



Clinical Utility Study

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Renalytix AI PLC

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

Clinical Utility Study Demonstrates Primary Care Physicians Highly Likely to Order KidneyIntelX to Inform Care Decisions

Value of KidneyIntelX Testing Demonstrated by Data from 401 Physician Study Presented at National Kidney Foundation 2021 Spring Clinical Meetings

NEW YORK, April 8, 2021 - [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX) announces findings presented in a Late-Breaking presentation at the [National Kidney Foundation's 2021 Spring Clinical Meetings \(NKF SCM21\)](#) titled [Clinical Utility of a New Prognostic Test to Predict the Risk of Kidney Function Decline in Diabetic Kidney Disease Patients](#). Results support that [KidneyIntelX](#) may be widely adopted by primary care physicians (PCPs) and that the easy-to-understand risk score and recommended care path on the report could help improve care for patients at high risk for progressive kidney function decline or failure. The findings from this study are significant for clinicians, health systems, payers and patients in understanding the value of KidneyIntelX testing in large scale adult diabetic kidney disease (DKD) populations.

"Clear and objective utility evidence like these results presented at the NKF Spring Clinical Meeting this week are critical for evaluating the value of innovative new approaches for CKD assessment," said Elizabeth Montgomery, Vice-President, Learning Strategies and Primary Care Programs at the National Kidney Foundation. "This is important evidence for clinicians, decision-makers and payers as it illustrates the benefits of focusing on preserving kidney health in the earliest stages of the disease when new therapeutics, patient engagement and specialist referral have the potential to delay or prevent progression. The results of the study involving 401 primary care physicians show what can be possible for improving outcomes and quality of life for patients who otherwise are likely to progress to end-stage kidney disease, dialysis or transplant," commented Ms. Montgomery.

In the study, 98% of PCPs would order testing if reimbursement was established, the FDA had provided clearance, and it was commercially available. Additionally, the KidneyIntelX risk score was consistently ranked as very important in their overall clinical decision-making process. The study included 401 board-certified PCPs from across the U.S. practicing across different care settings and

payer models who care for DKD patients today. These clinicians reviewed written patient profiles including key clinical attributes for evaluating DKD and determining the best care plan for their patients. When a KidneyIntelX result was available, the study PCPs were approximately 1.5 times more likely to appropriately prescribe SGLT2 inhibitors (SGLT2i) and angiotensin II receptor blockers (ARB) for their high-risk patients. They were also nearly 2.5 times more likely to appropriately refer their high-risk patients to a specialist. These findings confirm that KidneyIntelX provides actionable information for understanding a patient's risk of progression in early-stage kidney disease, through which it can inform actions to delay or prevent progression when kidney function is at levels that support a normal life. More timely and appropriate treatment decisions should ultimately improve outcomes and lead to decreased health-care costs.

"We know there is under-utilization of proven therapies in patients with early stage DKD, particularly regarding ARBs to control blood pressure and SGLT2 inhibitors to manage diabetes," stated Steve Coca, MD, Co-Founder of RenalytixAI. "This study suggests that the assessment of future risk for kidney disease progression based on KidneyIntelX scoring can potentially overcome the inertia towards application of medical therapies and patient-directed care plans in early stages of their disease when intervention can have the greatest benefit for preserving kidney health and quality of life. Further evidence assessing the value KidneyIntelX will be generated in prospective utility studies that we are currently conducting. This significant body of real-world evidence data is being designed to serve as a model for informing clinical teams and health systems on how to maintain kidney health and improve outcomes while reducing the burden of kidney failure in these at-risk populations."

The study was conducted by Boston Healthcare Associates, a global strategy consulting firm that advises clients on how to optimize innovation value in a complex clinical and economic environment that transforms patient care and significantly improve health outcomes, with funding from RenalytixAI. Interested parties can now find an abstract on the study in the NKF SCM21 2021 Abstract and E-Poster Gallery [here](#).

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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.¹ 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 <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 physician acceptance, 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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