Regeneron Applauds Supreme Court's Unanimous Opinion Striking Down Amgen's PCSK9 Patent Claims and Supporting Scientific Innovation

May 18, 2023

Decision ends nearly decade-long patent dispute related to Regeneron-invented Praluent® (alirocumab)

TARRYTOWN, N.Y., May 18, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) applauds the United States Supreme Court's unanimous opinion[1] ending a nearly decade-long patent dispute related to the Regeneron-invented PCSK9 inhibitor, Praluent® (alirocumab). The decision affirms the United States Court of Appeals for the Federal Circuit's opinion, which held that Amgen's asserted U.S. PCSK9 patent claims were invalid.

This ruling validates Regeneron's longstanding position on this matter and represents an unequivocal win for America's innovation economy, its scientists, and researchers. Most importantly, it is a win for patients who rely on the lifesaving discoveries made through years of research and investment by the biopharma community. The justices rejected an attempt to radically change the longstanding legal standard for patent validity under the enablement doctrine – a move that would have blocked progress for entire classes of molecules, deterred innovative competition, and led to potential increases of drug prices.

"Bringing innovative new therapies to patients is the core mission of Regeneron, and we were proud to deliver Praluent as the first FDA approved PCSK9 inhibitor," said Leonard S. Schleifer, M.D., Ph.D., Founder and Chief Executive Officer of Regeneron. "This Supreme Court decision protects access to this medicine and defends our industry and others against overreaching patent claims that cover an entire therapeutic category and could have a chilling effect on bringing life-saving medicines to people in need."

"This decision affirms the longstanding law on enablement and functional claiming, such that you need to enable the full scope of the claims without unreasonable experimentation," said Joseph J. LaRosa, Executive Vice President, General Counsel and Secretary of Regeneron. "We're gratified that the Supreme Court has affirmed the position we have held for nearly ten years that Amgen's PCSK9 patents were overly broad and inconsistent with established case law."

We thank the Justices for their consideration of this matter and the many groups, individuals and the U.S. government who supported our defense of scientific innovation.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 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, hematologic conditions, 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 more information, please visit www.Regeneron.com or follow @Regeneron on Twitter.

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® (alirocumab) discussed in this press release (as well as other patent litigation and related proceedings relating to Praluent, EYLEA® (aflibercept) Injection, and REGEN-COV® (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, 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 products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned; 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 the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron's collaborators, licensees, 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; the ability of Regeneron to manage supply chains for multiple products and 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 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 and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable) to be cancelled or terminated; and the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business. 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, 2022 and its Form 10-Q for the quarterly period ended March 31, 2023. 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).

Regeneron Media Contact:
Alexandra Bowie
Tel: +1 914-847-3407
alexandra.bowie@regeneron.com

Regeneron Investor Contact:
Mark Hudson
Tel: +1 914-847-3482
mark.hudson@regeneron.com

[1] Amgen v. Sanofi et. al., https://www.supremecourt.gov/opinions/22pdf/21-757_k5g1.pdf.

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