



## Data Supportive of KidneyIntelX Utility in Minorities and Veterans to Be Presented at the National Kidney Foundation Spring Clinical Meeting

April 12, 2023

*In a clinical decision effectiveness study, KidneyIntelX classified more Black vs non-Black patients as high risk for progression of chronic kidney disease, resulting in increased prescription of SGLT2-inhibitor drug therapy*

*Additional study results illustrate how KidneyIntelX is aligned with the Veteran's Health Administration care practice guidelines for risk assessment in early-stage kidney disease and the introduction of novel therapies and timely referral to clinical specialists*

LONDON and SALT LAKE CITY, April 12, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) today announced that two scientific presentations have been accepted at the upcoming National Kidney Foundation Spring Clinicals Conference taking place in Austin, Texas (April 11-15). The studies entitled the "**Impact of KidneyIntelX testing on novel medication prescription in a diverse patient population**" and "**Diabetic kidney disease epidemiology in US veterans**" show the importance of using KidneyIntelX bioprognosis in early stage kidney disease and diabetes patients to blunt the effects of health inequity, help guide proper drug prescription to patients in need, and support established clinical guidelines to slow or stop unnecessary progression to late stage kidney disease, kidney failure and dialysis.

During National Kidney Month in March, Renalytix participated at a national and global level by hosting several events including a national webinar entitled, "**Diabetic Kidney Disease: Importance of Early Risk Assessment for Optimal Outcomes**" with Dr. Joseph Vassalotti, Clinical Professor of Medicine, in the Division of Nephrology, at Icahn School of Medicine at Mount Sinai and Chief Medical Officer for the National Kidney Foundation. The webinar is now on-demand and available on [www.kidneyintelx.com](http://www.kidneyintelx.com) or via this [link](#).

### National Kidney Foundation Clinical Spring Conference Data Presentations Include:

#### **Impact of KidneyIntelX testing on novel medication prescription in a diverse patient population**

KidneyIntelX was recently introduced into the Wake Forest-Atrium Health System to predict progressive decline in kidney function. In 590 patients with (type 2 diabetes) T2D and early stage CKD, despite similar eGFR, UACR and HbA1c in the Black vs. non-Black populations, the proportion of Black patients in the high-risk category was 3x higher than non-Black (15 vs. 5%). Identifying the highest risk patients gives the potential to prescribe novel medications, such as SGLT2-inhibitors to help stop or slow the progression of disease. The KidneyIntelX risk score identified those patients at highest risk which resulted in appropriately selecting SGLT2-inhibitors for the right patients. Due to the KidneyIntelX score, SGLT2-inhibitors usage markedly increased in Blacks who were scored as high risk (8.3% pre-test to 25% usage post-test) and increased from 19% to 32% in those scored as intermediate risk. These data demonstrate that health care providers can use KidneyIntelX for risk stratification to guide treatment plans and can be implemented in population health initiatives toward prevention of complications and improved healthcare equity.

The data will be showcased from April 12-14 in the Poster Hall at the Austin Convention Center and the [e-poster](#) is now online at the NKF website.

#### **Diabetic kidney disease epidemiology in US veterans**

Diabetes is the leading cause of chronic kidney disease, which is a major burden on the US Veterans Health Administration (VHA) at a cost of approximately \$18 billion in 2014 and an area of clinical focus at the VHA. Identifying veterans at highest risk is essential to define gaps in DKD management. In a patient cohort of more than 685,000 veterans with T2D and CKD, the authors identified a gap in current standard of care in which patients with early stage DKD (stages 1 and 2) may be left underdiagnosed or undetected, since the majority of patients (79%) were first identified with CKD at Stage 3a or 3b. More than one out of ten patients at earlier DKD stages (G1A2 – G3b) progressed to the next or higher stage within a year, and more than half of patients at earlier DKD stages progressed to advanced stages or died within five years. These findings demonstrate that T2D and CKD in veteran populations may progress rapidly due to a higher prevalence of comorbidities in the veteran population. In accordance with the goals of VHA Directive 1053, early recognition and management of CKD allows clinicians more opportunities to protect kidney health and reduce the risk of kidney failure.

This study demonstrates that the Renalytix KidneyIntelX solution as a risk assessment tool for early-stage CKD is well aligned with established Veteran's Health Administration care guidelines and the 2020 Directive 1053 recommending a validated risk prediction model to support clinical decision making in the management of patients with CKD.

The data will be showcased from April 12-14 in the Poster Hall at the Austin Convention Center and the [abstract](#) is now online at the NKF website.

#### **About Kidney Disease**

Kidney disease is a public health epidemic affecting over 850 million people globally.<sup>1</sup> The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people<sup>2</sup>, have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3<sup>3</sup>. 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.<sup>3</sup>

#### **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](http://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](http://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, 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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