Annexon Receives PRIME Designation from the EMA for ANX007 for the Treatment of Geographic Atrophy

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PRIME Designation Granted Based on Phase 2 ARCHER Trial Results, which Showed Meaningful Preservation of Visual Function in Patients with Geographic Atrophy

ANX007 is the First Therapeutic Candidate to Receive PRIME Designation by the EMA for the Indication of Geographic Atrophy

Company Engaging with U.S. and EU Regulatory Authorities to Determine the Optimal Global Pivotal Phase 3 Program for ANX007

BRISBANE, Calif., Oct. 24, 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 announced that the European Medicines Agency (EMA) has granted Priority Medicine (PRIME) designation to ANX007 for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The EMA granted this designation, which provides enhanced development support for priority medicines that target an unmet need, based on the Phase 2 ARCHER trial data that showed a statistically significant, durable, and dose-dependent preservation of visual function in patients with GA, as well as preclinical data supporting the protective effect of ANX007 against photoreceptor damage.

“GA is a progressive disease impacting millions of elderly people worldwide, which severely limits their independence. There is a need for a treatment that provides the benefit both patients and physicians *most* desire —preservation of vision,” said Douglas Love, president and CEO of Annexon. “The data from our Phase 2 ARCHER trial were the first to show a durable and dose-dependent preservation of visual function across multiple measures, including a statistically significant impact on the best corrected visual acuity (BCVA) functional endpoint. We believe PRIME designation supports the potential for ANX007 to address this critical need. As we look ahead, our focus remains on engaging with U.S. and EU regulatory authorities to optimally design and expedite a global pivotal Phase 3 program for ANX007 and bring this novel treatment to patients as quickly as possible.”

The EMA’s PRIME designation 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. These medicines are considered priority medicines by the EMA, whose aim is to optimize development plans and speed up evaluations so these medicines that address significant unmet medical needs can reach patients faster.

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 to protect photoreceptor synapses and cells essential for vision. ANX007 is the first therapeutic candidate to receive PRIME designation for the treatment of GA.

In the randomized, multi-center, double-masked, sham-controlled Phase 2 ARCHER clinical trial, ANX007 demonstrated a trend on the anatomical-based primary endpoint, but showed 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 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.

The six-month off-treatment follow-up period of the ARCHER Phase 2 trial has been completed and Annexon plans to report the final results from the study at the American Academy of Ophthalmology 2023 Annual Meeting to be held November 3-6, 2023, in San Francisco, Calif.

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 five 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 clinical-stage biopharmaceutical company utilizing a distinct scientific approach to stop C1q and all inflammatory aspects of classical complement pathway activation before it starts. As the only company solely focused on shutting down C1q, Annexon is developing a fit-for-purpose pipeline of therapeutics designed to provide meaningful benefits across multiple diseases of the body, brain and eye. With proof-of concept data in both Guillain-Barré syndrome 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: ability of ANX007 to preserve vision and protect photoreceptor damage; the plans to further a global pivotal Phase 3 program in ANX007; the potential benefit of ANX007, if approved, compared to existing therapies; the potential ability to reach patients faster with the PRIME designation; market size;; 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 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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