Annexon Announces Presentations Highlighting ANX007 Functional and Structural Differentiation in Geographic Atrophy at the Macula Society 48th Annual Meeting

February 13, 2025

Data Reinforce Neuroprotective Effect of C1q Blockade with ANX007 Against Inflammation and Neuronal Damage

BRISBANE, Calif., Feb. 13, 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 ANX007 in geographic atrophy (GA) at the Macula Society 48th Annual Meeting being held February 12-15 in Charlotte Harbor, 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), as well as significant preservation of central retinal photoreceptors necessary for visual acuity.

Details of the presentations, which are available on the publications page of the company's website, are as follows:

"Impact of C1q Inhibition on Visual Acuity Protection and Central Subdomain Anatomical Preservation with ANX007 in the Phase 2 ARCHER Trial"

- Presenter: Dr. Rahul Khurana, Northern California Retina Vitreous Associates and UCSF
- Date/Time: Thursday, February 13, 2025, 8:05 am Eastern Time (ET)

"C1q Inhibition Attenuates Microglia-Induced Neuronal Injury: Implications for GA and Neurodegenerative Diseases"

- Presenter: Dr. Eleonora Lad, MD, PhD, Duke Eye Center, North Carolina
- Date/Time: Thursday, February 13, 2025, 8:10 am 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 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 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 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 the ARCHER II trial; 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.

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