CHMP recommends approval of Praluent® (alirocumab) to reduce cardiovascular risk in people with established atherosclerotic cardiovascular disease

PARIS and TARRYTOWN, NY – February 4, 2019 – The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Praluent® (alirocumab), recommending a new indication as an adjunct to correction of other risk factors. Praluent should be used in addition to a maximally tolerated dose of statin or can be used alone in patients intolerant to or inappropriate for statin therapy.

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.

The CHMP opinion is based on data from ODYSSEY OUTCOMES, a Phase 3 cardiovascular outcomes trial that assessed the effect of Praluent 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 European Commission is expected to make a final decision in the coming months. Data from ODYSSEY OUTCOMES has 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 major adverse cardiovascular events (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 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 EU, U.S., Japan, Canada, Switzerland, Mexico and Brazil. 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.

In the EU, Praluent has been initially 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 results of ODYSSEY OUTCOMES, which evaluated the effect of Praluent on cardiovascular morbidity and mortality, are currently under evaluation by a number of regulatory authorities worldwide. To date, only the CHMP has completed its assessment.

**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 VelociImmune® 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](http://www.regeneron.com) or follow @Regeneron on Twitter.
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.
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; 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, 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. 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.

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