



## 1,112 Patient Study Demonstrates Clinical Utility and Care Benefits of KidneyIntelX™ Risk Stratification in Stage 1 to 3 Diabetic Kidney Disease Patients

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**Late-breaking data presented at American Diabetes Association Scientific Sessions® demonstrates increased adherence to care guidelines for physicians using KidneyIntelX risk assessment to improve outcomes, alleviate patient suffering, and reduce significant financial burden associated with rapidly progressing chronic kidney disease**

NEW YORK and SALT LAKE CITY, June 10, 2022 (GLOBE NEWSWIRE) -- Deployment of Renalytix's (NASDAQ: RNLX) (LSE: RENX) KidneyIntelX™ bioprognostic™ testing in 1,112 adult diabetic kidney disease (DKD) patients at Mount Sinai Health System demonstrated utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients. The Mount Sinai clinical utility data was presented as a late-breaking ePoster session on June 5<sup>th</sup> at the American Diabetes Association 82<sup>nd</sup> Scientific Sessions® in New Orleans. In the study, more than half of KidneyIntelX prognostic tests were ordered by primary care physicians, followed by endocrinologists. Application of guideline-based care, including therapeutics and appropriate specialist consultation, increased in proportion to reported risk of rapid progressive decline in kidney function (e.g., low, intermediate, or high risk).

"Before KidneyIntelX, we did not have a way to effectively predict which patients with early stage DKD are at higher risk for progressive loss of kidney function and kidney failure," said Joji Tokita, M.D., Clinical Director, Division of Nephrology, and Associate Professor, Medicine (Nephrology), Icahn School of Medicine at Mount Sinai. "Nearly 95 percent of patients with chronic kidney disease are in stages 1 through 3, but its progression is often asymptomatic until it progresses to end stages and the damage is often irreversible. End-stage kidney disease results not only in poor quality of life for patients, but significant and costly care that can include cardiovascular complications, increased hospitalizations, dialysis and transplant. I'm encouraged to see the real-world application of KidneyIntelX by my primary care colleagues, where we can follow guideline-based care to reduce patient risk early and change the trajectory of disease progression and costs."

"Understanding the clinical utility of diagnostic tools like KidneyIntelX in a real-world setting is critical to increasing access and availability of our testing in the United States," said Tom McLain, President, Renalytix. "The findings from this clinical utility study reinforce the growing body of evidence demonstrating that KidneyIntelX can help to address significant unmet needs in DKD. An easy to understand, actionable risk score and care path allows primary care physicians to act early before health declines and significant kidney damage can occur."

The breakdown of risk in the real-world evidence (RWE) population was similar to what was observed in peer-reviewed, published KidneyIntelX clinical validation cohorts: High risk 13% vs. 17%; intermediate 40% vs. 37%; and low risk 46% vs 46%. In the 1,112 patients tested, KidneyIntelX re-stratified patient's risk from standard kidney function metrics (eGFR and UACR) and identified high risk adult patients with type 2 diabetes that were in stages 1, 2, and 3 of chronic kidney disease (CKD). Most importantly, the KidneyIntelX test helped physicians overcome the inertia seen with novel therapeutics proven to slow CKD progression and reduce associated patient cardiovascular event risk. As compared to patients who scored low risk, there were increases in use of anti-hypertensives, a 6-fold increase in the initiation of guideline-recommended treatments (SGLT-2 inhibitors or GLP-1 receptor agonists), and a nearly 3-fold increase in referrals to nephrologists, endocrinologists or dietitians. In the high-risk patient category, 20% of patients were referred to a specialist. Additionally, there was an increase in appropriate use of SGLT-2 inhibitor prescriptions by increased level of risk score.

"Even in my diabetes patients that are vigilant with their care, KidneyIntelX has proven to be a valuable tool to understand their risk of rapid kidney disease progression and take early action," said Aida Vega, M.D., Associate Professor of Medicine (General Internal Medicine), Icahn Mount Sinai, and Director, Primary Care Program, Mount Sinai Doctors Faculty Practice. "Informed decision making and individualized care for CKD patients is vital in preventing associated complications and progression to end stage renal disease. The earlier we can understand the risk of rapid progression of the disease, the sooner we can take action to improve and preserve health for these patients."

There are approximately 71,000 patients with type 2 diabetes and chronic kidney disease in the Mount Sinai Health System across New York City. Clinical utility study results are being prepared to be published in a peer reviewed publication in 2022. The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region.

KidneyIntelX is available clinically as a laboratory developed test. It has 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.

KidneyIntelX includes technology that was initially developed by Mount Sinai faculty. This technology has been licensed by Mount Sinai to Renalytix. Mount Sinai and a small number of Mount Sinai faculty inventors have a financial interest in Renalytix. Mount Sinai also has representation on the Renalytix Board of Directors.

### 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>2</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 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](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 also received Breakthrough Device Designation from the U.S. Food and Drug Administration and has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the evidence, visit [www.kidneyintelx.com](http://www.kidneyintelx.com).

### **About the Mount Sinai Health System**

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care—from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in the country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians in the top 1% of all physicians nationally by *U.S. News & World Report*.

### **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 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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