Annexon Selected by EMA to Participate in Product Development Coordinator Pilot for Vonaprument (ANX007) for Dry Age-Related Macular Degeneration with Geographic Atrophy

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New Pilot Appoints Designated Product Development Coordinator to Navigate Regulatory Interactions, Respond to Ad-hoc Queries, and Support Evidence Planning

Vonaprument Selected by EMA as One of ~20 PRIME Development Programs in the Pilot

Vonaprument Has the Potential to Be the First Treatment Approved in Europe and the U.S. for Dry AMD with Geographic Atrophy Based on Protection of Visual Acuity and Visual Structures

BRISBANE, Calif., Aug. 07, 2025 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing a late-stage clinical platform of novel therapies for people living with devastating classical complement-mediated neuroinflammatory diseases of the body, brain, and eye, today announced that the European Medicines Agency (EMA) has selected vonaprument (formerly ANX007) to participate in the Product Development Coordinator (PDC) pilot.

Vonaprument is a first-in-kind, non-pegylated antigen-binding fragment (Fab) that is designed to block C1q locally in the eye with an intravitreal formulation. It has received Priority Medicine (PRIME) designation in Europe and Fast Track Designation from the U.S. Food and Drug Administration (FDA) and is the only investigational therapy in geographic atrophy (GA) to show significant vision preservation on the endpoints of best corrected visual acuity (BCVA) and low luminance visual acuity (LLVA).

The PDC pilot was launched by the EMA in July 2025 to strengthen stewardship through development support activities. With background and expertise in the therapeutic area of the product, the PDC is charged with helping PRIME designation holders efficiently navigate through various regulatory interactions, including expedited scientific advice, marketing authorization application (MAA) submission readiness activities and ad-hoc queries throughout the development program.

“We are honored that vonaprument has been selected by the EMA to participate in the PDC pilot. This selection reflects the EMA’s commitment to fostering development support of vonaprument through faster, more flexible and expert-driven mechanisms,” said AJ Acker, senior vice president of regulatory, quality and clinical safety at Annexon. “We value this opportunity to partner with the EMA in real time to help shape a strong and comprehensive submission. As a potential first-ever treatment for dry AMD with GA in Europe, we look forward to advancing vonaprument through this pilot toward registration.”

Vonaprument is currently being evaluated in ARCHER II, a global, randomized, double-masked, sham-controlled pivotal Phase 3 trial designed to assess both visual acuity and structural measures to satisfy the global registration path in the U.S. and Europe. ARCHER II enrollment was completed in July 2025, and topline pivotal data is expected in the second half of 2026.

About Phase 3 ARCHER II Trial
ARCHER II is a global, randomized, double-masked, sham-controlled Phase 3 trial that has enrolled more than 630 patients with advanced dry AMD/geographic atrophy (GA). Patients will be randomized 2:1 to receive a monthly dose of vonaprument or sham procedure. The primary endpoint is the prevention of ≥15-letter loss of best corrected visual acuity (BCVA), which represents three lines on the standard Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. The primary analysis will occur at least 12 months from dosing. Proportion of patients experiencing BCVA ≥15-letter loss is a well-established functional endpoint that has served as the basis for numerous ophthalmology drug approvals by the Food and Drug Administration (FDA) and European Medicines Agency (EMA). Secondary endpoints in ARCHER II include safety, low-luminance visual acuity (LLVA), and photoreceptor integrity (EZ). Topline data are expected in the second half of 2026.

About Vonaprument (formerly ANX007) and Phase 2 ARCHER Trial
Vonaprument is an antigen-binding fragment (Fab) antibody designed as a first-in-kind therapeutic to selectively inhibit C1q, the initiating molecule of the classical complement pathway and a key driver of neurodegeneration. In advanced dry age-related macular degeneration (AMD) or geographic atrophy (GA), C1q binds to photoreceptor synapses, causing aberrant activation of the classical pathway with synapse loss, inflammation and neuronal damage that results in vision loss. Intravitreal administration of vonaprument fully stopped C1q and classical pathway activation. In animal models, the murine analog of vonaprument protected against loss of photoreceptor synapses and cells to preserve function.

