Annexon Submits Tanruprubart Marketing Authorization Application to the European Medicines Agency for Guillain-Barré Syndrome

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Potential to Be the First Targeted Fast-Acting Therapy for GBS, Setting a New Standard of Care

BLA Submission with U.S./European Data from FORWARD Trial Planned in 2026

BRISBANE, Calif., Jan. 08, 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 announced it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for tanruprubart for the treatment of Guillain-Barré syndrome (GBS).

“Annexon’s first regulatory submission marks a defining milestone for patients and for the company and represents the first of several important registrational catalysts anticipated from our lead programs in 2026,” said Douglas Love, president and chief executive officer of Annexon. “In the landmark Phase 3 study, tanruprubart was shown to rapidly stop neuroinflammation, enabling GBS patients to recover faster and more completely from this sudden, life-threatening disease that has no approved disease modifying therapies. Accordingly, we look forward to working closely with the EMA during the review, and to further collaborating with regulatory authorities worldwide to make available the first targeted treatment for GBS. This submission is an important step on many fronts as we move closer to achieving our mission of helping millions of patients impacted by devastating neuroinflammatory diseases live their best lives.”

GBS is an acute neuroinflammatory disease involving damage to peripheral nerves necessary for movement and even breathing, and often rapidly progresses to severe weakness or complete paralysis that requires intensive care. It affects at least 150,000 people worldwide each year with no U.S. Food and Drug Administration (FDA) approved treatments. Available treatments are slow, suboptimal, and have not been shown to stop underlying neuroinflammation. In contrast, tanruprubart is an investigational, first-in-class antibody designed to block classical complement-driven inflammation at its source and has been observed in GBS to act almost immediately with a single infusion to stop early nerve damage. Tanruprubart has received European and FDA Orphan Drug designations, indicating a recognized need for better treatments.

The MAA submission dossier for tanruprubart included a comprehensive data package demonstrating rapid impact on markers of neuroinflammation and disease, with patients recovering faster and more completely on both functional and clinical disability outcome measures:

- **Significant improvement with treatment and favorable risk/benefit analysis** shown in two randomized, placebo-controlled studies: proof-of-concept and pivotal Phase 3 studies conducted in Southeast Asia where there is high disease prevalence, recognized medical expertise, and the ability to run gold standard placebo-controlled studies.
- **Robust generalizability package** demonstrated classical complement as a key driver of GBS regardless of geography and tanruprubart treatment outcomes applicable to Western patient populations. The package is supported by a large U.S. and Southeast Asian biomarker dataset, population pharmacokinetics (PK) analysis of tanruprubart across U.S., E.U. and Southeast Asian studies, and a Real-World Evidence study matching Phase 3 patients to IVIg- or plasma exchange-treated Western patients from a 2,000-patient, prospective GBS observational study.

Hugh Willison, MBBS, PhD, professor emeritus of neurology of University of Glasgow added, “GBS is a sudden, debilitating disease that robs patients of their independence despite treatment with IVIg or plasma exchange, which require intensive, multi-day administration and provide incomplete benefit for many patients. The potential for a new targeted, disease-modifying immunotherapy that can rapidly achieve full target engagement after a single dose represents an exciting advance for physicians and the patients they serve.”

Annexon continues to evaluate tanruprubart in the 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 tanruprubart across geographies. A Biologics License Application (BLA) submission to the FDA with data from the FORWARD study is planned in 2026.

About Tanruprubart

Annexon’s lead investigational therapy, tanruprubart, is a first-in-class targeted and rapid-acting agent designed to reduce inflammation and nerve damage by stopping C1q activity in the peripheral and central nervous systems. 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 neuroinflammatory damage on nerve cells, allowing patients to recover sooner, regain independence and return to pre-illness activities. Tanruprubart has received both Fast Track and Orphan Drug designations from the FDA as well as orphan drug designation from the EMA for the treatment of GBS.

About Guillain-Barré Syndrome

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. The peripheral nerve damage progresses rapidly, causing acute 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 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 tanruprubart, if approved, compared to existing therapies; the potential for tanruprubart to be the first targeted fast-acting therapy for GBS and set a new standard of care*;* anticipated timing and results of regulatory interactions related to tanruprubart, including the timing of the company's planned BLA submission to the FDA; the design, objectives and timing of the open-label tanruprubart FORWARD study; the company's expectation of timing of initial PK, pharmacodynamics, early impact on function and biomarkers, and safety data; the company's ability to achieve regulatory approval for tanruprubart; 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, including if the FDA and comparable foreign regulatory authorities do not accept data from clinical trials for product candidates outside the United States; 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.

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