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

Positive results of clinical validation study for *KidneyIntelX™* to be presented at ADA Scientific Sessions 2020

Accompanying manuscript supports ongoing commercialisation and regulatory milestones

NEW YORK, June 10, 2020 – Renalytix AI plc (LSE: RENX), a commercial-stage artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs, announces that results from a multi-centre clinical validation of *KidneyIntelX* will be presented at the American Diabetes Association (ADA) Scientific Sessions to be held from 12-16 June 2020.

Highlights

- Expanded multi-centre validation study demonstrates *KidneyIntelX* can identify patients at the highest risk of early stage diabetic kidney disease with more accuracy than existing care methods
- *KidneyIntelX* achieved a 62% Positive Predictive Value (PPV) in the top 16% of the population (vs a PPV of 41% for the existing standard of care)
- Data to be presented at ADA annual conference and submitted to FDA under RenalytixAI's Breakthrough Device designation
- Further validation to support the ongoing commercialisation of *KidneyIntelX*, targeting more than 12 million Americans with DKD and highlights the need for better risk stratification tools to improve patient outcomes

The annual ADA Scientific Sessions is one of the largest global conferences on diabetes and typically attracts attendance of over 15,000 people from 115 countries. This year's conference is being held online.

In the study conducted in a cohort of 1,146 patients with Type 2 diabetes patients and existing early stage diabetic kidney disease (DKD, Stages 1-3), the *KidneyIntelX* assay accurately predicted a composite endpoint of rapid kidney function decline (RKFD), 40% sustained decline in kidney function, or kidney failure (persistent stage 5 chronic kidney disease (CKD), dialysis or kidney transplantation) over a 5 year time frame.

An accompanying manuscript has been published providing details of the primary analysis and numerous sub-analyses which demonstrate robust performance of the *KidneyIntelX* test in a multi-centre context, including patients from the Mount Sinai BioMe Biobank and the Penn Medicine Biobank.
(https://www.medrxiv.org/content/10.1101/2020.06.01.20119552v1)

The results from this multi-centre validation build upon the initial performance reported in a single-centre validation study (https://www.biorxiv.org/content/10.1101/587774v1) published previously and presented at ASN Kidney Week 2019.

The primary objective of the expanded multi-centre validation study was to demonstrate if the *KidneyIntelX* artificial intelligence-enabled algorithm was able to predict which patients are at highest risk of adverse kidney outcomes with more accuracy than existing standard of care. The optimised *KidneyIntelX* assay, combining measurements of biomarkers soluble tumor necrosis factor receptor (sTNFR1, sTNFR2) and kidney injury molecule-1 (KIM-1) and clinical data from electronic health records, achieved a 62% Positive Predictive Value (PPV) in the top 16% of the population. This is compared with a PPV of 41% for the standard of care (KDIGO risk strata) and outperformed an optimized clinical model using several clinical data alone recently published (Nelson et al. JAMA 2019) ($p< 0.001$ for both comparisons).

Patients in the *KidneyIntelX* high-risk group were seven-fold more likely than patients in the low risk group to experience the composite endpoint over the 5 year period. Notably, 46% of the study population were categorized as low risk by *KidneyIntelX,* and in this group, only 9% (Negative Predictive Value 91%) of patients experienced the composite outcome.

The data presented in this study will form part of an expanded performance data set for *KidneyIntelX* currently being finalized for submission to FDA under Breakthrough Device designation. Renalytix AI intends to provide further updates on this process in the near term as appropriate.

This data supports the ongoing commercialisation of *KidneyIntelX*, targeting more than 12 million Americans with DKD. While only 20% of patients with DKD will experience progression over a 5 year period, DKD accounts for nearly half of all cases of ESKD.

While studies have shown that nephrology care can slow the progression of CKD/DKD (as well as reduce costs), it is impossible for nephrologists to see all patients with stage 1-3 DKD, therefore better risk stratification tools are needed to facilitate referrals for the appropriate patients.

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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 chronic kidney disease (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 kills more people than breast and 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 RenalytixAI

Renalytix AI 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.