Real-World Evidence Shows KidneyIntelX™ Utility

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Renalytix plc

("Renalytix" or the "Company")

New Published Real-World Evidence Shows KidneyIntelX™ Utility

Real-World Utility Data Demonstrates KidneyIntelX Optimizes Clinical Management in Early-Stage Chronic Kidney Disease Across Multiple Physician Specialties

KidneyIntelX individualizes clinical decisions beginning at primary care where impacts of new therapies, blood pressure strategies and timely referral can have maximal effect on outcomes and cost in patients with type 2 diabetes and chronic kidney disease

LONDON and SALT LAKE CITY, April 19, 2023 (GLOBE NEWSWIRE) -- Renalytix (NASDAQ: RNLX) (LSE: RENX) announces the release of new real-world evidence case studies published in the peer reviewed journal *Diabetic Nephropathy* entitled: *"The Need for Risk Stratification in Type 2 Diabetes and Chronic Kidney Disease: Proposed Clinical Value of KidneyIntelX."* The publication underscores the importance of enabling early risk assessment in diabetic kidney disease to reduce likelihood of progression to kidney failure and dialysis.

Key themes emerging from multi-disciplinary clinical advisory panel using KidneyIntelX:

· Lack of kidney disease education and patient awareness in the primary care setting is a real barrier to care management.
· A significant opportunity exists for type 2 diabetic patients to learn about CKD management to improve health behavior and medication compliance.
· Lack of risk assessment tools in primary care can prohibit identification of patients at high risk for kidney disease progression in early stages (G1-G3).
· Primary care represents a key point of contact for the entire diabetic kidney disease population.
· Guideline recommendations to mitigate kidney disease effects in diabetes patients are not optimally followed in routine clinical treatment.
· Earlier specialist referral of higher risk diabetic kidney disease patients can mitigate patient overload in nephrology.

This publication highlights the limitations of current tools commonly used in chronic kidney disease (CKD) management and how KidneyIntelX can optimize care with the examination of four patient cases under clinical management by four different physicians. Type 2 diabetes is a leading cause of CKD which is a costly and growing epidemic in the United States with more than $100 billion annually spent by Medicare alone. Of the 15 million patients with type 2 diabetes and CKD, more than 90% are in the early stages of CKD (stages G1-G3). Bioprognostic™ tools, such as KidneyIntelX, incorporate well-validated prognostic protein biomarkers integrated with key clinical variables from a patient's health record can help predict rapid kidney function decline in these early-stage CKD patients, proactively optimize care, and change the trajectory of chronic kidney disease before severe or irreversible kidney damage occurs.

According to Michael Donovan, PhD, MD, Chief Medical Officer at Renalytix: *"This independent review reinforces the importance of KidneyIntelX early prognosis in patients with kidney disease and type 2 diabetes. These utility results were well represented in 'real-time' with the reported case studies and the introduction of the KidneyIntelX bioprognosis supporting*

clinical decision making and care optimization across a spectrum of kidney event risk."

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About Kidney Disease

Kidney disease is a public health epidemic affecting over 850 million people globally.[1] The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people[2], have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3[3]. Despite its magnitude, early-stage (1-3) CKD is underdiagnosed and undertreated, largely because it's asymptomatic at this time in the disease. As many as 9 in 10 adults with CKD, and 2 in 5 adults with severe CKD do not know they have the condition.[3]

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis™ for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed its KidneyIntelX laboratory developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D and early CKD (stages 1-3). We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit www.renalytix.com.

About KidneyIntelX™

KidneyIntelX™ is a laboratory developed test demonstrated to be a reliable, bioprognostic™ methodology that yields a simple-to-understand, custom risk score, enabling prediction of which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate or high risk for rapid progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has a demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). KidneyIntelX has received Breakthrough Device Designation from the U.S. Food and Drug Administration and Renalytix has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the evidence, visit www.kidneyintelx.com.

Sources

1 https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/
2 https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
3 https://www.cdc.gov/kidneydisease/basics.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 benefits of KidneyIntelX, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery, mitigate patient overload in nephrology, address systemic inequalities 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 31, 2022, 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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