



Regeneron Advances Allergy Pipeline with Two Positive Phase 3 Trials Evaluating First-in-Class Antibody-Blockers of Cat and Birch Allergies

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In separate cat and birch allergen-challenge trials, single doses of allergen-specific antibody blockers significantly reduced allergy symptoms compared to placebo

Data from these trials will support further Phase 3 development

TARRYTOWN, N.Y., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced results evaluating its first-in-class investigational allergen-blocking antibodies in allergen-challenge Phase 3 trials in adults with moderate-to-severe cat or birch allergies. Both trials met their respective primary and key secondary endpoints. Data from the Phase 3 trials will be presented at an upcoming medical conference and will inform confirmatory Phase 3 trials.

"Millions suffer from the debilitating effects of allergies, which can cause severe symptoms in the eyes, nose, skin and even trigger asthma. To try to alleviate this suffering, millions undergo allergy desensitization shots, often several times a week for several years, and often with disappointing results. The purpose of these burdensome allergy shots is to try to build up allergen-blocking antibodies in the body. We wondered whether we could instead manufacture and directly provide allergen-blocking antibodies," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron, and a co-inventor of this new approach to allergy. "These recent Phase 3 allergen challenge trials, together with our earlier Phase 2 trials, provide compelling evidence that our first-in-class approach can have the potential to provide profound allergy relief – rapidly and durably after a single treatment – decreasing ocular, nasal and even asthma measures. We see significant relief at the earliest assessment timepoint, and lasting for over three months, in both our cat and birch allergy programs."

In these "ocular allergen challenge" Phase 3 trials, patients received direct ocular instillation of the allergen (either cat dander or birch pollen) at day 8 following a single subcutaneous administration of the allergen-blocking antibodies. Trial endpoints assessed signs and symptoms of ocular allergy measured after instillation of allergen in the eye.^a Earlier Regeneron trials evaluated "nasal allergen challenges" and "environmental exposure unit (EEU) allergen challenges."

Allergen-blocking antibody treatment in Cat-allergen "Ocular Challenge" Trial:

Cat allergy is one of the most common indoor allergens, affecting more than 20 million patients in the U.S. alone, often resulting in severe ocular, nasal and respiratory symptoms despite standard of care therapies (ranging from topical and systemic antihistamines to allergy-desensitization shots; about a million patients in the U.S. initiate cat allergy desensitization shots each year). REGN1908 and REGN1909 are two fully human monoclonal antibodies (mAbs) targeting and blocking FelD1 – the most dominant cat allergen – which "doggedly" clings to clothes, shoes and furniture, making it challenging to avoid even in cat-free indoor environments.

In the Phase 3 trial, cat-allergic participants were randomized to receive a single dose of the FelD1-blocking antibody combination therapy (REGN1908 and REGN1909, n=33) or placebo (n=31).

- The primary endpoint of ocular itch and both key secondary endpoints of conjunctival redness and skin prick testing – assessed one week after the single treatment with FelD1-blocking antibodies – were met with high degree of statistical significance in the overall population. Itch was reduced by 52% (p<0.0001), conjunctival redness by 39% (p<0.0001) and skin prick reactivity by 44% (p<0.0001).
- In a post-hoc exploratory analysis of patients whose cat allergy was more specifically driven by FelD1 (the majority of the population, and the target patients for the confirmatory trial), reductions in ocular itch and conjunctival redness were greater compared to the overall population (ocular itch reduction of 64% and conjunctival redness reduction of 49%).
- The combination therapy was generally well-tolerated, with no serious treatment-related adverse events or adverse events leading to trial discontinuation reported; the trial is ongoing for further safety follow-up. Additional Phase 3 development is planned to begin in the first half of 2026.
- The results in this "ocular challenge" trial are similar to earlier trials using "[nasal allergen challenge](#)" and "[EEU allergen challenge](#)," which evaluated nasal and respiratory symptoms including asthma induction in those trials. In those earlier trials, statistically and clinically meaningful improvement was also seen at the earliest assessment done at 8 days following administration of REGN1908 and REGN1909, with durable benefit maintained for at least 3 months.

