

October 30, 2024



ProMIS Neurosciences Presents Positive Data from PMN310 Phase 1a Clinical Trial at the 17th Clinical Trials on Alzheimer's Disease Conference

Results indicated PMN310 was generally well-tolerated and monthly dosing can provide CSF levels adequate for target engagement

Initiation of Phase 1b clinical trial in Alzheimer's disease patients planned for year-end 2024

CAMBRIDGE, Massachusetts and TORONTO, Ontario, Oct. 30, 2024 (GLOBE NEWSWIRE) -- ProMIS Neurosciences Inc. (Nasdaq: PMN), a 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 presented positive results from all five cohorts from the Phase 1a, single ascending dose clinical trial of its lead product candidate, PMN310, at the 17th Clinical Trials on Alzheimer's Disease (CTAD) Conference taking place from October 29 – November 1, 2024 in Madrid, Spain.

PMN310 is an investigational humanized monoclonal antibody (mAb) designed and developed to selectively target soluble amyloid beta oligomers (A β Os), which ProMIS believes to be the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques.

The Phase 1a clinical trial was a randomized, double-blind, placebo-controlled study evaluating the safety, tolerability and pharmacokinetics of PMN310 in 40 healthy volunteers in the United States ([NCT06105528](#)). PMN310 was generally well-tolerated in all five single-ascending dose cohorts (2.5, 5, 10, 20 and 40 mg/kg) of the Phase 1a clinical trial and, importantly, crossed the blood brain barrier in healthy volunteers in a dose dependent manner with pharmacokinetics suggesting that monthly dosing may provide levels of PMN310 adequate for target engagement in AD patients. The complete dataset from all five cohorts reinforces previously reported data from the first four cohorts of the Phase 1a trial announced in July 2024 found [here](#).

"We are pleased to present additional results from our first-in-human Phase 1a clinical trial of PMN310 that demonstrated PMN310 was generally well tolerated and achieved concentrations in the cerebrospinal fluid indicating its potential for target engagement in AD patients," said Larry Altstiel, M.D., Ph.D., Chief Medical Officer of ProMIS Neurosciences. "Importantly, these results have confirmed the dosing levels for our planned 12-month, multiple ascending dose Phase 1b clinical trial in 100 patients with mild cognitive impairment due to AD and early AD, which we plan to initiate by year-end 2024. This is a significant

milestone for ProMIS, and we were pleased to share our progress at this at this year's CTAD Conference."

Details of the poster presentation are as follows:

Title: Phase 1a Single Ascending Dose Study of PMN310, a monoclonal antibody directed against toxic A β oligomers

Date/Time of Presentation: Wednesday, October 30 at 3:00pm – 5:00 CET

Authors: Larry Altstiel, Johanne Kaplan, Ebrima Gibbs, Misty Lamendola, Wendy Luca, Gavin Malenfant, Mark Maginn, Yanyan Han, Neil Cashman

The abstract presentation is available on the Posters and Publications page of the Company's website at www.promisneurosciences.com.

PMN310 builds on a large body of scientific evidence that points to the role of soluble amyloid-beta oligomers (A β O) as a primary driver of Alzheimer's disease pathology. By selectively targeting toxic oligomers, ProMIS seeks to expand therapeutic options beyond those treatments that target amyloid plaques, which it believes could provide a differentiated treatment for AD patients.

Initiation of the PMN310 Phase 1b study is planned for the fourth quarter of 2024.

About the Phase 1a Clinical Trial

The Phase 1a clinical trial was a randomized, double-blind, placebo-controlled study in 40 healthy volunteers in the United States ([NCT06105528](https://clinicaltrials.gov/ct2/show/study/NCT06105528)). The study consisted of five single ascending dose (SAD) cohorts and was designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of intravenous doses of PMN310. The five dosing cohorts were 2.5, 5, 10, 20 and 40 mg/kg. The decision to escalate dosing was made by a data safety monitoring board based on analysis of safety data. Serum PMN310 concentrations were collected before, and at the end of the infusion and at 0.5, 1, 2, 4, 8, 12, 24, 36, 72, 192 hours and approximately biweekly after infusion. CSF collection was done at day 3 and day 29 after dosing to determine CSF concentration of PMN310. For more information on the Phase 1a, Double-Blind, Placebo-Controlled, Single Ascending Dose Study of the Safety, Tolerability and Pharmacokinetics of PMN310 Infusions in Healthy Volunteers study ([NCT06105528](https://clinicaltrials.gov/ct2/show/study/NCT06105528)), please visit www.clinicaltrials.gov.

About PMN310

PMN310 is a humanized monoclonal antibody (mAb) designed and developed based on its selectivity for soluble amyloid beta oligomers (A β Os), which ProMIS believes are the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaque. Soluble A β Os have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β Os, PMN310 aims to directly address the growing body of evidence suggesting that they represent a primary underlying cause of the neurodegenerative process in Alzheimer's disease.

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. Using this unique approach, the Company is developing novel antibody therapeutics for AD, ALS and MSA. ProMIS has offices in Cambridge, Massachusetts and Toronto, Ontario.

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", "excited to", "targets", "expects" or "does not expect", "is expected", "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 results from its Phase 1a study and the potential implications thereof, the Company's expectations regarding its clinical development of its lead product candidate, PMN310, for AD, the Company's plans to advance into a Phase 1b multiple ascending dose study in AD patients in the fourth quarter of 2024, statements relating to the potential for such studies to provide the first proof-of-concept data for PMN310, and the potential that PMN310 has the potential to positively benefit patients with AD, 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 A β 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 the results of nonclinical studies and early clinical trials are not necessarily predictive of future results with PMN310, 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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