

RENALYTIX AI

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

March 15, 2021

NEW YORK, March 15, 2021 (GLOBE NEWSWIRE) -- [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, provides an update on the establishment of the Medicare Coverage of Innovative Technology (MCIT) pathway to provide a coverage pathway for Medicare beneficiaries nationwide for innovative medical devices and diagnostic tests designated under the Breakthrough Device review program and with market authorization by the U.S. Food and Drug Administration (FDA).

Centers for Medicare & Medicaid Services (CMS) will delay the implementation date of the MCIT rule by 60 days, beginning a 30-day comment period to solicit additional public feedback on the rule. RenalytixAI expects the MCIT rule, as is or amended, will become effective within the expected 2021 FDA review and clearance period for KidneyIntelX and will have no material effect on the RenalytixAI business plan.

RenalytixAI's lead product, KidneyIntelX, was granted FDA breakthrough designation in [May 2019](#) and submitted its final FDA application in August 2020. The MCIT rule has bipartisan support in Congress and is considered by many as a key program to drive medical innovation and improve countless lives. Further background and details are contained in the Company's announcement on January 13, 2021.

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About Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year, kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

* <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About RenalytixAI

RenalytixAI (LSE: RENX) (NASDAQ: RNLX) is a developer of artificial intelligence-enabled clinical in vitro diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's lead product is KidneyIntelX.com (visit www.kidneyintelx.com) which is being designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit www.renalytixai.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 potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully distributed and marketed, our ability to take advantage of the MCIT program, our expectations regarding the timing and impact of the MCIT rule, 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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