May 8, 2023

ProMIS Neurosciences Announces FDA Clearance of Investigational New Drug (IND) Application for PMN310 in Alzheimer's Disease

TORONTO, Ontario and CAMBRIDGE, Massachusetts, May 08, 2023 (GLOBE NEWSWIRE) --

- *In preclinical studies, PMN310 demonstrated the ability to selectively target and protect against pathogenic Aβ oligomers*
- *The IND clearance of PMN310 in the Alzheimer's disease indication paves the way for initiation of clinical evaluation*

ProMIS Neurosciences Inc. (TSX: PMN) (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 it has received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for PMN310 for the treatment of AD. PMN310 is a novel monoclonal antibody which is designed to be highly selective for toxic oligomers of amyloid-beta (Aβ) that are believed to be a major driver of AD.

"Receiving IND clearance for PMN310 marks an important corporate milestone as we continue towards our goal of delivering next-generation therapy to patients with Alzheimer's disease who have limited options to slow cognitive decline," said Gail Farfel, Ph.D., Chief Executive Officer of ProMIS Neurosciences. "Our preclinical data demonstrated PMN310's greater selective binding to toxic oligomers compared to other Aβ-directed antibodies, which we believe supports the potential clinical profile of PMN310. We look forward to advancing PMN310 into clinical development and sharing what we learn from this innovative work."

In preclinical studies, PMN310 showed strong *ex vivo* target engagement of toxic oligomers in brain samples from patients with AD, with little or no diversion by Aβ monomers or plaque. In a recent presentation of *in vitro* data at the AD/PD 2023 conference, PMN310 was the least impacted by monomer competition, compared to other Aβ-directed antibodies, resulting in an overall greater ability to target toxic oligomers. In addition, PMN310 was not observed to bind to plaque, potentially reducing the risk of Aβ-related imaging abnormalities (ARIA) observed with plaque-binding antibodies. The Company believes these data support a potentially differentiated clinical profile when compared to other antibody therapeutic candidates in AD.

With the IND clearance for PMN310, the Company plans to initiate a Phase 1a clinical trial

designed to evaluate the pharmacokinetics, safety and tolerability of a range of PMN310 doses in healthy adult volunteers.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences Inc. is a development 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 is based on the use of two complementary techniques. The Company applies its 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. ProMIS is listed on Nasdaq and the Toronto Stock Exchange under the symbol PMN.

Forward-Looking Statements

Neither the TSX nor Nasdaq has reviewed and neither accepts 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", "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 targeting of toxic misfolded proteins that the Company believes may directly address fundamental AD pathology (including the belief and understanding that toxic oligomers of amyloid-beta are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, the initiation of the Company's first-in-human study, and its ability to enroll the requisite number of patients, dose each patient in the intended manner and progress the study, statements related to the presentation of data and the significance of such data, ProMIS' pipeline, management's belief that its patented platform technology has created an antibody candidate specific to toxic misfolded oligomers known to be present in Alzheimer's disease, and management's belief that this specificity may indicate greater therapeutic potential due to lower 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 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. 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
Suzanne Messere, Managing Director
suzanne.messere@sternir.com
Tel. 212 698-8801

Source: ProMIS Neurosciences Inc.