

RENALYTIX AI

30 September 2019

This announcement contained inside information

Renalytix AI plc

("RenalytixAI", the "Company" or the "Group")

CMS Issues Preliminary Medicare Pricing Determination for *KidneyIntelX*[™]

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces that Centers for Medicare & Medicaid Services ("CMS") has published its preliminary determination for national Medicare pricing for the Company's *KidneyIntelX*[™] test to be included in the national 2020 Clinical Laboratory Fee Schedule¹. The preliminary determination sets a price of \$950 for each test. CMS considered recommendations received through an open meeting and brief comment period along with the consensus of an independent advisory panel.

A public comment period follows the publication of these preliminary determinations with comments accepted by CMS up until October 27. Final pricing determinations are expected to be published in November 2019 and will become effective on January 1, 2020. The price set for *KidneyIntelX* will be effective for a three-year period, ending on December 31, 2022. The Company intends to pursue coverage determinations from both Medicare and private insurance payors at this pricing level beginning in 2019 for patients with kidney disease and Type 2 diabetes.

One of the greatest drivers of health care cost today is patients with rapidly-progressing diabetic kidney disease who are not identified in time and who face progressive kidney failure and unplanned transition to dialysis. Approximately 12 million people have diabetic kidney disease in the United States². Each year kidney disease results in the death of more people than breast and prostate cancer³.

KidneyIntelX is designed to predict progression of kidney disease and ultimately improve outcomes and health care system economics in patients with Type 2 diabetes and existing kidney disease. *KidneyIntelX* uses machine-learning algorithms to assess a combination of predictive blood-based biomarkers and features from a patient's electronic health record to generate a prognostic risk score for rapid-progression of kidney disease.

In a recent study published on-line, April 1, 2019⁴, the rate of rapid progression of kidney disease for patients identified as *high-risk* by *KidneyIntelX* was shown to be approximately 10 times greater than patients identified in the *low risk* group. For patients experiencing rapid progression of kidney disease, and therefore most likely to advance toward end-stage renal disease and dialysis, there are several clinical management strategies and proven therapeutic options to slow the rate of disease progression and/or halt its progress.

This announcement follows confirmation of the vote in favour of recommending 'crosswalk' pricing for *KidneyIntelX* by the independent Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests as referenced in the Company's results release dated September 3, 2019.

A further announcement is expected in November following confirmation of the final pricing determination for *KidneyIntelX* from Medicare.

Notes

¹ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html

Click on link: "CY 2020 – Clinical Laboratory Fee Schedule Test Codes Preliminary Determinations [ZIP, 48KB]"

² <https://cjasn.asnjournals.org/content/12/12/2032>

³ <https://www.ncbi.nlm.nih.gov/pubmed/30738630>

⁴ <https://www.biorxiv.org/content/10.1101/587774v1>

The person responsible for arranging the release of this announcement on behalf of the Company is James McCullough, CEO.

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About Kidney Disease

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have chronic kidney disease. It is reported 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 die in the United States while waiting for a kidney transplant.

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

About RenalytixAI

RenalytixAI 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 products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery.

For more information, visit renalytixai.com