Renalytix Completes Agreement with Veterans Administration to Integrate KidneyIntelX Testing across all Electronic Health Record systems

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Significant milestone will make KidneyIntelX accessible to 960,000 veterans with chronic kidney disease

LONDON and SALT LAKE CITY, Jan. 09, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) today announced the execution of a Co-operative Research and Development Agreement (CRADA) with the U.S. Veterans Health Administration Innovation Ecosystem (VHA IE) to install the KidneyIntelX solution inside the VA Health System's Cloud Infrastructure and interface it with the VA Electronic Health Record Systems. This marks a significant milestone in enabling providers at 171 VA Medical Centers (VAMCs) and related outpatient clinics to order and receive test results in a seamless manner.

The outputs from this agreement will be instrumental in ensuring that Veterans and their providers have the same access to the benefits of early-stage risk assessment of patients with diabetic kidney disease (DKD) by KidneyIntelX and the improvements in care and outcomes that have been demonstrated in published studies in other health systems[1]. By installing the KidneyIntelX platform inside the VA infrastructure through this innovative approach, one of the first such implementations by the VA, the stringent requirements for the security of Veteran's health information and data will be assured.

The KidneyIntelX solution will complement the Department of Veterans Affairs (VA) / Department of Defense (DoD) into the clinical practice guideline for the management of CKD (Version 4.0-2019 Care Directive 1053) entitled, Chronic Kidney Disease Prevention, Early Recognition and Management[2]. According to the March 17, 2020, Veterans Health Administration (VHA) Directive 1053, approximately 960,000 Veterans, or 11%, meet the established criteria for chronic kidney disease (CKD). However, less than half of those Veterans, 320,000, or 5%, have been formally diagnosed with CKD. The annual VHA cost related to CKD is estimated to be $19 billion dollars. Given that 65% of the Veterans who may have CKD may be improperly or not diagnosed and treated, this collaboration represents a significant opportunity for the VHA to immediately initiate a broader CKD assessment for chronic disease population health management.

Integration with multiple systems such as the VA Computerized Patient Record System (CPRS), Cerner, and Veterans Information Systems and Technology Architecture (VistA) will streamline operations to overcome adoption hurdles and enable access to KidneyIntelX for a large, at-risk patient population.

The program will commence immediately and will be implemented on a phased basis over an approximate 18-month period.

According to Fergus Fleming, Chief Technology Officer of Renalytix, *"The opportunity to work collaboratively with the VHA Innovation Ecosystem and Office of Information Technology (OIT) at a national level to integrate KidneyIntelX within the VA cloud is transformational, and reaching this milestone significantly advances our shared value proposition for this collaboration, to introduce an innovative approach for early risk assessment of CKD into care for this important population."*

Renalytix became an authorized laboratory service provider for all government health locations under the General Services Administration (GSA) contract announced in April, 2021.

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[1] Tokita J, Vega A, et al. Real World Evidence and Clinical Utility of KidneyIntelX on Patients With Early-Stage Diabetic Kidney Disease: Interim Results on Decision Impact and Outcomes. J Prim Care Community Health. 2022 Jan-Dec; 13:21501319221138196.

[2] VHA 2019 Care Directive 1053: Chronic Kidney Disease Prevention, Early Recognition and Management.

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 people[2], have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3[3]. 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 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 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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