U.S. Federal Circuit Court of Appeals Rules in Favor of Regeneron and Sanofi in Praluent® (alirocumab) Patent Litigation

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TARRYTOWN, N.Y., Feb. 11, 2021 /PRNewswire/ --

Upholds decision by U.S. District Court to invalidate Amgen's patent claims directed to PCSK9 antibodies

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the United States Court of Appeals for the Federal Circuit upheld the decision by the U.S. District Court for the District of Delaware that Amgen's asserted patent claims directed toward PCSK9 (proprotein convertase subtilisin/kexin type 9) antibodies are invalid based on lack of enablement. The Federal Circuit ruling means that Regeneron and Sanofi have successfully invalidated all five of Amgen's asserted claims relevant to Praluent® (alirocumab).

"We are pleased with today's decision by the Federal Circuit, which affirms our longstanding position that Amgen's patents claiming PCSK9 antibodies purely by their function are overly broad and invalid," said Joseph LaRosa, Executive Vice President, General Counsel and Secretary, Regeneron. "Praluent was developed using Regeneron's proprietary technology, and the Federal Circuit validated that Amgen has no claim to Praluent or its development, helping to provide closure on this matter."

This decision follows the October 2020 ruling by the European Patent Office's (EPO) Technical Board of Appeal that also invalidated certain functional claims of Amgen's European patent directed to PCSK9 antibodies.

Regeneron has sole rights for Praluent inside the U.S. and Sanofi possesses sole rights for Praluent outside the U.S. Each party is solely responsible for funding development and commercialization expenses in their respective territories.

About Praluent (alirocumab)
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 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 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 for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost 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, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such

as *VelocImmune*, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through 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 or follow @Regeneron on Twitter.

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® (alirocumab) discussed in this press release (as well as other patent litigation and related proceedings pertaining to Praluent, EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), and REGEN-COV™ (casirivimab and imdevimab)), 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's 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 Product Candidates and new indications for Regeneron's Products; uncertainty of market acceptance and commercial success of Regeneron's Products (such as Praluent) and Regeneron's 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 Regeneron's Product Candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; 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 Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron'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; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products (including without limitation Praluent) and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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 Regeneron's 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, collaboration, or supply 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. 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, 2020. 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 or otherwise) 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).

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