RENALYTIX**AI**

Medicare sets US national price for KidneyIntelX™

December 3, 2019

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US National pricing of $950 effective as of January 1st, 2020

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces that that the Centers for Medicare and Medicaid Services ("CMS") has released the Final 2020 Clinical Laboratory Fee Schedule ("CLFS") and has set a national price for the Company's *KidneyIntelX™* test. Under the 2020 fee schedule, the price for *KidneyIntelX™* with a unique reimbursement code (0105U) is set at $950 and becomes effective on 1 January 2020. This price will remain in effect for a three-year term from January 2020 until December 2022.

This announcement follows the publication by CMS of its preliminary determination, announced by the Company on 30 September 2019 (RNS: 0452O).

The inclusion of *KidneyIntelX™* on Medicare's CLFS will accelerate RenalytixAI's contracting efforts with private insurance payors as several large insurance plans in the United States use Medicare's CLFS to determine test pricing. Based on this development RenalytixAI will expand the market focus for *KidneyIntelX™* to a US national programme, with a significant expansion in covered lives expected to take place beginning in 2020 and 2021.

Tom Mclain, President and Chief Commercial Officer, said: "*We are pleased that CMS has priced KidneyIntelX™ in the year of our national launch programme. Historically, coverage and pricing have lagged innovative test launches by three to five years. We believe this accelerated timeframe for KidneyIntelX™ pricing reflects the benefit of improved patient outcomes by delaying or preventing the onset of end-stage renal disease and kidney failure, as well as the expected cost reductions that can be delivered to healthcare systems across the United States.*"

With an established CPT code and CMS pricing, RenalytixAI expects additional factors will help catalyze volume growth and insurance coverage for *KidneyIntelX™* over the next 24 months, including:

1) the complementary clinical and economic value in using *KidneyIntelX™* alongside existing care guidelines for diabetic kidney disease patients;

2) the outcome and utility data that will be generated through collaborations with key US health systems; and

3) the achievement of an FDA clearance.

In Q4 calendar 2019, RenalytixAI achieved initial revenues from its *KidneyIntelX™* pharmaceutical testing programme and expects testing revenue growth to build in the second half of the financial year ending June 2020, subject to approval of its New York based clinical laboratory by the State of New York to report testing results. The Company also expects additional strategic initiatives to be implemented which will further expand distribution and accessibility for *KidneyIntelX™*. These additional strategic initiatives will be announced in the coming months as appropriate.

One of the greatest drivers of health care cost today is patients whose kidney disease is not diagnosed in time and who face kidney failure and unplanned transition to dialysis. Each year kidney disease kills more people than breast and prostate cancer[2].

In a recent study published April 1 2019[3], diabetic kidney disease patients who scored *high-risk* by *KidneyIntelX™* testing were 10 times more likely to experience kidney failure than those who scored *low-risk* by testing. 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 recently proven therapeutic options to slow the rate of disease progression and/or halt its progress.

Notably in the same study, greater than 95% of patients with a low *KidneyIntelX™* score did not experience any progression of their kidney disease over the next 5 years. As a result, even though these patients have known diabetic kidney disease, they are unlikely to progress with their disease further and can remain at a primary care physician level for monitoring.

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 kidney disease. It is reported that 9 out of 10 adults with chronic kidney disease 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[4]. 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.

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

Notes

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

2 https://www.ncbi.nlm.nih.gov/pubmed/30738630

3 https://www.biorxiv.org/content/10.1101/587774v1