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

Major step towards detecting cancer in blood

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care, central laboratory and molecular diagnostics business, announces the result of a collaboration which is a major step towards the goal of routine and reliable detection of cancer cells in blood samples.

EKF Molecular Diagnostics has been working with GILUPI, an innovator in medical devices for *in vivo* isolation of rare cells directly from a patients' blood stream, using GILUPI CellCollector™ with EKF's PointMan™ DNA Enrichment technology.

The first results of a collaboration between EKF Molecular Diagnostics and GILUPI has successfully demonstrated the detection of gene mutations from as few as three or less cells isolated in a model *in vitro* system and from the blood of lung cancer patients. PointMan DNA Enrichment was used to detect and analyse cells with known mutation status that had been collected on GILUPI CellCollectors under laboratory conditions. The known mutations were those typically seen in lung (EGFR) and colorectal (KRAS) cancer. Positive results using PointMan assays for KRAS (codon 12/13) and EGFR (T790M and L858R) from cell lines with known mutations and patients were confirmed by Sanger sequencing and showed conformance with known mutation status.

Andrew Webb, CEO of EKF Molecular Diagnostics Ltd, commented: "These results are a clear indication of the utility of PointMan DNA enrichment on low cell numbers, in this case those isolated using the GILUPI CellCollector both *in vitro* and *in vivo*. We look forward to continuing this important work with GILUPI to validate our findings.

"This achievement is in line with the Company's vision to change current DNA extraction and detection practices and address the fast growing companion diagnostics market. Current collaborations focus on the unmet requirements for patient monitoring from peripheral samples negating the requirement for a surgical procedure to obtain a tissue biopsy and screening for early cancer diagnosis."

Klaus Luecke, CEO and co-founder of GILUPI said: "This is a major step forward for both companies and also for the future testing and monitoring of cancer patients. The isolation and subsequent characterisation of low numbers of circulating tumour cells from the blood of cancer patients will become increasingly important as a liquid biopsy as a method to monitor disease progression and response to therapy.

"We hope that less-invasive and more frequent testing will become routine using our combined technologies with significant patient benefits. GILUPI is looking forward to further cooperation with EKF Molecular Diagnostics to continue to build the evidence

base for the combined technologies."

The preliminary results will be available for discussion at the EKF Booth at ASCO (May 30th - June 3rd 2014, Booth 4109, McCormick Place, Chicago, IL).

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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™ 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.

About GILUPI

GILUPI is a medical device company with focus on the development and production of new innovative products for the *in vivo* isolation of rare cells from the circulation. These products are based on a unique patented technology. Currently, the main focus of GILUPI is the diagnostics market for cancer.

The company started as a small research department in Potsdam in 2006. Today, GILUPI is a medium-sized company (about 25 employees) that runs clinical trials and has its own quality management and marketing. Since 2011, GILUPI´s own production facility has been established at a second site in Greifswald, Germany.

The patented process of the GILUPI CellCollector™ production is based on the generation of biocompatible surface polymers, which prevent undesirable interactions with blood components and which can bind antibodies. Thus, they enable the enrichment of specific target cells from the blood.

About the GILUPI CellCollector™ - Detector for cancer

Cancer is often detected at a relatively late stage. Furthermore, cancer is a mixture of heterogeneous cells, which undergo molecular changes over the duration of the disease. This is not always detectable by current biopsy procedures. Individual oncological targeted therapies will become more and more important in tomorrow`s personalized medicine. The identification of the right drug for the specific patient is the upcoming challenge. The fundamental problem with cancer patients is the systematic nature of the disease - not the localized tumour. Metastatic dissemination is the main cause of death by cancer, primarily due to its deterrent effect on successful treatment.

To address the mentioned unmet medical need circulating tumour cells (CTCs) are highly discussed as liquid biopsy. CTCs are cells which detach from the primary tumour and travel through the circulation. The significance of CTCs in relation to predicting the prognosis has been shown in numerous clinical studies. CTCs can reflect molecular alterations of the tumour in the course of the disease. The characterization of these cells can enable physicians to immediately respond and to tailor the therapy for the individual conditions of the patient.

The GILUPI CellCollector™ directly detects CTCs *in vivo* in the blood stream, with the advantage of screening high volume of blood. In clinical studies, CTCs were detected in 70% of the GILUPI CellCollector™ applications in lung, breast, colorectal and prostate cancer patients. After CE approval of the first product at the end of 2012, also the secondary product has been approved recently.

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