Medicare issues final Local Coverage Determination

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This announcement contains inside information for the purposes of Article 7 of the UK version of Regulation (EU) No 596/2014 which is part of UK law by virtue of the European Union (Withdrawal) Act 2018, as amended ("MAR"). Upon the publication of this announcement via a Regulatory Information Service, this inside information is now considered to be in the public domain.

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

Medicare Issues Final Coverage Determination for kidneyintelX.dkd

Company has Achieved Prerequisites for Growing Test Adoption with FDA Authorization, Clinical Outcomes Data, Inclusion in Clinical Guidelines, and Broad Insurance Coverage

LONDON and NEW YORK, 14 June 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces that on June 13, 2024 Medicare issued a final Local Coverage Determination ("LCD") for the Company's kidneyintelX.dkd testing. The final LCD can be accessed at LCD - KidneyIntelX and KidneyIntelX.dkd Testing (L39726) (cms.gov), and is effective for dates of service on or after August 1, 2024. The established Medicare price for kidneyintelX.dkd is $950 per test. Distinct CPT Codes (Common Procedural Terminology Codes) have been established for kidneyintelX.dkd and is published in CMS' 2024 Clinical Lab Fee Schedule.

The LCD specifies coverage for use of kidneyintelX.dkd for patients with diagnosed Type 2 diabetes and Stage 1-3b Chronic Kidney Disease is reasonable and necessary. Any specified limitations for use conform to the U.S. Food and Drug Administration ("FDA") label for kidneyintelX.dkd. The LCD was issued by National Government Services ("NGS"). NGS is a subsidiary of Elevance Health, Inc. (previously Anthem, Inc.), a Medicare Administrative Contractor responsible for claims processing for testing performed in the Company's New York City laboratory.

"With final Medicare Coverage, an FDA authorization, and an April recommendation in the international clinical guidelines, kidneyintelX.dkd is poised to be a preventative medicine standard for 14 million people in the United States living with diabetes and kidney disease. We expect this Medicare coverage will prompt additional major coverage decisions and help accelerate testing adoption," said James McCullough CEO of Renalytix. "We remain focused on incremental sales growth in targeted US regions with a now significantly lower cost of operations."

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About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an artificial intelligence enabled *in-vitro* diagnostics and laboratory services company that is the global founder and leader in the field of bioprognosis™ for kidney health. In late 2023, our kidneyintelX.dkd test was recognized as the first and only FDA-authorized prognostic test to enable early-stage CKD (stages 1-3b) risk assessment for progressive decline in kidney function in T2D patients. By understanding how disease will progress, patients and clinicians can take action earlier 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, and the commercial prospects of KidneyIntelX. 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; and that the Company has only recently commercially launched KidneyIntelX. 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, and any risks that may be contained in any subsequent filings that the Company makes with the SEC . 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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