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RenalytixAI Forms Core Investigator Group for Kidney Transplant Advanced Diagnostic Program

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Investigators include leading transplant clinicians from Emory University, the University of Manitoba, the Westmead Hospital Sydney, and Icahn School of Medicine at Mount Sinai.

Renalytix AI plc(LON: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announced today the formation of the core investigator group to support clinical and regulatory pathways for a portfolio of advanced diagnostic and prognostic solutions in kidney transplant known collectively as *FractalDx*. This follows the Company's announcement on January 2, 2019 that stated it had exercised its option from the Icahn School of Medicine at Mount Sinai ("ISMMS") for the exclusive license to technology and data underlying the *FractalDx* product portfolio.

Products under development from *FractalDx* are anticipated to be part of the extended RenalytixAl pipeline following the introduction of *KidneyIntelX* in 2019 for the diagnosis of fast-progressing chronic kidney disease. RenalytixAl hopes to commercialize a range of advanced diagnostic tests that are expected to aid in accurate dosing of immune-suppression therapy and in making significant improvements in the identification of and monitoring for kidney transplant rejection.

The *FractalDx* technology is based primarily on sequencing biomarkers from a patient's blood using widely available instrument platforms such as Illumina sequencers.

"Our hope is that FractalDx will give us the ability to tailor immunosuppressive therapy to the personal needs of the patient. The current therapeutic practice of 'one size fits all' dosing results in unnecessary complications including infection, cancers or avoidable rejections," said Dr. Barbara Murphy, Dean for Clinical Integration and Population Health, Professor and System Chair Medicine and Nephrology, at the Icahn School of Medicine at Mount Sinai, and Chair of the Scientific Advisory Board of RenalytixAl. "We have the technology to support development of a test that will apply personalized medicine to kidney transplant patients to guide administration of immunosuppression with the aim of improving outcomes."

"There are major unmet needs that limit the survival and effectiveness of kidney transplantation. The FractalDx diagnostic program has the potential to identify patients at increased risk for poor outcomes at a stage when intervention is still possible," said Dr. Christian P. Larsen, MD, DPhil, Professor of Surgery, Division of Transplantation Emory University. "It is important that we develop the next generation of diagnostics and determine how best to incorporate them into the care team workflow to reduce risk and maximize the benefit from immunosuppressive therapy for our transplant recipients."

RenalytixAl is forming the core investigator group now, ahead of its expected initiation of the clinical validation for the first diagnostic product from the portfolio, beginning in the second half of 2019.

The initial investigator appointments include:

- Philip O'Connell, MD Clinical Professor in Medicine, Director of the Centre for Transplant and Renal Research at the Westmead Institute for Medical Research, and Director of Transplant Medicine and the Clinical Islet Transplant Program at the Westmead Hospital Sydney
- Christian P. Larsen, MD, DPhil Professor of Surgery, Division of Transplantation, Department of Surgery and the former dean of the Emory University School of Medicine, and Founding Director of the Emory Transplant Center
- Barbara Murphy, MD Dean for Clinical Integration and Population Health, Professor and System Chair Medicine and Nephrology, at the Icahn School of Medicine at Mount Sinai
- Peter Nickerson, MD, FRCPC Clinical Nephrologist, Professor of Internal Medicine and Immunology, and Associate Dean for Research at the University of Manitoba, and Executive Medical Director, Organs and Tissue Office, at the Canadian Blood Services
- Weijia Zhang, PhD Director, Integrative Bioinformatics and Professor of Medicine, at the Icahn School of Medicine at Mount Sinai

Kidney transplantation is on the rise in the United States and globally. From 2017 to 2018, the number of kidney transplants performed in the U.S. rose from 19,849 to 21,168.¹ Contributing to the critical unmet need, approximately 7 percent of kidney transplants fail within one year, and approximately 17 percent fail within three years² which leads to additional patient complications and growing medical treatment cost.

¹ United Network for Organ Sharing (UNOS), 2019

² National Kidney Foundation, 2019

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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 RenalytixAl

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 <u>renalvtixai.com</u>.

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