Publication of clinical utility study in The AJMC

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

Data Results Published in American Journal of Managed Care demonstrate adoption and clinical utility of KidneyIntelX™ with Primary Care Physicians

98% of 401 Primary Care Physicians confirmed KidneyIntelX has value as a risk decision tool in their adult patients with type 2 diabetes and chronic kidney disease stages 1-3b.

Published study complements KidneyIntelX clinical utility data published at American Diabetes Association Annual Conference demonstrating improvements in guideline recommended care, including therapeutic managements and specialist consultation

NEW YORK, NY and SALT LAKE CITY, UT August 8, 2022 (GLOBE NEWSWIRE) - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) today announced the publication of a clinical utility study in *The American Journal of Managed Care* confirming Primary Care Physicians (PCPs) understand the value of KidneyIntelX™ in determining appropriate guideline-recommended treatment decisions in their adult patients with type 2 diabetes (T2D) and early chronic kidney disease stages 1-3 (diabetic kidney disease). The study of 401 geographically diverse clinicians was conducted by Boston Healthcare Associates, a third party specialized in medical device evaluation, clinical development, and data management.

The published study complements recently published data from a real-world evidence clinical utility study of 1,112 adult DKD patients presented at the recent American Diabetes Association 82nd Scientific Sessions and the European Congress of Internal Medicine. These combined published results confirm the significant benefit of using KidneyIntelX in the Primary Care setting to direct care towards improving kidney health and reducing the significant financial burden associated with DKD.

*"The study publication announced today is a key element of a comprehensive evidence development program," said Tom McLain**, President of Renalytix.** "This program was designed to address the evidence requirements of payers, regulators, clinicians, and guideline setting bodies. The increasing volume of real-world evidence being generated from our health systems partnerships, presented at the ADA conference, confirms clinical utility, and indicates adoption of KidneyIntelX in the clinical setting."*

*"We now have evidence that indicates that KidneyIntelX is not only clinically valued by PCPs but is also useful in aiding clinical decision making in the real-world setting, helping ensure that patients are on the right care path at the right time," **said Michael J. Donovan, Ph.D., M.D., Chief Medical Officer of Renalytix.** "The adoption rate among PCPs as reported at the 2022 ADA late-breaking poster session on our real-world evidence study and the published clinical utility study underscores both the clinical need and clinician confidence in using KidneyIntelX to provide actionable risk stratification. In the real-world setting, this was associated with a 6-fold increase in the initiation of guideline-recommended treatments, and a nearly 3-fold increase in appropriate referrals."*

Results demonstrate growing awareness among PCPs in terms of the recognized value of KidneyIntelX in clinical decision making:

- The significance of these results was supported by a rigorous, analytical framework created to be highly representative of real-world care today and included 42 unique patient profiles and was designed to show what happens when KidneyIntelX is included vs. not included in patient care.
- The KidneyIntelX test had a greater relative importance than the standard of care (eGFR and UACR) for PCPs in prescribing guideline-recommended therapies and deciding when to consult with a specialist.

- 98% of PCPs responded they were somewhat, very, or extremely likely to use KidneyIntelX to predict which of their patients will experience rapid progressive kidney function decline.
- A behavioral shift among PCPs was examined after the introduction of KidneyIntelX. Approximately 80 percent of PCPs in the study noted risk assessment would support the decision to take more aggressive, guideline recommended clinical actions in high-risk, early stage (stage 1 through 3b) diabetic kidney disease patients.

"Adoption of KidneyIntelX among primary care physicians could play an important role in changing how we treat patients with diabetic kidney disease, by allowing for timely intervention in the early stages 1-3 of disease, when primary care physicians have the power to delay or prevent progression," ***said Dr. Stephen Brunton, MD, FAAFP, CDCES, Primary Care Education Consortium, Family Practitioner and Executive Director of the Primary Care Metabolic Group.*** *"This study adds to the growing body of clinical utility evidence showing how advanced prognosis tools like KidneyIntelX could help make more informed decisions in the management of patients, especially in early disease, and limit progression to end stage kidney disease."*

A total of 401 PCPs participated in the published clinical utility study. Respondents were recruited to ensure broad generalizability of results based on geographic and care model distribution, as well as a representative distribution of types of health insurance coverage. The geographic distribution of respondents was representative of the geographic distribution in the United States. The study was funded by a research grant from Renalytix.

The full study is available here.

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About Kidney Disease

Kidney disease is a public health epidemic affecting over 850 million people globally.[2] The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people[3], have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3[4]. 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 with 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™

KidneyIntelXTM is a laboratory-developed test demonstrated to be a reliable, bioprognosticTM 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 also received Breakthrough Device Designation from the U.S. Food and Drug Administration and has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the

evidence, visit www.kidneyintelx.com.

Sources

1 Saran R, Robinson B, Abbott KC, Bragg-Gresham J, Xiaoying C. U.S. Renal Data System 7 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States. *Am J* 8 *Kidney Dis*. 2020;75(1):S1-S64.
2https://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 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 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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