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ProMIS Neurosciences Doses First Patients in Phase 1b PRECISE-AD Trial of PMN310 for Alzheimer's Disease

Rapid Enrollment and Dosing of First Patients Encouraging and Underscores Unmet Need for Better Treatment Options for Alzheimer's Disease

Six-month Interim Results Expected in 1H 2026 with Topline Results Anticipated in 2H 2026

CAMBRIDGE, Massachusetts, Feb. 25, 2025 (GLOBE NEWSWIRE) -- ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company focused on the generation and development of antibody therapeutics targeting toxic misfolded proteins in neurodegenerative diseases such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and multiple system atrophy (MSA), today announced important progress in the PRECISE-AD Phase 1b clinical trial with the dosing of multiple patients with its lead drug candidate, PMN310, designed for the treatment of Alzheimer's disease (AD). The dosing of several patients marks an important milestone in assessing the safety, tolerability, and pharmacokinetics of PMN310 and underscores ProMIS's commitment to addressing the urgent need for targeted therapies in AD by selectively targeting toxic oligomers, which we believe to be a key driver of disease progression.

PMN310 is a humanized monoclonal antibody (mAb) designed and developed to selectively target only soluble amyloid-beta oligomers (AβOs), which are believed to be the most toxic and pathogenic form of Aβ, while avoiding any binding to Aβ monomers and amyloid plaques.

"The initiation of dosing in multiple patients in our Phase 1b PRECISE-AD trial marks a significant milestone for ProMIS Neurosciences," said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "With a growing need for more effective and safer treatments for Alzheimer's disease, we are excited to take this critical step toward demonstrating PMN310's potential to make a real difference for patients and their families. We look forward to generating clinical data and furthering our commitment to transforming Alzheimer's treatment."

"The PRECISE-AD trial has been carefully designed to generate potentially robust clinical data, including biomarker insights and efficacy signals that will guide the next phase of development. We believe PMN310's selective binding to toxic Aβ oligomers and not to plaque or monomers differentiates it from other drugs currently on the market or in development and we believe we have the potential to deliver a more effective and well-tolerated treatment for patients suffering from Alzheimer's disease," added Mr. Warma.

"As physicians dedicated to advancing Alzheimer's research, we are excited to be part of the

PRECISE-AD trial evaluating PMN310," said Yaneicy Gonzalez-Rojas, M.D. and Ahmad Aswad, M.D., Investigators of the PRECISE-AD clinical trial. "Alzheimer's disease remains one of the greatest unmet medical needs, and patients urgently need new treatment options that are both effective and well-tolerated. Current AD treatments offer only modest efficacy and are often accompanied by significant side effects, such as ARIA. PMN310's novel and selective targeting of amyloid oligomers has shown disease modifying capacity for AD in preclinical models, which we believe is promising and offers hope to Alzheimer's patients and their loved ones."

About PRECISE-AD Phase 1b Clinical Trial

The ongoing PRECISE-AD Phase 1b clinical trial (NCT06750432) is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics (PK) of multiple ascending doses (5, 10, 20 mg/kg) of intravenous PMN310 in patients with Stage 3 and Stage 4 AD. The study will also evaluate key biomarkers and clinical measures of efficacy to gather data on PMN310's therapeutic potential. The PRECISE-AD study plans to enroll approximately 100 subjects across 22 active sites in the United States. Eligible patients will be dosed monthly at one of the three dose levels or placebo over 12 months with assessment of safety, tolerability, PK, and pharmacodynamic blood- and brain-based markers of treatment effect at baseline and every three months. Frequent MRI scans throughout the study will be conducted to monitor for emergence of ARIA.

About PMN310

PMN310 is a humanized monoclonal antibody (mAb) designed and developed based on its selectivity for soluble amyloid-beta oligomers (AβOs), which are believed to be the most toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. Soluble AβOs have been observed to be potent neurotoxins that bind to neurons, impair synaptic function and induce neurodegeneration. By selectively targeting toxic soluble AβOs, PMN310 aims to directly address the growing body of evidence indicating they may be the primary underlying cause of the neurodegenerative process in Alzheimer's disease. PMN310 has successfully completed a Phase 1a clinical study (NCT06105528), a double-blind, placebo-controlled, single ascending dose study of the safety, tolerability and pharmacokinetics of PMN310 infusions in healthy volunteers.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences Inc. is a clinical stage biotechnology company focused on generating and developing antibody therapeutics selectively targeting toxic misfolded proteins in neurodegenerative diseases such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and multiple system atrophy (MSA). The Company's proprietary target discovery engine applies a thermodynamic, computational discovery platform - ProMIS™ and Collective Coordinates - to predict novel targets known as Disease Specific Epitopes on the molecular surface of misfolded proteins. PMN310, the Company's lead product candidate for the treatment of AD, is a differentiated, humanized monoclonal antibody that has been designed to specifically bind toxic Aβ oligomers and to not bind plaque or monomers. Oligomers are known to drive disease progression in AD and PMN310 appears to selectively bind oligomers. PMN 310 has successfully completed a Phase 1a clinical study and is dosing Alzheimer's disease patients in a Phase 1b clinical trial in AD patients. ProMIS has offices in Cambridge, Massachusetts and Toronto, Ontario.

Forward-Looking Statements

Nasdaq has not reviewed and does not accept responsibility for the adequacy or accuracy of this release. 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”, “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, including enrollment and dosing for its Phase 1b clinical trial, and planned timing for completion and anticipated data readout of interim and full results from the Phase 1b clinical trial in AD patients, the potential for such studies to provide the first proof-of-concept data for PMN310, the potential that PMN310 has the potential 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 oligomers of Aβ are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, a computationally-derived Aβ vaccine for AD and the Company’s PMN310 antibody and vaccine candidate and management’s belief that its patented platform technology has created an antibody candidate specific to toxic misfolded oligomers known to be present in AD, therapeutic activity and preferential targeting of toxic soluble aggregates by Aß-directed antibodies and the potential implications thereof. 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 preclinical results or early results may not be indicative of future results, 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, 2023 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.

For further information:

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