

RENALYTIX AI

RenalytixAI and Joslin Diabetes Center Build on Proprietary Kidney Biomarker Portfolio for KidneyIntelX Platform

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Agreement provides RenalytixAI with exclusive option to access intellectual property surrounding a comprehensive panel of novel biomarkers in kidney disease

NEW YORK, April 14, 2021 (GLOBE NEWSWIRE) -- [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX) announced today that it has entered into an exclusive option agreement with Joslin Diabetes Center for patent filings on certain additional novel biomarkers in kidney disease for development and deployment in the KidneyIntelX *in vitro* prognostic platform.

These novel biomarkers have the potential to provide additional clinical utility for understanding early disease progression and risk of kidney failure, therapeutic response, and the mechanistic pathways of kidney disease beyond the inflammatory and tubular injury markers that are currently captured by KidneyIntelX. RenalytixAI plans to begin evaluating these novel biomarkers in expanded clinical validation studies beginning in the second half of 2021.

"These proprietary blood biomarkers have the potential to significantly expand the utility of the KidneyIntelX platform, particularly in understanding how to efficiently enroll and characterize appropriate participants in new drug validation trials. We believe they could also contribute to a better understanding of patient response to approved drug therapies," said Fergus Fleming, Chief Technology Officer, RenalytixAI. "We look forward to working with Joslin and other research and pharma collaborators to build a platform to advance our understanding of underlying causal pathways of kidney disease, and bring precision medicine solutions to clinical practice."

In 2018, RenalytixAI secured an exclusive license from Joslin Diabetes Center to intellectual property relating to sTNFR1 and sTNFR2, both of which have been extensively validated as highly prognostic biomarkers in multiple settings and are integral to the KidneyIntelX test.

"We are pleased to extend our collaboration with RenalytixAI and advance our shared objective to translate high-quality research findings into clinical practice, thereby improving care and outcomes for people with kidney disease worldwide," said Roberta Herman, MD, president and CEO of Joslin Diabetes Center.

The biomarker discoveries have been developed in the laboratory of Andrzej Krolewski, MD, PhD, former Section Head, now Senior Investigator, Genetics and Epidemiology at Joslin Diabetes Center and Professor of Medicine, Harvard Medical School, along with his research team at Joslin, as well as other collaborators. Dr. Krolewski and his team have been at the forefront of biomarker research in diabetic kidney disease and have contributed to some of the most important findings in this area over the past 20 years, including the intellectual property on RenalytixAI's existing licensed biomarkers, sTNFR1 and sTNFR2 in Diabetic Kidney Disease. Biomarkers include additional inflammatory and pro-fibrotic markers which have been shown to improve prognostic performance in identifying which patients will progress to kidney failure, and predict responses to therapy.

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 one out of two people with very low kidney function who are not on dialysis do not know they have CKD.² 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.

About RenalytixAI

RenalytixAI (LSE: RENX) (NASDAQ: RNLX) is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's lead product is KidneyIntelX, which has been granted Breakthrough Designation by the U.S. Food and Drug Administration and which is being designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). For more information, visit www.renalytixai.com

About Joslin Diabetes Center

Located in the Longwood Medical Area (LMA) of Boston, Massachusetts, Joslin Diabetes Center is the world's leading diabetes research, clinical care and education organization dedicated to the prevention, treatment and research towards a cure for diabetes. Joslin is an independent, non-profit institution affiliated with Harvard Medical School. For more information, visit www.joslin.org

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential benefits and utility of licensed biomarkers, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully distributed and marketed, our expectations regarding physician acceptance, reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only

recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the “Risk Factors” section of our annual report on Form 20-F filed with the SEC on October 28, 2020, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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