KidneyIntelX™ to Predict Major Adverse Kidney Events in COVID-19 Patients

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NEW YORK, April 20, 2020 /PRNewswire/ -- Renalytix AI plc (LSE: RENX), the AIM-traded developer of clinical grade artificial intelligence *in vitro* diagnostics for kidney disease, announces *that the KidneyIntelX™ platform will be used by investigators from the Icahn School of Medicine at Mount Sinai to assess the risk of adverse kidney events in patients diagnosed with COVID-19. Acute and chronic kidney disease is strongly associated with severity of disease and fatal outcomes in COVID-19 patients.* Evaluation of a patient's kidney risk status at the time of COVID-19 diagnosis, through recovery and during follow-on monitoring, can be of potentially high clinical value.

The *KidneyIntelX* platform will be used in a large study of COVID-19 admitted patients at Mount Sinai called "Pred-MAKER" *(Prediction of Major Adverse Kidney Events and Recovery). Pred-MAKER will study clinical features and biomarkers, including multiple* plasma biomarkers and urine proteomics and RNA sequences, *as predictors of major adverse kidney events in patients hospitalized with COVID-19. The study has been submitted for Institutional Review Board (IRB) review and approval.*

"Given the evidence that there is extensive systemic inflammation as well as kidney tubular injury in patients with COVID-19, the *KidneyIntelX* platform is well positioned to play a prominent role in understanding which patients are at highest risk of severe kidney complications and which patients are more likely to experience longer-term detrimental effects of COVID-19 infection," said Dr. Steven Coca, co-founder of RenalytixAI and co-Investigator in Pred-MAKER.

The overall goal of the study is to improve the understanding of mechanisms of COVID-19-associated kidney disease, and to leverage the *KidneyIntelX* platform to deploy comprehensive machine-learned prediction models that utilize clinical data along with plasma and urine biomarkers to risk stratify COVID-19 patients into low, medium and high-risk strata for major adverse events. Dr. Coca anticipates an accelerated timeline for the conduct of the study, given the current clinical work-load impact of COVID-19 at Mount Sinai and other New York City area hospitals.

The number of cases of COVID-19 requiring hospitalization and intensive care has been highest in the New York City metro area. The Mount Sinai Hospital and the Mount Sinai Health System have been severely affected by the enormous caseload of COVID-19 in March to April of 2020.[1] A system-wide effort led by Drs. Alexander Charney, Miriam Merad, and others, called the "Mount Sinai COVID-19 Biospecimen Collection",[2] began daily sampling of blood from people admitted with COVID-19 in early April and will serve as a robust resource for several research efforts including Pred-MAKER. Other faculty members in the Division of Nephrology at Mount Sinai involved specifically in Pred-MAKER include Drs. Evren Azeloglu (PI of the project), Girish Nadkarni, Lili Chan, Cijiang He, Barbara Murphy and several others.[3]

Acute and chronic kidney disease is strongly associated with COVID-19 severity and outcomes. Preliminary reports indicate that acute kidney injury (AKI) occurs in approximately 20% of patients hospitalized with COVID-19.[4] Moreover, the mortality rate in patients that experience AKI in the setting of COVID-19 is 2- to 7 times higher than patients without AKI.[5] In addition, reports suggest that 34-63% of COVID-19 patients develop significant proteinuria,[6] which is associated with a 3- to 15-fold increase in mortality. A recently published study, that utilized autopsy specimens from 26 patients that died of COVID-19 in China, demonstrated that there is evidence of the invasion of SARSCoV-2 into kidney tissue, along with significant acute tubular injury, endothelial damage, as well as glomerular and vascular changes indicative of underlying diabetic or hypertensive disease.[7]

While published reports on the incidence, severity and consequences of kidney disease in New York City and other urban centers in the United States are still lacking, it has been publicly noted that there is a severe shortage of dialysis nurses, dialysis machines and dialysis fluids to keep up with the burden of acute and chronic kidney disease in COVID-19 diagnosed patients in many New York City area hospitals.[8]

About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

* https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About RenalytixAI
RenalytixAI is a developer of clinical grade, artificial intelligence-enabled *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, and patient stratification for drug clinical trials. For more information, visit renalytixai.com

Notes:

1. As of April 14, 2,400 patients with COVID-19 have been successfully discharged from the Mount Sinai Health System, with another 1,955 patients currently hospitalized.
2. https://www.covid19hg.org/partners
3. Drs. Coca, Nadkarni, He, and Murphy receive financial compensation as consultants and clinical advisory board members for RenalytixAI, Inc., and own equity and/or options over equity in RenalytixAI. Dr. Murphy is a Non-Executive Director of RenalytixAI.
4. Zhou at al, Lancet; Arentz et al, JAMA

5. https://www.bmj.com/content/368/bmj.m1091, https://www.medrxiv.org/content/10.1101/2020.02.18.20023242v1
6. Cheng et al (Kidney Int 2020), Cau et al (medRxiv 2020), Anti-2019-nCoV Volunteers (medRxiv 2020)
7. https://www.kidney-international.org/article/S0085-2538(20)30369-0/fulltext
8. https://www.politico.com/news/2020/04/15/dialysis-kidney-coronavirus-188840

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