



## Regeneron and Sanofi Announce Plans to Make Praluent® (alirocumab) More Accessible and Affordable for Patients with the Greatest Health Risk and Unmet Need

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TARRYTOWN, N.Y. and PARIS, March 10, 2018 /PRNewswire/ -- To help ensure more affordable and timely access to patients most in need, Regeneron Pharmaceuticals (NASDAQ: **REGN**) and Sanofi will offer payers that agree to reduce burdensome access barriers for high-risk patients a further reduced net price for Praluent® (alirocumab) Injection, in alignment with a new value assessment for high-risk patients from the Institute for Clinical and Economic Review (ICER) available [here](#).

The companies will take a precision medicine approach to address the burden of cardiovascular disease (CV), focusing efforts on high-risk patients most vulnerable to future CV events, such as those who have suffered a previous coronary event and are unable to reduce their LDL cholesterol (LDL-C) below 100 mg/dL despite maximally-tolerated statin therapy.

In keeping with ICER's established "in confidence" procedures, Regeneron and Sanofi provided early access to data from the ODYSSEY OUTCOMES trial to enable a revised assessment of alicumab value incorporating the ODYSSEY OUTCOMES results. ICER is an independent organization that objectively evaluates the value of prescription drugs and other health care innovations.

"Inventing innovative medicines only matters if the people who need these products are able to access them - and that is unfortunately not the case with Praluent today," said Leonard S. Schleifer, MD, PhD, President and Chief Executive Officer of Regeneron. "We believe a new paradigm is needed in how all members of the healthcare community collaborate to ensure that patients are able to affordably access medical treatments they need. We commit to working with all health plans that agree to remove access barriers for high-risk patients to offer a more cost-effective net price for Praluent. We hope that our unprecedented approach to collaborating with payers and other stakeholders demonstrates that it is possible to bring major innovation to patients at a price that aligns with the value delivered."

"Too many patients in urgent need of additional treatment options on top of statins have faced tremendous hurdles to gain access to this important medicine. We are prepared to improve access and affordability, eliminating burdensome barriers for high-risk patients in need," said Olivier Brandicourt, MD, Chief Executive Officer, Sanofi. "We will begin working with payers to ensure that high-risk patients have appropriate access. This is the right thing to do for patients."

Regeneron and Sanofi will meet with health plans to discuss potential net pricing adjustments for those that agree to provide straightforward access for high-risk patients. The companies plan to work with cardiology healthcare professionals to define best practices in reducing barriers to access, in order to ensure that patients in need have their prescriptions filled quickly and efficiently.

### 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 major adverse CV events 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 CV morbidity and mortality has not been determined.

### Important Safety Information for the U.S.

Do not use Praluent if you are allergic to alicumab 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](http://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*<sup>®</sup> technologies, including *VelocImmune*<sup>®</sup> 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](http://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<sup>®</sup> (alirocumab) Injection; the 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 referenced in this news release, on the commercial success of Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers (such as Medicare and Medicaid), including those impacting further commercialization of Praluent; the likelihood of success of relevant strategies relating to Regeneron's products, such as the new precision-medicine approach for Praluent discussed in this news release; 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; 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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