RENALYTIXAI

Positive results from FractalDx study published

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Demonstrates ability to predict early rejection in kidney transplant

Supports successful development of a predictive blood test for transplant patients

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announces positive study results have been published in the Journal of Clinical Investigation (JCI) Insight.   These results show FractalDx portfolio technology can accurately predict early acute kidney rejection in transplant patients. Early detection of acute transplant rejection is a critical unmet medical need that directly effects transplant success and long-term patient survival. In addition, the published results suggest that FractalDx can be used to personalise and potentially optimise the administration of immunosuppression therapy in kidney transplant patients. This could mitigate toxic side effects and damage to the transplanted kidney arising from excessive dosing.

Lead investigator for the study was Dr. Barbara Murphy, Dean for Clinical Integration and Population Health, Professor and System Chair Medicine and Nephrology, at the Icahn School of Medicine at Mount Sinai (ISMMS).

Dr. Christian P. Larsen, Professor of Surgery, Division of Transplantation, Department of Surgery at the Emory University School of Medicine and member of the RenalytixAI Kidney Transplant Advisory Board, said: *"This study offers the possibility to bring an individualised approach to the therapy selection for kidney transplant recipients, particularly in relation to selection of immunosuppression regimen. Current standard of care provides limited opportunity to identify patients most at risk of early acute rejection, and therefore the availability of a non-invasive blood test prior to transplant as presented in this publication, would represent a significant advance for the field."*

The publication coincides with an oral presentation of key data from the study at the American Transplant Congress (ATC 2019), the Joint Annual Meeting of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST).[2]

Earlier this year, RenalytixAI initiated the planning process for clinical validation of the first diagnostic products from its *FractalDx* technology portfolio in-licensed from the Icahn School of Medicine at Mount Sinai in conjunction with the RenalytixAI core investigator group. Data results from this published study in JCI will help further inform the ultimate validation study design, indicated use trial end-points and scope. As previously announced, the core investigator group includes leading transplant clinicians from Yale School of Medicine, Emory School of Medicine, University of Alabama at Birmingham Medicine, Mount Sinai Health System, University of Manatoba, Westmead Hospital, Cleveland Clinic, and University of Oxford.

RenalytixAI intends to begin the clinical validation programme for its acute transplant rejection diagnostic from H2 2019 and to prepare in 2020 for formal launch as a laboratory developed test through its New York City clinical laboratory facility.

The *FractalDx* technology is based principally on sequencing biomarkers from a patient's blood using widely available instrument platforms. Products under development from the portfolio are anticipated to be part of the extended RenalytixAI pipeline following the introduction of *KidneyIntelX* in 2019 for the diagnosis of fast-progressing chronic kidney disease.

Notes

1 https://insight.jci.org/articles/view/127543

2 https://eventpilotadmin.com/web/page.php?page=IntHtml&project=ATC19&id=553

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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.