US Government coverage expanded

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THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION AS DEFINED IN ARTICLE 7 OF MAR. THE PERSON RESPONSIBLE FOR ARRANGING THE RELEASE OF THIS ANNOUNCEMENT ON BEHALF OF RENALYTIX IS JAMES MCCULLOUGH, CEO.

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

Renalytix Expands US Government Coverage for FDA Approved kidneyintelX.dkd Testing at $950

Data to be Presented Today at NGS Open Meeting Demonstrating Clinical Value of KidneyIntelX

LONDON and SALT LAKE CITY, February 29, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) ("Renalytix" or the "Company") announces that effective March 1, 2024, the United States Government has approved adding the company's Food and Drug Administration ("FDA") de Novo Marketing authorized test, kidneyintelX.dkd, to its 10-year Governmentwide Acquisition Contract (GWAC) for early-stage kidney disease bioprognostic™ testing services. Pricing for kidneyintelX.dkd is set at $950 per reportable result. The contract, effective through 2031 and offered through the General Services Administration (GSA), covers laboratory testing services provided by any government healthcare facility, including the U.S. Veterans Administration (VA), Department of Defense (DoD) military branches (the Army, Marine Corps, Navy, Air Force, Space Force, and Coast Guard), and Indian Health Services (IHS).

In addition, today National Government Services ("NGS"), a Medicare Administrative Contractor (MAC), is holding its first quarter Open Public Meeting that includes consideration of its proposed coverage policy for KidneyIntelX and kidneyintelX.dkd testing. As disclosed previously, NGS has adopted a consistent payment approach for KidneyIntelX testing that is expected to continue through the finalization of the proposed coverage policy.

During the Open Public Meeting, both representatives from Renalytix and third-party external experts will speak in support of coverage policy DL39726 for KidneyIntelX and kidneyintelX.dkd testing. Speakers will include:

- Dr. Tahir Effendi, MD, FACP, Internal Medicine Specialist at Hudson Shores Medical Group;
- Dr. Barry Freedman, MD, John H. Felts, III Professor of Medicine and Chief, Section on Nephrology at the Wake Forest University School of Medicine; and
- Dr. Joji Tokita, MD, Nephrologist and Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai.

During the meeting, the presenters will share data to demonstrate the clinical value of KidneyIntelX from studies enrolling a combined 9,000 patients from the Mount Sinai Health System and the Atrium/Wake Forest Health System who are being treated based on their initial risk assessment result. An expanded presentation of key data has been accepted for the National Kidney Foundation (NKF) Spring Clinical Meeting being held May 14-18, 2024.

Following the Open Public Meeting, NGS will review and respond to letters submitted during an open comment period that ends on March 23, 2024. Renalytix expects issuance of a final Local Coverage Determination ("LCD") could occur during fiscal year 2024. If the LCD is finalized in its proposed form, Medicare (through NGS) will provide coverage for KidneyIntelX and kidneyintelX.dkd testing, provided that the terms of the LCD are met.

Effective January 1, 2024, KidneyIntelX and kidneyintelX.dkd testing has been priced at $950 on the Centers for Medicare and Medicaid Services (CMS) Clinical Lab Fee Schedule ("CLFS"). The CLFS is a complete listing of the approved fees Medicare will pay for individual laboratory tests. It is used to reimburse clinical laboratories like Renalytix for their testing services. Published pricing for Clinical Laboratory Diagnostic Tests like kidneyintelX.dkd are effective for three years.
Collectively, these advancements are expected to facilitate insurance reimbursement for 10 million of the 14 million patients in the United States that fall within the FDA Authorized indication for use of kidneyintelX.dkd. The Company believes these collective advancements represent entering the final stage of comprehensive United States insurance coverage.

For further information, please contact:

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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.

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: timing and outcome of LCD determination, clinical utility of KidneyIntelX, and timing and amount of additional insurance contracts and covered lives. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. The Company may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on the Company's 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; the Company has only recently commercially launched KidneyIntelX; and risks relating to the impact on the Company's business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of its annual report on Form 10-K filed with the SEC on September 28, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 filed with the SEC on February 14, 2024, and other filings the Company makes with the SEC from time to time. All information in this press release is as of the date of the release, and the Company undertakes 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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