Submission seeking FDA Clearance of KidneyIntelX

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Renalytix AI PLC
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Renalytix AI plc
("RenalytixAI", the "Company")

RenalytixAI Files Submission Seeking U.S. FDA Clearance of KidneyIntelX

NEW YORK, August 26, 2020 - 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, announces that it has filed a submission seeking clearance of KidneyIntelX™ with the U.S. Food and Drug Administration (FDA). This FDA filing builds on the Company's regulatory and commercialization program, which includes the June 12, 2020 announcement that the New York State Department of Health has issued a clinical laboratory permit for commercial clinical testing of KidneyIntelX.

KidneyIntelX is designed to provide potentially critical new information to health care providers, insurance payors and population health managers in an effort to support optimization of care delivery, improve patient outcomes and reduce the $120 billion annual cost[1] of chronic and end-stage kidney disease to the United States healthcare system.

In May 2019, RenalytixAI announced that KidneyIntelX was granted Breakthrough Device designation by FDA, the first such designation for an artificial intelligence-enabled *in vitro* diagnostic for kidney disease publicly announced by any company. FDA clearance is now being sought for the intended use of KidneyIntelX, in conjunction with clinical evaluation, as an aid to further assess the risk of progressive decline in kidney function within a period of up to five years in patients over the age of 21 with type 2 diabetes and existing chronic kidney disease ("CKD"). Patients with CKD and type 2 diabetes account for 20-30 percent of the estimated 37 million U.S. patients with CKD[2].

Performance data provided by RenalytixAI in the FDA 510(k) submission is based on a multi-

center validation study of more than 1,100 patients demonstrating that KidneyIntelX accurately identifies patients in early CKD stages 1, 2 and 3 who are at highest risk of progressive decline in kidney function and/or kidney failure.

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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 percent of U.S. 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 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. RenalytixAI's products are being designed to make significant improvements in kidney disease diagnosis, clinical care, patient stratification for drug clinical trials and drug target discovery. For more information, visit www.renalytixai.com.

Sources

1 United States Renal Data System: https://www.usrds.org/media/2371/2019-executive-summary.pdf

2 https://pubmed.ncbi.nlm.nih.gov/29054846/

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: our ability to achieve regulatory clearance of KidneyIntelX from the FDA and the ability of KidneyIntelX to curtail costs of CKD and end-stage kidney disease 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 not yet 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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