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RenalytixAI and AKESOgen In Joint Venture Partnership for Expanded Testing Capacity and Pharma Services

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NEW YORK, Feb. 13, 2019 /PRNewswire/ -- RenalytixAl (AIM: RENX), a developer of artificial intelligence-enabled diagnostics for kidney disease, today announced the completion of a joint venture partnership agreement with AKESOgen, an industry-leading commercial laboratory facility and provider of clinical trial precision medicine services located in Atlanta, Georgia.

AKESOgen brings a state-of-the-art 14,000 square foot CLIA¹ certified and CAP² accredited laboratory facility that enables RenalytixAI to immediately scale operations to support additional business partnerships on a variable-cost basis without incurring additional fixed overhead. RENX AI Labs provides RenalytixAI with further operations outside of its recently configured New York City-based clinical laboratory operations in JLABS, a Johnson & Johnson Innovation center.

The joint venture, named RENX AI Labs, LLC, significantly expands the operational capacity available to RenalytixAI. RENX AI Labs will provide services directly to health systems and pharmaceutical companies located in all regions of the United States. The joint venture enables RenalytixAI to support prospective revenue-generating contract research, clinical diagnostic and clinical trial services that are part of the Company's core business model with *KidneyIntelXTM* and other products under development.

RENX AI Labs will help support the programs of pharmaceutical companies by applying AI-enabled diagnostics, beginning with *KidneyIntelX*, which is currently undergoing clinical validation, to improve patient characterization³ and enrich targeting of patients for drug clinical trials for renal disease. Better identification and characterization of enrolled patients has the potential to reduce trial cost and duration, and increases the likelihood of reaching successful outcomes. RENX AI Labs also has the capability to develop companion diagnostics under stringent quality-control processes.

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 and an estimated \$114 billion is spent annually treating chronic kidney disease in the US.

About AKESOgen

AKESOgen is an integrated Clinical Laboratory Improvement Amendments (CLIA) compliant and the College of American Pathologists (CAP) accredited genomics, genetics and bio-banking company that services the pharmaceutical, biotechnology, clinical, academic, and government sectors for clinical trials, diagnostic clinical testing, and research. Based in Atlanta, AKESOgen's services include providing high-throughput, biomarker profiling, microarray, sequencing, genomics, microbiome and epigenomics analysis utilizing different types of markers. For more information, visit <u>www.akesogen.com</u>.

About RenalytixAl

RenalytixAl 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 <u>renalytixal.com</u>.

Notes:

¹ The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program. <u>https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/</u>

² The College of American Pathologists (CAP's) Laboratory Accreditation Program accredits the entire spectrum of laboratory test disciplines with the most scientifically rigorous customized checklist requirements. <u>https://www.cap.org/laboratory-improvement/accreditation</u>

³ Characterization refers to an individual patient's disease status and underlying biology. Kidney disease biology and status may vary from patient to patient and could have a material impact on whether or not a patient qualifies for a particular drug enrollment criteria.

SOURCE RenalytixAl