



KidneyIntelX Clinical Utility and Health Economics Validated in Multiple Data Releases at American Society of Nephrology

October 17, 2022

Four presentations, including first clinical utility findings from multi-year real world evidence results from a major healthcare system underscore value of KidneyIntelX™ platform in improving cost economics for Medicare population

NEW YORK and SALT LAKE CITY, Oct. 17, 2022 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) today announced that four scientific presentations have been accepted at the upcoming American Society of Nephrology (ASN) Kidney Week (November 3-6, 2022) taking place in Orlando, Florida.

The presentations include a cost-effectiveness analysis that supports population-based KidneyIntelX testing for prognosis of early stage Diabetic Kidney Disease (DKD) (stage G1-G3b) as a cost effective strategy for a Medicare population in comparison to standard clinical management tools to treat DKD, as well as the first clinical utility findings from the multi-year real world evidence study at a major healthcare system with an emphasis on addressing disparities in healthcare access.

Scientific clinical and health economic presentations include:

Prognostic Risk Score for Kidney Disease Progression in African Americans Without Type 2 Diabetes by Nadkarni GN, Takale D, Stapleton S, Fleming F, and Coca SG:

Data will be presented on the KidneyIntelX platform in a cohort of African Americans (AAs) with non-diabetic CKD with and without the *APOL1* risk genotype. The new model with plasma sTNFR1, sTNFR2, and KIM-1 combined with clinical variables accurately risk-stratified AAs with and without APOL1 risk genotype for kidney outcomes. **Thursday, November 3, 2022 from 10:00 AM to 12:00 PM at the Exhibit Hall, Orange County Convention Center.**

Examining the Role of KidneyIntelX in Addressing Health Inequity in CKD by Freedman BI, Paige RA, Spainhour MH, Bagwell BM, Houlihan JA, and Lord RW:

The KidneyIntelX risk score was assessed for its ability to predict progressive decline in kidney function in patients with T2D and early-stage CKD in a major healthcare system. Initial results suggest that despite similar median eGFR and median UACR levels, African American patients tested with KidneyIntelX were three times more likely to be scored as high risk. It is hoped that with continued use in the setting, KidneyIntelX may allow PCPs and healthcare systems to optimize the allocation of treatments and clinical resources to those at highest risk, beyond traditional clinical metrics and potentially improve equity in outcomes. **Thursday November 3, 2022 from 10:00 AM to 12:00 PM at the Exhibit Hall, Orange County Convention Center.**

TNFR-1, TNFR-2, and KIM-1 Plasma Concentrations after COVID-19 and Association with Kidney Function by Chan L, Anandakrishnan N, Saha A, DeFronzo S, Mosoyan, Meliambro K, G, Wisnivesky J, Nadkarni G, Stapleton S, Fleming F, Coca SG, and Azeloglu E:

KidneyIntelX Biomarkers TNFR1, TNFR2, and KIM1 are associated with progression of kidney disease and these biomarkers have not been evaluated in patients who have recovered from COVID-19. In this study of patients who had COVID-19 and recovered, at the baseline visit, KIM-1, TNFR-1, and TNFR-2 levels were highest in patients who were previously hospitalized and had acute kidney injury (AKI) during hospitalization. The degree of biomarker elevation was associated with lower kidney function more than one year post-COVID. **Friday, November 4, 2022 from 10:00 AM to 12:00 PM at the Exhibit Hall, Orange County Convention Center.**

Cost-Effectiveness Analysis of a Prognostic Risk Assessment Test for Diabetic Kidney Disease G1-G3b in the United States by Cooper JT, Beltran K, Coca SG, and Schneider, JE:

The KidneyIntelX risk score can assist primary care providers in guiding resource utilization, prescription of new therapeutic agents and improve efficiency of care among physicians. The results concluded that population-based testing for prognosis of progression with KidneyIntelX in a DKD G1-G3b population was a cost-effective strategy for a Medicare population including factors associated with quality of life improvements in comparison to prognosis relying on the standard metrics of kidney function (eGFR) or albuminuria (UACR) alone, while use of KidneyIntelX use in the commercial population was shown to be a dominant strategy compared to these standard kidney metrics alone. **Saturday, November 5, 2022 from 10:00 AM to 12:00 PM at the Exhibit Hall, Orange County Convention Center.**

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.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 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, 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 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 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 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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