July 29, 2025



# ProMIS Neurosciences to Showcase Protein-Misfolding Drug Discovery Platform & PRECISE-AD Trial Design at the 2025 Alzheimer's Association International Conference

Presentation to highlight the Company's proprietary protein-misfolding platform, EpiSelect<sup>TM</sup>, used to develop PMN310

Posters highlighting PRECISE-AD, the Company's Phase 1b clinical trial design and optimization of biomarkers in AD

Progress with trial enrollment following DSMB recommendation to proceed to second dose level

CAMBRIDGE, Massachusetts , July 29, 2025 (GLOBE NEWSWIRE) -- ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company committed to the discovery and development of therapeutic antibodies selective for toxic oligomers associated with the development and progression of neurodegenerative diseases such as Alzheimer's Disease (AD), amyotrophic lateral sclerosis (ALS) and Parkinson's disease (PD), today announced it has been invited to present an overview of its ongoing PRECISE-AD trial in Alzheimer's Disease (AD) and its proprietary Discovery Platform, *EpiSelect<sup>TM</sup>*, at the Alzheimer's Association International Conference 2025 (AAIC) taking place in Toronto, Canada from July 27-31, 2025.

"We are pleased to share further details of our ongoing Phase 1b PRECISE-AD clinical trial evaluating PMN310, our novel therapeutic candidate for Alzheimer's disease," said Dr. Larry Altstiel, M.D., Ph.D., Chief Medical Officer of ProMIS Neurosciences. "PRECISE-AD was intentionally designed with a robust framework to assess both the safety and potential signs of efficacy of PMN310. PMN310 is designed to selectively target toxic amyloid-beta oligomers, which are considered a primary driver of Alzheimer's disease, while aiming to reduce the risk of safety issues observed with other therapies. We were encouraged by the recent recommendation from the independent Data and Safety Monitoring Board (DSMB) to proceed to the second dose level, and we have been enrolling patients swiftly into this second cohort."

"As of this week, more than 50% of the approximately 128 patients planned for the study have been enrolled, reflecting the pace of our clinical progress and the urgent need for new treatment options. To date, we have not observed any cases of amyloid-related imaging abnormalities (ARIA), including brain swelling or microhemorrhages. In addition, the U.S.

Food and Drug Administration (FDA) recently granted Fast Track designation to PMN310, which we believe recognizes the potential of this program to address an unmet medical need in Alzheimer's disease. We anticipate reporting six-month interim data from the study in the second quarter of 2026, with topline results expected by the fourth quarter of 2026," added Dr. Altstiel.

"The rapid enrollment in PRECISE-AD is a testament to the urgent need to bring new breakthroughs in treatment to Alzheimer's patients and providers," Dr. David Watson, Chief Executive and Founder of the Alzheimer's Research and Treatment Center and one of the treating physicians in the PRECISE-AD trial stated. "I am encouraged by the mechanism of ProMIS's PMN310, which has been designed to specifically target toxic A $\beta$  oligomers, and has the potential to provide a more favorable product profile and significantly improve the quality of life of AD patients."

"Additionally, we are pleased to have been invited to share data supporting the design process and validation of our proprietary target discovery engine, EpiSelect<sup>TM</sup>, which utilizes advanced computational discovery technologies to identify and target toxic misfolded proteins implicated in neurodegenerative and other misfolded protein diseases," said Neil Cashman, M.D., Chief Scientific Officer and Co-founder, ProMIS Neurosciences. "This precision targeting approach has enabled us to design novel therapeutic antibodies with a high degree of selectivity for the key underlying drivers of these conditions."

## **Presentation details**

**Title:** Protein misfolding-specific epitope identification for passive and active immunotherapy of neurodegenerative diseases

**Presenter:** Neil Cashman, M.D., Chief Scientific Officer and Co-founder, ProMIS Neurosciences

**Session:** Featured Research Session: Advancing Translational Success by Enhancing Predictive Validity in Neurodegenerative Diseases, Thursday, July 31, 2025: 10:00am – 11:30am Eastern Time

# Abstract Number: 98670

Title: PRECISE-AD, A Phase 1b, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of PMN310 in Patients with Early Alzheimer's Disease **Presenter:** Larry Altstiel, M.D., Ph.D., Chief Medical Officer, ProMIS Neurosciences **Session:** In Person Poster: Drug Development: Human, Wednesday, July 30, 2025: 7:30am – 4:15pm Eastern Time **Poster Number:** 103159

**Title:** Leveraging recent advances in biomarkers to optimize early phase drug development in Alzheimer's Disease

**Joint Presenter:** Garret Duncan, Statistician, Pentara Corporation and Johanne Kaplan, Ph.D., Chief Development Officer, ProMIS Neurosciences

**Session:** In Person Poster: Biomarkers: Biomarkers (non-neuroimaging), Monday, July 28, 2025: 7:30am – 4:15pm Eastern Time

Poster Number: 103841

Abstracts will be available on the Poster and Publications page of the Company's website

at <u>www.promisneurosciences.com</u> following the presentations.

## About PMN310 and the PRECISE-AD Clinical Trial

PMN310, the Company's lead product candidate for the treatment of AD, is a humanized monoclonal antibody that has been designed to be differentiated in its ability to selectively target only the toxic oligomers, avoiding plaque, thereby potentially reducing or eliminating 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.

Based on the encouraging results from the Phase 1a trial <u>NCT06105528</u>) of PMN310, ProMIS initiated PRECISE-AD, a Phase 1b clinical trial in AD patients. PRECISE-AD (<u>NCT06750432</u>) 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 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 A $\beta$ O 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.

### About ProMIS Neurosciences Inc.

ProMIS Neurosciences is a clinical-stage biotechnology company committed to the discovery and development of therapeutic antibodies 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<sup>™</sup>, predicts 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).

### **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 planned timing for completion and anticipated data readout of interim and full results in the second and fourth quarters of 2026, repsectively, 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 oligomers of AB are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity and the Company's expectations regarding the benefits of Fast Track Designation and management's belief that its proprietary target discovery engine can predict and identify toxic misfolded proteins implicated in the development and progression of neurodegenerative and other misfolded protein diseases. Statements containing forwardlooking 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 enrollment may not continue at the current rate, that clinical results or early results may not be indicative of future results, the Company's ability to retain and recognize the incentives conferred by Fast Track Designation for 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, 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.

For further information:

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