Positive Study Results Published for KidneyIntelX™ in Monitoring Patient Response to New Drug Therapy

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American Journal of Nephrology data demonstrates KidneyIntelX successfully monitors patient response to SGLT2 therapy in 1,325 CANagliflozin CardioVAScular Assessment Study (CANVAS) multinational clinical trial cohort patients

NEW YORK and SALT LAKE CITY, Jan. 11, 2022 (GLOBE NEWSWIRE) -- Renalytix (NASDAQ: RNLX) (LSE: RENX) announced the publication of positive study results for KidneyIntelX™ as a risk monitoring tool to assess impact and response to novel treatments for patients with diabetes and chronic kidney disease (CKD) at increased risk for cardiovascular events. These peer-reviewed findings were published in *The American Journal of Nephrology*.

“This positive study is further demonstration that KidneyIntelX can be used to provide the most effective care pathway for physicians, so patients get the right treatment, at the right time, early in the disease cycle,” said Michael J. Donovan, Chief Medical Officer, Renalytix. “Monitoring response to new medications over time is a core part of precision medicine utility for chronic kidney disease control, which could be enabled by KidneyIntelX to provide improved patient care.”

“To deliver effective care and cost savings, population health and primary care need to work together to implement simple, straightforward care pathways that can significantly improve patient outcomes,” said Jennifer Houlihan, Vice President of Value Based Care and Population Health for Wake Forest Baptist Health. “The CANVAS study results show that risk assessment and monitoring with KidneyIntelX can help primary care physicians and our care team deliver proactive therapeutic management in early-stage diabetic kidney disease. We know that by treating chronic diseases early, the benefits to the patient, health system and payers will be most significant.”

The data supports the value of KidneyIntelX to risk stratify disease, monitor treatment response, and assess changes in risk over time, proving clinical utility not only as a bioprognostic™ risk assessment tool, but also as a longitudinal monitoring tool. The study identified samples from patients with baseline diabetic kidney disease (DKD) to assess the association of baseline and changes in KidneyIntelX with subsequent DKD progression. This represents the third published, peer-reviewed clinical validation study and the first multinational study for KidneyIntelX.

The CANVAS (CANagliflozin cardioVascular Assessment Study) multinational clinical trial design provided the framework to demonstrate the role of KidneyIntelX risk stratification and response to the novel therapeutic in 1,325 participants from the trial with concurrent DKD and available baseline plasma samples. KidneyIntelX accurately risk-stratified this large multinational cohort for progression of DKD. Greater numerical differences in the eGFR slope for canagliflozin versus placebo were observed in those with higher baseline KidneyIntelX scores. Canagliflozin treatment reduced KidneyIntelX risk scores over time and changes in the KidneyIntelX score from baseline to one year were correlated with future risk of DKD progression, independent of the baseline risk score and treatment arm. These data also show that repeat testing of KidneyIntelX has prognostic and likely clinical utility, and serves as a known benefit in treating those living with DKD.

KidneyIntelX combines three proprietary biomarkers (sTNFR1, sTNFR2, and KIM-1), and seven clinical variables from a patient’s electronic health record with machine learning to generate a patient-specific risk score. In May 2019, KidneyIntelX was granted Breakthrough Device designation by the U.S. Food and Drug Administration, recognizing it as a clinically effective diagnostic tool for kidney disease with no other alternative in the U.S.

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.[2] Every day, 13 patients in the United States die while waiting for a kidney transplant.[3]

About Renalytix
Renalytix (NASDAQ: RNLX) (LSE: RENX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease, progression risk assessment. The Company’s lead product, KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is 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.

About KidneyIntelX
KidneyIntelX, is a first-of-kind solution that enables early-stage diabetic kidney disease (DKD) progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers and personalized data from the patient’s health record, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in DKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

Sources

1 https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
2 https://www.nicresearch.com/clinical-research-necessary-nephrology/

3 https://optn.transplant.hrsa.gov/

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, including economic savings, of 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 21, 2021, 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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