Climb Bio Announces CLYM116 Preclinical Data Highlighting Potential for Best-In-Class Therapeutic for IgAN

September 29, 2025

New preclinical data demonstrate deeper IgA reduction and a longer half-life compared to first-generation anti-APRIL monoclonal antibody

CLYM116 Phase 1 trial initiation expected in Q4 2025, with initial biomarker and dosing interval data anticipated mid-year 2026

Company to host R&D Spotlight Webcast today, September 29, 2025

WELLESLEY HILLS, Mass., Sept. 29, 2025 (GLOBE NEWSWIRE) -- Climb Bio, Inc. (Nasdaq: CLYM), a clinical-stage biotechnology company developing therapeutics for immune-mediated diseases, today announced results from a completed nonhuman primate (NHP) study comparing CLYM116 to sibeprenlimab, a first-generation anti-APRIL monoclonal antibody. The company is hosting a virtual investor event focused on CLYM116 today, Monday, September 29, 2025, at 8:00 a.m. ET. Climb Bio's management team will be joined by leading nephrologist Craig E. Gordon, MD, MS, who has over 20 years of experience treating patients with IgA nephropathy (IgAN) and was a co-director of the Evidence Review Team for the recently issued 2025 KDIGO Clinical Practice Guideline for IgAN.

"We are highly encouraged by the differentiated profile observed with CLYM116, as highlighted in our newly shared nonhuman primate data," said Aoife Brennan, President and CEO of Climb Bio. "CLYM116 is the only known 'sweeper' anti-APRIL monoclonal antibody in development, which we believe could provide a compelling clinical profile in IgAN. In this head-to-head preclinical study, our data have shown improvements in pharmacokinetic and pharmacodynamic measures – namely a longer half-life and deeper and more durable IgA reductions – as compared to sibeprenlimab, a first-generation anti-APRIL monoclonal antibody. These data highlight the potential for CLYM116 to provide a differentiated activity profile with less frequent dosing. Notably, the updated KDIGO treatment guideline published earlier this month highlights the need for more active management of IgAN, and we believe that the adoption of these approaches could expand the CLYM116 market opportunity. We are excited to advance CLYM116 development and look forward to initiation of a Phase 1 trial later this year, with initial data anticipated mid-year 2026."

CLYM116 Data & Event Highlights

New CLYM116 NHP data demonstrate improvement versus sibeprenlimab (first-generation anti-APRIL monoclonal antibody)

- Subcutaneous formulation demonstrated high bioavailability (~85%), with a favorable tolerability profile
- Prolonged exposure observed compared to sibeprenlimab, with a ~2-3 times longer half-life across doses
- Deeper and more prolonged IgA reduction observed compared to sibeprenlimab after a single subcutaneous administration at equivalent doses (6 mg/kg), with >70% maximal reduction in IgA observed with CLYM116
- Additional *in vivo* studies in mice showed enhanced APRIL elimination and antibody recycling relative to sibeprenlimab

CLYM116 advancing towards planned Phase 1 trial in healthy volunteers

- Phase 1 trial expected to initiate in Q4 2025, subject to regulatory clearance, with initial data, including biomarkers and projected dosing interval, anticipated mid-year 2026
- Parallel execution by Mabworks in China expected to provide a complementary Phase 1 dataset

IgAN represents a high unmet need indication, with a well-defined development path

- Progressive autoantibody-mediated renal disease, caused by APRIL-mediated production of pathogenic IgA and deposition of immune complexes in the glomeruli
- Damage to glomeruli leads to proteinuria, kidney injury and loss of kidney function, with 30-40% of patients developing kidney failure within 10 years of diagnosis
- Prior product approvals in IgAN provide precedent regarding study design and registrational endpoints, including use of proteinuria for accelerated approval and estimated glomerular filtration rate (eGFR) for full approval
- Biomarkers (APRIL, IgA) enable rapid assessment of clinical profile during early development

IgAN is a significant market opportunity, estimated at $10-20B in US alone

- Most common primary glomerular disease worldwide, with ~170,000 patients in the US alone
- Typically diagnosed early in life and is likely to require lifelong management
- KDIGO 2025 guideline recommends a lower threshold for biopsy to enable earlier diagnosis and recommends aiming for

stricter proteinuria control, with a goal of <0.5 g/day, ideally <0.3 g/day, which may result in earlier and more aggressive disease management
- Updated treatment guidelines highlight importance of reducing pathogenic IgA along with managing the consequences of existing nephron loss, potentially positioning anti-APRIL therapy as a core pillar in the future treatment of IgAN

Webcast Information
The live webcast will be accessible via the "Investors & Media" section of the Climb Bio website: https://ir.climbbio.com/, and an accompanying slide presentation will also be made available. 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 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 in development for IgA nephropathy. For more information, please visit climbbio.com.

About CLYM116
CLYM116 is a preclinical-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 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 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; expectations regarding the timing of submitting an investigational new drug application or clinical trial application submission for CLYM116; the anticipated timelines for initiating a clinical trial of CLYM116 and reporting initial data; the anticipated benefits of Climb Bio's 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 acquisition of Tenet Medicines, Inc. and its 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 preclinical 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; 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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