Business Update - Replacement

March 27, 2023

RNS Number : 3435U
Renalytix PLC
27 March 2023

The following amendment has been made to the 'Business Update' announcement released today, 27 March 2023 at 0700 under RNS No 2296U.

The real-world evidence data published in the Journal of Primary Care Community Health was published in November 2022.

All other details remain unchanged. The full amended text is shown below.

Renalytix plc

("Renalytix" or the "Company")

Business Update

LONDON and SALT LAKE CITY, March 27, 2023 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) provides the following business update.

Renalytix has further expanded its insurance coverage base for KidneyIntelX in the Northeast region of the United States with the execution of a coverage contract with EmblemHealth, one of the nation's largest not-for-profit health insurers serving over three million people in the New York Tri-State area.

The EmblemHealth contract and other previously established insurance coverage contracts including Healthfirst, Capital District Physicians Health Plan and Connecticare, build on the comprehensive insurance coverage portfolio necessary to transition to a full commercial payment model for KidneyIntelX prognostic testing in the New York and Connecticut state regions.

As previously disclosed on the Company's November 2022 quarterly earnings call, Renalytix is pursuing a strategy to achieve insurance coverage for KidneyIntelX for a majority of patients in specific United States regions containing large populations living with diabetes and kidney disease. Management believes achieving insurance payment for a majority of the population in KidneyIntelX's indicated use is essential for adoption to proceed. This is particularly important at a primary care or generalist physician level where KidneyIntelX testing is focused, as patients and doctors need to have a clear understanding of test billing practices and the amount of patient financial obligation, if any, once a test is performed.

Renalytix is working with health systems, as well as public and private payers to implement care models informed by KidneyIntelX early risk assessment in patients with diabetes and kidney disease to improve kidney health and reduce the number of dialysis starts.

Real-world evidence data from a large prospective study at Mount Sinai Health System in New York evaluating KidneyIntelX in the primary care setting published in the Journal of Primary Care Community Health in November 2022 demonstrated use of KidneyIntelX resulted in an increase in appropriate therapeutic management, timely specialist consultation or referral and observed improvements in HbA1C (diabetes health) in the high risk groups and UACR (kidney health) in the low and intermediate risk groups in as little at 6 months in patients with kidney disease and diabetes. Additional results from ongoing multi-center real world evidence studies on KidneyIntelX are expected to be released this summer.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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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 report 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, expectations regarding insurance and covered lives, 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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