KidneyIntelX™ Enables Monitoring of SGLT2 Inhibitor Therapy Response and Corresponding Risk Reduction Over Time

Study Results lay foundation for KidneyIntelX repeat testing, reimbursement, and pharma collaborations

NEW YORK, June 28, 2021 (GLOBE NEWSWIRE) -- Renalytix plc (LSE: RENX) (NASDAQ: RNLX) announces new data demonstrating KidneyIntelX™ can be effective at monitoring therapeutic response and improvements in kidney health over time in adults with type 2 diabetes. By accurately assessing therapeutic response, particularly in patients at high risk for kidney failure, KidneyIntelX can potentially address a major barrier for primary care physicians and specialists in using new pharmaceuticals to slow kidney disease and improve outcomes. The data from an international study of 1,100 individuals with diabetic kidney disease (DKD) in the CANagliflozin Cardiovascular Assessment Study (CANVAS), was presented at the American Diabetes Association 81st Scientific Sessions Virtual Meeting (June 25-29, 2021).

"Until now, primary care physicians have not had an optimal way to assess risk for kidney disease progression in their type 2 diabetes patients. KidneyIntelX provides early risk stratification which allows us to optimize and target patients in early stages of kidney disease with new medications such as SGLT2i, and moreover, these data support how KidneyIntelX can help monitor these patients and their response to treatment. It helps address an unmet need and gives the PCP a better call to action in the monitoring and effective pharmacy management of patients," said Marina Basina, Clinical Professor of Medicine (Endocrinology) at Stanford University School of Medicine.

These results will be further evaluated through a growing body of real-world evidence and clinical effectiveness data driven by the KidneyIntelX multi-institutional study network in over 6,000 patients. The network is assessing the ability of KidneyIntelX to 1) to appropriately risk stratify patients in early stage (stage 1, 2 and 3) kidney disease; 2) help guide the optimal medication regimen based on individualized risk assessment; and 3) monitor therapeutic response and kidney health using repeat testing over time. KidneyIntelX is being deployed to manage DKD populations beginning at primary care level in partnership with large health care systems including the University of Utah, the Mount Sinai Health System, and Atrium Health, Wake Forest Baptist Health.

"The ability of KidneyIntelX to assess SGLT2 inhibitor response and improvements in kidney health through repeat testing is a significant step towards broader utilization of new therapeutic agents to significantly reduce the risk of kidney failure. This is another demonstration of the unique value of the KidneyIntelX bioprognostic solution to assist in early and effective care management of the 12 to 15 million adults in the United States with diabetes and chronic kidney disease," said Michael J. Donovan, CMO at Renalytix.

The oral presentation titled, "Longitudinal Changes in KidneyIntelX and Association with Progressive Decline in Kidney Function in the CANVAS Trial," was presented at the American Diabetes Association 81st Scientific Sessions Virtual Meeting (June 25-29, 2021). The new analysis based on data from the CANVAS trial demonstrated that canagliflozin reduced the KidneyIntelX risk score compared with a placebo over time, and that changes in the KidneyIntelX score from baseline to one year were strongly prognostic for future risk of DKD progression, whether the changes were treatment-induced or due to natural disease progression.

These data are the second output in a series of analyses of the CANVAS cohort in conjunction with Janssen Research and Development including the role of KidneyIntelX in treatment decisions and monitoring therapeutic effect. The first set of results were presented earlier this year in April at the World Congress of Nephrology which demonstrated that KidneyIntelX is effective in identifying high risk patients with DKD who are more likely to benefit from aggressive pharmaceutical management to slow progression.

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.

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

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 Renalytix

Renalytix (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.renalytix.com,

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 benefits of repeat testing with KidneyIntelX, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully adopted by physicians and 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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