Late-Breaking KidneyIntelX Evidence Released at 83rd American Diabetes Association Scientific Sessions

July 7, 2023

12 Months KidneyIntelX™ in vitro prognostic testing continued to demonstrate clinical actions that lead to improvement in both diabetes (A1C reductions) and kidney health (eGFR slope improvement) in patients with Type 2 Diabetes and Chronic Kidney Disease

LONDON and SALT LAKE CITY, July 07, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) today announced late-breaking new clinical data demonstrating that KidneyIntelX *in vitro* prognostic use was associated with post-test actions that led to sustained improvements in both type 2 diabetes and chronic kidney disease health through 12 months. The results are from the evaluation of 2,317 patients being followed in a large real-world evidence (RWE) study in New York City. The twelve-month outcome data were presented at the American Diabetes Association (ADA) 83rd Scientific Sessions held June 23-26, 2023, in San Diego, California.

There are approximately 14 million adults with diabetic kidney disease in the U.S. today[1], and that number could more than double by the year 2060[2] due to rising trends in obesity and diabetes. KidneyIntelX is designed for use in patients with type 2 diabetes and stages 1-3 of kidney disease (early-stage diabetic kidney disease, DKD) to assess which patients are at low, intermediate, or high risk for a rapid progressive decline in their kidney function.

Type 2 Diabetes Improvements Evidenced by Hemoglobin A1c in Higher Risk Groups:

In patients classified as high risk, median A1C levels improved by 0.7%, a decrease from 8.2% (pre-test) to 7.5 (post-test) at one year ($p< 0.001$); median HbA1c decreased from 7.5% to 7.3% for patients in the intermediate risk group ($p=0.001$), and median A1C decreased from 7.1% to 7.0% in the low risk patients. ($p=0.9$).

These results support that the previously published improvement in A1C levels observed at six months pre and post KidneyIntelX testing, has been sustained for the full year, especially in the higher-risk patients.

Kidney Disease Improvement or Stability Demonstrated by Median eGFR Slope Improvement Across all Risk Groups

GFR slope is widely accepted as a clinical measure to determine the progression of chronic kidney disease (CKD). In patients classified as high risk by KidneyIntelX, median eGFR slope improved from -7.1 (pre-test) to 4.5ml/min/1.73m^2 (post-test) at one year ($p=0.01$), indicating a slowed progression of their disease. For patients with an intermediate risk score, median eGFR slope was stable at -1.5 (pre vs. post-test) to -1.4ml/min/1.73m^2 at one year ($p=0.6$) while patients classified as low risk, the median eGFR slope improved from -1.9 (pre-test) to -0.28 ml/min/1.73 m^2/year ($p<0.01$), further highlighting a need for broad engagement at both ends of the risk spectrum.

This data builds upon the RWE 6-month interim results published in the *Journal of Primary Care and Community Health* (November 2022) which demonstrated a reduction in the amount of urinary (albumin) protein in the low and intermediate KidneyIntelX risk groups.

The authors concluded that the use and deployment of KidneyIntelX to risk stratify patients with early-stage diabetic kidney disease was associated with escalation in various actions taken to optimize cardio-metabolic-kidney health, including guideline-based pharmacy management and specialist consultation. Furthermore, glycemic control and kidney health improved post-KidneyIntelX testing, with the largest improvements observed in those scored as high-risk.

Importantly this data demonstrates that implementation of KidneyIntelX in patient care leads to improved clinician and patient engagement directed to slowing the progression of diabetic kidney disease and associated cardiovascular complications.

In addition, during the ADA meetings, the Company presented validation data from a new IVD assay developed utilizing the KidneyIntelX platform. The risk score calculation was updated to incorporate the new race-free eGFR calculation, the availability of contemporary patient cohorts reflecting recent changes in care for diabetic kidney disease, and simplification of test inputs to enhance clinical adoption in the primary care setting.

The updated version of KidneyIntelX utilizes the same three biomarkers, and three clinical features. It was validated in an external cohort with overall excellent performance characteristics which included diverse subgroups of the intended use population.

Commenting on the data releases at the American Diabetes Association 83rd Scientific Sessions, Dr. Michael Donovan, Chief Medical Officer at Renalytix adds, “We are at an important inflection point in the overall understanding and management of kidney disease progression in the type 2 diabetic patient population. Precision based tools such as the KidneyIntelX assay provide a patient-level biological assessment of (DKD) disease potential for which population-based algorithms based on standard clinical variables will never be able to achieve.”

About Chronic 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, more than 38 million people, currently have chronic kidney disease (CKD). Diabetes is the leading cause of kidney failure, accounting for 44% of new cases. 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 Type 2 Diabetes

More than 37 million Americans have diabetes (about 1 in 10), and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over age 45, but more and more children, teens, and young adults are also developing the disease[2]. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with Type 2 Diabetes are undiagnosed[3]. Type 2 diabetes affects many major organs, including the heart, blood vessels, nerves, eyes and kidneys. Diabetic Kidney Disease develops in 30-50% of Type 2 diabetes patients[4].

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 rapidly 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 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). 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/diabetes/basics/type2.html
3 https://www.cdc.gov/diabetes/data/statistics-report/index.html
4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5297507/

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 impact KidneyIntelX can have on patients’ care management, the commercial prospects of KidneyIntelX, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding reimbursement decisions and the ability of KidneyIntelX and other potential tests developed using the KidneyIntelX platform to curtail costs of chronic and end-stage kidney disease, optimize care delivery, 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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