Annexon to Present Phase 2 ARCHER Data on Protection of Vision and Photoreceptors with ANX007 in Geographic Atrophy at the Floretina-ICOOR 2024 Meeting

December 5, 2024

Only Program that has Demonstrated Significant Vision Protection in Standard and Low Light Conditions and Significant Preservation of Photoreceptors in the Fovea Region Critical for Visual Acuity

Pivotal Phase 3 ARCHER II in GA Actively Enrolling with Data Expected Second Half 2026

BRISBANE, Calif., Dec. 05, 2024 (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 the company will present analyses of ANX007 from the completed Phase 2 ARCHER trial in geographic atrophy (GA) at the Floretina-ICOOR 2024 meeting being held December 5-8 in Florence, Italy. ANX007 is a first-in-kind, non-pegylated antigen-binding fragment (Fab) designed to block C1q locally in the eye with an intravitreal formulation.

Details of the presentations are as follows:

“Unlocking Structure/Function Relationships in GA: Central Subdomain Preservation and Visual Acuity Protection with C1q Inhibition”

- Session: Podium presentation
- Presenter: Dr. Jeffrey S. Heier, Ophthalmic Consultants of Boston, and investigator in ARCHER
- Date/Time: Thursday, December 5, 2024, 15:12-15:15 pm CEST
- Location: San Frediano Room

“**Prevention of Visual Acuity Loss and Preservation of Photoreceptors by ANX007 in Dry Age-Related Macular Degeneration (AMD)/Geographic Atrophy (GA) in the Phase 2 ARCHER Trial, Including in Patients with Less Advanced Disease**”

- Session: Podium presentation
- Presenter: Dr. Paulo Eduardo Stanga, The Retina Clinic London and Institute of Ophthalmology, University College London, UK
- Date/Time: Thursday, December 5, 2024, 15:21-15:24 pm CEST
- Location: San Frediano Room

Annexon Symposium: “Protection of Vision and Structure in GA”

- “C1q Driven Neurodegeneration: Impacts on Structure and Function”
  - Dr. Peter Kaiser, Cleveland Clinic of Ohio
- “ANX007: Visual Acuity Protection and Safety in the Phase 2 ARCHER Trial”
  - Dr. Charles C. Wykoff, Research Institute at Houston Methodist, Weill Cornell Medical College, Retina Consultants of Texas, and an investigator in ARCHER
- “Linking Structure to Function: Protection of Vision-Associated Structures with ANX007”
  - Dr. Anat Loewenstein, Tel Aviv Medical Center
- Date/Time: Friday, December 6, 2024, 13:45-16:30 pm CEST
- Location: Santo Spirito Room

“C1q inhibition: Functional and Structural Protection in dry AMD / GA via a Novel Neuroprotective Mechanism”

- Session: New Horizons in Retinal Diagnosis and Treatments
- Presenter: Douglas Love, President and Chief Executive Officer of Annexon
- Date/Time: Saturday, December 7, 2024, 12:12 - 12:18 pm CEST
- Location: San Giovanni Room

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 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 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, ANX007 demonstrated consistent protection against vision loss across multiple measures in a broad population of patients with 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 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 Annexon
Annexon Biosciences (Nasdaq: ANNX) is harnessing classical complement-driven neuroinflammation to advance potentially 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 neuroinflammatory diseases where they start. 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. When they thrive, we thrive. 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; ANX007's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; the potential therapeutic benefit of ANX007; 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.

Investor Contact:
Joyce Allaire
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com

Media Contact:
Sheryl Seapy
Real Chemistry
949-903-4750
sseapy@realchemistry.com