RenalytixAI Announces Partnership with the University of Michigan to Extend KidneyIntelX™ Use to Broad CKD Populations and Data Sharing Agreement with a Top Ten Global Pharmaceutical Company

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NEW YORK, June 30, 2020 /PRNewswire/ -- Renalytix AI plc (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs, today announced a partnership with the University of Michigan ("UM") to extend the application of the KidneyIntelX™ platform to an expanded population of patients with established Chronic Kidney Disease (CKD) or at risk of developing CKD. RenalytixAI also announces a data sharing agreement with a top ten global pharmaceutical company.

Partnership agreement with the University of Michigan
RenalytixAI has entered into a partnership with the University of Michigan ("UM") under which RenalytixAI will be given access to the Clinical Phenotyping Resource and Biobank Core ("C-PROBE") of the UM George M. O'Brien Kidney Translational Core Center comprising of over 800 patients with a broad etiology of CKD with up to 10 years of follow up. Additionally, through this partnership, RenalytixAI has obtained an exclusive option under which it can license certain intellectual property surrounding the biomarker urinary Epithelial Growth Factor ("uEGF"). Prof. Matthias Kretzler and his team at UM have shown uEGF to be highly predictive of incident and progressive CKD[1].

The first phase of the partnership with UM, expected to be completed in 2020, will study the potential role of uEGF in further enhancing the prognostic performance of the KidneyIntelX platform in identifying patients at highest risk of fast-progressing Diabetic Kidney Disease ("DKD") and kidney failure. Significantly, through this partnership, RenalytixAI plans to advance the development and validation of the KidneyIntelX platform for expanded use in a broad CKD population.

The C-PROBE biobank provides RenalytixAI with access to a large repository of longitudinally followed CKD patients with matched urine and plasma samples coupled with extensive medical records. The patient population in the CPROBE study includes a range of CKD subtypes including those related to Diabetes, Hypertension and Glomerular Disease which combined, account for over 75 percent[2] of all cases worldwide.

Data sharing agreement with a leading top ten global pharmaceutical company
RenalytixAI also announces that it has entered into a data sharing agreement with a top ten global pharmaceutical company providing RenalytixAI with access to a deep data repository from completed clinical studies in DKD. RenalytixAI plans to analyze this data in combination with corresponding biomarker data to evaluate KidneyIntelX performance in predicting patients' responses to novel therapeutic agents indicated to slow or prevent kidney function decline. Data analysis will also include evaluation of KidneyIntelX over multiple time points within a six year follow-up period, potentially demonstrating the value of dynamic, repeated KidneyIntelX measurements.

"The primary aim of our research has always been the translation of findings to clinical practice in order to improve patient care and kidney health," said Prof. Matthias Kretzler, Warner-Lambert/Parke-Davis Professor of Medicine, Nephrology/Internal Medicine, and Computational Medicine and Bioinformatics, University of Michigan Medical School. "The C-PROBE cohort was established with the express aim of enabling this translation to take place. We are very excited to partner with RenalytixAI in this endeavor and firmly believe that KidneyIntelX platform is an ideal vehicle to integrate the results of our work on uEGF with other biomarkers, bioinformatics and clinical research, with the goal of providing new, powerful solutions in managing CKD."

"These partnerships are both significant developments for our technology development roadmap and strategic objectives for the company," said Fergus Fleming, Chief Technology Officer and Co-founder of RenalytixAI. "Access to these data sets and samples potentially demonstrates the value of the KidneyIntelX platform and our ability to collaborate with leaders in discovery, clinical care and novel therapeutic development for kidney disease. We expect that gaining access to this clinical trial data, biomarker technology and the C-PROBE cohort will be key milestones in the development of expanded indications for KidneyIntelX, potentially allowing us to offer solutions to a greater number of the approximately 37 million patients currently estimated to have CKD."

KidneyIntelX is a first-in-class in vitro diagnostics platform that employs a proprietary artificial intelligence-enabled algorithm to combine diverse data inputs including validated blood-based biomarkers, a patient's genetics and extensive personalized patient data from EHR systems to generate a unique patient risk score. The current intended use for the test targets patients with CKD and type 2 diabetes which accounts for 20-30 percent of the estimated 37M US patients with CKD[3].

About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention ("CDC") estimates that 15% of US adults, or 37 million people, currently have CKD. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease results in more deaths than breast or prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.
* https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About C-PROBE
The Clinical Phenotyping Resource and Biobank Core (C-PROBE) of the University of Michigan George M. O'Brien Kidney Translational Core Center is designed to expedite the application of nascent laboratory discoveries to human subjects in the quest to treat and prevent kidney disease. Specific aims of C-PROBE include: 1) maintain a cohort of 800 adult participants with kidney disease from diverse backgrounds from University of Michigan, Renaissance Renal Research Institute, University of Illinois, Chicago, Wayne State University and Temple University; 2) add 300 pediatric participants with kidney disease from University of Michigan and Levine Children's Hospital, Charlotte, NC, to enhance scientific exploration and collaboration on

affected individuals throughout the life span; 3) provide longitudinal phenotypic characterization of the C-PROBE cohort (including demographic, clinical and laboratory data) utilizing a multi-dimensional relational clinical research data management system to promote and support translational investigation; and 4) maintain a specimen biobank for the purpose of sharing and distributing urine, blood, DNA, and kidney biopsy tissue samples to biomedical research investigators according to agreed repository governance policies. C-PROBE is structured and governed to optimally harness and maximize the use of resources for conducting translational research in kidney disease. Given the collaborative multi-disciplinary network of scientific expertise, this core is singularly suitable to accelerate medical advancement to address the public health burden of kidney disease.

About University of Michigan and Michigan Medicine
Michigan Medicine comprises three hospitals, 125 clinics and home care operations that handle more than 2.3 million outpatient visits a year. Michigan Medicine includes the top ranked U-M Medical School and the University of Michigan Health System, which includes the C.S. Mott Children's Hospital, Von Voigtlander Women's Hospital, University Hospital, the Frankel Cardiovascular Center and the Rogel Cancer Center. Michigan Medicine's adult hospitals were ranked no. 11 in the nation by U.S. News and World Report in 2019-20 and C.S. Mott Children's Hospital was the only children's hospital in Michigan nationally ranked in all 10 pediatric specialties analyzed by U.S. News and World Report for 2019-20. The UM Medical School is one of the nation's biomedical research powerhouses, with total research spending of more than $500 million annually.

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

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the development of KidneyIntelX, including statements of expected development timelines, the potential to expand indications for KidneyIntelX, the potential value of RenalytixAI's partnership with UM and data access agreement with a pharmaceutical company. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. All information in this press release is as of the date of the release, and the company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

1. https://pubmed.ncbi.nlm.nih.gov/26631632/
2. US Renal Data Systems
3. https://pubmed.ncbi.nlm.nih.gov/29054846/

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