SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Praluent® (alirocumab) now approved in European Union to reduce the risk of cardiovascular events in patients with established cardiovascular disease

- Approval is based on ODYSSEY OUTCOMES trial of 18,924 patients who recently suffered an acute coronary syndrome such as a heart attack
- Praluent is the only EU-approved PCSK9 inhibitor with cardiovascular outcomes data that shows an association with reduced death from any cause

PARIS and TARRYTOWN, NY – March 15, 2019 – The European Commission (EC) has approved a new indication for Praluent® (alirocumab), to reduce cardiovascular (CV) risk in adults with established atherosclerotic CV disease (ASCVD) by lowering low-density lipoprotein cholesterol (LDL-C) levels as an adjunct to correction of other risk factors.

> *"Many patients with atherosclerotic cardiovascular disease often struggle to control their high LDL-cholesterol levels, despite lifestyle modifications and treatment with statins, and some have already experienced cardiovascular events,"* said John Reed, M.D., Ph.D., Global Head of Research & Development, Sanofi. *"These patients could face a higher risk of another life-threatening cardiovascular event, and Praluent's new indication in Europe offers a risk-reduction focused lipid-lowering treatment option to physicians and patients."*

ASCVD is an umbrella term, defined as a build-up of plaque in the arteries that can lead to reduced blood flow and a number of serious conditions such as stroke, peripheral artery disease and acute coronary syndrome (ACS), which includes heart attack and unstable angina.

> *"Despite treatment with the current standard of care including statins, many Europeans with established cardiovascular disease are still unable to control their cholesterol,"* said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer, Regeneron. *"In the large, prospective ODYSSEY OUTCOMES clinical trial, Praluent reduced the risk of major cardiovascular events, including heart attack, stroke and unstable angina, and was associated with reduced death from any cause."*

The EC approval is based on data from ODYSSEY OUTCOMES, a Phase 3 CV outcomes trial that assessed the effect of adding Praluent to maximally-tolerated statins in 18,924 patients who had an ACS between 1-12 months (median 2.6 months) before enrolling in the trial. Results from the ODYSSEY OUTCOMES trial were published in *The New*

England Journal of Medicine in 2018. The trial met its primary endpoint, showing that Praluent significantly reduced the relative risk of major adverse CV events (MACE) by 15% in patients who had suffered a recent ACS. MACE occurred in 903 patients (9.5%) in the Praluent group and in 1,052 patients (11.1%) in the placebo group (HR 0.85; 95% CI, 0.78 to 0.93; p<0.001). Additionally, Praluent was associated with a 15% lower risk of death from any cause; which occurred in 334 (3.5%) patients in the Praluent group and 392 (4.1%) patients in the placebo group (HR 0.85; 95% CI, 0.73 to 0.98; nominal significance). Adverse events were similar between the Praluent and placebo groups, except for injection site reactions (Praluent 3.8%, placebo 2.1%).

Praluent is the only PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor available in two starting doses as a single 1 milliliter (mL) injection (75 mg and 150 mg) once every two weeks and can also be administered as 300 mg once every four weeks (monthly), enabling physicians to tailor treatment based on an individual patient's LDL-C-lowering needs. Data from ODYSSEY OUTCOMES have also been submitted to the U.S. Food and Drug Administration (FDA), with a target action date of April 28, 2019.

About ODYSSEY OUTCOMES

ODYSSEY OUTCOMES assessed the effect of Praluent on the occurrence of MACE in patients who had experienced an ACS 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 5 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 (0.65-1.29 mmol/L), 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 (1.29 mmol/L) (n=2,615). Some patients who switched to 150 mg switched back to 75 mg if their LDL-C fell below 25 mg/dL (0.65 mmol/L) (n=805), and patients who experienced two consecutive LDL-C measurements below 15 mg/dL (0.39 mmol/L) while on the 75 mg dose (n=730) stopped active Praluent therapy for the remainder of the trial.

About Praluent

Praluent® (alirocumab) 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 was developed by Regeneron and Sanofi under a global collaboration agreement.

Praluent is approved in more than 60 countries worldwide, including the European Union (EU), U.S., Japan, Canada, Switzerland, Mexico and Brazil. In the EU, Praluent is approved for use to reduce CV risk in adults with established ASCVD by lowering LDL-C, as an adjunct to correction of other risk factor. The effect of Praluent on CV morbidity and mortality is currently under review and not yet approved by any regulatory authority outside of the 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 ASCVD who require additional lowering of LDL-C.

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, 2018. 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 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 possible approval by the U.S. Food and Drug Administration (the "FDA") of the update to the Prescribing Information for Praluent to include the effect of Praluent in reducing the overall risk of major adverse cardiovascular events referenced in this press release; the impact of the recent and any potential future U.S. government shutdowns on the anticipated timing of the FDA regulatory action relating to Praluent referenced in this press release; uncertainty of market acceptance and commercial success of Regeneron's products (such as Praluent) 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 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; 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; 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 (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; 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; risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation and other proceedings relating to Praluent, EYLEA® (aflibercept) Injection, and Dupixent® (dupilumab) Injection, the ultimate outcome of any such proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; and 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. 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-K for the year ended December 31, 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).