RNS Number: 3149S

**EKF Diagnostics Holdings PLC** 

23 September 2014

# EKF Diagnostics Holdings plc ("EKF" or "the Company")

## US research collaboration to develop blood tests for cancer patients

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care, central laboratory and molecular diagnostics business, announces that it has entered into a two year research collaboration with Massachusetts General Hospital (MGH), a global leader in successfully bridging innovative science with state-of-the-art clinical medicine, to develop PointMan assays that can effectively detect treatable cancer mutations in blood samples.

The collaboration agreement has been signed following a detailed evaluation of PointMan DNA enrichment technology by MGH and will cover a two year long project focussing on lung, breast and skin cancer.

MGH will use PointMan DNA enrichment technology for the detection of genetic variation in circulating tumour cells (CTCs) isolated from a patient's blood using MGH's CTC-Chip instrument. CTCs are shed by primary tumors allowing the cancer to metastasise. CTCs are extremely rare in whole blood and their isolation and characterisation could offer clinicians a routine method with which to diagnose, treat and monitor the progress of various cancers. The main difficulty in successfully analysing CTCs has been the ability to detect low level mutations sufficiently and to create assays that are sensitive enough to provide meaningful data; difficulties which PointMan may be able to effectively overcome.

EKF Molecular will design and develop high sensitivity assays which will be utilised by MGH with a view to clinically validating PointMan in the detection of existing and novel mutations, a major step towards the improvement of patient outcomes in the hospital.

Andrew Webb, CEO of EKF Molecular Diagnostics Ltd, commented: "The results of an initial assessment, and now this two year collaboration, moves us even closer to the routine use of blood based tests for cancer rather than a tissue biopsy. The combination of MGH's CTC-Chip instrument and the easy to use and quick to perform PointMan technology should make this approach to cancer detection and monitoring available, ultimately, to the majority of molecular testing laboratories."

Dr Daniel A. Haber, Director at Massachusetts General Hospital Cancer

Center and Kurt J. Isselbacher, Peter D. Schwartz Professor of Oncology, Harvard Medical School, commented: "We have been studying the sensitivity of DNA enrichment technology as a way to detect and monitor specific mutations in cancers from patients utilising circulating tumour cells isolated from a simple blood sample. I am hopeful that the combination of such technology with our CTC-Chip technology will have the potential to improve the clinical management of our patients."

Dr Shyamala Maheswaran, of the Massachusetts General Hospital Cancer Center and Associate Professor of Oncology at Harvard Medical School, who was principal investigator for the collaboration, commented: "This study demonstrated incredible sensitivity for mutations that are relevant to lung cancer, breast cancer and melanoma. During the course of the two-year research collaboration, we will look for other potential target genes associated with these and other cancer types."

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### About EKF Diagnostics Holdings plc - www.ekfdiagnostics.com

EKF Diagnostics Holdings plc was formed in July 2010 following the acquisition of EKF-diagnostic GmbH for €14.32m and refocused its strategy to one of building a substantial point of care diagnostics business. As part of this strategy, the Group has integrated three further acquisitions, Quotient Diagnostics Limited (acquired in September 2010), Argutus Medical Limited (acquired in December 2010) and Stanbio Laboratory L.P. (acquired in June 2011). In 2013 EKF established a new subsidiary, EKF Molecular Diagnostics Ltd, to focus on molecular and companion diagnostics and acquired 360 Genomics Ltd, a business that owns diagnostics technologies for cancer gene detection.

The Company, with its head office in Cardiff and operations in London, Germany, Poland, Russia, Ireland and the US, is a leading diagnostics business, focussing on the development, production and distribution of chemical reagents and analysers for the testing of Glucose, Lactate, Haemoglobin, Haematocrit and HbA1c.

In March 2011 EKF entered into a distribution agreement with Alere Inc ("Alere"), a global diagnostics company, under which Alere was appointed the exclusive distributor of EKF's CLIA waived Hemo Control device and cuvettes in the US, Canada and United Kingdom. The device is distributed in the US under the name HemoPoint H2.

In March 2014, EKF acquired Separation Technology, Inc., a Florida based manufacturer of in vitro diagnostics devices for the haematology testing. In April 2014, EKF completed the acquisitions of Selah Genomics Inc., a US based developer of molecular diagnostics for personalised medicine and DiaSpect Medical AB., a Swedish based manufacturer of point-of-care haemoglobin analysers.

### **About PointMan™**

PointMan $^{\text{m}}$  provides a reliable and highly sensitive determination of the presence or absence of a mutation in the DNA sequence. Mutations are associated with diseases such as cancer and importantly the patient's response to treatment, known as personalised healthcare.

PointMan™ works by targeting the PCR (polymerase chain reaction) towards the mutant sequence whilst suppressing the amplification of the non-mutated (wild type) sequence and this means that these enriched samples contain artificially high levels of mutated DNA, significantly enhancing detection. This drives the sensitivity of the PointMan™ technology far beyond existing PCR technology (PointMan™ can detect 1 mutant gene in 100,000 normal gene copies against the nearest technology that detects 1 in 100).

The efficiency of PointMan™ therefore maximises the use of smaller biopsy samples as well as allowing multiplexing of mutations in a single test rather than many individual tests as current competing technologies do.

This information is provided by RNS
The company news service from the London Stock Exchange

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