

RENALYTIX AI

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Renalytix AI plc
("RenalytixAI" or the "Company")

RenalytixAI and University Medical Center Groningen to evaluate *KidneyIntelX™* for early identification and guiding therapeutic treatment of diabetic kidney disease

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces a collaboration with University Medical Center Groningen (UMCG), Netherlands, to evaluate *KidneyIntelX™* across over 3,500 patients with Type II Diabetes. The study will assess how effectively *KidneyIntelX™* identifies patients with fast-progressing kidney disease who would be most likely to benefit from new drug therapies to prevent or slow down their progression to end-stage renal disease and dialysis.

As part of the planned evaluation, the *KidneyIntelX™* test will be performed at multiple time points on over 9,000 patient samples from completed clinical trial biobanks, providing valuable insight into the potential utility of *KidneyIntelX™* as a predictor of response to breakthrough therapies for the treatment of diabetic kidney disease.

Hiddo J.L. Heerspink, Pharm.D., Department of Clinical Pharmacy and Pharmacology, UMCG and lead investigator in the planned evaluation, said: *"The ability of KidneyIntelX™ to discriminate fast-progressing kidney disease offers pharma the potential to enrich clinical trials with patients most likely to benefit most from novel drug therapies. Additionally, the potential to predict drug response in these patients is critically important to directing clinical use of new therapies."*

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 high global costs of Chronic Kidney Disease and end-stage renal disease. In the United States healthcare system alone, these costs are estimated at \$114 billion per annum. RenalytixAI expects to commercially launch *KidneyIntelX™* as a laboratory developed test in its CLIA laboratory facilities in the US in H2 2019.

It is anticipated that initial data from this collaboration will be published in early 2020 and is expected to support prospective revenue generating clinical trial and clinical diagnostic applications of *KidneyIntelX™*. Better identification and characterization² of enrolled patients has the potential to reduce the cost and duration of clinical trials and increases the likelihood of reaching successful outcomes.

Expense associated with this project which is attributable to RenalytixAI has already been accounted for in existing projections.

Notes

- ¹ *The Clinical Laboratory Improvement Act (CLIA) programme 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.*
- ² *Characterisation refers to an individual patient's disease status and underlying biology. Kidney disease biology and status may vary from patient to patient and could have a material impact on whether or not a patient qualifies for enrollment to a clinical trial.*

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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.

About University Medical Center Groningen (UMCG)

The UMCG is the only university medical center in the northern part of the Netherlands with representation of all medical specialties. Research at the UMCG is characterised by a combination of fundamental and patient orientated clinical research. The interaction between these two stimulates the development of new clinical and research opportunities. The UMCG focuses on healthy ageing and personalized medicine in all priority areas: research, clinical care and education.