PreCyte and CIDR Announce $3M SBIR Phase IIB Funding for the Further Development of the Indicator Cell Assay Platform (iCAP) for Early Detection of Alzheimer's Disease

PreCyte, Inc. a developer of innovative diagnostic tests for neurodegenerative and cancer, and the Center for Infectious Disease Research (CIDR) announced today that the National Institute on Aging (NIA) of the National Institutes of Health (NIH) has awarded PreCyte a Small Business Innovation Research (SBIR) Phase IIB grant to support further optimization, validation and development of the Indicator Cell Assay Platform (iCAP) for blood-based diagnosis of pre-symptomatic Alzheimer's disease and mild cognitive impairment (MCI) due to Alzheimer's disease. The award will provide PreCyte with approximately $3M over three years.

September 13, 2018 (SEATTLE, WA) – PreCyte, Inc. a developer of innovative diagnostic tests for neurodegenerative and cancer, and the Center for Infectious Disease Research (CIDR) announced today that the National Institute on Aging (NIA) of the National Institutes of Health (NIH) has awarded PreCyte a Small Business Innovation Research (SBIR) Phase IIB grant to support further optimization, validation and development of the Indicator Cell Assay Platform (iCAP) for blood-based diagnosis of pre-symptomatic Alzheimer's disease and mild cognitive impairment (MCI) due to Alzheimer's disease. The award will provide PreCyte with approximately $3M over three years. In preliminary studies supported by the NIA of the NIH, PreCyte demonstrated 69% sensitivity and 91% specificity by blind independent validation, distinguishing preclinical and early symptomatic AD samples from normal controls (maximum performance on 27 independent samples from two cohorts, p-value 6.5E-3). The present award will support development of the assay for the initial application in clinical trials support. The analysis will be conducted in collaboration with CIDR and leading academic centers. PreCyte has an exclusive license for the iCAP technology from the Institute for Systems Biology (ISB), a world-renowned center for systems biology in Seattle.

"Development of an effective treatment for Alzheimer's has been challenging, but recent evidence suggests approaches targeting preclinical and early symptomatic stages of Alzheimer's disease are very promising. There is great clinical need for minimally invasive and in-expensive tests like the iCAP for detection at these early stages." said Robert Lipshutz, PhD, CEO of PreCyte. "We greatly appreciate the funding of the NIH to support our collaboration with key opinion leaders in the field and the development of our first test for early detection of Alzheimer's disease. We further look forward to our continued collaboration with CIDR and other leading clinical centers."

"We are very enthusiastic about developing the iCAP for clinical trial support. We feel that the assay can significantly reduce cost and shorten the duration of clinical trials for Alzheimer's disease treatments by rapidly selecting subjects at pre-symptomatic or early symptomatic stages." said Jennifer Smith, PhD, CSO of PreCyte. "A strength of the iCAP is the unique multicomponent readout for each subject, which we have found may be useful for staging disease. We are hopeful that it will eventually be used as a clinical endpoint for trials, and to select subclasses of patients responsive to certain treatments."

"This is a very exciting collaboration. We look forward to continuing to work with PreCyte and hope to make a significant impact in the treatment Alzheimer's and other diseases", said John Aitchison, president, CIDR.

About iCAP
The indicator cell assay platform (iCAP) is analogous to the early pregnancy test in which, without knowing what to look for, the patient's blood or urine was injected into a rabbit and readout was the response of the rabbit's ovaries to the sample. In the iCAP, patient serum is applied to specifically selected standardized indicator cells and the response of the cells provides the readout. The indicator cell assay exploits cells' natural capability to amplify and integrate multi-analyte signals. The assay has been demonstrated to be 94% accurate for the detection of ALS in a murine model.

About PreCyte
PreCyte is a privately held molecular diagnostics company focused on developing minimally invasive tests for the early detection and monitoring of neurodegenerative disease and cancer. http://www.precyte.net

About CIDR
CIDR is a non-profit biomedical research institute founded in 1976 and focused on global health and infectious disease. Since 2012 and under the direction of current president, John Aitchison, the organization specializes in applying and developing systems biology approaches to infectious disease. They are committed to impacting human health through innovation and a global perspective of disease mechanisms. Since 1976, CIDR has grown to a staff of about 250, which includes 13 faculty members and laboratory groups.

Please Note: This news release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the results, timing, costs and regulatory review of our studies and clinical trials; the results of studies of our product candidates conducted by others; our ability to obtain future funding on acceptable terms; our ability to obtain regulatory approval of our product candidates; the possible impairment of, or inability to obtain, intellectual property rights; and innovation by our competitors. The content is solely the responsibility of the company and does not necessarily represent the official views of the National Institutes of Health.

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