Annexon Expands Vonaprument Phase 3 Program in Geographic Atrophy with Addition of Month 24 Dual Primary Endpoint Complementing Month 15 Primary Endpoint and Launch of Open-Label Extension Study

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BRISBANE, Calif., Aug. 12, 2026 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing the next generation platform of targeted immunotherapies for multiple neuroinflammatory diseases that impact nearly 10 million people worldwide, today announced the addition of a Month 24 dual primary endpoint to complement the current Month 15 primary endpoint in its Phase 3 ARCHER II trial, and launch of an open-label extension (OLE) study of vonaprument for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA). With a dual primary endpoint strategy, ARCHER II can achieve success in protecting against vision loss at either Month 15 or 24, which are independent efficacy timepoints.

“Our objective is to maximize the best-in-class potential of vonaprument to preserve visual acuity for millions of patients at risk of irreversible vision loss. The strong power and execution of our Phase 3 ARCHER II trial provide a clear opportunity to seamlessly incorporate a Month 24 dual primary endpoint while maintaining the Month 15 primary endpoint,” said Douglas Love, president and chief executive officer of Annexon. “As ARCHER II was already designed to remain masked through Month 24, this strategic addition allows us to also evaluate the longer-term profile of vonaprument for inclusion into the label without change to the study operation. We look forward to delivering the Month 15 data milestone on schedule in the fourth quarter of this year and delivering Month 24 data thereafter as a separate and additional assessment.”

In the ongoing global, double-masked Phase 3 ARCHER II trial, all eligible patients have received at least 12 months of treatment, with masked event accrual in line with projections. The study retains strong statistical power and continues to be well-executed with a low discontinuation rate (<10%) and high compliance (>95%), reinforcing significant enthusiasm by physicians and patients. Upon completion of Month 24, all patients have the option to receive monthly vonaprument treatment in the OLE study. The OLE study is designed to evaluate the long-term safety and benefit of vonaprument in patients with GA.

An independent Data Monitoring Committee (DMC) will assess the primary endpoint of the overall study at Month 15, and the Company expects to report the DMC’s assessment in the fourth quarter of 2026. Following this assessment, the DMC may recommend that the ARCHER II overall study has met its Month 15 primary endpoint, enabling the planned analysis of the trial's two sub-studies, with results anticipated in the first quarter of 2027; or it may recommend that the study continues until the Month 24 primary endpoint analysis. Completion of ARCHER II, including the Month 24 analyses, is expected in the third quarter of 2027.

Vonaprument has received FastTrack Designation from the U.S. Food and Drug Administration and is the only GA program to receive PRIME designation from the European Medicines Agency (EMA). Vonaprument was also selected by EMA for the exclusive Product Development Coordinator (PDC) pilot launched in July 2025 to assist PRIME designation holders in navigating regulatory interactions, including expedited scientific advice, Marketing Authorisation Application submission readiness activities, and ad-hoc queries throughout the development program.

About Vonaprument (formerly ANX007)
Vonaprument is a clinical-stage investigational antigen-binding fragment (Fab) 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. It is formulated for intravitreal (IVT) administration, with the potential to be the first targeted vision-preserving therapy for GA. Vonaprument involves a differentiated neuroprotective approach designed to protect photoreceptor cells and retinal function by blocking C1q and the entire classical pathway, while allowing for normal immune activity of the lectin and alternative complement pathways. Vonaprument has been granted Fast Track designation from the U.S. Food and Drug Administration (FDA) and is the first therapeutic candidate for the treatment of GA to receive Priority Medicine (PRIME) designation from the EMA for the treatment of GA.

About the Phase 2 ARCHER Trial
ARCHER is a successfully completed, randomized, multi-center, double-masked, sham-controlled Phase 2 trial that evaluated vonaprument in a broad population of patients with GA. Across multiple measures, vonaprument consistently preserved visual function and ellipsoid zone retinal structure, reinforcing the therapeutic potential of protecting photoreceptor health early in disease progression. Vonaprument provided significant, time and dose-dependent protection from vision loss as measured by confirmed best corrected visual acuity (BCVA) ≥15-letter loss, 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 was also shown to protect key retinal structures important for vision, including significant protection of photoreceptors as measured by optical coherence tomography (OCT). 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 the Phase 3 ARCHER II Trial
ARCHER II is an ongoing global, pivotal, Phase 3 sham-controlled, double-masked trial of vonaprument in 659 patients with GA, a disease driven by early photoreceptor degeneration leading to vision loss. Enrollment was completed in July 2025. The primary endpoints of this two-year trial are the proportion of patients with confirmed best corrected visual acuity 15-letter loss at two consecutive visits, measured through months 15 and 24. Best corrected visual acuity (BCVA) ≥15-letter loss represents three lines on the standard Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. 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 FDA and European Medicines Agency. Secondary endpoints in ARCHER II include safety, LLVA, and photoreceptor integrity (EZ). A global registration path has been established with U.S. and European regulators for ARCHER II. ARCHER II is a single protocol that will also be analyzed as two sub-studies after meeting the primary endpoint. Topline results from the Month 15 primary analysis are expected in the fourth quarter of 2026.

About Annexon
Annexon Biosciences (Nasdaq: ANNX) is advancing the next generation platform of targeted immunotherapies for nearly 10 million people worldwide living with serious neuroinflammatory diseases. Our founding scientific approach focuses on C1q, the initiating molecule of a potent inflammatory pathway that when misdirected can lead to tissue damage and loss of function in a host of diseases. Our targeted therapies are designed to stop classical complement-driven neuroinflammation at its source to provide meaningful functional benefit and alter the course of disease. 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," "target," "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 potential for vonaprument to be the first targeted vision-preserving therapy for GA; timing of and results from the Phase 3 ARCHER II trial, including expected month 15 primary endpoint in the fourth quarter of 2026 and the month 24 dual primary endpoint analyses expected in the third quarter of 2027; planned analysis of the ARCHER II trial's two sub-studies, with results anticipated in the first quarter of 2027; opportunity for patients to receive monthly vonaprument treatment in the OLE study; the company's ability to commercialize its product candidates, if approved; and continuing advancement 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 company's history of net operating losses; the company's ability to obtain necessary capital to fund its clinical programs; the potential for delays in the company's clinical trials; the potential for the company's product candidates to not receive regulatory approval, including if the FDA and comparable foreign regulatory authorities determine that the company's submission package is not sufficient or require the company to provide additional data in patients that are not feasible to obtain; 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 Securities and Exchange Commission. 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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