

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

Study demonstrates machine learning can significantly improve prediction of rapid kidney function decline in patients with diabetes

RenalytixAI machine learning approach outperformed current standard of care in 1,369 patient study

Renalytix AI plc (AIM: RENX), the developer of artificial intelligence-enabled diagnostics for kidney disease, announces publication of results generated by a confirmation study.

Highlights

- Study demonstrated that combining the Company's sTNFR 1, sTNFR2 and KIM-1 biomarkers with the analysis of data from de-identified electronic health records can significantly improve prediction of rapid kidney function decline ("**RKFD**") compared to widely used approaches
- A total of 1,369 patients were part of the study, including 871 patients with Type 2 diabetes and 498 patients of African ancestry
- The study incorporating a "random forest" inference approach to machine learning significantly outperformed standard clinical metrics for prediction of patients experiencing RKFD
- The study also demonstrated a high negative predictive value can be achieved for approximately 1/3 of patients with existing kidney disease who are unlikely to experience RKFD

The algorithms used in this study are at the core of the Company's AI-enabled diagnostic product, *KidneyIntelX™*.

The manuscript, entitled *"Prediction of rapid kidney function decline using machine learning combining blood biomarkers and electronic health record data"*, concludes that for patients with Type 2 diabetes or of African Ancestry with the high-risk *APOL1* genotype, a machine learning model, derived from blood biomarkers sTNFR 1, sTNFR2, and KIM1, and the analysis of de-identified data from a patient's electronic health records, significantly improved prediction of RKFD over standard clinical models and models without blood biomarkers.

A rigorous, multi-center clinical validation study has recently been initiated with c. 5,000 patient blood samples and features from patient electronic health records from the Icahn School of Medicine at Mount Sinai, Emory University and the University of Pennsylvania. Pending satisfactory completion of this further validation study and CLIA certification having been granted, commercial launch of *KidneyIntelXTM* is expected in the second half of 2019.

Full details of the manuscript can be found on bioRxiv, a free online archive and distribution service for unpublished preprints in the life sciences - <u>https://www.biorxiv.org/content/10.1101/587774v1</u>

Lead author is Girish Nadkarni, Department of Internal Medicine, Icahn School of Medicine at Mount Sinai, and co-senior authors of the manuscript are Michael Donovan, Department of Pathology, Mount Sinai and Steven Coca, Department of Internal Medicine, Mount Sinai.

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.

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