



# Publication of new real world evidence

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

### Published Real World Evidence Demonstrates KidneyIntelX™ Improved Clinical Decisions and Outcomes in High-Risk Patients with Early-Stage Diabetic Kidney Disease

*Risk scoring by KidneyIntelX resulted in a 4.5-fold increase in new drug prescriptions (for SGLT2 inhibitors) for high risk compared to low risk patients, an observed reduction of HbA1c levels in the highest risk patients, an overall increased use of antihypertensive therapeutics, and an observed early reduction in albumin to creatine ratio levels in the low and intermediate risk groups.*

*KidneyIntelX risk assessment was incorporated into Mount Sinai Health System's Ambulatory Care Pathway and its Population Health Ambulatory Pharmacy and Condition Management programs for 1,686 patients with early stage diabetic kidney disease seen by 75 providers at 20 clinical sites, the majority at primary care.*

**LONDON and SALT LAKE CITY, Nov. 29, 2022 (GLOBE NEWSWIRE)** -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces the publication of [new real-world evidence \(RWE\)](#) in *Primary Care and Community Health* demonstrating the Company's KidneyIntelX bioprognostic™ test resulted in changed clinical decision making for patients in the early-stage of diabetic kidney disease (DKD) being cared for within the Mount Sinai Health System's Population Health Ambulatory Pharmacy and Condition Management programs. The majority of patients were being treated by their primary care physician.

Prediction of risk for kidney disease progression in early-stage DKD is often not assessed at the primary care level, resulting in more than 50,000 individuals per year with diabetes progressing to kidney failure, dialysis or a kidney transplant. By integrating an easily interpretable, accurate prognostic tool that assigns a risk score for progressive decline in kidney function, KidneyIntelX enables providers to act earlier to slow or stop the progression to kidney failure.

*"The data is greatly encouraging for millions of early stage 1-3 DKD patients where we lack patient-specific risk assessment tools to adjust appropriate care. Utilizing KidneyIntelX to identify which patients can most benefit from guideline-based therapies such as SGLT2 inhibitors, more education on diabetes and CKD, and referrals to specialists such as dietitians, diabetologists, and/or nephrologists, is an opportunity to swing the pendulum from suboptimal to optimal care," said Robert Fields, MD, MHA, Executive Vice President and Chief Population Health Officer for the Mount Sinai Health System.*

**According to Michael J. Donovan, PhD, MD, Chief Medical Officer at Renalytix,** *"The impacts of KidneyIntelX early risk assessment, even at this interim 6 month time point, are very encouraging that we can proactively move to control cost and outcomes in diabetes and kidney disease. Enabling primary care physicians to recognize risk and clinically manage patients DKD can potentially eliminate unnecessary events from uncontrolled disease progression, including kidney failure and dialysis. We look forward to continuing published data releases at the one-year mark."*

Key points from the prospective study:

- The study was conducted in collaboration with the Mount Sinai Health System's Population Health Ambulatory Pharmacy and Condition Management programs and included 1,686 patients seen by 75 providers at 20 clinical

sites.

- The RWE study demonstrated that patients with early-stage DKD and a high risk KidneyIntelX score received higher frequency of clinical management visits, introduction to guideline-recommended medications, and specialist referral for disease management compared to those who were identified as low or intermediate risk patients.
- The risk breakdown of the RWE study population was similar [to the clinical validation cohort](#) (high risk 12% vs. 17%, intermediate risk 40% vs. 37%, and low risk 48% vs 46%, respectively).
- **Frequency of follow up visits:** 53% of all KidneyIntelX high risk patients had a follow-up visit within 1-month of their KidneyIntelX test and 57% had action taken (medication change or referral) within 3-months, compared to 13% and 35%, respectively, for low risk patients.
- **Medication management:** When evaluating new or modified prescriptions for hypertension at six months, both ACEi and ARBs achieved a greater than 20% change in patients with hypertension in the high risk group vs. the low risk group. Medication management for use of SGLT2 inhibitors was even more pronounced; 25% of patients in the high risk group received new SGLT2i prescriptions vs. 7% in the low risk group, a 4.5-fold increase. Thus, KidneyIntelX enabled physicians to take guideline-recommended clinical actions in high risk, early stage (stage 1-3b) diabetic kidney disease patients.
- **Specialist referrals:** New referrals by risk group were 6% for low risk, 12% intermediate risk and 15% high risk.

The full study is available [here](#).

KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to Renalytix. The RWE study is being conducted at the Mount Sinai Health System, New York, NY, and funded by Renalytix. Mount Sinai and Mount Sinai faculty have a financial interest in Renalytix. Mount Sinai also has representation on the Renalytix Board of Directors.

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#### **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).

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

Mount Sinai Health System is one of the largest academic medical systems in the New York metro area, with more than 43,000 employees working across eight hospitals, over 400 outpatient practices, nearly 300 labs, a school of nursing, and a leading school of medicine and graduate education. Mount Sinai advances health for all people, everywhere, by taking on the most complex health care challenges of our time - discovering and applying new scientific learning and knowledge; developing safer, more effective treatments; educating the next generation of medical leaders and innovators; and supporting local communities by delivering high-quality care to all who need it.

Through the integration of its hospitals, labs, and schools, Mount Sinai offers comprehensive health care solutions from birth through geriatrics, leveraging innovative approaches such as artificial intelligence and informatics while keeping patients' medical and emotional needs at the center of all treatment. The Health System includes approximately 7,300 primary and specialty care physicians; 13 joint-venture outpatient surgery centers throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and more than 30 affiliated community health centers. We are consistently ranked by *U.S. News & World Report's* Best Hospitals, receiving high "Honor Roll" status, and are highly ranked: No. 1 in Geriatrics and top 20 in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Neurology/Neurosurgery, Orthopedics, Pulmonology/Lung Surgery, Rehabilitation, and Urology. New York Eye and Ear Infirmary of Mount Sinai is ranked No. 12 in Ophthalmology. *U.S. News & World Report's* "Best Children's Hospitals" ranks Mount Sinai Kravis Children's Hospital among the country's best in several pediatric specialties. The Icahn School of Medicine at Mount Sinai is one of three medical schools that have earned distinction by multiple indicators: It is consistently ranked in the top 20 by *U.S. News & World Report's* "Best Medical Schools," aligned with a *U.S. News & World Report* "Honor Roll" Hospital, and top 20 in the nation for National Institutes of Health funding and top 5 in the nation for numerous basic and clinical research areas. *Newsweek's* "The World's Best Smart Hospitals" ranks The Mount Sinai Hospital as No. 1 in New York and in the top five globally, and Mount Sinai Morningside in the top 20 globally. For more information, visit <https://www.mountsinai.org> or find Mount Sinai on [Facebook](#), [Twitter](#), and [YouTube](#).

### **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 future impact of KidneyIntelX on clinical decision-making and outcomes, 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. The results presented in this press release are interim results; subsequent interim results and full results may vary and may not be consistent with these interim results. 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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