# RENALYTIXAI

# Clinical findings published in Diabetologia

April 6, 2021

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

**Multi-Center Study Finds KidneyIntelX 72% More Effective Than Current Standard of Care In Identifying Early-Stage Patients at High Risk for Kidney Disease Progression and Failure**

*Clinical findings published in the April issue of Diabetologia, the official journal
of the European Association for the Study of Diabetes*

**NEW YORK, April 6, 2021** - RenalytixAI plc (LSE: RENX) (NASDAQ: RNLX), announced today that KidneyIntelX™ more accurately predicted progressive kidney function decline and kidney failure in a multi-center, diverse cohort of 1,146 type 2 diabetes patients with early-stage (stages 1, 2, and 3) kidney disease versus the current standard of care. The results of the study, which is the second peer-reviewed clinical validation study on KidneyIntelX, have been published in *Diabetologia*, the official journal of the European Association for the Study of Diabetes (EASD).

Strong performance of the KidneyIntelX platform is attributed in part to its proprietary, blood-based biomarker technologies, exclusively licensed from the Joslin Diabetes Center and the Mount Sinai Health System.

Notably, KidneyIntelX was observed to be highly effective at both ends of the risk spectrum. In the study, KidneyIntelX more accurately identified and segmented patients into three risk categories (low, intermediate and high) when compared to clinical models, including the current standard of care, the KDIGO risk stratification algorithm. When guideline-recommended urine albumin to creatinine ratio testing was performed, the positive predictive value (PPV) for progressive decline in kidney function was 69% for those scored as high-risk by KidneyIntelX versus the 40% identified as highest-risk by KDIGO categorization. This is a 72% improvement compared to standard of care. In addition, only 7% of those scored as low-risk by KidneyIntelX experienced progression (i.e., negative predictive value of 93%).

"Diabetes is one of the leading causes of kidney failure in the United States. Appropriate treatment for kidney disease is a significant challenge in type 2 diabetes patients," said Dr. Marina Basina, Clinical Professor, Medicine - Endocrinology, Gerontology, & Metabolism, Stanford Medicine and Medical Director of Inpatient Diabetes, Stanford Health Care. "Data from the KidneyIntelX risk assessment platform could significantly improve the care path for diabetes patients and delay the severe consequences of diabetic kidney disease. Identifying the risk for kidney disease complications in diabetic patients in the earlier stages of the disease is essential to improving kidney health and reducing health care costs."

Accurate segmentation of patient groups based on risk will yield benefits from targeted clinical care plans. High-risk patients identified earlier in the disease cycle can be prioritized to receive precision medicine and optimized care management to slow or arrest progressive kidney disease, while low-risk patients can avoid unnecessary treatments, follow-up visits and anxiety. KidneyIntelX has the potential to uniquely inform health care providers, insurance payors and population health managers about the expected rate of progression and risk of failure in early-stage kidney disease patients. KidneyIntelX is expected to support optimization of care delivery, improve patient outcomes and reduce the $120 billion annual cost of kidney disease to the United States Medicare system.[1]

"Given these additional clinical study findings, we are confident that KidneyIntelX will be adopted as part of the standard of care in assessing the risk of progressive kidney decline in individuals with early-stage diabetic kidney disease," said Michael J. Donovan, MD, Ph.D., Chief Medical Officer, RenalytixAI. "These results published in *Diabetologia* further validate our rigorous scientific and clinical approach, which is focused on early detection and aggressive clinical intervention for those found to be at the highest risk."

The Diabetologia article entitled, "*Derivation and validation of a machine learning risk score using biomarker and electronic patient data to predict progression of diabetic kidney disease,*" is available at https://link.springer.com/article/10.1007/s00125-021-05444-0.

*For further information, please contact:*

| | |
|---|---|
| **Renalytix AI plc** | www.renalytixai.com |
| James McCullough, CEO | **Via Walbrook PR** |
| | |
| **Stifel (Nominated Adviser, Joint Broker)** | **Tel: 020 7710 7600** |
| Alex Price / Nicholas Moore | |
| | |
| **Investec Bank plc (Joint Broker)** | **Tel: 020 7597 4000** |
| Gary Clarence / Daniel Adams | |
| | |
| **Walbrook PR Limited** | **Tel: 020 7933 8780** or renalytix@walbrookpr.com |
| Paul McManus / Lianne Cawthorne | Mob: 07980 541 893 / 07584 391 303 |

**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 one out of two people with very low kidney function who are not on dialysis do not know they have CKD.[2] 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.

**About KidneyIntelX**

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, inherited genetics and personalized patient data from electronic health record, or EHR, systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

**About RenalytixAI**

RenalytixAI (LSE: RENX) (NASDAQ: RNLX) 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. The Company's lead product is KidneyIntelX, which has been granted Breakthrough Designation by the U.S. Food and Drug Administration and which is being designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). For more information, visit www.renalytixai.com

**Sources**

[1] United States Renal Data System

[2] https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully distributed and marketed, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. 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. These risks and uncertainties include, among

others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our annual report on Form 20-F filed with the SEC on October 28, 2020, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake 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.

END


MSCEANLLEFNFEFA