Annexon Biosciences Completes Enrollment in ARCHER Phase 2 Trial of Novel C1q Inhibitor, ANX007, in Patients with Geographic Atrophy

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Topline efficacy and safety data expected in first half of 2023

BRISBANE, Calif., April 07, 2022 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement medicines for patients with classical complement-mediated autoimmune, neurodegenerative and ophthalmic disorders, today announced the completion of enrollment in the Phase 2 ARCHER trial evaluating its anti-C1q candidate, ANX007, in patients with geographic atrophy (GA). Annexon plans to report topline data on the primary endpoint in the first half of 2023, following 12 months of treatment, with full data expected after the conclusion of the six-month off-treatment period.

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. Currently, there are no approved treatment options to prevent the onset or progression of GA. It is estimated that one million people in the United States and three million people globally suffer from GA. ANX007 is formulated for intravitreal administration and purposefully designed for localized inhibition of C1q and the classical cascade. In a Phase 1b trial, ANX007 was well-tolerated and demonstrated full target engagement and inhibition of C1q in the eye for at least four weeks.

“We are very pleased to have completed enrollment in our ARCHER trial ahead of schedule, which is a testament to the strong efforts by our team and the enthusiasm among patients and their treating physicians for a novel treatment,” said Douglas Love, Esq., president and chief executive officer of Annexon. “Excess classical complement activity in the retina is a potential driver of GA, and by stopping the classical complement pathway *at its start*, we believe we may halt the detrimental immune response and nerve damage that occurs in the eye. With nearly half of patients enrolled having non-foveal lesions, the ARCHER trial is designed to evaluate slowing of GA lesion growth in both patients who are at risk for faster progression and in the overall patient population. We’re continuing to follow patients in the trial and look forward to assessing and reporting initial findings in the first half of 2023.”

“People living with GA are faced with the devastating consequences and the loss of quality of life as their vision declines, which is made even more difficult as we wait for an effective treatment to become available,” said Peter K. Kaiser, M.D., Professor of Ophthalmology, Cole Eye Institute, Cleveland Clinic. “As a leading cause of blindness, there remains an urgent need for treatments that may reduce the rate of GA lesion growth and preserve visual function. I’m encouraged by the early clinical and preclinical data shown with ANX007 and believe Annexon’s approach to targeting aberrant complement activity at the start of the pathway holds great promise.”

ARCHER is a randomized, multi-center, double-masked, placebo-controlled Phase 2 clinical trial that enrolled a total of 270 patients with GA. The trial will evaluate both monthly and every other month dosing schedules of ANX007. Patients will be stratified by lesion location, with nearly half of enrolled participants having non-foveal lesions, a risk factor for more rapid progression. The primary efficacy endpoint will assess change in GA lesion area, as evaluated by fundus autofluorescence (FAF).

About ANX007

ANX007 is an antigen-binding fragment (Fab) formulated for intravitreal administration that is designed for localized inhibition of C1q and the classical complement pathway in neurodegenerative diseases of the eye. In a Phase 1b trial, ANX007 was well-tolerated and demonstrated full target engagement and inhibition of C1q in the eye for at least four weeks. Intravitreal ANX007 protected photoreceptor cells and retinal function in published preclinical studies. ANX007 is currently being evaluated in patients with GA in the ongoing Phase 2 ARCHER trial, and topline efficacy and safety data are expected in first half of 2023.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company pioneering a new class of complement medicines designed to stop the classical complement pathway at its start, C1q, to bring therapies to patients with classical complement-mediated autoimmune, neurodegenerative, and ophthalmic disorders. The company’s proprietary complement-targeting platform utilizes well-researched classical complement-mediated autoimmune and neurodegenerative processes triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is advancing a broad portfolio of innovative product candidates designed to block the activity of C1q and the entire classical complement pathway, which may provide more complete protection against complement-mediated disorders of the body, brain and eye. The company’s pipeline includes three clinical-stage drug candidates, ANX005 (intravenous administration), ANX007 (intravitreal administration), and ANX009 (subcutaneous administration), as well as a robust early-stage pipeline of preclinical and discovery stage programs. Annexon is deploying a disciplined, biomarker-driven strategy designed to improve the probability of technical success of its portfolio. For more information, visit www.annexonbio.com.

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