RenalytixAI Initiates Clinical Validation Study of AI-Enabled KidneyIntelX™ for Diagnosing Fast-Progressing Kidney Disease

January 23, 2019

Validation study to assess approximately 5,000 patients with participation from a multi-center group of leading U.S. investigators

NEW YORK, Jan. 23, 2019 /PRNewswire/ -- Renalytix AI plc (LON: RENX), a developer of artificial intelligence-enabled diagnostics for kidney disease, today announced the start of its clinical validation study for its lead diagnostic, *KidneyIntelX*™. *KidneyIntelX* is designed to diagnose and improve clinical management of patients with Type II diabetes and those of African ancestry with fast-progressing kidney disease in an effort to curtail the estimated $114 billion cost[1] of chronic and end-stage kidney disease to the United States healthcare system. As outlined at the time of IPO, RenalytixAI expects to commercially launch *KidneyIntelX* as a laboratory developed test in its CLIA[2] laboratory facilities to health systems and drug developers in H2 2019.

The expanded validation study program now includes leading investigators from Johns Hopkins Medicine, Emory University, the Icahn School of Medicine at Mount Sinai, Northwestern University, Harvard University, and Brigham and Women's Hospital. *KidneyIntelX* will use machine learning algorithms to assess the combination of predictive blood-based biomarkers, including sTNFR1, sTNFR2, and KIM1, in combination with electronic health record information.

"The scale and clinical breadth of this validation provides a rare opportunity to evaluate how AI can aid our ability to detect fast-progressing kidney disease. *KidneyIntelX* will give doctors a powerful tool to identify which individuals with kidney disease are likely to progress to end-stage disease and should be treated more aggressively," said Dr. Michael J. Donovan, Professor of Pathology, Icahn School of Medicine at Mount Sinai, and Chief Medical Officer of RenalytixAI.

"*KidneyIntelX* leverages three proven blood biomarkers validated in dozens of previous studies algorithmically combined with features from large electronic health record databases to identify progressive kidney disease. This approach can greatly improve the identification of patients at highest need of aggressive clinical intervention at any stage to slow or prevent progression to kidney failure," said Dr. Barbara Murphy, Dean for Clinical Integration and Population Health, and Murray M. Rosenberg Professor and Chair, Samuel Bronfman Department of Medicine, Icahn School of Medicine at Mount Sinai, and Chair of the Scientific Advisory Board of RenalytixAI.

Identification of patients with chronic kidney disease (CKD) who are at risk of, or are experiencing, rapid kidney function decline is challenging. However, the *KidneyIntelX* test will significantly improve the identification of these patients in the early stages of CKD, thereby improving care and outcomes for these patients through early initiation or escalation of treatment strategies.

The clinical validation will assess approximately 5,000 patient blood samples and electronic health records sourced from a multi-center collaboration including Emory University and Mount Sinai. Participating investigators include: Dr. Arshed Quyyumi, Director of the Emory Clinical Cardiovascular Research Institute; Dr. Chirag Parikh[3], Director of Nephrology at Johns Hopkins; Dr. Joseph Bonventre, Director of Nephrology at Brigham and Women's Hospital; Dr. Susan Quaggin[3], Chief of Nephrology and Hypertension at Northwestern University; Dr. Tamara Isakova[3], Director, Institute for Public Health and Medicine - Center for Translational Metabolism and Health, Associate Professor of Medicine (Nephrology and Hypertension) at Northwestern University; and Dr. John Quackenbush[3], Chair of Biostatistics at Harvard. Mount Sinai investigators will include Dr. Michael J. Donovan, Professor of Pathology; Dr. Fadi El Salem, Associate Professor of Pathology; Dr. Steven Coca[3], Associate Chair of Research for the Department of Medicine; and Dr. Girish Nadkarni[3], Clinical Director of The Charles Bronfman Institute for Personalized Medicine, and Co-Director of Mount Sinai's Bio*Me*™ BioBank.

"I'm pleased that Mount Sinai innovators and critical infrastructure such as Bio*Me*™ BioBank significantly contribute to the advancement of diagnostics and prognostics for treating kidney disease," said Dr. Erik Lium, Executive Vice President of Mount Sinai Innovation Partners. "Through this partnership with RenalytixAI and the combined resources of major medical centers to enhance the study, *KidneyIntelX* will address the needs of patients with impaired kidney function that may lead to renal failure."

The expanded validation patient cohort increases the statistical power of *KidneyIntelX* and is expected to provide additional insight into the design of the planned clinical utility study. Data from the clinical validation study will also be used to support the submission of *KidneyIntelX* for U.S. Food and Drug Administration review in 2019.

About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. In the United States alone, over 40 million people are classified as having chronic kidney disease, with nearly 50 percent of individuals with advanced (Stage IV) disease unaware of the severity of their reduced kidney function. As a result, many patients progress to kidney failure in an unplanned manner, ending up having dialysis in the emergency room without ever seeing a clinical specialist, such as a nephrologist. Every day 13 patients die in the United States while waiting for a kidney transplant.

About RenalytixAI
RenalytixAI is a developer of artificial intelligence-enabled clinical diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's solutions are being designed to make significant improvements in kidney disease diagnosis and prognosis, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com.

[1] United States Renal Data System - https://www.usrds.org/adrhighlights.aspx.

[2] The Clinical Laboratory Improvement Act (CLIA) program regulates laboratories that perform testing on patient specimens in order to ensure

accurate and reliable test results. The Food and Drug Administration defines a Laboratory Developed Test (LDT) as an in vitro diagnostic test that is manufactured and used within a single laboratory. When a laboratory develops a test system such as an LDT in-house without receiving FDA clearance or approval, CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment.

[3] Member of the RenalytixAI Advisory Board.

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