Regeneron Prevails over Amgen in Antitrust PCSK9 Lawsuit Protecting Biotech Innovation and Patient Access to Life-Saving Treatments

May 15, 2025 at 2:02 PM EDT

Federal court jury found Amgen liable for violating antitrust and tort laws by using cross-therapeutic bundled rebates to prevent Praluent® (alirocumab) from competing in the market

Jury awarded Regeneron $135.6 million dollars of compensatory damages and $271.2 million dollars in punitive damages

TARRYTOWN, N.Y., May 15, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) applauds the jury verdict in the U.S. District Court for the District of Delaware that found that Amgen Inc. violated antitrust and tort laws by creating a bundling scheme that illegally leveraged its blockbuster anti-inflammatory drugs Enbrel® (etanercept) and Otezla® (apremilast) to convince pharmacy benefit managers (PBMs) to select Repatha® (evolocumab) as the exclusive PCSK9 category product over Praluent® (alirocumab). The jury found that Amgen violated the Clayton Act, the Sherman Act, the New York State Donnelly Act, the California Cartwright Act and Delaware tort law.

Enbrel and Otezla are therapeutically different medicines that do not treat the heart conditions that Praluent or Repatha address. Amgen threatened to withhold rebates unless PBMs preferred Repatha and excluded Praluent. Amgen prevented Regeneron from competing on a level playing field and unfairly denied patients access to Praluent. This anticompetitive practice shut out an innovative therapy from the PCSK9 marketplace, not based on clinical merit or price. Because of Amgen's size and unrelated product portfolio, their anticompetitive actions ultimately hurt competition and patients.

The jury awarded Regeneron $135.6 million dollars of compensatory damages. The jury also awarded Regeneron $271.2 million dollars in punitive damages. Punitive damages may be awarded to punish a party for outrageous conduct and deter a party, and others like it, from engaging in similar conduct in the future.

"Patients rely on the biotech industry to find solutions for their most urgent medical conditions. At Regeneron, we take this responsibility very seriously and are committed to delivering breakthrough therapies that improve patient lives. To achieve this, companies must be able to compete fairly based on the clinical and economic value of their products. Larger companies should not be allowed to use anticompetitive tactics to push competitors out of the market," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "Fair competition is critical as it expands patient access to life-changing therapies and drives innovation forward so we can continue to address the medical challenges of tomorrow."

"Since the FDA approved Praluent in 2015, Amgen has tried to remove and exclude Praluent from the market. After a failed patent litigation campaign, they pivoted toward an anticompetitive bundling scheme that created a dangerous precedent that virtually eliminated all competition," said Joseph J. LaRosa, Executive Vice President, General Counsel and Secretary of Regeneron. "Today's verdict validates Regeneron's efforts to help protect patient access to our innovations and provides a clear sign that anticompetitive efforts will not remain unchecked."

Regeneron thanks the jury for their time and thoughtful consideration of the facts of this case.

Regeneron's lead counsel was Jonathan D. Polkes of White & Case LLP.

About Praluent
Praluent inhibits the binding of PCSK9 to the LDL 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 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.

In addition to the U.S., Praluent is approved in 60 countries, including the European Union, Japan, Canada, Switzerland and Brazil.

About Regeneron's *VelocImmune* Technology
Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's co-Founder, President and Chief Scientific Officer George D. Yancopouloswas a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite*® technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create a substantial proportion of all original, FDA-approved fully human monoclonal antibodies. This includes Dupixent® (dupilumab), Libtayo®

(cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg). In addition, REGEN-COV®(casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024.

Indications and Important Safety Information

PRALUENT is an injectable prescription medicine used:

- in adults with cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of chest pain conditions (unstable angina) requiring hospitalization.
- along with diet, alone or together with other cholesterol-lowering medicines in adults with high blood cholesterol levels called primary hyperlipidemia (including a type of high cholesterol called heterozygous familial hypercholesterolemia [HeFH]), to reduce low-density lipoprotein cholesterol (LDL-C) or bad cholesterol.
- along with other LDL-lowering treatments in adults with a type of high cholesterol called homozygous familial hypercholesterolemia, who need additional lowering of LDL-C.
- along with diet and other LDL-C lowering treatments in children aged 8 years and older with HeFH to reduce LDL-C.

It is not known if PRALUENT is safe and effective in children who are younger than 8 years of age or in children with other types of high cholesterol (hyperlipidemias).

Important Safety Information
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 of 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 medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Stop using PRALUENT and 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, hives, severe itching, trouble breathing, or swelling of the face, lips, throat, or tongue.

The common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site; flu or flu-like symptoms; diarrhea; muscle pain; muscle spasms; and bruising. 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. In children aged 12 to 17 years, it is recommended that PRALUENT be given by or under the supervision of an adult. In children aged 8 to 11 years, PRALUENT should be given by a caregiver.

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 full Prescribing Information.

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 by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as VelociSuite, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

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 litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation the antitrust litigation discussed in this press release), risks associated with intellectual property of other parties and pending or future litigation relating thereto, 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 outcome of any post-trial motions or other appeals relating to the jury verdict discussed in this press release; 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, including without limitation Praluent® (alirocumab); 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; 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 and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products (such as Praluent) 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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 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, 2024 and its Form 10-Q for the quarterly period ended March 31, 2025. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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Source: Regeneron Pharmaceuticals, Inc.