



Payer Budget Impact Analysis Projects Significant Savings from KidneyIntelX™ Testing at Primary Care Level

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Peer reviewed publication in Journal of Medical Economics supports payer coverage for early-stage risk assessment and care management in the primary care office

NEW YORK and SALT LAKE CITY, Aug. 26, 2021 (GLOBE NEWSWIRE) -- [Renalytix Plc](#) (NASDAQ: RNLX) (LSE: RENX) today announced the publication of results from an external chronic kidney disease budget impact analysis projecting 5-year savings of \$1.1 billion for a population of 100,000 patients with type 2 diabetes (T2DKD) and chronic kidney disease tested with the Renalytix KidneyIntelX™ testing solution. Savings were driven by more effective pharmacy management and appropriate specialist referral compared to current standard of care for patients at high risk for disease progression and kidney failure.

The detailed clinical and cost analysis concluded that health systems and insurance plans would realize these significant cost savings based on slowed disease progression (52% of savings), delayed, or prevented dialysis and transplants (32% of savings), and reduced dialysis crashes (11% of savings). Given the costs associated with current standard of care, the addition of an actionable bioprognostic™ approach to predict kidney function decline in T2DKD patients, stages 1-3b resulted in a projected 5-year savings of \$1.1 billion associated with KidneyIntelX.

"These findings are significant and further demonstrate that predicting kidney disease risk at its earliest stages – when it matters most – is a major benefit to patients, providers and payers," said CDPHP president and CEO, Dr. John D. Bennett.

Budget impact analysis (BIA) is a key element in securing payer coverage in the U.S. market. BIA is an economic assessment that estimates the financial consequences of adopting a new, high value intervention like KidneyIntelX. The analysis takes a payer's perspective to evaluate whether a new intervention is affordable. It uses a short-term time horizon, up to 5 years. The model analyzes the direct costs of specific resources needed to implement KidneyIntelX informed care in the PCP office with savings associated with changes in care delivery. That result is multiplied by the number of people affected by the intervention. The results of the analysis provide an understanding of the total budget required to provide the intervention. The size of the population is explicitly considered for this analysis. The focus of a BIA is the direct costs of specific resources needed to put the intervention into effect, such as testing, pharmacy management, and specialist care. Consistent with best practices, sensitivity analyses were conducted to evaluate the impact of core assumptions related to physician compliance and disease progression.

Renalytix will further expand its health economic and utility evidence through separate cost-effectiveness analyses evaluating whether intervention with KidneyIntelX testing provides value, defined as cost relative to health outcome, relative to current standard of care. These analyses will be completed in conjunction with three large real-world evidence studies with Mount Sinai Health System, Wake Forest/Atrium Health and University of Utah Health.

The budget impact model was developed in collaboration with Boston Healthcare Associates (BHA), an external firm, in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) good practices. BHA researchers evaluated the budget impact of management using KidneyIntelX as compared with standard of care over a 5-year horizon in patients with diabetic kidney disease (DKD). Results are detailed in, "[Payer Budget Impact of an Artificial Intelligence In Vitro Diagnostic to Modify Diabetic Kidney Disease Progression](#)," published in the Journal of Medical Economics.

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 one out of two people with very low kidney function who are not on dialysis do not know they have CKD.¹ 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.

¹ <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About KidneyIntelX™

KidneyIntelX, is a first-of-kind, platform that employs a proprietary artificial intelligence-enabled algorithm to combine diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, 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 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, which has been granted Breakthrough Designation by the U.S. Food and Drug Administration and which 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 potential benefits, including economic savings, of KidneyIntelX, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, 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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