



## Utility Study

June 3, 2021

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Renalytix AI PLC

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

### **Utility Study Indicates KidneyIntelX Risk Assessment can Address Treatment Ambiguity in Primary Care**

*Clinicians affirm need for accurate early-stage diabetic kidney disease risk assessment to improve patient outcomes and reduce healthcare costs*

**NEW YORK, June 3, 2021** - [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX) today announced results from a new utility study. The study confirmed the importance of risk assessment testing in addressing treatment ambiguity in the early stages of diabetic kidney disease (DKD) and improving patient engagement and adherence, two major barriers to slowing or preventing DKD progression and preserving kidney health. In clinical studies, KidneyIntelX has shown to accurately predict progression of DKD, suggesting that KidneyIntelX risk assessment could support primary care physicians in making appropriate treatment decisions and slowing or preventing DKD progression.

In this qualitative study involving 16 primary care physicians, 100% of clinician study participants confirmed that early-stage kidney risk assessment, like that provided by KidneyIntelX, will help to address suboptimal therapy, which can lead to rapid progression, increased hospital admissions, emergency room visits, potential kidney failure, need for dialysis, decreased quality of life, and increased costs.

**Dr. Joseph Vassalotti, Chief Medical Officer of the National Kidney Foundation (NKF) and Clinical Professor at the Icahn School of Medicine Mount Sinai Health System commented,** *"The NKF believes primary care physicians have the power to change the outcome for the vast majority of individuals with early-stage kidney disease who are at risk for progressive kidney disease. Americans living with kidney diseases universally express the preference for early diagnosis. This study confirms the compelling data presented at this year's NKF Spring Clinical Meeting that KidneyIntelX could be widely adopted by primary care physicians (PCPs) and could alter how at-risk populations with type-2 diabetes can receive early education and therapeutic intervention to reduce DKD complications and kidney failure.*

*"At NKF we are fueled with urgency to significantly improve the long-term outcomes that restore full lives for people living with kidney diseases. We encourage PCPs embrace the ability to manage kidney disease risk early to protect their patient's kidney health."*

In the study, 94% of PCP participants found that kidney disease was difficult to manage in their type 2 diabetes patients. Accurate risk stratification is a critical unmet need and can lead to delays in effective, early interventions.

The study was based on qualitative interviews with sixteen PCPs treating DKD patients. Participating PCPs specialized in internal medicine or family medicine and worked across the major settings of care in the U.S., including private practices, academic medical centers, and integrated delivery networks. Four main themes in DKD were analyzed in the study: Screening Practices; Perceived Knowledge Gaps; Treatment Variability; and the Importance of Risk Stratification. The publication titled, "[A Qualitative Study Documenting Unmet Needs in the Management of Diabetic Kidney Disease \(DKD\) in the Primary Care Setting](#)," was published in BMC Public Health on May 17, 2021.

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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.<sup>1</sup> 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. Every day, 13 patients in the United States die while waiting for a kidney transplant.

**About KidneyIntelX**

KidneyIntelX, is a first-of-kind, bioprognostic<sup>TM</sup> platform that employs a proprietary artificial intelligence-enabled algorithm to combine diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

**About Renalytix**

Renalytix (LSE: RENX) (NASDAQ: RNLX) is a developer of artificial intelligence-enabled clinical in vitro diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's lead product is KidneyIntelX, which has

been granted Breakthrough Designation by the U.S. Food and Drug Administration and which is being 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](http://www.kidneyintelx.com)). For more information, visit [www.renalytix.com](http://www.renalytix.com).

#### Sources

1 <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.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 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 28, 2020, 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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