Annexon to Present Data Reinforcing the Neuroprotective Effects of ANX007 and C1q Inhibition in Geographic Atrophy at the ARVO 2024 Annual Meeting

May 1, 2024

Additional data from the Phase 2 ARCHER trial demonstrating protection of visual acuity and anatomical structure following ANX007 treatment will be featured as an oral presentation

New preclinical data on the pathogenic role of C1q on photoreceptor synapse elimination and the protection of photoreceptors and their function from C1q blockade in GA will be featured as a poster presentation

BRISBANE, Calif., May 01, 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 have two presentations at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting being held May 5-9, 2024 in Seattle, Washington. Additional Phase 2 clinical results of ANX007 from the ARCHER trial in geographic atrophy (GA), including further analyses of visual acuity and photoreceptor preservation, will be presented as an oral presentation. Also, new preclinical data on the role of C1q in the pathogenic elimination of photoreceptor synapses and protection of photoreceptors and their function with C1q blockade in GA will be presented as a poster presentation.

Details of the presentations are as follows:

Oral Presentation: “Protection Against Vision Loss by ANX007: Results from the Phase 2 ARCHER Clinical Trial”

- Abstract #: 2791
- Session: AMD; Clinical research II
- Presenter: Dr. David S. Boyer, Retina-Vitreous Associates Medical Group, California
- Date/Time: Tuesday, May 7, 2024, 9:15 – 9:30 a.m. PT
- Location: Seattle Convention Center, Arch Building Room 612

Poster Presentation: “C1q inhibition protects photoreceptor synapses and preserves retinal function in a preclinical model of photoreceptor degeneration”

- Abstract #: 3944
- Session: Neuroprotection in the retina
- Presenter: Dr. Alessia Tassoni, Associate Director at Annexon Biosciences
- Date/Time: Tuesday, May 7, 2024, 3:30 – 5:15 p.m. PT
- Location: Seattle Convention Center, Arch Building, Exhibit Hall, Posterboard #A0463

Additional presentation details and abstracts are available on the ARVO 2024 website here.

About ANX007 and Phase 2 ARCHER Trial
ANX007 is a fragment antigen-binding (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 GA, C1q binds to photoreceptor synapses early in the disease process, causing aberrant activation of the classical pathway with synapse loss, inflammation and neuronal damage that results in vision loss. Intravitreal administration of ANX007 fully stops C1q and classical pathway activation, and in animal models, its murine analog protects photoreceptor synapses and cells essential for vision. ANX007 is the first therapeutic candidate for the treatment of GA to receive 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 in a broad population of patients with GA. Specifically, topline data reported in May 2023 and presented at the American Society of Retina Specialists (ASRS) Annual Meeting in July 2023 showed that ANX007 provided statistically significant, time and dose-dependent protection from vision loss in patients with GA, measured by best corrected visual acuity (BCVA) ≥ 15 letter loss, the widely accepted and clinically meaningful functional endpoint. Protection from vision loss was also shown in multiple additional 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 lost was maintained during the subsequent six-month off-treatment period, the rate of decline for BCVA ≥ 15-letter vision began to parallel that of sham, providing additional support for the observed on-treatment protection. 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 Geographic Atrophy
Geographic atrophy (GA) is an advanced form of dry age-related macular degeneration (AMD), an eye disease that is the leading cause of blindness in the elderly. GA is a chronic progressive neurodegenerative disorder 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 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. Annexon's novel scientific approach targets upstream C1q to block the classical complement inflammatory cascade before it starts, and its therapeutic candidates are designed to provide meaningful benefits across multiple autoimmune, neurodegenerative and ophthalmic diseases. With proof-of concept data in Guillain-Barré syndrome, Huntington's disease and geographic atrophy, Annexon is rigorously advancing its mid-to late-stage clinical trials to bring their potential treatments to patients as quickly as possible. 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, statements about: data from the ARCHER trial of ANX007 in patients with GA; ANX007's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; the potential for robust, dose and time dependent preservation of vision loss in the broad patient population; ANX007's ability to provide a growing and durable treatment effect over time; continued development of ANX007; the potential benefits from treatment with anti-C1q therapy; 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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