Annexon Presents ARCHER Trial Results at ASRS 2023 Highlighting Potential of ANX007 as a Differentiated Treatment for Geographic Atrophy

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Additional analyses support consistent protection from vision loss

Annexon to engage with regulatory agencies to determine optimal path forward for ANX007

Company to hold investor conference call on Monday, July 31, 2023, at 1:30 p.m. PT / 4:30 p.m. ET

BRISBANE, Calif., July 30, 2023 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement-based medicines for patients with classical complement-mediated autoimmune, neurodegenerative and ophthalmic disorders, today presented results from the ongoing ARCHER trial in patients with geographic atrophy (GA), underscoring ANX007's potentially distinct neuroprotective mechanism of action and demonstration of consistent protection from vision loss. Data were presented during an oral presentation titled, "Treatment of Geographic Atrophy Secondary to Age-Related Macular Degeneration with Intravitreal ANX007: Results of the ARCHER Study," at the American Society of Retina Specialists (ASRS) 2023 Annual Meeting taking place July 28 – August 1, 2023 in Seattle.

"Notwithstanding recent advances in the field of geographic atrophy, preservation of vision remains a central need for the millions of people living with GA around the world," said Jeffrey S. Heier, M.D., director of the Retina Service and Retina Research, Ophthalmic Consultants of Boston, and an investigator in ARCHER. "The results from ARCHER demonstrated dose and time dependent protection of visual function in GA across multiple measures. I am excited by the potential of ANX007 and its distinct neuroprotective mechanism of action, which could offer physicians a chance to preserve vision in a broad population of patients."

Topline data reported in May 2023 showed that ANX007 demonstrated statistically significant, dose-dependent protection from vision loss in patients with GA, measured by best corrected visual acuity (BCVA) ≥15 letter loss, a widely accepted functional endpoint. Protection from vision loss was also shown in additional prespecified measures of visual function, including low luminance visual acuity (LLVA) and low luminance visual deficit (LLVD).

Annexon conducted additional analyses to further evaluate the effect of ANX007 treatment on BCVA and GA lesion area. Results presented today at ASRS included:

- Risk reduction for BCVA ≥15 letter loss was maintained in a more conservative analysis, in which events occurring at the last single-point visit were excluded.
- ANX007's impact on BCVA ≥15 letter loss was consistent across patients' baseline characteristics, including lesion size, lesion location, multifocality and others, and was not driven by any one patient subgroup.
- In addition to protection against ≥15 BCVA letter loss, ANX007's impact on BCVA ≥10 letter loss and BCVA ≥20 letter loss demonstrated consistent, dose-dependent protection from vision loss.
- Mean change in BCVA at month 12 was supportive of protection of visual function in a dose-dependent manner.
- ANX007 was generally well-tolerated through month 12, with no increase in CNV rates between the treated and sham arms and no events of retinal vasculitis reported.

In addition, as part of an investor conference call taking place Monday, July 31 at 1:30 p.m. PT / 4:30 p.m. ET, Annexon will share additional analyses, including:

- While the primary endpoint of mean rate of change (slope) in GA lesion area compared to sham at 12 months did not reach statistical significance in the ARCHER trial, additional analyses showed that ANX007's effect on lesion size showed a trend toward greater effect in the second six months of study for both treatment groups, suggesting that ANX007's impact on lesion growth may increase with time.
- In a fellow-eye analysis, comparison of sham, monthly (EM) and every-other-month (EOM) treatment groups in the subset of patients with bilateral GA, a consistent dose-dependent trend for protection against ≥15 BCVA letter loss at the 12-month time point was shown. No protection was demonstrated in sham whereas a 74% reduction for EM and 47% reduction for EOM was demonstrated against the corresponding fellow eye groups.
- In a preliminary 6-month off-treatment analysis assessing vision loss after ANX007 treatment was discontinued, the rate of decline in patients with BCVA ≥15 letter loss in the treated groups accelerated to parallel the decline in the sham group. Benefit gained during therapy was maintained, but the groups progressed in parallel once treatment ended, providing independent support of ANX007's beneficial impact while on treatment.

The six-month off-treatment follow-up period of the ARCHER trial is ongoing, and Annexon plans to report final results following study conclusion.

