



Positive clinical outcome data for KidneyIntelX

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Renalytix AI PLC

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

KidneyIntelX Demonstrates Performance and Informs Treatment Decisions in Multinational CANagliflozin CardioVAScular Assessment Study (CANVAS)

*Data from 1,325 CANVAS Participants with Baseline DKD Scored with KidneyIntelX
Presented at International Society of Nephrology World Congress of Nephrology 2021*

NEW YORK, April 20, 2021 - [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX) announces the [findings of a new study](#) in which the commercially available [KidneyIntelX](#) test accurately predicted progression of diabetic kidney disease (DKD) in a multinational cohort from the CANagliflozin CardioVAScular Assessment Study (CANVAS)¹ with early-stage DKD (stages 1-3). The clinical outcome data suggests that KidneyIntelX risk assessment could support primary care physicians in making appropriate therapeutic intervention decisions with early-stage DKD patients to effectively delay progression and reduce the risk of adverse events.

Results presented showed comparable risk-stratification with prior validation studies,² in which participants identified by KidneyIntelX as high risk (15% of the study population, which was comprised of adults with type 2 diabetes and DKD stages 1-3 from 667 centers in 30 countries) had more than an 8-fold higher rate of disease progression compared with those that scored low risk (42% of the population). In contrast, the application of the guideline-recommended KDIGO (Kidney Disease: Improving Global Outcomes) risk classification tool, based on kidney function and urine albumin concentration, only provided a 2.5-fold gradient for DKD progression among study participants identified as high risk compared with those scored as low risk.

This data, presented at the [International Society of Nephrology World Congress of Nephrology 2021 \(WCN '21\)](#), is the first of a series of outcomes from the analysis of the CANVAS cohort in conjunction with Janssen Research and Development including the role of KidneyIntelX in treatment decisions and monitoring therapeutic effect.

Dr. David W. Lam, MD, Medical Director Mount Sinai Clinical Diabetes Institute and first author on the presentation, said: "KidneyIntelX performed very well in a multi-national cohort of individuals with type 2 diabetes and early-stage DKD. The new data from CANVAS supports primary care physicians using the KidneyIntelX score to risk stratify and make informed care decisions with their patients. The results also advance the concept that there is most to be gained from early-stage intervention and the protective effects

of SGLT2i on kidney function decline in those that score as highest risk for progression with KidneyIntelX."

Access to the CANVAS trial cohort, which compared the SGLT2i inhibitor canagliflozin versus a placebo, and collected blood samples in most participants, supported that baseline risk stratification with KidneyIntelX identified individuals most likely to benefit from canagliflozin vs. placebo. Canagliflozin is FDA approved to reduce the risk for end-stage renal disease, worsening of kidney function, cardiovascular death, and hospitalization for heart failure among adults with type 2 diabetes and DKD. Data presented also showed that there was a 3-fold greater magnitude in the protective effect of canagliflozin on longitudinal eGFR slope (a measure of kidney function and cardiovascular risk) for study participants at high baseline risk who received SGLT2i therapy compared with those who scored as low risk.

The data was shared in a poster presentation titled "*Clinical Utility of KidneyIntelX in Patients with Early Stages of Diabetic Kidney Disease in CANVAS Participants.*" The poster can be found through the [KidneyIntelX site](#) and the study abstract is available through [Kidney International Reports](#).

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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 one out of two people with very low kidney function who are not on dialysis do not know they have CKD.³ 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-of-kind, bioprognostic™ 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. [Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes | NEJM](#)
2. <https://link.springer.com/article/10.1007/s00125-021-05444-0>
3. <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.

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