Climb Bio Announces CLYM116 Phase 1 Data Demonstrating Prolonged Half-Life and Best-In-Class APRIL Suppression Supporting Every-12-Week Dosing in IgA Nephropathy

September 3, 2026

~29-day half-life

Single 320 mg dose of CLYM116 drove near-complete APRIL suppression and 60-75% IgA/Gd-IgA1 suppression through 12 weeks

CLYM116 generally well-tolerated, with no serious adverse events, dose-limiting toxicities, or hypogammaglobulinemia

Phase 2 NAVIGATE-2 trial in IgA nephropathy ongoing; anticipate initial data in H1 2027, Phase 3 study initiation in 2027

Company to host R&D Spotlight Webcast today, September 3 at 8:00 a.m. ET

WELLESLEY HILLS, Mass., Sept. 03, 2026 (GLOBE NEWSWIRE) -- Climb Bio, Inc. (Nasdaq: CLYM), a clinical-stage biotechnology company developing therapeutics for patients with immune-mediated diseases, today announced positive initial data from the ongoing Phase 1 trial evaluating CLYM116, an anti-APRIL monoclonal antibody, and provided updates on its strategy for further development in IgA nephropathy.

“We are thrilled with the compelling initial data for CLYM116,” said Aoife Brennan, M.B., Ch.B., President and Chief Executive Officer of Climb Bio. “APRIL is a clinically validated target in IgA nephropathy, and we designed CLYM116 to raise the bar on how completely and how durably it can be suppressed. As a sweeper antibody, CLYM116 was engineered to facilitate the degradation of APRIL rather than simply bind it. Our initial data show that this mechanism translated to rapid and durable APRIL suppression and substantial reductions in IgA and Gd-IgA1, with a favorable safety and tolerability profile. We believe this combination of depth, durability, and the potential for an every-12-week dosing regimen supports a best-in-class profile for CLYM116 in IgAN with the potential to meaningfully improve patient care. We look forward to sharing data from our ongoing NAVIGATE-2 study in IgAN in the first half of 2027 as we continue to progress this program toward a pivotal study.”

The data presented today are from the Company’s ongoing Phase 1 trial of CLYM116. This randomized, double-blind, placebo-controlled, single-ascending-dose (SAD) and multiple-ascending-dose (MAD) study enrolled 46 subjects and was designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneous (SC) CLYM116 in healthy volunteers.

CLYM116 Key Data and Highlights

- CLYM116 demonstrated a favorable safety and tolerability profile with no serious adverse events, dose-limiting toxicities, or hypogammaglobulinemia
- ~29-day half-life projected based on CLYM116 320 mg MAD, threefold longer than sibeprenlimab
- >90% free APRIL suppression following a single 320 mg dose, with potential for sustained APRIL suppression with an every-12-week (Q12W) dosing regimen
- ~60-75% IgA, Gd-IgA1, and IgM suppression following a single 320 mg dose, with suppression maintained through 12 weeks
- PK/PD modeling further supports Q12W dosing of CLYM116

CLYM116 Development and Next Steps

- Ongoing Phase 2 NAVIGATE-2 trial in IgA nephropathy (IgAN) is a randomized, open-label study
  - Evaluating an 800 mg loading dose of CLYM116, followed by 400 mg Q8W or Q12W
  - Intended to support the advancement of the Q12W regimen into Phase 3
- High concentration (200 mg/mL) formulation developed, enabling delivery of 400 mg in a single, SC injection
  - Pre-filled syringe development complete for use in registrational study
  - Autoinjector in development, enabling a patient-friendly launch presentation
- Development strategy designed to confirm a single regimen to advance into registrational study

Upcoming Milestones

- Additional data from the ongoing Phase 1 study and initial reporting of Beijing Mabworks Biotech Co., Ltd. (Mabworks)

Phase 1 healthy volunteer study in China to be presented at an upcoming medical meeting in the fourth quarter of 2026
- Initial data from NAVIGATE-2 Phase 2 anticipated in the first half of 2027
- Initiation of Phase 3 registrational study anticipated in 2027

Webcast Information
The live webcast is accessible via the "News & Events" section of the Climb Bio website: https://ir.climbbio.com/. A webcast replay will be available on the Climb Bio website beginning approximately two hours after the webcast event and will be archived for at least 30 days.