“We're encouraged by the breadth and depth of the ARCHER data, which demonstrate robust, dose and time dependent preservation of vision loss in the broad patient population as measured by clinical assessments important to the healthcare community and patients,” said Douglas Love, chief executive officer of Annexon. “Looking ahead, our priority is to advance ANX007 in GA as efficiently as possible, and we will meet with regulators later this year to determine the optimal path forward.”

Conference Call Information
Annexon management will host a conference call, joined by Dr. Heier, on Monday, July 31, 2023 at 1:30 p.m. PT / 4:30 p.m. ET. The webcast and accompanying slides will be available under the ‘Events & Presentations’ section on the Investors & Media page at www.annexonbio.com. A replay of the webcast will be archived on the Annexon website for 30 days. Dial-in information for conference participants may be obtained by registering for the event here.

ARCHER Trial Design
ARCHER is a randomized, multi-center, double-masked, sham-controlled Phase 2 clinical trial comparing the safety and efficacy of ANX007 in patients with GA secondary to age-related macular degeneration (AMD). The study enrolled a total of 270 patients, stratified by GA lesion size, location and choroidal neovascularization (CNV) in the fellow eye at the time of enrollment. Patients had an average age of 80 years and, importantly, were well balanced for baseline visual acuity (BCVA between 58.3 and 58.5). Ninety-six percent of patients enrolled were from the United States.

Patients were randomized to receive an intravitreal dose of 5mg ANX007 monthly (n=89), 5mg ANX007 every other month (n=92) or sham monthly or every other month (pooled n=89) for a treatment period of 12 months, followed by a six-month off-treatment period. The primary outcome measure of the study was the rate of change in GA lesion growth (slope) from baseline as measured by fundus autofluorescence (FAF) through 12 months for the study eye. The study included multiple pre-specified visual function measures to assess the effects of ANX007 on vision: change from baseline in BCVA, change from baseline in low-luminance best corrected visual acuity (LLVA) and change in baseline from low-luminance visual acuity deficit (LLVD). Top line results from the study were reported in May 2023.

About ANX007
GA is a disease of vision loss driven by the loss of photoreceptor cells, a type of neuron. Annexon was founded on the discovery that C1q, the initiating molecule of the classical complement cascade, is a driver of neurodegenerative disease. C1q binds to synapses (neuronal connections) in disease, triggering activation of the classical complement cascade with immune cell recruitment, neuroinflammation, synapse loss, and neuronal damage. In GA, C1q anchors classical pathway activation on photoreceptor cell synapses and outer segments to cause inflammation and photoreceptor cell loss. Inhibiting C1q blocks all downstream components of the classical cascade to protect synapses and photoreceptors, providing a unique neuroprotective mechanism. Annexon’s neuroprotective mechanism is distinct from inhibition of C3 or C5, which do not inhibit upstream component of the classical cascade that contribute to photoreceptor damage. Further, selective inhibition of the classical cascade leaves the lectin and alternative complement pathways in place for normal homeostatic and immune functions. Preclinical models have demonstrated that inhibition of C1q protected photoreceptor synapses and cells and importantly, photoreceptor cell function.

About Geographic Atrophy
Geographic atrophy (GA), also known as atrophic age-related macular degeneration (AMD) or dry AMD, has a genetic link to aberrant complement activity and can lead to blindness caused by damaged and dying retinal cells. It is estimated that one million people in the United States and five million people globally suffer from GA.

About Annexon
Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company seeking to bring game-changing medicines to patients with classical complement-mediated diseases of the body, brain and eye. The classical complement pathway within the immune system, when overactivated, drives inflammation in a host of autoimmune, neurodegenerative and ophthalmic diseases. Annexon is advancing a new class of complement medicines targeting the early classical cascade and all downstream pathway components that contribute to disease, while selectively preserving the beneficial immune functions of other complement pathways. Annexon is rigorously developing a pipeline of diversified product candidates across multiple mid- to late-stage clinical trials, with clinical data anticipated throughout 2023 and beyond.

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: topline 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; continued development of ANX007; market size; meeting with regulators to determine the optimal path forward; plans to report final results following study conclusion; the potential benefits from treatment with anti-C1q therapy; 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 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.

The contents of the company's website at www.annexonbio.com and the webcast and accompanying slides accessible through the company's website are not incorporated by reference into this press release.

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