Annexon Outlines 2024 Priorities with Late-Stage Clinical Milestones Across Upstream Complement Portfolio for Autoimmune, Ophthalmic and Neurodegenerative Diseases

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ANX005 Phase 3 Pivotal Data in Guillain-Barré Syndrome (GBS) On Track for First Half of 2024;
Potential to be First Approved Treatment for GBS Patients in the U.S.

ANX007 Global Pivotal Program in Geographic Atrophy (GA) to Initiate Mid-2024;
First Pivotal Trial Using Vision Preservation as Primary Outcome Measure in GA

Clinical Proof-of-Concept Study of ANX1502 First-in-Kind Oral Small Molecule Inhibitor of the Classical Pathway to Initiate in First Half of 2024

Recent Successful $125 Million Financing Extends Operating Runway into Second Quarter 2026

BRISBANE, Calif., Jan. 07, 2024 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement-based medicines for people living with devastating inflammatory-related diseases, today outlined its strategic priorities for 2024 with late-stage clinical milestones, including ANX005 for Guillain-Barré syndrome (GBS), ANX007 for geographic atrophy (GA) and its first-in-kind oral small molecule complement inhibitor, ANX1502, for a range of autoimmune indications.

“Our distinct classical complement portfolio has been built over 10 years of research focused on stopping C1q-driven inflammation activated on diseased tissue in complement-mediated diseases of the body, brain and eye. The robust and consistent functional outcome data generated by our flagship and next wave programs has reinforced our founding thesis of stopping the classical complement disease process where it starts,” said Douglas Love, president and CEO of Annexon.

“This is a pivotal time for Annexon, with registration programs for our two lead candidates, numerous late- and mid-stage clinical catalysts expected across our portfolio, and a strong balance sheet to fuel our priority programs to meaningful inflection points. We are proud of what we’ve accomplished over our decade-long history and are excited by the potential to achieve our goal of bringing transformative therapies to millions of patients with debilitating autoimmune, ophthalmic and neurodegenerative diseases.”

2024 Strategic Priorities
Annexon is sharply focused on mid- to late-stage development of three value-driving programs:

ANX005 for GBS: Report Pivotal Data from Phase 3 Trial in GBS in First Half of 2024

- GBS is a serious autoimmune condition of the nervous system that can lead to sudden paralysis and even death in otherwise healthy individuals. GBS impacts more than 12,000 people annually in the U.S. and Europe, and there are currently no approved therapies for GBS in the U.S.
- Annexon is conducting a randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical trial (N=241) designed to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of ANX005 in patients with GBS. The study completed enrollment in 2023 and the company is on-track to report Phase 3 data in the first half of 2024.
- ANX005 was granted orphan drug designation by the EMA for the treatment of GBS based on a meta-analysis of past studies with ANX005 and intravenous immunoglobulin (IVIg). In a completed proof-of-concept, placebo-controlled Phase 1b trial, ANX005 showed rapid and consistent improvement in muscle strength that translated into observable gains in health status, including a reduction in the need of mechanical ventilation, as well as improvement in neuronal damage and clinical function in patients with GBS.

ANX007 for GA: Initiate Global Registration Program in GA, with Vision Preservation as the Primary Outcome Measure, in the First Half of 2024

- GA is an advanced form of dry age-related macular degeneration (AMD), an eye disease that is the leading cause of vision loss in the elderly, that affects an estimated eight million people globally.
- In the randomized, multi-center, double-masked, sham-controlled Phase 2 ARCHER clinical trial, ANX007 was the first and only program to show statistically significant and consistent protection against vision loss in a broad population of patients with GA.
- Annexon plans to initiate ARCHER II, a global, sham-controlled Phase 3 clinical trial in patients with GA in mid-2024. ARCHER II is designed to confirm the results from the Phase 2 ARCHER trial, and potentially expedite the path to regulatory approval in Europe.
- Annexon also plans to initiate the ARROW clinical trial, an injection-controlled head-to-head study against SYFOVRE® (pegcetacoplan injection) in late 2024. ARROW has the potential to underscore ANX007’s unique mechanism of action and provide critical differentiation on visual function.
- 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.

ANX1502 for Autoimmune Disease: Advance First-in-Kind Oral Small Molecule Inhibitor into Proof-of-Concept Clinical Trial in Patients in the First Half of 2024

- ANX1502 is a potential first-in-kind oral small molecule inhibitor of the classical complement pathway that targets the active form of C1s, an enzyme associated with C1q.
- In the Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy volunteers, ANX1502 was generally well-tolerated, achieved target levels of active drug and showed supportive impact on a pharmacodynamic biomarker of complement activity that support its clinical advancement.
- Annexon plans to advance a tablet formulation of ANX1502 into a proof-of-concept trial designed to assess pharmacodynamics and efficacy in patients with cold agglutinin disease (CAD) in the first half of 2024. Following the successful completion of the proof-of-concept study, Annexon intends to evaluate ANX1502 in additional serious complement-mediated autoimmune diseases with the aim of providing efficacy with enhanced dosing flexibility and convenience for long-term treatment of chronic autoimmune conditions.

42nd Annual J.P. Morgan Healthcare Conference

Mr. Love will present an overview of Annexon and outline the company's pipeline updates at the 42 nd Annual J.P. Morgan Healthcare Conference on Wednesday, January 10, 2024, at 2:15 p.m. PT in San Francisco. A live webcast of the event can be accessed under the 'Events & Presentations' section on the Investors page at www.annexonbio.com. A replay of the webcast will be archived on the Annexon website for 30 days following the presentation.

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 targeting 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: the timing of completion of Phase 3 trial of ANX005 in patients with GBS; the potential therapeutic benefit of ANX005; potential benefit of ANX005, if approved, compared to existing therapies; timing of initiation of the ARCHER II and ARROW trials; 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 and ANX1502; ability to advance ANX1502 into a tablet formulation; market size for the various product candidates; 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.

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