New England Journal of Medicine publishes positive detailed results from Praluent® (alirocumab) cardiovascular outcomes trial

- Praluent significantly reduced major adverse cardiovascular events by 15% (p<0.001)
- Praluent was associated with a 15% lower risk of death from any cause (hazard ratio [HR] 0.85; 95% confidence interval [CI], 0.73 to 0.98)\(^1\)
- Additional analyses, including mortality, to be presented at upcoming American Heart Association Scientific Sessions, November 10–12


The trial met its primary endpoint, showing that Praluent® (alirocumab) significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who had suffered an acute coronary syndrome (ACS), which included a heart attack or unstable angina. 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).

Death from any cause was less frequent among Praluent-treated patients. Praluent was associated with a 15% lower risk of death; death occurred in 334 (3.5%) patients in the Praluent group and 392 (4.1%) patients in the placebo group (HR 0.85; 95% CI, 0.78 to 0.93; p<0.001).\(^1\)

The NEJM publication also includes results for MACE and other secondary endpoints including death, according to subgroups of baseline LDL-C (low-density lipoprotein cholesterol) levels, which are described in detail in the Supplementary Appendix. The data showed that patients with higher LDL-C at baseline (at least 100 mg/dL) were at greater risk of MACE, as well as other secondary endpoints including death. Moreover, the greater risk-reduction occurred in this category of patients: in the Praluent group MACE was reduced by 24% (HR 0.76; 95% CI, 0.65 to 0.87) and death from any cause was 29% lower (HR 0.71; 95% CI, 0.56 to 0.90) compared to placebo.\(^2\)

\(^1\)Analyses for the death endpoints in the overall study fell outside of the statistical hierarchy; and in accordance with recently implemented NEJM policies, the hazard ratio (HR) and its confidence interval (CI) were published, but no P-values were reported.
\(^2\)Analyses of the death endpoint based on baseline LDL-C levels were not included in the statistical hierarchy; and in accordance with recently implemented NEJM policies, the hazard ratio (HR) and its confidence interval (CI) were published, but no P-values were reported.
Adverse events were similar between groups except for injection site reactions (Praluent 3.8%, placebo 2.1%).

Results of the ODYSSEY OUTCOMES trial were presented at the American College of Cardiology’s 67th Annual Scientific Session & Expo in March 2018. Additional analyses, including mortality, will be presented later this week at the American Heart Association Scientific Sessions 2018.

“Despite the use of statins, many patients with coronary heart disease go on to have recurrent cardiovascular events, underscoring the need for additional treatment options. This need is particularly urgent among patients with acute coronary syndrome and LDL-C levels that remain high despite best possible application of statin therapy,” said Dr. Gregory G. Schwartz, M.D., Ph.D., University of Colorado School of Medicine, Aurora, CO, and co-chair of the trial. “These data in the New England Journal of Medicine show that adding alirocumab to intensive or maximum tolerated statin treatment significantly reduced the risk of future cardiovascular events. This benefit was heightened among study patients with higher LDL-C levels at baseline.”

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

Click here for additional information on the ODYSSEY OUTCOMES trial and Praluent.

**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 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, 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
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).