

EKF Diagnostics Holdings plc
("EKF", the "Company")

**Exclusive worldwide licence and collaboration agreement with Icahn
School of Medicine at Mount Sinai, NY**

*Renalytix AI PLC to develop Artificial Intelligence solutions
for early identification and management of kidney disease*

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, announces that its subsidiary, Renalytix AI PLC, has signed an exclusive license and collaboration agreement with the Icahn School of Medicine at Mount Sinai in New York, USA, ("Mount Sinai") (the "Agreement").

As previously announced at the time of the Company's most recent results, EKF is in the process of spinning out its solid tumour necrosis factor ("sTNFR") biomarker technology into Renalytix AI Inc ("Renalytix AI"), a separate entity, registered in the USA. The Directors believe the sTNFR biomarker technology has the potential to deliver significant upside value for EKF shareholders. The Directors of Renalytix AI PLC are exploring funding options for that business, including equity funding. Existing EKF shareholders would have a continuing interest in the Renalytix AI business and the opportunity to participate in any separate equity funding of Renalytix AI PLC.

Key highlights of the Agreement

- sTNFR biomarkers and AI technology deployed against de-identified clinical data from Mount Sinai's 3 million patient electronic data warehouse and 43,000 patient records from the BioMe™ BioBank repository¹
- First pre-market approved product expected to launch in the US in H1 2019 for improved disease detection / care management, with the intention of gaining Food and Drug Administration ("FDA") approval in 2020
- Kidney disease affects an estimated 120 million people in the US and EU (c. 12% of the population), with 90% of these unaware they are at risk
- \$98bn in costs to Medicare attributed to preventable chronic kidney disease and dialysis annually

Under the Agreement, Mount Sinai will be able to use EKF's sTNFR biomarkers alongside artificial intelligence ("AI") technology to mine patient data and quickly identify which candidates are at the highest risk of progressive Diabetic Kidney Disease ("DKD") potentially leading to End Stage Renal Disease

("ESRD"), a disease which costs the US healthcare system nearly \$100 billion annually.

Mount Sinai is one of the largest integrated healthcare systems in the US, caring for diabetics and patients of African ancestry, the two major population groups most affected by kidney disease and dialysis. As part of the agreement, Renalytix AI PLC will look to leverage de-identified clinical data from Mount Sinai's substantial data warehouse containing over 3,000,000 patient health records and its 43,000 patient *BioMe*TM BioBank repository to create an advanced learning system to monitor and flag patients at risk for kidney disease and unplanned "crashes" requiring costly dialysis treatment.

Plans for Renalytix AI

Subject to funding, the first product is expected to launch in H1 2019, targeting the significant costs to the US Medicare system of preventable dialysis and chronic kidney disease. Additional major US based healthcare systems are also expected to participate in clinical utility data collection and commercial launch.

Upon successful completion of clinical validation in late 2018, Mount Sinai has agreed to participate in testing several thousand at-risk patients in an Institutional Review Board-approved clinical utility study in 2019, at an estimated cost of \$6 million. Renalytix AI will prepare its initial AI applications for FDA review and expanded validation through collaborations with leading academic medical centres, pharmaceutical and patient advocacy organisations in the United States and Europe with work planned to begin this year, aiming for FDA approval in 2020.

Barbara Murphy, MD, Dean for Clinical Integration and Population Health and Chair of the Department of Medicine at the Icahn School of Medicine at Mount Sinai, and Chair of the Renalytix AI Scientific Advisory Board said: *"Our ability to apply the power of artificial intelligence against such a deep repository of data and disease specific biomarkers has the potential to change the game for all of our diabetic patients and other populations at risk for kidney disease."*

Julian Baines, Chief Executive Officer of EKF and Executive Chairman of Renalytix AI, added: *"This is a significant partnership for Renalytix AI with one of the largest hospital groups in the United States. Coupling its technology with the Mount Sinai patient database will improve patient care in End Stage Renal Disease, a significant unmet medical need. The fact that so many patients on dialysis have never seen a specialist has to change, both from a patient care and cost perspective. I believe that this partnership will result in Renalytix AI being leaders in the field of kidney care, alongside Mount Sinai."*

(1) The BioMe biobank is an electronic medical record (EMR)-linked biobank that enables researchers to conduct genetic, epidemiologic, molecular, and genomic studies quickly and efficiently on large collections of research specimens linked with medical information.

Enquiries:

EKF Diagnostics Holdings plc

Christopher Mills, Non-Executive Chairman
Julian Baines, CEO

www.ekfdiagnostics.com

Tel: 029 2071 0570

Richard Evans, FD & COO

N+1 Singer (Nomad & Broker)

Aubrey Powell / Shaun Dobson

Tel: 020 7496 3000

Walbrook PR Limited

Paul McManus / Lianne Cawthorne

Tel: 020 7933 8780

or ekf@walbrookpr.com

Mob: 07980 541 893 / 07584 391 303

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest integrated delivery system encompassing seven hospital campuses, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai's vision is to produce the safest care, the highest quality, the highest satisfaction, the best access and the best value of any health system in the nation.

The System includes approximately 7,100 primary and specialty care physicians; 10 joint-venture ambulatory surgery centers; more than 140 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and 31 affiliated community health centers. The Icahn School of Medicine is one of 3 medical schools that have earned distinction by multiple indicators: ranked in the top 20 by U.S. News & World Report's "Best Medical Schools", aligned with a U.S. News & World Report's "Honor Roll" Hospital, No. 13 in the nation for National Institutes of Health funding, and among the top 10 most innovative research institutions as ranked by the journal Nature in its Nature Innovation Index. This reflects a special level of excellence in education, clinical practice, and research. The Mount Sinai Hospital is ranked No. 18 on U.S. News & World Report's "Honor Roll" of top U.S. hospitals; it is one of the nation's top 20 hospitals in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Geriatrics, Nephrology, and Neurology/Neurosurgery, and in the top 50 in four other specialties in the 2017-2018 "Best Hospitals" issue. Mount Sinai's Kravis Children's Hospital also is ranked in six out of ten pediatric specialties by U.S. News & World Report. The New York Eye and Ear Infirmary of Mount Sinai is ranked 12th nationally for Ophthalmology and 50th for Ear, Nose, and Throat, while Mount Sinai Beth Israel, Mount Sinai St. Luke's and Mount Sinai West are ranked regionally.

Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

AGRFKKDDKKBPPN admin Licence and collaboration agreement signed 27537630 A Thu, 05/31/2018 - 07:00 LSE RNS Company Announcement - General EKF