



## U.S. District Court Invalidates Amgen Patent Claims Targeting PCSK9

August 28, 2019 at 4:56 PM EDT

TARRYTOWN, N.Y. and PARIS, Aug. 28, 2019 /PRNewswire/ --

### Court rules in favor of Regeneron and Sanofi in ongoing Praluent® (alirocumab) patent litigation

[Regeneron Pharmaceuticals, Inc.](#) (NASDAQ: **REGN**) and Sanofi announced today that the U.S. District Court for the District of Delaware ruled in their favor and found as a matter of law that Amgen's asserted patent claims for antibodies targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) are invalid based on lack of enablement.

"Today's decision by the U.S. District Court for the District of Delaware validates our position that Amgen's patents are overly broad and invalid," said Joseph LaRosa, Executive Vice President, General Counsel and Secretary, Regeneron. "Praluent was developed using Regeneron's proprietary science and technology and the judge has confirmed our position by issuing this ruling."

Today's ruling overturned portions of an earlier jury verdict upholding the validity of three claims. On February 25, 2019, a jury previously found in Regeneron and Sanofi's favor that two other asserted Amgen patent claims are invalid. This means that Regeneron and Sanofi have successfully invalidated all five asserted Amgen patent claims.

"It has been our longstanding belief that all of Amgen's asserted U.S. PCSK9 patent claims are invalid, and we are pleased today's decision reaffirms this," said Karen Linehan, Executive Vice President and General Counsel, Sanofi.

#### About Praluent

Praluent® (alirocumab) inhibits the binding of PCSK9 to the low-density lipoprotein (LDL) receptor and thereby increases the number of available LDL receptors on the surface of liver cells to clear LDL, which lowers LDL cholesterol (LDL-C) levels in the blood. Praluent was developed by Regeneron and Sanofi under a global collaboration agreement and invented by Regeneron using the company's proprietary *VelocImmune*® technology that yields optimized fully-human monoclonal antibodies.

Praluent is approved in more than 60 countries worldwide, including the U.S., European Union (EU), Japan, Canada, Switzerland, Mexico and Brazil. In the U.S., Praluent is approved to reduce the risk of heart attack, stroke and unstable angina requiring hospitalization in adults with established cardiovascular disease. Praluent is also approved as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C.

#### 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 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, infectious diseases, pain and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*<sup>®</sup> technologies, such as *VelocImmune*<sup>®</sup> 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.

### **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

### **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, risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation pertaining to Praluent<sup>®</sup> (alirocumab) Injection discussed in this press release (as well as other patent litigation and related proceedings pertaining 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; 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; uncertainty of market acceptance and commercial success of Regeneron's products (such as Praluent) 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; 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; 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; 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; 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; 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 and its Form 10-Q for the quarterly period ended June 30, 2019. 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 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 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 Contacts:**

#### **Sanofi Contacts:**

##### **Media Relations**

Joe Ricculli  
Tel: +1 (914) 847-0405

[joseph.ricculli@regeneron.com](mailto:joseph.ricculli@regeneron.com)

##### **Media Relations**

Nicolas Kressmann  
Tel: +1 (732) 532-5318

[nicolas.kressmann@sanofi.com](mailto:nicolas.kressmann@sanofi.com)

##### **Investor Relations**

Justin Holko  
Tel: +1 (914) 450-3514

[justin.holko@regeneron.com](mailto:justin.holko@regeneron.com)

##### **Investor Relations**

George Grofik  
Tel: +33 (0)1 53 77 45 45

[ir@sanofi.com](mailto:ir@sanofi.com)

 View original content: <http://www.prnewswire.com/news-releases/us-district-court-invalidates-amgen-patent-claims-targeting-pcsk9-300908759.html>

SOURCE Regeneron Pharmaceuticals, Inc.