November 20, 2023

ProMIS Neurosciences Doses First Subjects in Phase 1a Clinical Trial of PMN310 to Treat Alzheimer's Disease

Advances novel monoclonal antibody designed to be highly selective for toxic oligomers of amyloid-beta (Aβ) in first-in-human study

TORONTO, Ontario and CAMBRIDGE, Massachusetts, Nov. 20, 2023 (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 announced that the Company dosed the first subjects in a first-in-human Phase 1a clinical trial of PMN310 as a potential treatment for Alzheimer's disease (AD). PMN310 is the Company's novel monoclonal antibody that is designed to be highly selective for toxic oligomers of amyloid-beta (Aβ), which are believed to be a major driver of AD.

"Initiation of this milestone study of PMN310 marks our transition to a clinical stage company. We are excited to bring our precision medicine approach into the clinic in hopes of developing better therapeutics for neurodegenerative diseases," said Gail Farfel, Ph.D., Chief Executive Officer of ProMIS Neurosciences. "During the third quarter, we raised more than $20 million through a private placement financing, which meaningfully strengthens our balance sheet and supports ProMIS through potentially value-creating milestones."

"In this Phase 1a clinical trial, we will enroll up to five cohorts of eight adult healthy volunteers, each receiving a single dose of PMN310. We expect to have initial safety and pharmacokinetic (PK) data to share in the first half of 2024. We remain committed to investigating our hypothesis that selective targeting of toxic Aβ oligomers while avoiding monomer distraction and plaque binding will potentially provide differentiation on both safety and efficacy in AD treatment response."

"Results from the Phase 1a study will facilitate dose selection for subsequent Phase 1b study in patients with Mild Cognitive Impairment (MCI) due to AD and patients with mild AD. This study will leverage recent results from a third-party clinical study, which demonstrated that plasma and cerebrospinal fluid (CSF) efficacy biomarkers can show a treatment response in as little as three months with oligomer-focused therapy. In addition, our Phase 1b study will provide important insights into the safety profile of PMN310, which we anticipate may differentiate PMN310 from other available and potentially disease-modifying treatments."

About the Phase 1a Clinical Trial

The study titled, “A Phase 1a, Double-Blind, Placebo-Controlled, Single Ascending Dose Study of the Safety, Tolerability and Pharmacokinetics of PMN310 Infusions in Healthy Volunteers,” is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and PK of single ascending doses of intravenous PMN310 in healthy adult volunteers. Eligible subjects will participate in the 85-day study with one optional follow up assessment at Day 120. Primary PK data will be obtained from day 1 to day 29.

More information about the Phase 1 clinical trial can be found atwww.clinicaltrials.gov or click here.

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 Toronto, Ontario and Cambridge, Massachusetts.

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 planned timing for completion and anticipated data readout of the Phase 1a clinical trial and the anticipated use of proceeds from the private placement. 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 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 information form available on www.SEDAR.com, in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2022 and the section entitled "Risk Factors" in its Post-Effective Amendment No. 1 to Form S-1, filed March 17, 2023, each as filed with the Securities and Exchange Commission, and subsequent quarterly reports. 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:
Stern Investor Relations
Anne Marie Field, Managing Director
annemarie.fields@sternir.com
Tel. 212-362-1200

Source: ProMIS Neurosciences Inc.