Annexon Showcases Tanruprubart Data Demonstrating Improved Clinical Outcomes in Guillain-Barré Syndrome (GBS) at 2025 Peripheral Nerve Society (PNS) Annual Meeting

May 19, 2025

First Oral Presentation of the Tanruprubart Real-World Evidence (RWE) Study by International Guillain-Barré Syndrome Outcomes Study (IGOS) Researchers Highlights Benefits over Current Standard of Care in Matched Patient Populations

Poster Presentations on New Pivotal Phase 3 Analyses Underscore Tanruprubart's Rapid and Sustained Treatment Effect and Improvement in Quality of Life Compared to Placebo

BRISBANE, Calif., May 19, 2025 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing a late-stage clinical platform of novel therapies for people living with devastating classical complement-mediated neuroinflammatory diseases of the body, brain, and eye, today presented oral and poster presentations highlighting improved outcomes with tanruprubart (formerly ANX005) at the 2025 Peripheral Nerve Society (PNS) Annual Meeting being held May 17-20, 2025 in Edinburgh, UK.

GBS is a neuromuscular emergency and rare autoimmune disease that affects at least 150,000 people worldwide each year, with no FDA-approved therapies. In its acute phase, GBS rapidly progresses toward severe weakness that can lead to sudden and complete paralysis, often requiring intensive care and mechanical ventilation. Tanruprubart is a first-in-kind monoclonal antibody designed to block C1q, the initiating molecule of the classical complement cascade, with a single infusion to halt ongoing neuroinflammation and nerve damage in the early phase of GBS to improve and expedite overall recovery.

"These compelling clinical results presented at PNS depict how a rapid gain in muscle strength can lead to a better state of health with a single infusion of tanruprubart in a real world setting," said Henk-André Kroon, M.D., senior vice president of Translational Medicine at Annexon. "Currently, outcomes for GBS patients around the world remain poor, and we are grateful to our collaborators at IGOS for conducting this prespecified analysis showing the significant improvement with tanruprubart compared to standard of care. As the potential first targeted immunotherapy in GBS, we are eager to move tanruprubart forward for patients in need, with the aim of transforming the global treatment landscape for GBS."

RWE Findings Demonstrate Benefits with Tanruprubart over Current Standard of Care in Matched Patient Populations

Results of the pivotal Phase 3 trial are reinforced by a RWE study that matched tanruprubart-treated patients from the pivotal Phase 3 trial with patients predominantly from western countries included in the IGOS registry who were treated with current standard of care, intravenous immunoglobulin (IVIg) or plasma exchange (PE). In the RWE study, tanruprubart showed a rapid increase in muscle function resulting in a sustained and more complete recovery compared to IVIg or PE:

- By Week 1, patients treated with tanruprubart showed approximately a ten-point improvement in muscle strength over patients treated with IVIg or PE, a clinically meaningful benefit as measured by Medical Research Council (MRC) sumscore and an indicator for future recovery potential
- Patients treated with tanruprubart were approximately three times more likely to be in a better state of health than patients on IVIg or PE on the GBS-Disability Scale (GBS-DS) at Weeks 4, 8, and 26

New Pivotal Phase 3 Trial Analyses Reinforce the Rapid and Sustained Clinical Benefits of a Single Dose of Tanruprubart

- Tanruprubart 30 mg/kg halted inflammation and nerve damage resulting in clinical benefits as early as Week 1, including rapid improvements in muscle strength, mobility, balance, and coordination that were maintained through Week 26
- Tanruprubart-treated patients rapidly regained the ability to move independently, do personal tasks, and return to a range of routine daily living activities
- Tanruprubart demonstrated a greater degree of efficacy amongst patients with disease characteristics more commonly observed in western countries, supporting the potential of tanruprubart to benefit patients worldwide

Presentations are available on the publications page of the company's website.

About Tanruprubart (formerly ANX005)

Annexon's lead investigational therapy, tanruprubart, is a first-of-its kind selective, targeted and rapid-acting agent designed to reduce inflammation and nerve damage by stopping C1q activity in the peripheral and central nervous systems. In GBS, tanruprubart is designed to seek out C1q and prevent its binding to targets on peripheral nerves. Tanruprubart is administered intravenously and has been observed to act almost immediately in blocking C1q function. The aim of an effective treatment in GBS is to rapidly stop the autoimmune damage on nerve cells, allowing patients to regain muscle strength sooner and to regain independence and return to pre-illness activities. Tanruprubart has received both Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration as well as orphan drug designation from the European Medicines Agency for the treatment of GBS.

About Guillain-Barré Syndrome (GBS)
GBS is a rare neuromuscular emergency resulting from an acute autoantibody and classical complement-mediated attack on peripheral nerves that generally occurs post-infection in otherwise healthy persons. It is an acute, rapidly progressive disease with a narrow timeframe for therapeutic intervention. GBS results in the hospitalization of more than 22,000 people annually in the U.S. and Europe. In its acute phase, the peripheral nerve

damage progresses rapidly, causing sudden and complete neuromuscular paralysis that can lead to significant morbidity, disability and mortality. Currently, there are no approved treatments for GBS in the U.S. The long-term disease burden associated with GBS has led to a multi-billion-dollar annual economic cost to the U.S. healthcare system alone. More information about the impact of GBS is available at MoveGBSForward.com.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is developing therapeutics that stop classical complement-driven neuroinflammation as first-in-kind treatments for millions of people living with serious neuroinflammatory diseases of the body, brain and eye. Our novel scientific approach focuses on C1q, the initiating molecule of classical complement's potent inflammatory pathway that when misdirected can lead to tissue damage and loss. By targeting C1q, our immunotherapies are designed to stop this neuroinflammatory cascade in disease before it starts. Our pipeline spans three diverse therapeutic areas – autoimmune, neurodegenerative and ophthalmic diseases – and includes targeted investigational drug candidates designed to address the unmet needs of over 8 million people worldwide. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. 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," "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: the ability of tanruprubart to block C1q activity in the peripheral and central nervous systems with a single infusion; the potential therapeutic benefit of tanruprubart, if approved, compared to IVIg/plasma exchange or existing therapies; the clinical and regulatory status of tanruprubart; the planned presentation of RWE at upcoming conferences; the ability to translate the results of the RWE study to a broad population of GBS patients; the impacts of the new education campaign (Move GBS Forward™); 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.

Investor Contact:

Joyce Allaire
LifeSci Advisors
jallaire@lifesciadvisors.com

Media Contact:

Sheryl Seapy
Real Chemistry
949-903-4750
sseapy@realchemistry.com