Renalytix and Partners Awarded $10 Million Grant

January 26, 2023

RNS Number : 8999N
Renalytix PLC
26 January 2023

Renalytix plc

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

Renalytix and Partners Awarded $10 Million Horizon Europe Grant to Advance Personalized Medicine in Treating CKD Throughout Europe and the United States

Award for consortium of industry, academic and clinical research leaders to develop personalized drug response tests in chronic kidney disease

LONDON and SALT LAKE CITY, Jan. 26, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces the launch of PRIME-CKD*, a consortium of industry, academic and clinical research leaders, that aims to validate and implement in clinical practice, novel biomarker-based tests that predict response to existing drugs used by patients with chronic kidney disease (CKD). PRIME-CKD is funded by Horizon Europe, the European Union's key funding program for research and innovation. The total budget of the project is $10 million over a projected five-year period with approximately 10% of the budget targeted for commercial translation activities to be undertaken by Renalytix.

We expect the project to benefit from Renalytix's substantial expertise in biomarker research translation and existing intellectual property on urinary Epidermal Growth Factor (uEGF) for which Renalytix has exclusive access from the University of Michigan. The project is closely aligned with Renalytix's objective of expanding the clinical utility of the KidneyIntelX platform beyond prognosis to prediction and monitoring of drug response.

The consortium brings together leading experts from 11 academic institutions, together with partners from patient representative foundations and regulatory agencies. A full listing of consortium members is provided below.

The PRIME-CKD consortium is committed to demonstrating the utility of novel biomarkers as tools for better selection of drug therapies for patients, for use both in daily clinical practice and innovative clinical trials. Notably, if certain biomarkers are successful, the PRIME-CKD program will seek qualification of these biomarkers through the European Medicines Agency and the United States Food and Drug Administration (FDA) for this purpose.

Hiddo J.L Heerspink, the program coordinator from the University Medical Center Groningen, Netherlands, said: "*Results from this project are expected to translate into significant patient benefits and decreased societal costs associated with CKD by helping ensure that patients receive the most effective therapy, at the right time, to slow or prevent the kidney failure requiring dialysis or transplant.*"

Fergus Fleming, Chief Technology Officer of Renalytix who will serve on the steering committee for PRIME-CKD and lead the implementation of the research outputs into clinical practice, added: *"The opportunity to participate in the PRIME-CKD program combined with ongoing development of novel biomarkers from our collaboration with Joslin Diabetes Center and planned data generation in completed clinical studies expected in 2023, further strengthens KidneyIntelX as a precision medicine platform in CKD."*

The PRIME-CKD program builds on breakthrough findings in the Innovative Medicine Initiative 2 program BEAt-DKD (https://www.beat-dkd.eu/) which was initiated in 2016 and identified novel biomarkers of disease progression and treatment response in patients with diabetic kidney disease. *"I am excited to be involved in the PRIME-CKD program which builds upon the strong kidney research pipeline and precision medicine vision developed in Europe over the last years,"* **said Professor Maria F. Gomez, PRIME-CKD steering committee member and coordinator of the BEAt-DKD consortium from**

Lund University Diabetes Centre, Sweden. The PRIME-CKD consortium will further develop the evidence-based tools and roadmap to unlock the potential of precision medicine in the management of CKD.

*__PRIME-CKD__ is Personalized Drug Response: Implementation and Evaluation of CKD
**__Participating Organizations__: Academisch Ziekenhuis Groningen (NL), Renalytix (IE), University of Michigan The Regents of the University of Michigan (US), Lund University (SE), Region Hovedstaden Hillerod (DK), Universitaetskliinikum Hamburg Eppendorf (DE), Universita Degli Studi Della Campania Luigi Vanvitelli (IT), University of Leicester (UK), Alma mater Studiorum - Universita Di Bologna (IT), IRCCS Azienda Ospedaliero-Universitaria di Bologna (IT), Fundación para la Investigación del Hospital Clinico de la Comunitat Valenciana, Fundación Incliva (ES), Hessels + Grob (NL), Agentschap College Ter Beoordeling van Geneesmiddelen (NL), Universitätsklinikum Erlangen (DE), Nierstichting (NL).

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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 approximately 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 about 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: Renalytix's participation in the PRIME-CKD program, the potential benefits associated with PRIME-CKD and the partnership with leading academic institutions, partners from patient representative foundations and regulatory agencies, the timing and success of the PRIME-CKD program, 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, and the ability of KidneyIntelX to 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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