Update on MCIT Rule

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This announcement contains inside information

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

Update on MCIT Rule
to Provide National Medicare Coverage for FDA Breakthrough Devices and Diagnostics

NEW YORK, September 14, 2021 - Renalytix plc **(NASDAQ: RNLX) (LSE: RENX)** provides an update on developments related to the Medicare Coverage of Innovative Technology (MCIT) rule to provide a coverage pathway for Medicare beneficiaries to access FDA-cleared or approved breakthrough devices during an initial four year period after FDA clearance or approval.

Following a previously announced delay in the implementation of the final rule establishing the MCIT pathway, the Centers for Medicare & Medicaid Services (CMS) issued a proposal to repeal the final rule prior to implementation on December 15, 2021. CMS stated that it believes there are other ways to achieve the goal of providing innovation and access to important new technologies including future policies and potential rulemaking. CMS is now providing a public comment period to allow stakeholders to provide input on the proposed repeal.

Independent of MCIT, Renalytix has continued to develop clinical evidence to support Medicare coverage at the local level from a Medicare Administrative Contractor (MAC), which it could receive as early as mid-calendar 2022. Coverage from a MAC would allow for Medicare reimbursement at $950 for any Medicare beneficiary in the United States receiving KidneyIntelX testing. The Company will continue to build revenue momentum this year with Mount Sinai Health System, under the General Services Administration-awarded contract, and through other private and public payers.

James McCullough, CEO, commented: *"The proposed repeal of the rule is a disappointing setback for diagnostic innovation. Given our trajectory for accumulating real-world utility evidence, however, we do not believe there will be a material impact on the KidneyIntelX business plan and are confident of continuing success to secure comprehensive government and private insurance reimbursement for KidneyIntelX."*

The person responsible for this announcement is James McCullough, CEO.

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About KidneyIntelX

KidneyIntelX, is a first-of-kind, solution that enables early-stage diabetic kidney disease progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

About Renalytix

Renalytix (LSE: RENX) (NASDAQ: RNLX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease, progression risk assessment. The Company's lead product is KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). 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: the commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. 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 28, 2020, 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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