Annexon Provides 2025 Outlook with Strong Momentum Accelerating into Breakthrough Year

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ANX005 First Potential Targeted Therapy for Guillain-Barré Syndrome Advancing Towards 1H 2025 BLA Submission

ANX007 First Potential Neuroprotective Therapy for Geographic Atrophy Expected to Complete Enrollment of Phase 3 ARCHER II Trial in 2H 2025

ANX1502 First Oral C1s Inhibitor On Track for Clinical Proof of Concept Data in 1Q 2025

Cash Runway into 2H 2026 to Achieve Key Milestones

BRISBANE, Calif., Jan. 13, 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 announced its 2025 outlook and key catalysts for its flagship programs: ANX005 in Guillain-Barré syndrome (GBS), ANX007 in geographic atrophy (GA), and oral small molecule ANX1502 for a host of diseases.

“Founded ten years ago, Annexon has pursued an intentional path to transform the complement landscape and thereby drive immense value by effectively translating our pioneering science into potential treatments for millions of patients suffering from complement-mediated neuroinflammatory diseases. With significant progress and achievements across our diverse and wholly-owned complement portfolio, we’re more encouraged than ever by the opportunity for each of our potentially best-in-class flagship programs, and we remain laser focused on our mission to help scores of patients live their best lives,” said Douglas Love, president and chief executive officer of Annexon.”

Mr. Love continued, “Specifically regarding the flagship programs, our ANX005 program is most advanced and positioned to displace current standard of care in GBS as the first potential targeted treatment to rapidly improve muscle strength and restore normal function in this devastating neurological condition, and we are preparing our BLA submission for the first half of 2025. Additionally, our ANX007 registrational Phase 3 ARCHER II trial in GA is designed to replicate the significant vision preservation observed in the ARCHER proof-of-concept trial, and enrollment is on pace for completion in the second half of 2025. Finally, ANX1502, our first-in-kind oral C1s inhibitor, is advancing toward clinical proof-of-concept data in the first quarter of 2025 with the potential to disrupt the landscape treating a range of autoimmune and other diseases currently managed with infused biologics. With significant catalysts approaching, we’re excited to take advantage of our strong momentum and are well-positioned for a breakthrough year ahead.”

2025 Strategic Priorities and Key Catalysts

- **ANX005 for GBS:** Potential to be the first targeted therapy for GBS
  - Successful pivotal Phase 3 trial showed ANX005 helped patients get better sooner with rapid improvement in muscle strength and more complete functional recovery than placebo through 6 months, and provided an important benefit in the burden of care by enabling patients to walk or be off ventilation earlier
  - Real World Evidence (RWE) study matched ANX005-treated patients from the pivotal Phase 3 study with a Western world patient population predominantly from Europe and North America treated with current standards of care (intravenous immunoglobulin (IVIg) or plasma exchange (PE)). Consistent with Phase 3, ANX005 showed rapid increase in muscle strength with more complete recovery over IVIg or PE.
  - **Next Milestone: BLA Submission targeted for first half of 2025**
- **ANX007 in GA:** Only investigational therapy to show significant vision preservation on the endpoints of best corrected visual acuity (BCVA) and low light visual acuity (LLVA) in GA
  - Successful Phase 2 ARCHER data showed significant protection of vision in both standard and low light conditions, as well as enhanced visual protection in patients with healthier eyes, and structural protection of photoreceptors in the central fovea that are associated with visual acuity
  - Ongoing global registrational Phase 3 ARCHER II trial, a well-powered, sham-controlled study with a robust safety database, expected to enroll ~630 patients and use BCVA protection against ≥15-letter loss as primary outcome measure
  - **Next Milestone: Phase 3 ARCHER II trial enrollment to be completed in second half of 2025; data expected in second half of 2026**
- **ANX1502 for Autoimmune Conditions:** First-in-kind oral C1s inhibitor with convenient and flexible dosing
  - Completed bridging study in healthy volunteers from a liquid suspension formulation to a twice-daily tablet with safety and pharmacokinetic profile similar or better than previous studies
  - Ongoing open label single arm study in cold agglutinin disease (CAD) evaluating enteric-coated tablet formulation

with improved tolerability will inform next steps for later-stage clinical development

- **Next Milestone: Clinical proof of concept data in CAD and update on future target indications in first quarter of 2025**

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is developing therapeutics that stop classical complement-driven neurodegeneration 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," "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: the potential therapeutic benefit of ANX005, if approved, compared to existing therapies; anticipated timing of BLA submission for ANX005; potential benefit of ANX005, if approved, compared to IVIg/plasma exchange or other existing therapies; the company's ability to achieve regulatory approval for ANX005; the potential therapeutic benefit of ANX007; timing of the ARCHER II trial; ANX007's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; timing of proof-of-concept data for ANX1502; the company's ability to commercialize its product candidates, if approved; continued development of ANX007 and ANX1502; 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.

Investor Contact:

Joyce Allaire
LifeSci Advisors
jallaire@lifesciadvisors.com

Media Contact:

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