



## Regeneron and Sanofi to Lower Net Price of Praluent® (alirocumab) Injection in Exchange for Straightforward, More Affordable Patient Access for Express Scripts Patients

May 1, 2018

TARRYTOWN, N.Y. and BRIDGEWATER, N.J. and ST. LOUIS, May 1, 2018 /PRNewswire/ --

- *Agreement provides Praluent at lower net price and enables streamlined patient access based on physician attestation*
- *Express Scripts to pass on savings to eligible patients from the participating commercial health plans*
- *Express Scripts has selected Praluent as the exclusive PCSK9 inhibitor therapy on its National Preferred Formulary as of July 1, 2018*

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced they will lower the net price of Praluent® (alirocumab) Injection in exchange for straightforward, more affordable patient access from Express Scripts. Praluent will become the exclusive PCSK9 inhibitor therapy on the Express Scripts national formulary. The agreement significantly simplifies the documentation necessary to secure insurance coverage and may help reduce out-of-pocket costs for eligible patients. Despite having the broadest U.S. formulary coverage of any PCSK9 inhibitor, many patients have been unable to access Praluent because of the complicated utilization management process required by some insurance companies and high patient out-of-pocket costs.

The agreement takes effect on July 1, 2018 for commercial patients covered by the Express Scripts National Preferred Formulary (approximately 25 million individuals in total). Physicians will submit a simplified attestation form confirming that Praluent is appropriate for the patient based on the U.S. FDA-approved indication and patient history. This is a significant simplification compared to many current utilization management processes that involve multiple steps and lengthy documentation, including submitting laboratory results and detailed patient histories.

"This paradigm-shifting agreement is designed to break the gridlock so that Praluent is finally able to reach patients most in need," said Leonard S. Schleifer, MD, PhD, President and Chief Executive Officer of Regeneron. "U.S. cardiologists have experienced unprecedented challenges in securing access for Praluent for patients who were clearly appropriate, but were denied coverage. This agreement sets a new standard in industry and payer collaboration that we hope will serve as a model for how to make innovative medicines more accessible and affordable."

Also beginning on July 1, 2018, Express Scripts will pass a portion of the Praluent rebates it receives from Regeneron and Sanofi directly to people enrolled in participating commercial health benefit plans, including many of those offered by employers. Praluent patients enrolled in such participating plans should see lowered out-of-pocket costs at the pharmacy.

"This patient-centric approach addresses head-on the frustrations caused by complex pre-authorization requirements that can hamstring physicians and restrict access to an important medicine," said Michelle Carnahan, Sanofi Senior Vice President, Head of North America Diabetes and Cardiovascular Business. "In this new era of shared responsibility across healthcare players, this collaboration with Express Scripts is a frontrunner by making Praluent both accessible and affordable to patients who may most benefit from it."

"We are proud to work with Regeneron and Sanofi to further expand access and deliver greater value to patients who need Praluent," said Steve Miller, M.D., Senior Vice President and Chief Medical Officer, Express Scripts. "Our specialized care team at Accredo pairs patients with expert specialist pharmacists who have deep understanding of cardiovascular disease and familial hypercholesterolemia. Our holistic approach to care ensures patients get the full benefit of innovative medicines like Praluent."

This is the first agreement since Regeneron and Sanofi [announced](#) in March 2018 that they would lower the net price of Praluent for payers willing to reduce access barriers for appropriate patients.

### About Praluent (alirocumab) Injection

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-cholesterol (LDL-C) levels in the blood. Praluent was discovered using Regeneron's proprietary *VelocImmune*® technology that yields optimized fully-human antibodies, and is being jointly developed and commercialized 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.

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.

### Important Safety Information for Praluent

Do not use Praluent if you are allergic to alirocumab 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*® 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](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, 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

#### About Express Scripts

Express Scripts is leading the way for tens of millions of people by aligning with plan sponsors, taking bold action and delivering patient-centered care to make better health more affordable and accessible.

Headquartered in St. Louis, Express Scripts provides a full range of integrated pharmacy benefit management services, including home delivery pharmacy care, specialty pharmacy care and benefit management, benefit-design consultation, drug utilization review, formulary management and medical and drug data analysis, that guide patients and plans toward better health by prioritizing care and increasing savings. Our services drive down the cost of care for employer-funded, Medicare, Medicaid and Public Exchange plans, and create the headroom needed to keep patients' cost-share low, access broad, and do more for those who are challenged by high out-of-pocket costs. Express Scripts also distributes a full range of biopharmaceutical products and offers innovative medical benefit management services.

For more information, visit [Lab.Express-Scripts.com](http://Lab.Express-Scripts.com) or follow @ExpressScripts on Twitter.

#### 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® (*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 that assessed the potential of Praluent to reduce cardiovascular events, on the commercial success of Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers (such as Medicare, Medicaid, and, as discussed in this news release, Express Scripts), including those impacting further commercialization of Praluent (such as the agreement with Express Scripts relating to Praluent discussed in this new release); the likelihood of success of relevant strategies relating to Regeneron's products, including Praluent; 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.

#### **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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