Annexon to Present on the Neuroprotective Effects of ANX007 at the 2025 ARVO Annual Meeting and the Retina World Congress

May 7, 2025

Phase 2 ARCHER Data Support Therapeutic Potential for ANX007 to Preserve Vision in Patients who have Dry Age-related Macular Degeneration (AMD) with Geographic Atrophy (GA)

Phase 3 ARCHER II Trial Enrolling Globally

BRISBANE, Calif., May 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 presentations on the neuroprotective effect of ANX007, including consistent benefits of C1q inhibition against inflammation and neuronal damage across diseases. The presentations will take place at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting being held May 4-8 in Salt Lake City, Utah and at the 2025 Retina World Congress being held May 8-11 in Fort Lauderdale, Florida.

ANX007 is a first-in-kind, non-pegylated antigen-binding fragment (Fab) designed to block C1q locally in the eye with an intravitreal formulation. ANX007 is the only investigational therapy in GA to show significant vision preservation on the endpoints of best corrected visual acuity (BCVA) and low luminance visual acuity (LLVA).

ARVO Annual Meeting Poster Presentation

"Microglia-induced neuronal injury attenuation with C1q Inhibition: Outcomes in Geographic Atrophy (GA) and Huntington's Disease (HD)"

- Presenter: Ajay E. Kuriyan, M.D., Retina Specialist, Wills Eye Hospital and Associate Professor of Ophthalmology at Sidney Kimmel Medical College of Thomas Jefferson University
- Date/Time: Wednesday, May 7, 2025, from 10:15 am to 12:00 pm Eastern Time (ET)

Retina World Congress Oral Presentation

"**Visual Function Outcomes in the Phase 2 ARCHER Trial of ANX007, a C1q Inhibitor, in Participants with dry AMD with GA: Number Needed to Treat Analysis**"

- Presenter: Priya Vakharia, M.D., Retina Specialist, Retina Vitreous Associates of Florida
- Date/Time: Saturday, May 10, 2025, at 10:30 am Eastern Time (ET)

About ANX007 and Phase 2 ARCHER Trial
ANX007 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 ANX007 fully stopped C1q and classical pathway activation. In animal models, the murine analog of ANX007 protected against loss of photoreceptor synapses and cells to preserve function.

ANX007 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 in the European Union, 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, ANX007 demonstrated consistent protection against vision loss across multiple measures in a broad population of patients with dry AMD and GA. ANX007 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). ANX007's treatment effect increased over the course of the on-treatment portion of the study, suggesting that ANX007 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. ANX007 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). ANX007 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 Phase 3 ARCHER II Trial
ARCHER II is a global, randomized, double-masked, sham-controlled Phase 3 trial expected to enroll approximately 630 patients with geographic atrophy (GA) secondary to age-related macular degeneration who will be randomized 2:1 to receive a monthly dose of ANX007 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 between 12 and 18 months from dosing initiation based on the accumulation of target events (patients in the overall study experiencing BCVA ≥15-letter loss on consecutive visits). 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 U.S. 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 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 ANX007 to block upstream C1q; the clinical and regulatory status of ANX007, including expectations regarding the Phase 3 ARCHER II trial; and the neuroprotective effect of ANX007, including consistent benefits of C1q inhibition against inflammation and neuronal damage across diseases. 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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