Climb Bio Announces Pipeline Progress and Strategic Priorities for 2026

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First patients dosed in budoprutug PrisMN Phase 2 trial in pMN, with initial data expected second half 2026

Dosing ongoing in budoprutug Phase 1b/2a trial in ITP and Phase 1b trial in SLE; achieved regulatory clearance for SLE IND in China

First patients dosed in CLYM116 Phase 1 healthy volunteer study

Anticipating a data-rich 2026, with initial readouts from all ongoing budoprutug and CLYM116 studies

Strong financial position with cash runway expected into 2028

WELLESLEY HILLS, Mass., Jan. 08, 2026 (GLOBE NEWSWIRE) -- Climb Bio, Inc. (Nasdaq: CLYM), a clinical stage biotechnology company developing therapeutics for patients with immune-mediated diseases, today announced progress updates for its budoprutug and CLYM116 programs. The Company also highlighted its strategic priorities and key anticipated milestones for 2026 and refreshed its financial guidance.

“Reflecting on 2025, we set out with ambitious goals, and I am proud of the substantial progress made across our clinical development and corporate objectives,” said Aoife Brennan, M.B., Ch.B., President and Chief Executive Officer of Climb Bio. “We are now primed for a fulsome evaluation of budoprutug, our anti-CD19 monoclonal antibody, with the initiation of four clinical trials and the clearance of our China IND. We also rapidly advanced CLYM116, our anti-APRIL monoclonal antibody, into the clinic and dosed our first subjects in less than one year after announcing the in-licensing transaction. Across the portfolio we achieved 20 regulatory clearances to conduct clinical trials and activated 45 trial sites globally, a testament to our robust clinical execution.”

“Looking ahead, 2026 is poised to be a transformative and data-rich year for Climb, with initial readouts expected from all our ongoing trials,” continued Dr. Brennan. “With CLYM116 for IgAN, budoprutug in pMN, ITP, and SLE, and the potential to evaluate lupus nephritis in a separate, parallel China SLE trial, our pipeline has the potential to address the high unmet need which exists across renal and other B-cell mediated diseases. Together, the anticipated datasets from our ongoing studies will inform the next steps in our mission to deliver differentiated treatments for immune-mediated diseases with substantial therapeutic and commercial potential.”

2025 Major Accomplishments and Pipeline Status

Budoprutug anti-CD19 monoclonal antibody

- **Initiated Phase 2 Trial in Primary Membranous Nephropathy (pMN):** In November 2025, FPI was achieved in the PrisMN Phase 2 trial. The study is designed to evaluate pharmacodynamics (including B cells, anti-PLA2R, and total immunoglobulin) and preliminary efficacy (including complete and partial remission) in pMN patients with persistent proteinuria despite optimized RAAS inhibition, and to identify a dose to carry forward into Phase 3 clinical development. In November 2025, the Company also published budoprutug pMN Phase 1b long-term outcome data at the 2025 American Society of Nephrology (ASN) Kidney Week that demonstrated long-term control of proteinuria.
- **Initiated Phase 1b/2a Trial in Immune Thrombocytopenia (ITP):** Dosing is ongoing in the open-label, dose-escalation Phase 1b/2a clinical trial of budoprutug in relapsed/refractory ITP designed to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy, including B cell depletion and platelet counts. At the 2025 American Society of Hematology (ASH) conference in December, the Company presented a poster detailing the Phase 1b/2a trial design.
- **Initiated Global Phase 1b Trial in Systemic Lupus Erythematosus (SLE) and Received Regulatory Clearance of SLE IND in China:** Dosing is ongoing in the global, open-label, dose-escalation Phase 1b trial of a single dose of budoprutug in moderate to severe SLE to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy, including B-cell depletion, autoantibody levels, and clinical activity. In December 2025, the Company received clearance of its investigational new drug application (IND) in China to initiate a separate, parallel China Phase 1b trial in SLE, which will complement our ongoing study and also seek to enroll SLE patients who have lupus nephritis.
- **Initiated Subcutaneous (SC) formulation Phase 1 Trial:** First cohorts were dosed in the Phase 1 trial in healthy volunteers, which is designed to evaluate bioavailability, pharmacokinetics, and pharmacodynamics, including B cell depletion, of the subcutaneous formulation of budoprutug.

