Annexon Biosciences Announces Clinical and Preclinical Data Highlighting Potential of Complement-Targeting Programs at the 63rd ASH Annual Meeting & Exposition

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BRISBANE, Calif., Dec. 13, 2021 (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, announced safety and dose-response data from its Phase 1 clinical trial of ANX009, the company's subcutaneously administered product candidate that is designed to block the activity of C1q and the entire classical complement pathway. In addition, Annexon reported preclinical data supporting the role of the complement pathway in warm autoimmune hemolytic anemia (wAIHA). The data were presented during two poster sessions at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition.

"We are pleased to present these data at ASH, which further support our approach of targeting C1q in order to fully block the downstream components of the complement pathway," said Sanjay Keswani, MBBS, FRCP, executive vice president and chief medical officer of Annexon. "ANX009 was shown to be well-tolerated with complete and sustained C1q inhibition, supporting its continued clinical advancement. In addition, as we continue to progress our clinical program with ANX005 for the treatment of wAIHA, these *in vitro* analyses provide important insights into the role that complement activation plays in wAIHA and the potential to enrich for patients most likely to respond to anti-C1q therapy in our clinical studies."

Poster Title: *Safety, Tolerability, and Clinical Pharmacology of ANX009, an Inhibitory Antibody Fab Fragment Against C1q, Administered Subcutaneously to Healthy Volunteers (3166)*
Data Summary: ANX009 is an antigen-binding fragment (Fab) that disrupts autoantibody complement activation through the inhibition of C1q. It is being developed as subcutaneously administered treatment for antibody-mediated autoimmune diseases of blood and vascular tissues. Data reported in the poster are from a single and multiple ascending dose Phase 1 trial of ANX009 in 48 healthy volunteers. Findings demonstrated that ANX009 was well-tolerated across all doses with no drug-related safety, dose-limiting toxicities, serious adverse events, or adverse events leading to discontinuations. Further, a dose-response was observed across dose cohorts with notable reductions in C1q in serum. Taken together, the findings support the clinical advancement of ANX009 in patients with complement-mediated autoimmune disorders.

Poster Title: *Evidence of Classical Complement Pathway Involvement in a Subset of Patients with Warm Autoimmune Hemolytic Anemia (2001)*
Data Summary: Autoimmune hemolytic anemia (AIHA) is a constellation of diseases caused by autoantibodies targeting red blood cells (RBCs) with or without complement activation, with the two main types being cold agglutinin disease (CAD) and wAIHA. To understand additional methods to suggest evidence of complement activation in AIHA patients, Annexon conducted a series of *in vitro* studies using patient blood samples. Findings from a modified *in vitro* complement deposition assay suggest that sera from CAD patients and a subset of wAIHA patients possess autoantibodies capable of triggering classical pathway C4 deposition on the surface of healthy human RBC. The company believes multiple factors may affect complement deposition in this assay and is assessing how these and other *in vitro* assay results may be translated to demonstrate classical complement pathway involvement in AIHA patients *in vivo* in an ongoing Phase 0 non-interventional trial. Annexon is also currently evaluating ANX005 in a Phase 2 clinical trial for the treatment of wAIHA patients with evidence of classical complement activity.

About Annexon
Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company developing a new class of complement medicines for patients with classical complement-mediated autoimmune, neurodegenerative, and ophthalmic disorders of the body, brain, and eye. The company's pipeline is based on its platform technology addressing a broad spectrum of well-researched classical complement-mediated autoimmune and neurodegenerative diseases triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is advancing a portfolio of innovative product candidates designed to block the activity of C1q and the entire classical complement pathway: ANX005 (intravenous administration), ANX007 (intravitreal administration), and ANX009 (subcutaneous administration). 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.

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," "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: continuing advancement of the company's innovative portfolio; timing of data from clinical trials; timing of completion of clinical studies and clinical development milestones; the company's ability to deliver on its objectives; the implementation of the company's business model and strategic plans for its business and product candidates, including potential treatment indications and additional indications that the company may pursue. 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 COVID-19 or other 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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