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ProMIS Neurosciences Initiates Natural History Study of Blood-Based Biomarkers in Alzheimer's Disease

Biomarkers offer opportunity to make go/no-go decisions for investigational therapies as early as Phase 1

TORONTO and CAMBRIDGE, Mass., Feb. 26, 2020 (GLOBE NEWSWIRE) -- ProMIS Neurosciences, Inc. (TSX: PMN) (OTCQB: ARFXF), with Toronto Memory Program, Canada's largest and most experienced memory clinic and site for drug treatment trials in Alzheimer's disease (AD) has initiated a pilot longitudinal study to assess the level of blood-based biomarkers in early AD with the support of Parexel, one of the world's leading global clinical research organizations (CROs). ProMIS will leverage Parexel's significant data management and central nervous system (CNS) expertise for the study, which it will use as the historical control arm for its anticipated Phase 1 study of PMN310, a novel antibody that selectively targets the toxic oligomeric species of amyloid beta, a root cause of AD. The dataset will help ProMIS detect a treatment signal as early as Phase 1, potentially allowing for rapid proof-of-concept at a fraction of the expense associated with traditional clinical trials. The dataset will be made available as a communal resource for Alzheimer's researchers.

"Alzheimer's patients and their families have endured far too many late-stage therapy failures," said Sharon Cohen, MD, FRCPC, Medical Director of Toronto Memory Program and Principal Investigator of the study. "A new generation of blood-based biomarkers offers researchers the opportunity to measure treatment success much earlier than with traditional methods. As both a clinician and researcher, being able to detect a treatment signal in Phase 1 allows me to proceed with confidence knowing I'm focused on a validated therapy candidate with credible potential for success with my patients."

Parexel will support ProMIS on the assimilation and management of this large data set, aimed at helping the industry derive important insights to drive the development of future therapies.

"As a truly patient-focused CRO, it's an incredibly exciting time to be involved in Alzheimer's disease therapy research as we await FDA's decision regarding the first disease-modifying therapy, aducanumab," shared Sy Pretorius, MD, Executive Vice President and Chief Medical and Scientific Officer, Parexel. "Harnessing the power of biomarker data holds great potential in helping to reach the next generation of innovation with the ultimate goal of bringing more therapies to market for Alzheimer's patients, their caregivers and their families."

“The U.S. Food and Drug Administration (FDA) has indicated it will accelerate approval of potential Alzheimer’s disease therapies if researchers can demonstrate meaningful biomarker changes,” said James Kupiec, MD, Chief Medical Officer for ProMIS Neurosciences, the study sponsor. “The Alzheimer’s research community has desperately needed a reliable, reproducible way to measure a drug’s effectiveness earlier than Phase 2 or 3 at which time so much money, patient hardship and time have been expended. The expected dataset could help facilitate the detection of a meaningful signal as early as Phase 1. This is really critical as it may enable us to advance only the best candidates with the highest potential for success. We look forward to using these data to advance PMN310 quickly. In addition, we will offer the biomarker dataset to the research community to help advance additional therapies.”

Several highly sensitive biomarkers are currently in development that could measure neuronal injury more accurately and/or more conveniently than current standards. Significantly, this new generation of blood-based biomarkers may afford drug developers a convenient means to measure the effectiveness of potential disease-modifying therapies as early as Phase 1, sparing patients, investors and researchers the time, expense and anguish associated with late-stage clinical trial failures.

Toronto Memory Program will lead this non-interventional natural history study which will measure the concentrations of neurofilament light chain (NfL) and other blood-based biomarkers on a monthly basis for a period of six months in AD patients with early stage disease. Designed to support multiple centers and up to 100 patients, the study will evaluate the plasma concentration of these biomarkers over the course of the study as well as visit-to-visit variability. The monthly data collection mirrors the design of a Phase 1 interventional trial where monthly blood draws to evaluate plasma biomarker levels coincide with monthly treatments/infusions.

The depth of the biomarker data from the natural history study will offer a powerful historical reference group with multiple monthly data points per patient.

About ProMIS Neurosciences

ProMIS Neurosciences, Inc. is a development stage biotechnology company focused on discovering and developing antibody therapeutics selectively targeting toxic oligomers implicated in the development and progression of neurodegenerative diseases, in particular Alzheimer’s disease (AD), amyotrophic lateral sclerosis (ALS) and Parkinson’s disease (PD). The Company’s proprietary target discovery platform is based on the use of two complementary thermodynamic, computational discovery engines – ProMIS and Collective Coordinates – to predict novel targets known as Disease Specific Epitopes on the molecular surface of misfolded proteins. Using this unique precision approach, the Company is developing novel antibody therapeutics for AD, ALS and PD. ProMIS is headquartered in Toronto, Ontario, with offices in Cambridge, Massachusetts. ProMIS is listed on the Toronto Stock Exchange under the symbol PMN, and on the OTCQB Venture Market under the symbol ARFXF.

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Source: ProMIS Neurosciences Inc.