Annexon Announces Initiation of Phase 2/3 Trial of ANX005 in Patients with Guillain-Barré Syndrome

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SOUTH SAN FRANCISCO, Calif., Dec. 21, 2020 (GLOBE NEWSWIRE) -- Today, Annexon, Inc. ("Annexon") (Nasdaq: ANNX), a clinical stage biopharmaceutical company developing novel therapies for patients with classical complement-mediated disorders of the brain, body, and eye, announced that patient dosing has started in a Phase 2/3 clinical study of full-length monoclonal antibody, ANX005, to treat Guillain-Barré Syndrome (GBS). GBS is a rare, acute, antibody-mediated autoimmune disease that impacts the peripheral nervous system and can lead to acute paralysis and/or permanent disability from nerve loss.

"We are pleased to advance our GBS program into later-stage clinical development, bringing us closer to potentially delivering a much-needed treatment option to patients combatting this debilitating disease," said Douglas Love, president and chief executive officer of Annexon. "The advancement of ANX005 also continues to inform our ongoing clinical development across a host of additional complement-mediated autoimmune and neurodegenerative diseases."

Currently there are no approved therapies in the United States for GBS. ANX005 has received both Fast Track and Orphan Drug designations for the treatment of GBS.

"There is strong scientific rationale that blocking initiation of the classical complement cascade through specific inhibition of C1q has potential as a therapeutic intervention for GBS," said Hugh Willison, M.D., Professor of Neurology, Head of Neuroinflammation, Glasgow Biomedical Research Centre. "This anti-C1q approach is designed to act early in the disease course to prevent nerve damage and irreversible neurological disability in GBS patients."

About the Clinical Trial and ANX005

The randomized, placebo-controlled Phase 2/3 trial is designed to evaluate the efficacy of ANX005 in improving disability in GBS patients. In addition to this study, Annexon has fully enrolled a global GBS drug-drug interaction (DDI) trial assessing safety and potential pharmacokinetic effect of ANX005 co-administered with IVIg in GBS patients. Data are anticipated from the GBS DDI trial in early 2021. Annexon completed a Phase 1b trial of ANX005 in patients with GBS that demonstrated full target engagement of C1q in serum and the cerebrospinal fluid (CSF), as well as a significant reduction in neurofilament light chain (NfL), a well-accepted biomarker shown to be elevated in patients with GBS and correlated with disease severity and clinical outcomes.

ANX005 is an IV formulated monoclonal antibody designed to inhibit C1q and the entire classical complement pathway. ANX005 is intended to treat patients with antibody-mediated autoimmune and complement-mediated neurodegenerative disorders. Annexon has completed a Phase 1b monotherapy clinical trial of ANX005 in GBS and has received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration for the treatment of GBS.

More information can be found at www.annexonbio.com.

About Annexon, Inc.

Annexon is a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the brain, body and eye. The company's pipeline is based on its platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is deploying a disciplined, biomarker-driven development strategy designed to identify patients, and to measure target engagement and response to treatment. 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," "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: advancement of the company's clinical and preclinical programs; timing of data from clinical trials; and the implementation of the company's business model and strategic plans for its business and product candidates, including potential treatment indications and additional indications which 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 filed with the Securities and Exchange Commission (SEC) on November 16, 2020 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.

Investor Contacts: Jennifer Lew, Chief Financial Officer Annexon Biosciences jlew@annexonbio.com Sara Michelmore smichelmore@macbiocom.com Media Contacts: Miriam Mason Annexon Biosciences mmason@annexonbio.com Caroline Rufo, Ph.D. crufo@macbiocom.com