



KidneyIntelX data shows ability to assess risk

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

KidneyIntelX™ Demonstrates Ability to Assess Risk of Heart Failure Hospitalization and Death in Large International Diabetic Kidney Disease Patient Cohort

Data shared in oral presentation at American Diabetes Association 82nd Scientific Sessions® and published in Kidney360 highlights importance in early understanding of cardiovascular risk, a leading cause of death in patients with diabetes and chronic kidney disease

NEW YORK, NY and SALT LAKE CITY, UT June 6, 2022 - Renalytix (**NASDAQ: RNLX**) (**LSE: RENX**) announces that KidneyIntelX™ successfully risk-stratified adult patients with type 2 diabetes and early-stage chronic kidney disease (stages 1 through 3) for key clinical outcomes, including heart failure hospitalizations and death. Individuals with diabetic kidney disease (DKD) are not only at risk of kidney disease progression, but also face an increased risk of heart failure and death, due to the significant interconnection of the cardiovascular, renal, and metabolic systems.

This data builds on KidneyIntelX clinically validated performance in assessing the risk for rapid progressive decline in kidney function in adult patients with DKD and was presented in an oral presentation on June 3rd at the American Diabetes Association 82nd Scientific Sessions® in New Orleans. The study was conducted using a subgroup analysis of KidneyIntelX in the multi-national CANagliflozin cardioVascular Assessment Study (CANVAS). The results have also been published in *Kidney360* online, viewable [here](#).

In the CANVAS study, the team of investigators assessed the ability for KidneyIntelX to risk-stratify adult patients with DKD for their risk of clinically meaningful endpoints. Application of KidneyIntelX to this population showed that those with high-risk KidneyIntelX scores were at a three-fold higher risk for hospitalization for heart failure (HHF), severe kidney disease progression or death. Moreover, those individuals who scored as high-risk in this study were most likely to benefit from treatment with canagliflozin vs. placebo.

"This data reinforces the benefit of KidneyIntelX in better informing primary care who treat patients with early diabetic kidney disease (stages 1 through 3). For these patients, cardiovascular disease is the most common cause of death and KidneyIntelX may be able to help drive guideline-recommended care, including therapies that reduce cardiovascular and renal risk," said Steven G. Coca, DO, MS, Co-Founder of Renalytix. "In addition, these results show the potential of KidneyIntelX to enrich clinical trials for patients at higher risk of these complex conditions, which could improve trial efficiency for pharmaceutical companies."

Diabetic kidney disease related metabolic conditions, including heart disease, chronic kidney disease and diabetes, are the leading causes of death worldwide and account for up to 20 million deaths in the U.S. annually.

KidneyIntelX is offered clinically as a laboratory-developed test. It has been validated in two large cohorts to accurately yield a simple-to-understand, custom risk score, predicting which adult patients with type 2 diabetes and chronic kidney disease stages 1-3 are at low, intermediate or high risk for rapid progressive decline in kidney function. KidneyIntelX is available across the country, where all patient tests are processed by a Renalytix Clinical Laboratory.

Full oral presentation and abstract is available for conference attendees [here](#)..

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 people², have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3³. 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.²

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 with 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 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 also received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) and has been submitted to the FDA 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>

For further information, please contact:

Renalytix plc

James McCullough, CEO

www.renalytix.com

Via Walbrook PR

Stifel (Nominated Adviser, Joint Broker)

Alex Price / Nicholas Moore

Tel: 020 7710 7600

Investec Bank plc (Joint Broker)

Gary Clarence / Daniel Adams

Tel: 020 7597 4000

Walbrook PR Limited

Paul McManus / Lianne Applegarth / Alice Woodings

Tel: 020 7933 8780 or renalytix@walbrookpr.com

Mob: 07980 541 893 / 07584 391 303 / 07407 804 654

CapComm Partners

Peter DeNardo

Tel: 415-389-6400 or investors@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, including economic savings, of KidneyIntelX, the potential benefits of KidneyIntelX in assessing risks beyond kidney disease, the potential clinical utility of KidneyIntelX in cardiovascular

care, 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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