Renalytix Commends HHS/CMS on Finalization of MCIT Rule to Provide National Medicare Coverage for FDA Breakthrough Devices and Diagnostics

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Creates Pathway for Beneficiary Access to KidneyIntelX for Medicare Beneficiary Kidney Disease Populations

NEW YORK, Jan. 13, 2021 (GLOBE NEWSWIRE) -- The Centers for Medicaid & Medicare (CMS) announced the establishment of the Medicare Coverage of Innovative Technology (MCIT) pathway (**RIN:** 0938-AT88), to provide a coverage pathway for Medicare beneficiaries nationwide to have faster access to new, 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). Under MCIT, national Medicare coverage can become effective on the date of FDA approval or clearance of a breakthrough designated device and will continue for a period of four years. After a four-year period, continued coverage for Medicare beneficiaries will be based on one of three methods, 1) case-by-case coverage, 2) a local coverage determination, or 3) a national coverage determination.

“Having a clear path to national Medicare coverage for innovative products like KidneyIntelX provides a major catalyst to drive the robust research and clinical development programs necessary to address major unmet medical needs such as kidney disease,” stated Tom McLain, President, RenalytixAI. “MCIT will also encourage early engagement with FDA in developing new diagnostic tests and leverage the many benefits of Breakthrough Designation including priority review of needed technology. We appreciate the opportunity to work with FDA and CMS to tackle the critical issue of early stage prognosis to help slow or prevent kidney disease progression. This new coverage pathway will facilitate accelerated access to KidneyIntelX for Medicare beneficiaries and their primary care doctors to help assure a better quality of life and save lives.”

RenalytixAI’s lead product, KidneyIntelX, was granted FDA breakthrough designation in May 2019. After working closely with the FDA review team assigned to KidneyIntelX the company submitted its DeNovo 510K application for clearance in August 2020. Assuming FDA clearance is received in 2021, Renalytix will opt in for the automatic four-year National Medicare coverage period. In addition to the MCIT coverage pathway for the test, Renalytix has already designed a prospective utility and outcome study. The aim of the 2,000-patient study is to further demonstrate the clinical value of KidneyIntelX testing in delaying or preventing the progression of early-stage diabetic kidney disease.

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 (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 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 final prospectus filed with the SEC on July 17, 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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