Cue Biopharma Announces Preclinical Safety and Tolerability Data for CUE-401 for the Treatment of Autoimmune and Inflammatory Diseases

February 17, 2026

In two non-GLP studies, CUE-401 was well tolerated with no adverse events observed

Proof-of-concept studies reinforce promising preclinical profile and therapeutic potential of CUE-401

BOSTON, Mass., Feb. 17, 2026 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells for the treatment of autoimmune and inflammatory diseases, today announced preclinical safety and tolerability data that further supports the preclinical profile of CUE-401, the Company's lead autoimmune asset.

"We are very encouraged with this preclinical data, which demonstrated that CUE-401 was well tolerated, and no adverse events were observed," said Usman Azam, M.D., president and chief executive officer of Cue Biopharma. "Data generated from these preclinical studies represent an important addition to the growing evidence supporting the potential of CUE-401 as a first-in-class bifunctional tolerogenic agent for the treatment of autoimmune disease. We look forward to sharing further scientific data and details on the planned investigational new drug (IND) filing for CUE-401 in the upcoming months."

Study design and key data highlights include:
Two separate non-GLP studies in mice and non-human primates (NHPs) assessed the safety and tolerability of CUE-401 using a step-up dosing schedule, where animals successively received higher doses of CUE-401, weekly. CUE-401 was administered intravenously.

Murine Study (n=24, 12 males, 12 females)

- Animals received escalating doses of CUE-401 at 1 mg/kg, 3 mg/kg, and 10 mg/kg
- All dose levels were well tolerated, and no adverse events were observed

NHP Study (n=6, 3 males, 3 females)

- *Core study:* Animals received escalating doses of CUE-401 at 0.1 mg/kg, 0.3 mg/kg, and 1 mg/kg
- All dose levels were well tolerated in the core study with no adverse observations
- *Follow-up dosing:* Following observed tolerability and safety in the core study, animals were given an additional dose of CUE-401 a week later at 1 mg/kg (n=2 animals, 1 female, 1 male) or 3 mg/kg (n=4 animals, 2 male, 2 female)
- Repeat dosing of CUE-401 at 1 mg/kg was better tolerated than the repeat dosing at 3 mg/kg

About CUE-401
CUE-401 is a novel bifunctional therapeutic that incorporates an innovative TGF-beta breathing-mask moiety with Cue Biopharma's clinically validated interleukin 2 (IL-2) mutein in a single injectable biologic. The design of CUE 401 was inspired by Nobel Prize winning science in 2025 for the role of IL-2 and TGF-beta as essential components in helping establish immune tolerance by regulating FOXP3 signaling. CUE-401 is designed to promote immune regulation and tolerance by three complementary mechanisms: 1. Direct regulation of proinflammatory mechanisms by TGF-beta, 2. Expansion of existing Tregs by IL-2, and 3. Conversion of FOXP3- conventional CD4+ T cells into FOXP3+ induced Tregs through the coordinated provision of TGF-beta *and* IL-2 signals, both of which are required for the de novo induction of FOXP3 expression.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* and biologics are designed to harness the curative potential of the body's intrinsic immune system without the adverse effects of broad systemic immune modulation. CUE-401, the company's lead autoimmune asset, *is designed to act mechanistically both as a regulator of proinflammatory mechanisms, and as a master switch for regulatory T cell (Treg) differentiation to induce tolerance.* It is a highly innovative, tolerogenic bifunctional molecule combining a TGF-beta breathing-mask moiety with Cue Biopharma's clinically validated interleukin 2 (IL-2) mutein in a single injectable biologic.

Headquartered in Boston, Massachusetts, we are led by an experienced management team with deep expertise in immunology and protein engineering as well as the design and clinical development of protein biologics.

For more information please visit www.cuebiopharma.com and follow us on X and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the company's belief regarding the potential benefits and applications of its drug candidates and programs, including the company's plans to further advance its differentiating Immuno-STAT ® platform and lead autoimmune asset, CUE-401; the company's belief that CUE-401 is a potential first-in-class bifunctional tolerogenic agent for the treatment of autoimmune disease and the company's plans to file an IND application for CUE-401; and the company's business strategies, plans and prospects. Forward-looking statements, which are based on certain assumptions and describe the company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely," "promise" or other comparable terms, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company's ability to maintain its collaboration with ImmunoScape; the company's limited operating history, limited cash and a history of losses; the company's ability to obtain adequate financing to fund its business operations in the near term and successfully remediate its current "going concern" determination that it does not have sufficient capital on hand to continue operations beyond the next twelve months; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; its ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including possible effects on the company's operations and clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company's reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company's ability to obtain adequate financing to fund its business operations in the future and ability to continue as a going concern; the company's ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions and the other risks and uncertainties described in the Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the company's most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Investor Contact
Marie Campinell
Senior Director, Corporate Communications
Cue Biopharma, Inc.
mcampinell@cuebio.com

Media Contact
Jonathan Pappas
LifeSci Communications
jpappas@lifescicomms.com

Source: Cue Biopharma, Inc.