Allergen-blocking antibody treatment in Birch-allergen "Ocular Challenge" Trial:

Birch pollen is one of the most common seasonal allergens in the U.S., affecting more than 10 million people. About 35% of patients continue to experience moderate to severe symptoms despite standard of care therapy. REGN5713 and REGN5715 are two mAbs targeting and blocking BetV1, the dominant allergenic birch pollen protein.

In the Phase 3 trial, participants were randomized to receive a single dose of the BetV1-blocking antibody combination (REGN5713 and REGN5715, n=27) or placebo (n=27).

- The primary endpoint of ocular itch and both key secondary endpoints of conjunctival redness and skin prick testing – assessed one week after the single treatment with BetV1-blocking antibodies – were met with high degree of statistical significance. Itch was reduced by 51% (p<0.0001), conjunctival redness by 46% (p<0.0001), and skin prick reactivity by 44% (p<0.0001).
- The combination therapy was generally well-tolerated, with no serious adverse events or adverse events leading to trial discontinuation. Additional Phase 3 development is planned to begin by the end of the year.
- Prior “[nasal allergen challenge](#)” and “EEU allergen challenge”^b trials of REGN5713 and REGN5715 in patients with birch-induced allergic rhinitis revealed similarly rapid and profound benefit at the first assessment timepoint, with durable reduction of allergic rhinitis and conjunctivitis symptoms up to 3 months following a single subcutaneous administration of the allergen-blocking antibodies.

The cat and birch allergy programs are part of a broader allergy pipeline, which also includes an [ongoing proof-of-concept trial](#) in adults with severe food allergy. This [latter trial](#) involves ablating the cells making the IgE antibodies that initiate the allergen response (with a short-course treatment with Regeneron’s BCMAxCD3 bispecific antibody), followed by ongoing treatment with Dupixent to prevent the return of these cells. Initial results from the food allergy trial have been encouraging, showing the promise of this novel approach, and is expected to complete enrollment by the end of the year.

The safety and efficacy of these investigational medicines have not been fully evaluated by any regulatory authority.

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. Yancopoulos was 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), Inmazed[®] (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. The REGN1908 and REGN1909 cat allergen-blocking antibodies, as well as the REGN5713 and REGN5715 birch allergen-blocking antibodies, were also created using Regeneron’s *VelocImmune* technology.

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, 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 the REGN1908/REGN1909 combination therapy for cat allergy and the REGN5713/REGN5715 combination therapy for birch allergy as discussed in this press release; 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), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron’s Products and Regeneron’s Product Candidates (such as those referenced above); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron’s Product Candidates and new indications for Regeneron’s Products, such as the REGN1908/REGN1909 and REGN5713/REGN5715 combination therapies and other allergy therapies discussed or

referenced in this press release; 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 and Regeneron's Product Candidates (such as those referenced above) 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (such as the studies discussed or referenced in this press release) may be replicated and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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); 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; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (afibercept) Injection), 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. 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 June 30, 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>).

Contacts:

Media Relations

Hannah Kwagh

Tel: +1 914-847-6314

Hannah.Kwagh@regeneron.com

Investor Relations

Vesna Tosic

Tel: +1 914-847-5443

Vesna.Tosic@regeneron.com

^a The conjunctival allergen challenge was conducted with the Ora Conjunctival Challenge Model (Ora-CAC®.) Ocular itch was assessed on a 0-4 point Ora® Calibra Conjunctival Allergen Challenge Ocular Itching Scale. Conjunctival redness was assessed on a 0-4 point Ora® Calibra Ocular Hyperemia Scale.

^b E. A. Couroux P. Abstract of "A single dose of a combination of Bet v 1 antibodies provides durable efficacy in reducing allergic rhinitis symptoms for up to 3 months in patients with moderate-severe birch pollen allergy." EAACI Congress. May 2024.

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Source: Regeneron Pharmaceuticals, Inc.