Renalytix Appoints Joseph Hutson Vice President of Global Quality and Regulatory

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Hutson to Build on Renalytix Quality and Regulatory Strategy for KidneyIntelX Global Commercialization

NEW YORK and SALT LAKE CITY, July 22, 2021 (GLOBE NEWSWIRE) -- Renalytix Plc (NASDAQ: RNLX) (LSE: RENX) today announced the appointment of Joseph Hutson as its Vice President of Quality and Regulatory. Hutson brings 23 years of experience in the life sciences industry, including quality and regulatory leadership roles at Cardinal Health, CareFusion, Becton Dickinson and Abbott Diagnostics. He will lead teams focused on assuring compliance with United States and international Quality Management System regulations and standards and driving efficient approval for a series of products under the KidneyIntelX brand through review by the appropriate regulatory authorities including the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and other country specific regulatory bodies.

The KidneyIntelX commercial program is being designed to CLIA, CAP, ISO, FDA, and In Vitro Diagnostics Regulation (IVDR) regulations and international standards which will support global market access for current and future KidneyIntelX innovative products and services. KidneyIntelX is currently under FDA review for De Novo marketing authorization under Breakthrough Device designation. Hutson will contribute his knowledge and expertise to the efficient FDA review of this submission.

“The dynamic quality and regulatory environments in the United States, Europe and across the world are now a critical part of building competitive differentiation and gaining access to global markets. Without a robust Quality Management System and well-defined regulatory strategies for product development, approval, and marketing, it is impossible to remain product competitive,” said Hutson. “Particularly in an area as large and consequential to global health-care systems as kidney disease, implementing processes that can meet or exceed FDA regulations and IVDR’s standards of quality and safety will be the requirement to set a new level of care for early-stage prognosis and treatment.”

Most recently, at Abbott Molecular Diagnostics, Hutson led Quality, Global and Clinical Compliance and he played an integral role in the rapid development, FDA Emergency Use Authorizations, manufacturing scale up and global distribution of 50 million COVID-19 diagnostic tests throughout the world. Previously, he served as Worldwide Vice-President, Quality and Regulatory at Becton Dickinson Respiratory Solutions with responsibility for 31 locations in North and South America, Europe, and Asia and as Global Vice-President, Quality and Regulatory at CareFusion acquired by Becton Dickinson in 2015.

For further information, please contact:

Renalytix plc	www.renalytix.com
James McCullough, CEO	**Via Walbrook PR**
Stifel (Nominated Adviser, Joint Broker)	**Tel: 020 7710 7600**
Alex Price / Nicholas Moore	
Investec Bank plc (Joint Broker)	**Tel: 020 7597 4000**
Gary Clarence / Daniel Adams	
Walbrook PR Limited	**Tel: 020 7933 8780** or renalytix@walbrookpr.com
Paul McManus / Lianne Cawthorne	Mob: 07980 541 893 / 07584 391 303

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.[1] 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.

[1] https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About KidneyIntelX
KidneyIntelX, is a first-of-kind, bioprognostic™ platform that employs a proprietary artificial intelligence-enabled algorithm to combine diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

About Renalytix
Renalytix (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.renalytix.com.

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 for KidneyIntelX to receive regulatory approval from the FDA, our global market access strategy for KidneyIntelX, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully distributed and marketed, our expectations regarding reimbursement decisions, our plans for expansion of our business 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.