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ProMIS Neurosciences Announces Successful Humanization of Lead Product Candidate PMN310 for Alzheimer's Disease

Clinical trials evaluating PMN310 expected to initiate in 2019

TSX: PMN

TORONTO and CAMBRIDGE, MA, Sept. 19, 2017 /PRNewswire/ - ProMIS Neurosciences, Inc., a company focused on discovery and development of precision treatments for neurodegenerative diseases, today announced the successful humanization of its lead product candidate for Alzheimer's disease (AD), PMN310, a monoclonal antibody (mAb) targeting toxic prion-like forms of amyloid-beta oligomers (A β O).



"We have now completed a significant development milestone by producing a humanized version of PMN310 and, in the process, achieving a ten-fold increase in binding affinity for its conformational target on toxic A β O," stated Neil Cashman, MD, ProMIS' Chief Scientific Officer. "This increased affinity of PMN310, along with its selective targeting of prion-like forms of A β O, continues to support the development of PMN310 as a potentially impactful treatment for Alzheimer's disease."

ProMIS now plans to initiate cell line development of humanized PMN310 at a specialized contract research organization (CRO). Cell line development is the first critical step in the highly regulated manufacture of biologic therapeutics, including mAbs. Following successful cell line development, final manufacturing process and scale up will take place at a specialized contract manufacturing organization (CMO).

Commenting on today's announcement, Eugene Williams, ProMIS Executive Chairman, stated: "We look forward to continued progress with our Alzheimer's portfolio, targeting availability of clinical grade humanized PMN310 for evaluation in clinical trials planned to

start in 2019. In addition, we are also initiating several comparative preclinical evaluations of our lead product candidate, PMN310, against other clinical-stage antibodies to demonstrate a potential best in class profile with respect to safety and efficacy in Alzheimer's."

About PMN310.

PMN310 was designated ProMIS' first lead product candidate in January 2017, based on its ability to selectively bind prion-like forms of Amyloid beta oligomers (A β O), a recognized root cause of Alzheimer's disease (AD). PMN310 displays an optimal binding profile, as it does not bind to amyloid beta monomer or plaque. Recent experimental and clinical evidence indicates that soluble toxic A β O, propagating in a prion-like manner, but not plaque or amyloid beta monomer, are actually the primary drivers of neurodegeneration and cognitive decline in AD patients. Accordingly, prior clinical trials of products targeting monomer, and/or plaque, have either failed (monomer targeting) or shown dose limiting side effects, in particular neurovascular edema, or brain swelling (plaque targeting).

Subsequent to PMN310, two other ProMIS monoclonal antibodies (mAbs) for AD, PMN350 and PMN330 each directed against different targets on toxic A β O, were designated lead development candidates this year, as they also display the optimal, selective target product profile in both in vitro and in vivo tests.

The ProMIS mAbs for AD have all been created in the mouse (murine mAbs). Hence, humanization of the original murine mAbs is required for use as human therapeutics so that the product is not rejected as foreign by the patient. Humanization (also called CDR-grafting) is now a well-established technique for reducing the immunogenicity (rejection potential) of therapeutic mAbs from non-human sources, such as the mouse. Humanization can lead to no change, an increase or decrease in binding affinity of the mAb on a case by case basis. In the case of PMN310, humanization has led to a ten-fold increase in the product candidate's affinity (ability to bind and to stay bound to its target), thereby adding to its attractiveness as a lead product candidate for therapeutic development in AD.

Finally, ProMIS continues to focus on a precision medicine approach to AD. In this respect, the company is evaluating the binding profiles of each of the PMN series mAbs in several AD and non-AD brains, and comparing these to the binding profiles of other Ab antibodies either currently in development, or used in prior clinical trials. The company is also developing highly specific and sensitive assays to detect targets on toxic A β O in a cohort study of cerebrospinal fluid (CSF) from AD patients. The purpose of these two approaches is to assess population coverage as well as determine which of the PMN mAbs is the best therapeutic candidate for individual AD patients, thereby supporting a precision medicine approach to AD therapy.

About ProMIS Neurosciences, Inc.

ProMIS Neurosciences is a Toronto Stock Exchange (TSX) listed biotech company (trading symbol: PMN.TO), headquartered in Toronto, Ontario and with offices in Cambridge, Massachusetts. The mission of ProMIS is to discover and develop precision medicine therapeutics for effective treatment of neurodegenerative diseases, in particular Alzheimer's disease and ALS.

ProMIS Neurosciences' 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 (DSEs) on the molecular surface of misfolded proteins. Using this unique "precision medicine" approach, ProMIS Neurosciences is developing novel antibody therapeutics and specific companion diagnostics for Alzheimer's disease and ALS. In addition, ProMIS Neurosciences owns a portfolio of therapeutic and diagnostic patents relating to misfolded SOD1 in ALS, and currently has a preclinical monoclonal antibody therapeutic against this target.

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