# Climb Bio Announces FDA Fast Track Designation for Budoprutug for the Treatment of Primary Membranous Nephropathy

April 7, 2026

## *Global Phase 2 open-label clinical trial in pMN (PrisMN) enrolling, with initial data anticipated H2 2026*

WELLESLEY HILLS, Mass., April 07, 2026 (GLOBE NEWSWIRE) -- Climb Bio, Inc. (Nasdaq: CLYM), a clinical stage biotechnology company developing therapeutics for patients with immune-mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to budoprutug, the company's investigational anti-CD19 monoclonal antibody, for the treatment of primary membranous nephropathy (pMN)—a rare kidney disease for which there are currently no FDA-approved treatments.

"Fast Track Designation recognizes both the urgent need for new therapies in pMN and the compelling early clinical activity generated to date with budoprutug," said Edgar Charles, M.D., Chief Medical Officer of Climb Bio. "This designation provides the opportunity to support and accelerate our budoprutug development efforts and facilitate closer interaction with the FDA as we work to advance budoprutug into later-stage clinical studies for this serious immune-mediated kidney disease."

As previously reported, administration of budoprutug in a completed Phase 1b study in pMN demonstrated complete peripheral B-cell depletion in 100% (5/5) of patients, serologic remission in all (3/3) evaluable patients, and complete or partial clinical remission in all (5/5) participants by week 48. The safety profile was favorable with no clinically significant treatment-related serious adverse events observed. Long-term follow-up data demonstrated durable reductions in proteinuria, supporting further investigation of budoprutug as a potential disease modifying therapy for pMN.

Budoprutug is currently being studied in a Phase 2 global open-label, dose-range finding study (PrisMN), which is designed to evaluate pharmacodynamics, including B cells, anti-Phospholipase A2 Receptor (PLA2R) antibody levels, and total immunoglobulin, and preliminary efficacy, including complete and partial remission, in pMN patients with persistent proteinuria despite optimized renin-angiotensin-aldosterone system (RAAS) inhibition, and to identify a dose for Phase 3 clinical development. Climb Bio anticipates sharing initial data from this study in the second half of 2026.

**About Primary Membranous Nephropathy (pMN)**
Primary membranous nephropathy is an autoantibody mediated disease characterized by proteinuria, nephrotic syndrome, and progressive loss of renal function. Patients with uncontrolled disease may develop chronic kidney disease or end-stage kidney disease, requiring dialysis or transplantation. There are about 75,000 people in the U.S. living with pMN. Currently, there are no FDA approved therapies for pMN.

**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 with the potential 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 plasmablasts and certain plasma cells, key sources of pathogenic autoantibodies. Early clinical data suggest budoprutug may offer durable B-cell depletion, rapid reductions in autoantibodies, and clinical remission in primary membranous nephropathy (pMN). Budoprutug is being evaluated in clinical trials for pMN, immune thrombocytopenia (ITP), and systemic lupus erythematosus (SLE). A subcutaneous formulation is also in development to enable broader patient access. Budoprutug has been granted Orphan Drug Designation and Fast Track Designation by the FDA for the treatment of pMN.

**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; the anticipated timelines for announcing data from Climb Bio's ongoing Phase 2 clinical trial of budoprutug in primary membranous nephropathy; the expected benefits of Orphan Drug Designation and Fast Track Designation for the development of budoprutug in primary membranous nephropathy; 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,"

“suggest,” “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 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; 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; 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 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.

**Investors and Media**
Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com