

RENALYTIX AI

Commercial scale manufacturing milestone for KidneyIntelX™ test materials

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High quality production-scale batches of critical materials successfully produced

Key milestone achieved for scaled commercial test production

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces that its *in-vitro* diagnostic manufacturing programme has reached a critical development milestone for the production materials used to measure blood-based biomarkers in the *KidneyIntelX™* test. Multiple production-scale lots of the critical materials have been successfully produced and have met the stringent quality control specifications required to scale up manufacturing for commercial production. This milestone results from a successful collaboration with Meso Scale Diagnostics, LLC. ("MSD"), based in Rockville, Maryland, the world's leading provider of highly sensitive multiplex immunoassays.

The *KidneyIntelX™* diagnostic test will use machine learning algorithms to assess the combination of predictive blood-based biomarkers, including sTNFR1, sTNFR2 and KIM-1, and features from a patient's electronic health record, to identify those individuals most likely to experience fast-progressing kidney disease.

Fergus Fleming, Chief Technology Officer of RenalytixAI, said: "Working closely with MSD, we have successfully demonstrated that the *KidneyIntelX™* biomarkers sTNFR1, sTNFR2 and KIM-1 can be accurately measured using components manufactured in a highly automated, quality-controlled production facility. As a result, we have now secured our supply of biomarker assay components required to support scaled commercial testing."

James Wilbur, Ph.D., General Manager of MSD, noted: "Our validated V-PLEX immunoassay platform¹ was developed specifically for applications like personalised medicine where high-quality data and long-term consistency are essential. The components we are making for the *KidneyIntelX™* test use the same processes employed in the V-PLEX product line and will meet comparably stringent requirements."

Jacob Wohlstader, President and CEO of MSD, concurred: "MSD is dedicated to better patient care through supporting advanced personalised medicine testing. We are pleased to be working with RenalytixAI and look forward to the successful development of the *KidneyIntelX™* test."

KidneyIntelX™ is designed to improve clinical management of patients with Type II diabetes with fast-progressing kidney disease, in an effort to curtail the high global costs of Chronic Kidney Disease and end-stage renal disease. In the United States healthcare system alone, these costs are estimated at \$114 billion per annum. RenalytixAI expects to commercially launch *KidneyIntelX™* as a laboratory developed test in its CLIA laboratory facilities in the US in H2 2019.

Notes

1. V-PLEX multiplex immunoassays deliver reproducible, reliable results to support the most demanding analytical requirements. Offering exceptional dynamic range, high sensitivity, and lot-to-lot consistency, the V-PLEX multiplex assay platform can measure up to 10 biomarkers in a single test.

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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.

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. For more information, visit renalytixai.com.

About Meso Scale Diagnostics, LLC.

Meso Scale Diagnostics, LLC. (MSD) is a global leader in the development, manufacture, and commercialization of innovative assays and instruments for the measurement of molecules in biological samples for research use. MSD's proprietary MULTI -ARRAY technology enables its customers to profile many biomarkers simultaneously in a single sample without compromising assay performance. MSD's technology has been widely adopted by clinical laboratories, researchers in pharmaceutical companies, government institutions, and universities worldwide. As the company looks toward the future, it is expanding further into clinical applications and the emerging fields of personalized medicine and companion diagnostics.