

Annexon Accelerating Next Generation Targeted Immunotherapy Platform for Treatment of Neuroinflammatory Diseases with Multiple Registrational Milestones in 2026

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Tanruprubarb MAA Filed with Potential to Be the First Targeted Fast-Acting Therapy for Guillain-Barré Syndrome (GBS); BLA Submission with U.S./European Data Planned in 2026

Vonaprumment Pivotal Phase 3 Topline Data for Dry AMD with Geographic Atrophy (GA) on Track for Second Half of 2026 Evaluating Unprecedented Effect on Vision Protection

Proof-of-Concept Data for ANX1502, the First Oral C1 Inhibitor for Autoimmune Disease, Expected in 2026

Strong Financial Position Funds Operations into Late 2027 Well Past Anticipated Key Milestones

BRISBANE, Calif., Jan. 12, 2026 (GLOBE NEWSWIRE) -- [Annexon, Inc.](#) (Nasdaq: ANNX), a biopharmaceutical company advancing the next generation platform of targeted immunotherapies aimed at neuroinflammatory diseases that impact nearly 10 million people worldwide, today highlighted its 2026 strategic priorities and key milestones for its lead programs.

"2026 is a pivotal year for Annexon as we progress toward our first potential approval in GBS and pivotal Phase 3 data in GA," said Douglas Love, president and chief executive officer of Annexon. "Building on more than a decade of expertise stopping acute and chronic neuroinflammation at its source, our two registrational programs have both demonstrated meaningful patient benefit in well-controlled trials by significantly protecting function in devastating diseases. As a result, vonaprumment and tanruprubarb both have the potential to reset the standard of care in their respective diseases and help millions of patients live their best lives."

Mr. Love continued, "With tanruprubarb's Marketing Authorization Application (MAA) filed in Europe and the U.S./European FORWARD trial underway to support a planned U.S. BLA submission in 2026, we are increasingly focused on our vonaprumment GA program and its upcoming pivotal data later this year. The strong biologic rationale and unprecedented effect on vision protection demonstrated in the Phase 2 trial provide confidence in the potential of vonaprumment to replicate the findings and thereby preserve vision for the eight million people worldwide living with GA. With seasoned leadership and a strong financial position, we are energized by the year ahead and the potential to deliver significant value for patients and stakeholders."

2026 Strategic Priorities and Key Milestones

Vonaprumment– Potential to be the first targeted vision-preserving therapy for GA

- Ongoing Phase 3 ARCHER II trial is a global, pivotal, sham-controlled, double-masked trial. The primary endpoint is the proportion of patients who experience a best corrected visual acuity (BCVA) 15-letter loss confirmed at two consecutive visits, measured at month 15. Enrollment of 659 patients completed ahead of schedule and exceeded target patient numbers. Patient selection profile similar to the Phase 2 trial, with enrichment strategies designed to include patients at higher risk for vision loss.
- Global registration path established with U.S. and European regulators for ARCHER II, supporting the potential of vonaprumment to be the first treatment approved for protection of vision in patients who have dry AMD with GA.
- Consistent with its neuroprotective mechanism, vonaprumment provided significant protection of photoreceptors within the center of the retina necessary for visual acuity and significantly protected vision on multiple clinical measures.
- Annexon plans to host a GA Investor Day in March 2026 featuring management, key opinion leaders and retina experts to provide deeper insight on the vonaprumment program and its potential impact in the GA landscape.
- **Next Milestone: Topline Phase 3 ARCHER II trial data expected in second half of 2026.**

Tanruprubarb – Potential to be the first targeted fast-acting therapy for GBS

- MAA filed with European Medicines Agency with comprehensive data package demonstrating rapid impact on markers of neuroinflammation and disease activity, and patients recovering faster and more completely on both disability and functional outcome measures in placebo-controlled studies. Also submitted data showing improved outcomes versus standard of care intravenous immunoglobulin (IVIg) or plasma exchange (PE) in a Real-World Evidence study.
- Ongoing open-label FORWARD study in the U.S. and Europe, designed to support a broad label across pediatric and adult patients and further expand the use of tanruprubarb across geographies.
- **Next Milestone: BLA submission with U.S./European data from FORWARD trial planned in 2026.**

ANX1502 for Autoimmune Conditions – First-in-kind oral small molecule with convenient and flexible dosing

- Evaluation of pharmacokinetics (PK) and pharmacodynamics (PD) in relation to food intake, and reduction in complement activity (as a measure of target engagement), and bilirubin (as a measure of hemolysis) is ongoing in proof-of-concept (POC) trial in patients with cold agglutinin disease (CAD).

- Objective measurements of clinical activity in CAD patients are anticipated to be translatable across a host of neuromuscular autoimmune diseases.
- **Next Milestone: Update on POC trial in CAD anticipated in 2026.**

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is advancing the next generation platform of targeted immunotherapies for nearly 10 million people worldwide living with serious neuroinflammatory diseases. Our founding scientific approach focuses on C1q, the initiating molecule of a potent inflammatory pathway that when misdirected can lead to tissue damage and loss of function in a host of diseases. Our targeted therapies are designed to stop classical complement-driven neuroinflammation at its source to provide meaningful functional benefit and alter the course of disease. 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 the potential therapeutic benefit of tanrurprubart, if approved, compared to existing therapies; anticipated timing and results of regulatory interactions related to tanrurprubart, including the timing of the company's planned BLA submission to the U.S. Food and Drug Administration (FDA); the design, objectives and timing of the open-label tanrurprubart FORWARD study; the company's ability to achieve regulatory approval for tanrurprubart; the potential therapeutic benefit of vonaprument; timing of and results from the Phase 3 ARCHER II trial; vonaprument's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; the potential for vonaprument to be the first drug approved for dry AMD with GA; the potential for vonaprument and tanrurprubart to reset the standard of care; timing of proof-of-concept trial for ANX1502 in CAD and the company's ability to provide an update upon completion of its POC trial in 2026; the company's ability to commercialize its product candidates, if approved; the potential for the company to deliver significant value for patients and its stakeholders; 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 potential for delays in the company's clinical trials; the potential for the company's product candidates to not receive regulatory approval, including if the FDA and comparable foreign regulatory authorities determine that the company's submission package is not sufficient or require the company to provide additional data in patients that are not feasible to obtain; 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 Securities and Exchange Commission. 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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