Positive Interim Results for KidneyIntelX™ in Expanded Validation Study

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Data development plan review continues with FDA under Breakthrough Device Designation Process

Performance meets or exceeds targets for identifying Rapid Kidney Function Decline in patients with Type 2 diabetes and existing chronic kidney disease.

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces positive interim analysis of data from the *KidneyIntelX*™ expanded validation study. The results show that in a multi-centre cohort of Type 2 diabetes patients, the *KidneyIntelX*™ algorithm has met or exceeded required performance targets for identifying those patients experiencing rapid kidney function decline (RKFD)[1] and patients who eventually progressed to kidney failure and/or dialysis. The expanded validation programme data will support the ongoing regulatory process with the Food and Drug Administration ("FDA") under Breakthrough Device designation which was announced 2 nd May 2019.

Fergus Fleming, Chief Technology Officer of RenalytixAI, said: "*We have now completed the complex process of integrating electronic health record data and our proprietary blood biomarker measurements from over 3,000 patients with Type 2 diabetes from three independent, diverse population groups. KidneyIntelX™ continues to demonstrate significant performance improvements over current diagnostic standards and now in a multi-centre environment.*"

Initial performance targets, as outlined in a published study and publicly announced by RenalytixAI on 1st April 2019, illustrated that the *KidneyIntelX*™ machine learning algorithm significantly increased the ability to predict which patients went on to experience RKFD versus currently used diagnostic methods. Similarly, in the expanded validation study population, the positive predictive value ("PPV") of *KidneyIntelX*™ for RFKD in the Type 2 diabetes population exceeded 50% in those patients who were in the highest 15% of the risk distribution, and a negative predictive value of greater than 95% for patients unlikely to experience RKFD. This compares to a PPV of approximately 30% for standard of care methods. In addition, when the performance target was analysed for the clinical end-point of kidney failure within five years, in the interim results from the expanded validation study the PPV improved further.

Identifying high-risk patients more accurately and earlier can enable optimised clinical management and therapeutic options to slow kidney disease progression and help reduce the overall risk of developing end-stage kidney disease and unplanned or "crash" dialysis. In the United States healthcare systems alone, these costs are estimated at $114 billion per annum.

The Company announced on 23rd January 2019 the initiation of this validation study series to assess blood samples and electronic health records from patients with both Type 2 diabetes and patients of African ancestry. The Company intends to release further data updates in the near term including data relating to the multi-center, African ancestry patient cohort analysed by *KidneyIntelX*™ with the addition of a high-risk inherited gene known as *APOL1* into the algorithm.

The Company continues to work closely with FDA under Breakthrough Device designation to test *KidneyIntelX*™ in a final independent cohort of subjects that will form the basis for consideration in the ongoing regulatory approval process. RenalytixAI intends to provide further updates on this process in the near term as appropriate.

The *KidneyIntelX*™ artificial intelligence enabled *in vitro* diagnostic uses a machine learning algorithm to assess results from proprietary blood biomarkers in combination with information from a patient's electronic health record, to generate an RKFD score. The expanded validation study programme includes stored patient plasma samples and corresponding electronic health record features collected from three leading academic medical centres: Emory University, the Icahn School of Medicine at Mount Sinai and University of Pennsylvania. RenalytixAI expects to commercially launch *KidneyIntelX*™ in the US in H2 2019.

Notes

1. Rapid kidney function decline or RKFD is defined as a change in kidney function (glomerular filtration rate) of at least 5ml/min/1.73m^2/year

This announcement contains inside information. 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 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.