RNS Number : 5140D EKF Diagnostics Holdings PLC

28 October 2020

The announcement headed 'EKF & Kantaro Biosciences partner to market quantitative COVID-19 antibody testing in UK and Europe', released at 07:00 today by EKF Diagnostics Holdings PLC as RNS No. 4029D, is being re-released with Renalytix AI plc linked as a related company in the interests of market clarity. The announcement is unchanged and is reproduced in full below.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (MAR)

EKF and Kantaro Biosciences partner to market quantitative COVID antibody testing in UK and Europe

EKF to distribute Kantaro COVID-SeroKlir and COVID-SeroIndex quantitative COVID antibody tests in UK and Europe

Kantaro antibody testing technology supports assessment of immunity to COVID and vaccine development

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, announces a two year marketing and distribution agreement with Kantaro Biosciences, LLC ("Kantaro"), a joint venture between the Mount Sinai Health System and RenalytixAl plc (LSE: RENX / NASDAQ: RNLX), and manufacturing partner Bio-Techne Corporation (NASDAQ: TECH).

EKF will have exclusive rights to market and distribute *COVID-SeroKlir*, Kantaro's quantitative SARS-CoV-2 IgG antibody test kit in the UK and Germany and non-exclusive rights in Europe. For the research market, EKF will have non-exclusive rights to distribute *COVID-SeroIndex* across the UK and Europe. Kantaro antibody testing technology supports assessment of immunity to COVID, which is a potentially critical component to maintaining the flow of commerce locally and internationally, and to understanding the effectiveness of vaccination programs.

The agreement follows the receipt of the CE Mark certification approving the use of *COVID-SeroKlir* and *COVID-SeroIndex* for detecting the presence and the precise titer (level) of IgG antibodies. Measuring the level of neutralizing antibodies in addition to other antibodies a person produces as part of their immune response to COVID-19 virus exposure provides important information in assessing any likely protection against future re-infection.

Antibody tests are also an important component of a general health check to determine if a patient has had past COVID-19 infections, with or without symptoms,

including when there has not been a positive test measuring the presence of the virus. COVID-19 has been linked to an increased risk of potentially life-threatening complications, including cardiovascular, kidney and lung disease.

"EKF's robust footprint in regions affected by COVID-19 will allow us to get quantitative testing to patients and doctors as quickly as possible to help them assess immunity decision-making at both the individual level and for population-wide policy making," said Sara Barrington, Kantaro's Chief Commercial Officer. "We believe that quantitative antibody testing will help patients and businesses take control of their healthcare choices during this uncertain time."

Julian Baines, CEO of EKF, said: "EKF can drive rapid availability of COVID-SeroKlir kits and COVID-SeroIndex to a broad range of laboratories for immediate operation without needing specialized testing equipment. Quantitative testing can provide important support for determining public health strategies, informing healthcare decision making, and potentially verifying the effectiveness of vaccines as they become available."

COVID-SeroKlir and COVID-SeroIndex have demonstrated 97.8% sensitivity and 99.6% specificity for detecting COVID-19 specific IgG antibodies. Its high precision results from a two-step process that utilizes two virus antigens: the full-length spike protein and its receptor-binding domain (RBD). Both the COVID-SeroIndex and the COVID-SeroKlir tests are enzyme-linked immunoassays (ELISA), which means any clinical testing laboratory can use it in the EU without the need for proprietary equipment. The configuration of Kantaro's COVID-SeroIndex antibody testing kits is designed to assist research efforts and support policy making both at the EU level and worldwide.

The Kantaro antibody testing technology is based on research performed at the Icahn School of Medicine at Mount Sinai in New York City. The Mount Sinai technology has already been used in a highly diverse population of over 75,000 patient samples to screen for convalescent plasma donors and determine past infections in the clinical assessment of potentially life-threatening complications from COVID-19, including lung, kidney and cardiovascular disease.

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About EKF Diagnostics Holdings plc (www.ekfdiagnostics.com)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate analyzers in regular use across more than 100 countries. EKF specializes in developing tests for use in anemia and diabetes diagnosis and management, as well

as providing a portfolio of reagents for use in clinical chemistry analyzers.

About Kantaro Biosciences

Kantaro Biosciences ("Kantaro"), a Mount Sinai Health System venture, is dedicated to ensuring that high-quality diagnostic tests for critical health challenges are accessible. The company provides rigorous, results-driven and reproducible diagnostics to advance the care and well-being of people, communities and society. Kantaro specializes in the rapid scale-up of groundbreaking diagnostic innovations and the creation of partnerships to bring these crucial technologies to market. For more information, visit www.kantarobio.com and follow Kantaro on Twitter @kantarobio.

About Bio-Techne Corporation

Bio-Techne Corporation (NASDAQ: <u>TECH</u>) is a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities. Bio-Techne products assist scientific investigations into biological processes and the nature and progress of specific diseases. They aid in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With thousands of products in its portfolio, Bio-Techne generated approximately \$739 million in net sales in fiscal 2020 and has over 2,300 employees worldwide. For more information on Bio-Techne and its brands, please visit <u>www.bio-techne.com</u>.

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care-from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report*'s "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians are in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit https://www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.

About Renalytix Al plc

RenalytixAl 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 products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit <u>renalytixai.com</u>.

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