December 18, 2025

ProMIS Neurosciences Exceeds Target Enrollment in PRECISE-AD Phase 1b Clinical Trial of PMN310 in Alzheimer's Disease

Large, well-powered Phase 1b study, designed to generate clinically and biologically meaningful insights in early Alzheimer's disease

Clear and near-term value inflection points, with blinded 6-month interim data expected in Q2 2026 and final unblinded top-line results anticipated in Q4 2026

Cambridge, Massachusetts, Dec. 18, 2025 (GLOBE NEWSWIRE) -- ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company focused on the generation and development of antibody therapeutics and vaccines targeting toxic misfolded proteins in neurodegenerative diseases, such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and Parkinson's disease (PD), today announced completion of enrollment of 144 patients in its PRECISE-AD Phase 1b clinical trial, evaluating PMN310, the Company's lead therapeutic antibody candidate for the treatment of AD.

PRECISE-AD is a randomized, double-blind, placebo-controlled study in patients with mild cognitive impairment or early AD. The 12-month trial was designed to assess the safety, tolerability, pharmacokinetics, biomarker and clinical effects of PMN310, an antibody designed to be uniquely selective for toxic soluble amyloid-beta oligomers, widely believed to be the primary drivers of synaptic dysfunction and neurodegeneration in AD.

To date, PMN310 has demonstrated a favorable safety profile, with limited patient discontinuations and no treatment-related serious adverse events (SAEs) reported during the trial.

The Company remains on track to conduct a blinded 6-month interim analysis in Q2 2026, including an evaluation of key plasma and cerebrospinal fluid biomarkers, followed by final unblinded 12-month top-line analysis expected in Q4 2026.

"This is a major execution milestone for ProMIS and a potentially pivotal moment for the Alzheimer's field" said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "Completing enrollment and above our target in a rigorously designed, biomarker-rich study of this scale positions us to potentially confirm, clinically and biologically, for the first time the central role of toxic amyloid-beta oligomers in Alzheimer's disease. The safety profile we have observed thus far, with no treatment-related SAEs and minimal dropouts, reinforces our belief that PMN310 may offer a fundamentally differentiated approach that has the potential to significantly reduce the ARIA liability that has limited broader use of current

therapies. We believe the over-enrollment of PRECISE-AD may reflect strong enthusiasm among both patients and trial physicians for PMN310's differentiated mechanism and its potential for improved safety, underscoring the importance of the upcoming blinded interim analysis expected in Q2 2026 and final unblinded top-line results expected in Q4 2026."

About ProMIS Neurosciences Inc.

ProMIS Neurosciences is a clinical-stage biotechnology company committed to the discovery and development of therapeutic antibodies and vaccines selective for toxic oligomers associated with the development and progression of neurodegenerative and other misfolded protein diseases. The Company's proprietary target discovery engine, EpiSelect™, has been shown to predict novel targets known as Disease Specific Epitopes (DSEs) on the molecular surface of misfolded proteins that cause neurodegenerative and other misfolded protein diseases, including Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), multiple system atrophy (MSA), and Parkinson's Disease (PD). ProMIS has offices in Cambridge, Massachusetts (USA) and Toronto, Ontario (CAN).

About PMN310 and the PRECISE-AD Trial for Alzheimer's Disease (AD)

PMN310, the Company's lead product candidate for the treatment of AD, is a humanized monoclonal antibody designed to selectively target only amyloid-beta toxic oligomers, avoiding plaque, thereby potentially reducing or eliminating amyloid-related imaging abnormalities (ARIA) liability. In addition, because PMN310 may not be limited by off-target binding or side effects, PMN310 could potentially offer an improved efficacy profile over other amyloid-directed antibody therapeutics. PMN310 was granted Fast Track designation by the U.S. Food and Drug Administration in July 2025.

Based on the encouraging results from the Phase 1a trial NCT06105528) of PMN310, ProMIS initiated PRECISE-AD, a Phase 1b clinical trial in AD patients with targeted enrollment of 128 AD patients. PRECISE-AD (NCT06750432) is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of multiple ascending doses (5, 10, 20 mg/kg) of intravenous PMN310 in patients with Mild Cognitive Impairment due to AD and mild AD (Stage 3 and Stage 4 AD). PRECISE-AD will be the first study to examine the effects of a monoclonal antibody directed solely against toxic amyloid-beta oligomers on biomarkers associated with AD pathology and clinical outcomes. Safety will be a primary outcome of the study with particular emphasis on assessing whether, as a non-plaque binder, PMN310 may have a reduced risk of ARIA. The study is powered to provide 95% confidence for detection of ARIA. The study has been designed with a sample size intended to provide sufficient power to provide meaningful insight into effects of PMN310 on biomarkers and clinical outcomes. A blinded 6-month interim analysis is expected in Q2 2026 with final top line data expected in Q4 2026.

Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Certain information in this news release constitutes forward-looking statements and forward-looking information (collectively, "forward-looking information") within the meaning of applicable securities laws. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "pleased to", "look forward to",

“potential to”, “targets”, “expects” or “does not expect”, “is expected”, “excited about”, “an opportunity exists”, “is positioned”, “estimates”, “intends”, “assumes”, “anticipates” or “does not anticipate” or “believes”, or variations of such words and phrases or state that certain actions, events or results “may”, “could”, “would”, “might”, “will” or “will be taken”, “occur” or “be achieved”. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Specifically, this news release contains forward-looking information relating to the Company’s progress and expectations for its Phase 1b clinical trial in AD patients, including the number of participants enrolled, planned timing for completion and anticipated data readout of interim and full results in the second and fourth quarters of 2026, respectively, the potential for such studies to provide the first proof-of-concept data for PMN310, the potential for PMN310 to positively benefit patients with AD and to be a more effective and well-tolerated option, the targeting of toxic misfolded proteins in neurodegenerative diseases that the Company believes may directly address fundamental AD pathology (including the belief and understanding that toxic amyloid-beta oligomers are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity. Statements containing forward-looking information are not historical facts but instead represent management's current expectations, estimates and projections regarding the future of our business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by the Company as of the date of this news release, are subject to known and unknown risks, uncertainties and assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including, but not limited to, the risk that interim or early clinical data or other early preclinical data may not be indicative of future results from ongoing and planned clinical trials, the Company’s ability to fund its operations and continue as a going concern, its accumulated deficit and the expectation for continued losses and future financial results. Important factors that could cause actual results to differ materially from those indicated in the forward-looking information include, among others, the factors discussed throughout the “Risk Factors” section of the Company's most recently filed Annual Report on Form 10-K for the year ended December 31, 2024 and in its subsequent filings filed with the United States Securities and Exchange Commission. Except as required by applicable securities laws, the Company undertakes no obligation to publicly update any forward-looking information, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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Source: ProMIS Neurosciences Inc.