



Statement Regarding Decision of Opposition Division of the European Patent Office Regarding Amgen Patent Targeting PCSK9

November 30, 2018

Today the European Patent Office (EPO) issued its decision on the validity of Amgen's European patent covering PCSK9 antibodies, upholding Amgen's patent in amended form. We intend to appeal today's EPO decision, and we remain confident that the law and facts support our position.

This decision by the EPO is relevant only to this European patent, and is not binding on the national courts in Europe, but the decision may be taken into account by these courts. As we previously disclosed, Amgen has filed infringement lawsuits against Sanofi and Regeneron in Germany, France and the UK. The EPO proceedings run in parallel to the lawsuits in these countries.

We continue to believe that patients and physicians should have a choice of cholesterol-lowering therapies and that Praluent® (alirocumab) has a differentiated clinical profile. Data from the Praluent Phase 3 cardiovascular outcomes trial, ODYSSEY OUTCOMES, were recently [published](#) in *The New England Journal of Medicine*, describing the effect of Praluent in a trial of 18,924 patients who had a recent acute coronary syndrome (ACS), such as a heart attack.

About Praluent

Praluent inhibits the binding of PCSK9 (proprotein convertase subtilisin/kexin type 9) to the LDL (low density lipoprotein) 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 has been developed 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 (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 European Union, Praluent is indicated in adults with primary hypercholesterolemia (heterozygous familial 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 LDL-C goals with the maximum tolerated dose of a 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. The effect of Praluent on cardiovascular morbidity and mortality has not yet been determined.

Sanofi Contacts:

Media Relations

Anna Robinson

Tel: +33 (0)1 53 77 46 46

Anna.Robinson@sanofi.com

Investor Relations

George Grofik

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

ir@sanofi.com

Regeneron Contacts:

Media Relations**Sarah Cornhill**

Tel: +1 (914) 847-5018

Sarah.Cornhill@regeneron.com**Investor Relations****Mark Hudson**

Tel: +1 (914) 847-3482

Mark.Hudson@regeneron.com**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 pending or future 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Regeneron Forward-Looking Statements and Use of Digital Media

This statement 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 and other proceedings relating to Praluent® (alirocumab) Injection (including the European Patent Office proceedings discussed in this statement), 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; 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; 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; 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-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>).

