



Renalytix Announces Two Data Presentations on KidneyIntelX™ at American Diabetes Association 82nd Scientific Sessions®

June 2, 2022

Real-world clinical utility in 1,112 patients tested with KidneyIntelX

KidneyIntelX stratification for cardiovascular risk in 1,278 diabetic kidney disease patients

NEW YORK and SALT LAKE CITY, June 02, 2022 (GLOBE NEWSWIRE) -- Renalytix plc (**NASDAQ: RNLX**) (**LSE: RENX**) today announced its participation at the American Diabetes Association (ADA) 82nd Scientific Sessions® meeting in New Orleans from June 3-7, 2022. There will be two data presentations focused on the value of KidneyIntelX™ in care for adult patients with type 2 diabetes (T2D) and early-stage chronic kidney disease (CKD), including a late-breaking ePoster and an oral presentation.

The ePoster, “*Clinical Utility of KidneyIntelX on Patients with Early-Stage Diabetic Kidney Disease—A Real-World Evidence Study*” will be the first time Mount Sinai Health System is presenting data from its real-world evidence clinical utility study with Renalytix in 1,112 patients tested with KidneyIntelX. The poster will be presented to in-person and virtual conference attendees on June 5, at 12:00 p.m. CT, with commentary on behalf of the study investigators by Joji Tokita, M.D., Clinical Director, Division of Nephrology and Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai. Michael J. Donovan, Ph.D., M.D., Chief Medical Officer of Renalytix, will be available on-site for commentary.

A second oral presentation, “*KidneyIntelX Association with Clinical Outcomes in Diabetic Kidney Disease*” will be on June 3, at 4:45 p.m. CT by Steven G. Coca, D.O., M.S., Icahn School of Medicine at Mount Sinai, and Co-Founder of Renalytix.

“We’ve seen the ADA’s dedication to improving kidney health in people with T2D firsthand as part of our ongoing collaboration to develop a care pathway to advance screening, diagnosis and early-stage treatment for the 40% of these patients who will develop CKD,” said Tom McLain, President, Renalytix. “Chronic kidney disease can lead to significant complications for diabetes patients including cardiovascular disease and heart failure, and when left untreated can lead to dialysis and kidney transplant. Our mission is to give healthcare professionals new tools to understand an individual’s risk for rapid progression of CKD, allowing them to appropriately prescribe therapeutics and to utilize specialist consultation when necessary. We look forward to joining other industry leaders at this year’s Scientific Sessions in showcasing our research efforts.”

Renalytix will be exhibiting at booth #1803. The ePoster (Board No. 14) and oral presentation (Board No. 19) abstracts are available to conference attendees and public online through the 2022 [ADA Scientific Sessions Online Planner](#).

KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to Renalytix. Mount Sinai and Mount Sinai faculty, including Dr. Coca, 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.¹ The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people,² have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3.³ 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 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.

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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