



Clinical utility study data: further highlights

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

Primary Care Use of KidneyIntelX in Early Stage CKD Improved Clinical Care Delivery and Outcomes

First-in-class bioprognostic™ KidneyIntelX provided clear direction for primary care physicians to slow or stop progression of chronic kidney disease in adult diabetes patients

LONDON and SALT LAKE CITY, Dec. 1, 2022 (GLOBE NEWSWIRE) - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces additional highlights from the publication of data from a clinical utility study demonstrating that use of KidneyIntelX risk assessment in the primary care setting resulted in improved clinical decision making and observed clinical outcomes for 1,686 patients in the earliest stages of diabetic kidney disease (DKD). The results published in the [Journal of Primary Care and Community Health](#) evaluated the effectiveness of a health system driven care management program focused on treating DKD patients in the earliest stages of the disease (stages 1 to 3) before significant loss in kidney function and other complications can develop. Full published results were first announced on November 29, 2022.

Kidney disease in the US often goes untreated in the primary care setting, contributing to the more than 50,000 individuals per year with diabetes and chronic kidney disease (CKD) who progress to kidney failure, dialysis or kidney transplant. When not addressed in its earliest stages, CKD is difficult to proactively control, and patients can lose up to 90% of their kidney function as the condition worsens. By integrating a simple, actionable KidneyIntelX risk assessment result, primary care physicians are able to determine the appropriate and cost-effective treatment plan for their individual patients based on their risk level. The study results demonstrated that with actionable information about the risk for rapid progression, primary care clinical teams were able to act earlier, with the goal of slowing or potentially stopping the progression to kidney failure in patients at higher risk.

This study data is especially meaningful for overburdened clinical teams in the primary care community who lack accurate tools, time and resources to understand which type 2 diabetes patients are at highest risk for rapid progressive CKD decline. With KidneyIntelX risk assessment, they can adjust clinical care by optimizing medications developed to slow CKD progression, providing earlier consultation or referral to specialists, and increasing frequency of follow-up visits thereby promoting and preserving kidney function before irreversible damage occurs. The ability to predict CKD risk early could improve care and outcomes by reducing cardiovascular events, hospitalizations and emergency room visits.

Slowing the progression of diabetic kidney disease is also important to health systems and payers. Medicare alone spends an estimated \$85 billion on early stage CKD care each year, more than double the \$37 billion spent on end stage kidney disease care. By addressing kidney disease early, providers can better allocate resources and reduce costs across all stages of the disease.

The key highlights from this real-world evidence study publication include:

- 57% of high risk patients had action taken (medication change or referral) within 3-months, compared to 35% for low risk patients. Medication changes included introducing SGLT2 inhibitors to manage type 2 diabetes and CKD as well

as adjustments for ACEi/ARBs to manage hypertension.

- Notably clinical observations from the study showed a nearly 10% improvement in HbA1c levels in the high risk group in the first six months. This improvement type 2 diabetes management is most likely the result of both increased patient engagement combined with appropriate medication changes including the introduction of SGLT2 inhibitors.
- While other metrics such as eGFR and systolic blood pressure (SBP) remained unchanged at the 6-month data mark, there was a 15% improvement in albuminuria, an important indicator of overall kidney health, in the low and intermediate risk groups.

This evidence builds on a [previously published study](#) in the *American Journal of Managed Care* (AJMC), 2022 that indicated that 98% of PCPs were somewhat, very or extremely likely to use KidneyIntelX to predict which of their patients with DKD will experience rapid progressive decline in their kidney function.

According to Michael J. Donovan, PhD, MD, Chief Medical Officer at Renalytix, *"The impacts of KidneyIntelX early risk assessment, at 90 days and 180 days, are very encouraging as we can now state that we have observed early intervention in the highest risk patients can result in positive clinical outcomes, before kidney disease advances to a critical point. This prospective study in a real-world health care system setting demonstrates that risk informed care in the earliest stages of chronic kidney disease is not just a vision, it's a reality. Until the introduction of KidneyIntelX testing, there has not been a good way to allocate time and attention in the PCP practice to those patients at highest risk for progression to end stage renal disease. This published data shows that KidneyIntelX can help to drive urgency to action and increase patient engagement in the management of their disease."*

"These groundbreaking results demonstrate that we have the opportunity to make a tangible difference today in two of the most complex chronic disease conditions that the U.S. faces today: type 2 diabetes and chronic kidney disease. These results represent a triple win - they're good for the patient, they're good for the provider, they're good for the payer. We look forward to continuing to advance our clinical development program and to additional published data releases at the one-year mark," added Thomas McLain, President, Renalytix.

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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 people², have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3³. 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.³

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.

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 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.

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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