



Joint program with American Diabetes Association

January 4, 2022

RNS Number : 2538X

Renalytix PLC

04 January 2022

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

American Diabetes Association and Renalytix Partner to Prioritize Kidney Health in Type 2 Diabetes Population

National program establishes early care management, technology innovation and large health system engagement as a strategic priority for supporting the 34 million U.S. individuals living with diabetes

Arlington, VA and Salt Lake City, Utah (January 4, 2022) - The American Diabetes Association® (ADA) and Renalytix (**NASDAQ: RNLX**) (**LSE: RENX**) announced today a joint program to improve overall kidney health in patients with type 2 diabetes (T2D) in the United States, which is expected to grow from 34 million individuals today to nearly 60 million by 2060¹. The program intends to drive early detection and risk-informed care delivery to delay disease progression, reduce dialysis starts and improve overall health of chronic kidney disease (CKD) patients with diabetes nationally.

Dr. Nuha El Sayed, Vice President of Healthcare Improvement at the American Diabetes Association, said: *"Early identification and risk-informed care are critical to better health outcomes. Our work together will support the care of people with diabetes through primary care providers."*

Together, ADA and Renalytix will convene experts to advise and develop a comprehensive interprofessional risk-informed Diabetes Kidney Care Pathway and Model for optimal clinical treatment and risk reduction. The ADA and Renalytix will work together to define a plan for a second phase of the program to scale and deploy the model through partnerships with multiple health systems nationally. That effort will leverage milestones, KPIs, metrics and ongoing evaluation of the Pathway's effectiveness in changing outcomes for people with diabetes living with or at-risk for CKD.

James McCullough, CEO of Renalytix, said: *"This program combines technology, hospital system population health engagement and leading clinical experts to drive optimized care management at the earliest possible stage of kidney disease where better outcomes and cost control can be maximized. For individuals with diabetes and kidney disease, this is a powerful, comprehensive and bold model to engage this devastating disease beginning in primary care and close the gaps in front-line care."*

The number of adults with diagnosed diabetes is expected to reach 60 million by 2060 in the United States alone, with up to 40 percent expected to develop chronic kidney disease. Chronic kidney disease is a silent disease, that each year kills more people than breast and prostate cancer alone.

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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.² 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.³ Every day, 13 patients in the United States die while waiting for a kidney transplant.⁴

About Diabetes

Approximately 34.2 million Americans and an estimated 422 million people worldwide have diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diagnosed adult diabetes cases in the U.S.⁵ Diabetes is a chronic condition that occurs when the body does not properly produce or use the hormone insulin. If left uncontrolled, diabetes can lead to serious cardiovascular and renal comorbidities, including heart and kidney disease.⁶

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 81 years the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the nearly 122 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook ([American Diabetes Association](https://www.facebook.com/AmericanDiabetesAssociation)), Spanish Facebook ([Asociación Americana de la Diabetes](https://www.facebook.com/AsociaciónAmericanaDeLaDiabetes)), Twitter ([@AmDiabetesAssn](https://twitter.com/AmDiabetesAssn)) and Instagram ([@AmDiabetesAssn](https://www.instagram.com/AmDiabetesAssn)).

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 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://pubmed.ncbi.nlm.nih.gov/29903012/>
- 2 <https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html>
- 3 <https://www.nicresearch.com/clinical-research-necessary-nephrology/>
- 4 <https://optn.transplant.hrsa.gov/>
- 5 <https://www.cdc.gov/diabetes/basics/type2.html>
- 6 <https://www.cdc.gov/kidneydisease/publications-resources/link-between-ckd-diabetes-heart-disease.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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