July 21, 2025

ProMIS Neurosciences Granted Fast Track Designation by U.S. FDA for PMN310 in the Treatment of Alzheimer's Disease

FDA designation highlights the potential of PMN310 to deliver a more targeted approach to treating Alzheimer's Disease

CAMBRIDGE, Mass., July 21, 2025 (GLOBE NEWSWIRE) -- ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company committed to the discovery and development of therapeutic antibodies targeting toxic misfolded proteins in neurodegenerative diseases, such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and Parkinson's disease (PD), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to PMN310, the Company's lead therapeutic candidate in development for the treatment of Alzheimer's disease (AD).

The FDA Fast Track program is intended to accelerate the development of therapies that aim to address serious conditions and fill an unmet medical need. This designation enables enhanced engagement with the FDA, opening the door to a potentially more efficient path to approval for PMN310.

"This is a pivotal moment for ProMIS and the Alzheimer's community, as receiving Fast Track designation not only underscores the potential of PMN310 to address a critical unmet need, but also provides valuable opportunities for regulatory insight as we advance toward key clinical milestones," said Neil Warma, President and Chief Executive Officer of ProMIS Neurosciences. "We designed PMN310 with a goal of providing Alzheimer's patients with a safer and more efficacious treatment option, which we believe represents the next generation of Alzheimer's therapeutics. By selectively targeting only the most harmful, toxic forms of amyloid-beta, we believe PMN310 has the potential to reduce the serious side effects seen with current Alzheimer's treatments, namely brain swelling and bleeding known as ARIA, while also delivering improved therapeutic benefit to patients."

The ongoing PRECISE-AD Phase 1b trial is evaluating PMN310 in patients with early AD. The study is focused on characterizing safety, tolerability, pharmacokinetics, and disease-relevant biomarkers. ProMIS anticipates reporting interim six-month biomarker and safety data in Q2 '26 and final results in Q4 '26.

AD affects more than 6 million people in the U.S. and remains a leading cause of death and disability among older adults. Despite progress in the field, the need for safer, more targeted treatment options remains urgent.

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 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 (NCT06105528) of PMN310, ProMIS initiated PRECISE-AD, a Phase 1b clinical trial in AD patients. PRECISE-AD (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 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 AβO 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™, 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, 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 and the Company's expectations regarding the benefits of Fast Track Designation. 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 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:

Visit us at www.promisneurosciences.com

Please submit media inquiries to info@promisneurosciences.com

For Investor Relations, please contact:
Kaytee Bock Zafereo
katherine.bock@promisneurosciences.com

Source: ProMIS Neurosciences Inc.