RENALYTIXAI

FDA Grants Breakthrough Device Designation to KidneyIntelX™

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Provides Priority Regulatory Review of AI-Enabled Diagnostic for Fast-Progressing Kidney Disease

NEW YORK, May 2, 2019 /PRNewswire/ -- Renalytix AI plc (LON: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announced today that it has been granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA), for its lead diagnostic, *KidneyIntelX™*.This is the first such designation for an AI-enabled diagnostic for kidney disease publicly announced by any company.

KidneyIntelX is designed to diagnose and improve clinical management of patients with Type II diabetes with fast-progressing kidney disease, in an effort to curtail the estimated \$114 billion annual cost[1] of chronic and end-stage kidney disease to the United States healthcare system. The diagnostic will use machine learning algorithms to assess the combination of predictive blood-based biomarkers, including sTNFR1, sTNFR2 and KIM1, in combination with electronic health record information, to identify progressive kidney disease. *KidneyIntelX^{TM}* is being developed in close collaboration with the Mount Sinai Health System.

The FDA's Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review while preserving the statutory standards for premarket approval, 510(k) clearance and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

"This designation is a significant advancement towards our goal of bringing to market a solution that can greatly improve the identification and treatment of patients with chronic kidney disease," said Sally Bowden, chief operating officer, RenalytixAI. "We look forward to continuing to work closely with the FDA through this process, including on our data development plan, our clinical validation and our subsequent submission for regulatory clearance."

Erik Lium, Ph.D., executive vice president of Mount Sinai Innovation Partners said, "We're pleased RenalytixAI has received Breakthrough Designation for KidneyIntelX, providing the opportunity to work hand-in-hand with the FDA towards the goal of FDA submission. Renal disease represents an increasing healthcare crisis globally, and early detection and intervention is essential in changing the course of this disease."

A copy of the FDA's guidelines on the Breakthrough Device Program can be found at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

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.

About Mount Sinai Innovation Partners (MSIP)
Mount Sinai Innovation Partners (MSIP) is responsible for driving the real-world application and commercialization of Mount Sinai discoveries and inventions, and the development of research partnerships with industry. Our aim is to translate discoveries and inventions into health care products and services that benefit patients and society. MSIP is accountable for the full spectrum of commercialization activities required to bring Mount Sinai inventions to life. These activities include evaluating, patenting, marketing and licensing new technologies building research, collaborations and partnerships with commercial and nonprofit entities, material transfer and confidentiality, coaching innovators to advance commercially-relevant translational discoveries, and actively fostering an ecosystem of entrepreneurship within the Mount Sinai research and health system communities. For more information please visit www.ip.mountsinai.org.

[1] United States Renal Data System - https://www.usrds.org/adrhighlights.aspx.

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