) between 1-12 months (median 2.6 months) before enrolling in the trial, and who were already on intensive or maximally-tolerated statin treatment. Patients were randomized to receive Praluent (n=9,462) or a placebo (n=9,462) and were assessed for a 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 to clear LDL, which lowers LDL-C levels in the blood. Praluent is being developed by Regeneron and Sanofi under a global collaboration agreement.

Praluent is approved in more than 60 countries worldwide, including the U.S., Japan, Canada, Switzerland, Mexico and Brazil, as well as 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. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

About Regeneron Pharmaceuticals, Inc.

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

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting 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, 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

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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.

Regeneron Forward-Looking Statements

This press 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; 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, such as any changes to the prescribing information for Praluent based on data from the ODYSSEY OUTCOMES trial referenced in this press release; whether the submission of data from the ODYSSEY OUTCOMES trial to the relevant regulatory authorities referenced in this press release will be acceptable to such authorities and result in any changes to the prescribing information for Praluent; 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; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Praluent), 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, including without limitation Praluent; 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; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; the availability and extent of reimbursement of the Company's products (such as Praluent) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its 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, and Teva Pharmaceutical Industries Ltd. (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, including without limitation the patent litigation proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, and 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 U.S. Securities and Exchange Commission, including its Form 10-Q for the quarterly period ended September 30, 2018. 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).