CLYM116 anti-APRIL monoclonal antibody

- **Obtained Exclusive License to Develop and Commercialize CLYM116:** Entered into a technology transfer and exclusive license agreement with Beijing Mabworks Biotech Co., Ltd. (NEEQ Code: 874070, Mabworks) in January 2025 for the rights to develop and commercialize CLYM116 in the territory outside of Greater China.
- **Presented Preclinical Data:** Completed IND enabling studies and shared preclinical data highlighting the unique 'sweeper' mechanism and product profile at the 2025 ASN Kidney Week in November and reviewed the opportunity in IgAN at a CLYM116-focused R&D Spotlight Webcast in September 2025.
- **Initiated Phase 1 Clinical Trial:** In December 2025, the Company achieved FPI and completed dosing of the first cohort in the ongoing Phase 1 clinical trial in healthy volunteers to evaluate safety, pharmacokinetics, and pharmacodynamics.
- **Regulatory Clearance of Mabworks IND in China:** In December 2025, our partner, Mabworks, received clearance of its IND in China to initiate a Phase 1 trial.

Corporate Milestones and Cash Guidance

- Expanded senior leadership team with appointments of Edgar D. Charles, M.D., MSc as Chief Medical Officer, Perrin Wilson, Ph.D., as Chief Business Officer, Susan Altschuller, Ph.D., MBA as Chief Financial Officer, Adam Villa, MS, MBA as SVP, Technical Operations, and Ashley Jones as SVP, People & Workforce Strategy.
- Strengthened Board of Directors with the addition of industry veterans Kim Cobleigh Drapkin, CPA and Bo Cumbo.
- Refreshed financial guidance, with cash, cash equivalents, and marketable securities expected to fund operations into 2028.

2026 Anticipated Milestones

Budoprutug:

- **SC formulation Phase 1:** initial data from healthy volunteer study (H1 2026)
- **China SLE Phase 1b:** first patient dosed (H1 2026)
- **PrisMN (pMN) Phase 2:** initial data (H2 2026)
- **ITP Phase 1b/2a**: initial data, including preliminary efficacy (H2 2026)
- **SLE Phase 1b:** initial data, including preliminary efficacy (H2 2026)

CLYM116

- **Phase 1:** initial data from healthy volunteer study (mid-2026)

About Climb Bio, Inc.
Climb Bio, Inc. is a clinical-stage biotechnology company developing therapeutics for patients with immune-mediated diseases. The Company's pipeline includes, budoprutug, an anti-CD19 monoclonal antibody that has demonstrated B-cell depletion and 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 Budoprutug
Budoprutug is a clinical-stage, anti-CD19 monoclonal antibody being developed by Climb Bio to address a broad range of B-cell mediated, immune-driven diseases. Designed with enhanced effector function and low picomolar affinity, budoprutug targets and depletes CD19-expressing B cells, including plasma blasts that are key sources of pathogenic autoantibodies. Budoprutug clinical development is underway for three lead indications - primary membranous nephropathy (pMN), immune thrombocytopenia (ITP), and systemic lupus erythematosus (SLE). Early clinical data suggest budoprutug may offer durable B-cell depletion, rapid reductions in autoantibodies, and clinical remission in pMN. A subcutaneous formulation is also in clinical development to enable broader patient access and potential home-based dosing. Budoprutug has been granted orphan drug designation by the FDA for the treatment of pMN.

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" within the meaning of the Private Securities Litigation Reform Act of

1995, including without limitation statements regarding: future expectations, plans and prospects for Climb Bio; expectations regarding the therapeutic benefits, clinical potential and clinical development of budoprutug and CLYM116; the anticipated timelines for reporting initial data from Climb Bio's ongoing and planned clinical trials of budoprutug and CLYM116; the anticipated timeline for initiating Climb Bio's parallel Phase 1b clinical trial of budoprutug in patients with systemic lupus erythematosus in China and the projected enrollment of patients with systemic lupus erythematosus that have lupus nephritis; the anticipated benefits of Climb Bio's technology transfer and exclusive license agreement with Beijing Mabworks Biotech Co., Ltd. ("Mabworks"); the sufficiency of Climb Bio's cash resources for the period anticipated; and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," "will," "working" 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; changes in applicable laws or regulation; the possibility that Climb Bio may be adversely affected by other economic, business and/or competitive factors; 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 and nonclinical studies; 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; the outcome of any legal proceedings or other disputes; managing expenses; 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 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. In addition, 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.

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