Vonaprument has been granted Fast Track designation from the Food and Drug Administration and is the first therapeutic candidate for the treatment of GA to receive Priority Medicine (PRIME) designation in the EU, which provides early and proactive support to developers of promising medicines that may offer a major therapeutic advantage over existing treatments or benefit to patients without treatment options.

In the randomized, multi-center, double-masked, sham-controlled Phase 2 ARCHER clinical trial, vonaprument demonstrated consistent protection against vision loss across multiple measures in a broad population of patients with dry AMD and GA. Vonaprument provided statistically significant, time and dose-dependent protection from vision loss as measured by ≥ 15 letter loss on reading an eye chart with best corrected visual acuity (BCVA≥15), the widely accepted and clinically-meaningful functional endpoint. Significant protection from vision loss was also shown in other prespecified measures of BCVA and visual function, including low luminance visual acuity (LLVA) and low luminance visual deficit (LLVD). Vonaprument’s treatment effect increased over the course of the on-treatment portion of the study, suggesting that vonaprument may provide a growing and durable treatment effect over time. While benefit gained against vision loss was maintained during the subsequent six-month off-treatment period, the rate of decline for BCVA ≥ 15-letter vision after treatment termination began to parallel that of sham, providing additional support for the observed on-treatment protection. Vonaprument was also shown to protect key retinal structures important for vision, including significant protection of photoreceptors as measured by optical coherence tomography (OCT) and supported by slowing of loss of retinal pigment epithelial cells (RPE) near the fovea, as measured by fundus autofluorescence (FAF). Vonaprument was generally well-tolerated through month 12,

with no increase in choroidal neovascularization (CNV) rates between the treated and sham arms and no events of retinal vasculitis reported.

About Dry AMD and Geographic Atrophy
Dry age-related macular degeneration (AMD) is the most common form of AMD and geographic atrophy (GA) is an advanced form of dry AMD, an eye disease that is the leading cause of blindness in the elderly. Dry AMD and GA are chronic progressive neurodegenerative disorders of the retina involving the loss of photoreceptor synapses and cells in the outer retina. GA affects an estimated one million people in the United States and eight million people globally, severely limiting their independence and causing frustration, anxiety and emotional hardship. Effective treatments that preserve vision are still needed, as no currently approved therapies have been shown in clinical trials to significantly prevent vision loss.

About Annexon
Annexon Biosciences (Nasdaq: ANNX) is developing therapeutics that stop classical complement-driven neurodegeneration as first-in-kind treatments for millions of people living with serious neuroinflammatory diseases of the body, brain and eye. Our novel scientific approach focuses on C1q, the initiating molecule of classical complement's potent inflammatory pathway that when misdirected can lead to tissue damage and loss. By targeting C1q, our immunotherapies are designed to stop this neuroinflammatory cascade in disease before it starts. Our pipeline spans three diverse therapeutic areas – autoimmune, neurodegenerative and ophthalmic diseases – and includes targeted investigational drug candidates designed to address the unmet needs of over 8 million people worldwide. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. To learn more visit annexonbio.com.

Forward Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "suggest," "target," "on track," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, the ability of vonaprument to block upstream C1q, the clinical and regulatory status of vonaprument; vonaprument's distinct potential neuroprotective mechanism of action and potential to protect visual acuity and visual structures; the potential therapeutic benefit of vonaprument; timing and results from the Phase 3 ARCHER II trial; the potential for vonaprument to be the first treatment approved in Europe and the U.S. for dry AMD with GA; and Annexon's ability to rigorously advance mid- to late-stage clinical trials and continue development of the company's portfolio. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the ongoing off-treatment follow-up portion of the ARCHER trial and final results from the ARCHER trial; the company's history of net operating losses; the company's ability to obtain necessary capital to fund its clinical programs; the early stages of clinical development of the company's product candidates; the effects of public health crises on the company's clinical programs and business operations; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company's other filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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