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Renalytix AI plc
("RenalytixAI" or the "Company")

New York State Department of Health issues CLIA Certificate Number for Renalytix Lab

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces that the New York State Department of Health has issued a Clinical Laboratory Improvement Amendment (CLIA)¹ certificate under the Centers for Medicare & Medicaid Services (CMS) to the RenalytixAI commercial laboratory in New York City. This unique CLIA certificate number is an important initial step in the process towards certifying RenalytixAI to conduct commercial operations for testing patients in the State of New York.

All clinical and forensic laboratories and blood banks located in, or accepting patient specimens from, New York State must hold a New York State Department of Health clinical laboratory permit. The RenalytixAI New York Laboratory facility will now therefore be scheduled for an on-site survey by the State of New York Department of Health. RenalytixAI would be eligible for such a permit after successful completion of proficiency testing, on-site survey and validation requirements.

A laboratory can only perform under a CLIA license those clinical diagnostic tests for which the analytic and clinical performance characteristics have been established (i.e. validated), or, if already established (typically by the test manufacturer), verified at the site where the clinical diagnostic test will be performed. The laboratory must also hold the appropriate permit category for the test and must meet all other requirements related to on-site survey standards, personnel requirements, and proficiency testing.

Notes:

¹ The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The objective of the CLIA programme is to ensure quality laboratory testing. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA programme.

² United States Renal Data System - <https://www.usrds.org/adrhighlights.aspx>

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About Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. In the United States alone, over 40 million people are classified as having chronic kidney disease, with nearly 50 percent of individuals with advanced (Stage IV) disease unaware of the severity of their reduced kidney function. As a result, many patients progress to kidney failure in an unplanned manner, ending up having dialysis in the emergency room without ever seeing a clinical specialist, such as a nephrologist. Every day 13 patients die in the United States while waiting for a kidney transplant. The annual number of kidney transplants in the United States and worldwide is rising steadily, with nearly 20 percent of transplants failing within three years², highlighting the need for improved patient outcomes and better management of the growing cost of medical treatment associated with kidney transplant complications.

About RenalytixAI

RenalytixAI is a developer of artificial intelligence-enabled clinical diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's solutions are being designed to make significant improvements in kidney disease diagnosis and prognosis, clinical care, patient stratification for drug clinical trials, and drug target discovery.

The Company's *KidneyIntelX* diagnostic is being developed using predictive and proprietary blood-based biomarkers, together with machine learning algorithms and electronic health record information, to diagnose and improve the clinical management of patients with fast-progressing kidney disease. RenalytixAI is also evaluating *FractalDx*, a portfolio of advanced diagnostic and prognostic solutions for use in kidney transplant, with an expanded investigator group of senior KOLs including practitioners at major transplant centers.

For more information, visit renalytixai.com.