

RENALYTIX AI

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

FractalDx Positive Results Published in JASN

Published data on blood diagnostic for subclinical acute kidney transplant rejection and potential to tailor immunosuppressive therapy

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 American Society of Nephrology (JASN)¹, in a paper entitled, *A Peripheral Blood Gene Expression Signature to Diagnose Subclinical Acute Rejection*. The results are part of a continuing research programme from the FractalDx kidney transplant diagnostic portfolio and demonstrate a blood test can diagnose kidney rejection before clinical signs of kidney damage and may be used to tailor immunosuppressive therapy. The results demonstrate key information can be provided to a transplant clinician without the need for an invasive kidney biopsy.

This post-transplant diagnostic, known as *FractalDx ACR*, is the second of the candidate tests from the FractalDX portfolio in-licensed by RenalytixAI from the Icahn School of Medicine at Mount Sinai and is in addition to study results published on 7th June in the Journal of Clinical Investigation (JCI) Insight², detailing a pre-transplant test for the recipient, now called *Fractal Baseline Dx*, for prediction of early transplant rejection. The lead investigator for both studies 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) in conjunction with investigators from the Genomics of Chronic Allograft Rejection study (GoCAR)³ and collaborators from the University Hospital, Leuven, Belgium.

Dr. Barbara Murphy, Non-Executive Director of RenalytixAI, Dean for Clinical Integration and Population Health, Professor and System Chair Medicine and Nephrology, at the Icahn School of Medicine at Mount Sinai (ISMMS), said: *"In transplant, the inability to accurately identify rejection before any clinical signs appear has a significant impact on therapeutic management and long-term viability of the transplanted kidney. These study results demonstrate that non-invasive measurements may be used to stratify patients immunologically so that immunosuppressive therapy can be tailored to the individual patient needs."*

Current approaches, which use serum creatinine and invasive surveillance biopsies, lack sensitivity and accessibility, missing in the order of 20% of underlying rejections⁴ which contribute to kidney injury and loss. The published results show how the *Fractal Serial Dx* test can identify status of underlying inflammation, allowing surveillance of the transplant status without the need of a biopsy while serum creatinine is still within the normal range and before there is functional evidence of injury.

Data from this published study, together with data recently published in JCI Insight, form the basis for a comprehensive suite of clinical diagnostics tests to be used both pre and post-transplant in an effort to reduce incidence rate of over 30% of kidney transplant recipients who experience graft loss and rejection in the first five years post-transplant.

RenalytixAI intends to begin larger scale clinical validation of the *Fractal Serial Dx* described in the publication for diagnosis of Sub-Clinical Acute (or underlying) Rejection as early as the second half of calendar 2019, with formal launch as a laboratory developed test through its New York City clinical laboratory facility expected in 2020. 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://jasn.asnjournals.org/content/early/2019/07/04/ASN.2018111098>

² <https://insight.jci.org/articles/view/127543>

³The GoCAR study is a prospective, multicenter study (US and Australia) aimed at investigating the genetics and genomics associated with the development of allograft rejection or injury in kidney transplant recipients. Patients underwent surveillance biopsies pre-transplant (before implantation), and at 3, 6, 12, and 24 months after transplant. Patients were followed up for 2 years or until death.

⁴Am J Transplant. 2006 Apr;6(4):747-52. Subclinical rejection associated with chronic allograft nephropathy in protocol biopsies as a risk factor for late graft loss. Moreso F et al

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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.