About Climb Bio, Inc.
Climb Bio, Inc. is a clinical-stage biotechnology company with a mission to deliver high impact, disease-modifying medicines for individuals living with immune-mediated diseases, including those affecting kidney health. The Company's pipeline includes, budoprutug, an anti-CD19 monoclonal antibody that has potential to treat a broad range of B-cell mediated diseases, and CLYM116, an anti-APRIL monoclonal antibody being developed for IgA nephropathy. For more information, please visit climbbio.com.

About CLYM116
CLYM116 is a clinical-stage monoclonal antibody targeting APRIL (A Proliferation-Inducing Ligand), a key driver of pathogenic B-cell activity in autoimmune diseases. CLYM116 employs a novel pH-dependent bind-and-release 'sweeper' mechanism to potently block APRIL signaling, promote lysosomal degradation of APRIL, and recycle the antibody to extend its half-life. This differentiated design offers the potential for rapid, deep, and durable inhibition of APRIL with a favorable safety profile and less frequent dosing. CLYM116 is being advanced for the treatment of IgA nephropathy (IgAN) and may also have broader utility across other B-cell mediated diseases where APRIL plays a critical role.

Forward-Looking Statements
This press release contains "forward-looking statements," including without limitation statements regarding: future expectations, plans and prospects for Climb Bio; expectations regarding the therapeutic benefits, clinical potential and clinical development of CLYM116; the anticipated timelines for announcing clinical data from Climb Bio's ongoing and planned clinical trials; the anticipated timelines for enrolling patients in planned clinical trials; projections and estimates derived from pharmacokinetic and pharmacodynamic modeling; and other statements containing the words "anticipate," "believe," "continue," "could," "expect," "may," "plan," "potential," "should," "suggest," "target," "will," and similar expressions. Forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. Climb Bio may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. These risks and uncertainties include, but are not limited to, important risks and uncertainties associated with: the ability of Climb Bio to timely and successfully achieve or recognize the anticipated benefits of its technology transfer and exclusive license agreement with Mabworks; Climb Bio's ability to advance budoprutug and CLYM116 on the timelines expected or at all and to obtain and maintain necessary approvals from the U.S. Food and Drug Administration and other regulatory authorities; obtaining and maintaining the necessary approvals from investigational review boards at clinical trial sites and independent data safety monitoring boards; replicating in clinical trials positive results found in early-stage clinical trials or nonclinical studies; top-line data may change as more patient data become available and are subject to audit and verification procedures; competing successfully with other companies that are seeking to develop treatments for primary membranous nephropathy, immune thrombocytopenia, systemic lupus erythematosus, IgA nephropathy and other immune-mediated diseases; maintaining or protecting intellectual property rights related to budoprutug, CLYM116 and/or its other product candidates; managing expenses; the possibility that models used in clinical development may be inaccurate; changes in applicable laws or regulation; the possibility that Climb Bio may be adversely affected by other economic, business and/or competitive factors; and raising the substantial additional capital needed, on the timeline necessary, to continue development of budoprutug, CLYM116 and any other product candidates Climb Bio may develop. For a further discussion of other risks and uncertainties, and other important factors, any of which could cause Climb Bio's actual results to differ materially from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in Climb Bio's most recent filings with the U.S. Securities and Exchange Commission. The forward-looking statements included in this press release represent Climb Bio's views as of the date hereof and should not be relied upon as representing Climb Bio's views as of any date subsequent to the date hereof. Climb Bio anticipates that subsequent events and developments will cause Climb Bio's views to change. However, while Climb Bio may elect to update these forward-looking statements at some point in the future, Climb Bio specifically disclaims any obligation to do so, except as required by law. In addition, caution should be exercised when interpreting results from separate trials involving separate product candidates. Cross-trial comparisons may not be reliable as no head-to-head trials have been conducted, and differences exist between trial designs and participant characteristics.

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