Renalytix Reaches Enrollment Milestone for Building KidneyIntelX as Premier Precision Medicine Platform for Kidney Disease and Diabetes

March 29, 2022

KidneyIntelX RAPID biobank program and partners on track to reach over 30,000 biospecimens with matched electronic health records from multiple centers across the U.S.

NEW YORK and SALT LAKE CITY, March 29, 2022 (GLOBE NEWSWIRE) -- Renalytix plc **(NASDAQ: RNLX) (LSE: RENX)** today announced the proprietary Renalytix Accelerating Precision medicine In Diabetes (RAPID) biorepository is on track to exceed 4,000 unique patient biospecimens with matching, deidentified electronic health record data in 2022 through the Company's real-world evidence program. RAPID, in combination with unique contracted access to large medical center patient cohorts, enables KidneyIntelX™ improvements for its bioprognostic™ methodology and therapeutic response monitoring, and supports expanded regulatory and reimbursement initiatives beginning in calendar year 2022. The RAPID biorepository was initiated in 2020 as a key part of the Renalytix real-world evidence clinical study program to accelerate the development of precision medicine products and services.

With over 95% of KidneyIntelX tested patients from multiple real-world evidence programs now consenting for their samples and data to be used, Renalytix expects total biospecimen access for this KidneyIntelX precision medicine platform to exceed 30,000 unique patient specimens by calendar year 2024. The KidneyIntelX RAPID biorepository is expected to continue to grow into one of the largest real-world patient biobanks incorporating current and emerging care standards for kidney disease and diabetes, including use of innovative drug treatments such as SGLT2 inhibitors, GLP1 receptor agonists, and non-steroidal mineralocorticoid receptor antagonists.

"The RAPID biorepository is an invaluable and unique source of serial patient blood and data that can accelerate product validation and provide actionable insights to help patients suffering with kidney disease and diabetes. For the KidneyIntelX platform, this will allow us to drive the development of successive versions of KidneyIntelX to address important gaps in care," said Fergus Fleming, Chief Technology Officer, Renalytix. "Together with our many collaborators, we share the vision for a new future for kidney health, where patients and providers have access to tools for ensuring the right treatment for the patients at the right time."

Recent breakthroughs in therapies, such as SGLT2 inhibitors, GLP1 receptor agonists, and non-steroidal mineralocorticoid receptor antagonists, for the treatment of kidney and cardiovascular outcomes have intensified the need for precision medicine solutions such as KidneyIntelX to understand individual patient risk and the prediction of early-stage disease progression.

KidneyIntelX is the only kidney health platform that has received Breakthrough Device Designation from the U.S. Food and Drug Administration. KidneyIntelX has secured provider agreements with more than 30 state Medicaid programs and is also covered under various commercial insurance programs.

About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.[1] Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer.[2] Every day, 13 patients in the United States die while waiting for a kidney transplant.[3]

About Renalytix
Renalytix (NASDAQ: RNLX) (LSE: RENX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease, progression risk assessment. The Company's lead product, KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). For more information, visit www.renalytix.com.

About RAPID
The "Renalytix Accelerating Precision-medicine In Diabetes" cohort comprises of blood, urine and deidentified electronic health record data from subjects enrolled in multiple Real World Evidence studies sponsored by Renalytix across multiple sites. All participants included in the cohort have consented for their samples and data to be used for future research and development.

About KidneyIntelX
KidneyIntelX, is a first-of-kind solution that enables early-stage diabetic kidney disease (DKD) progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers and personalized data from the patient's health record, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in DKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

Sources

1 https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
2 https://www.nicresearch.com/clinical-research-necessary-nephrology/

3 https://optn.transplant.hrsa.gov/

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, expectations regarding the growth and utility of the RAPID biorepository, 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.

Media Contacts:
United States:
Chloe Beaudoin
Renalytix
(207) 333-7947
cbeaudoin@renalytix.com

Outside of the United States:
Walbrook PR Limited
Paul McManus / Lianne Applegarth / Alice Woodings
Tel: 020 7933 8780 or renalytix@walbrookpr.com
Mob: 07980 541 893 / 07584 391 303 / 07407 804 654