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

New colon cancer test opens up universal molecular testing Launch of the first affordable next generation sequencing test for cancer in the US

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care, central laboratory and molecular diagnostics business, announces the launch of its next generation sequencing ("NGS") technology PrecisionPath[™] in partnership with Greenville Health Systems ("GHS"), one of the leading cancer institutes in the US. For the first time patients will have wider access to affordable advanced NGS testing that can help doctors determine the most effective cancer treatments based on an individual's genetic profile.

The launch of the PrecisionPath[™] Colon by EKF's subsidiary Selah Genomics ("Selah"), follows a successful one year trial with GHS, one of the leading cancer institutes in the US, and will be the first commercial NGS panel molecular test for invasive colon cancer priced under US\$1,000 with a target turnaround time of less than 7 days per reportable result.

PrecisionPath[™] can be used by oncologists nationally to identify the specific growth drivers for colon cancer in an individual based on their genetic make-up and to, ultimately, ensure the most effective therapy is used at all times during treatment. By identifying the cancer's specific susceptibility to available treatments, PrecisionPath[™] will help oncologists select the most effective options for a patient based on the patient's tumor type.

The advantage of the PrecisionPath[™] Colon test panel is that it focusses on a key number of actionable biomarkers which provide maximum clinical utility at a more affordable cost. The panel provides a clear and concise report that differentiates between those genes with proven clinical utility and others under clinical trial investigation. As the body of evidence for clinical utility grows, reports will be updated accordingly, providing doctors with a means to routinely integrate genomic analysis into the everyday care of cancer patients.

Initially PrecisionPath[™] Colon will be available across GHS's oncology treatment centres. According to the American Cancer Society and the US National Cancer Institute, colorectal cancer (CRC) death is the second leading cause of cancer death in the US in men and women combined, with close to 50,000 patients predicted to die in 2015 and more than 130,000 new cases of colorectal cancer being diagnosed. In Europe, it is predicted that there will be

close to 450,000 new cases of colorectal cancer diagnosed in 2015. EKF will then expand the service throughout the US targeting oncologists and pathologists treating patients with invasive CRC. EKF intends to offer PrecisionPath[™] in additional indications, including lung cancer, breast cancer and melanoma beginning in late 2015.

EKF and GHS' commercialisation partnership strengthens an already successful relationship, which began in March 2012 with the formation of Selah's Clinical Genomics Centre at GHS. PrecisionPath[™] has been developed in close association with some of the US's leading cancer specialists from the initial piloting programme at the GHS Institute for Translational Oncology Research (GHS ITOR) in May 2013 until today's commercial launch. This partnership exists alongside the 18 month collaboration announced on 2 March 2015 which is part funded by Becton Dickinson and Company and brings together Selah's NGS technology and DecisionQ artificial intelligence-based decision support algorithms.

Julian Baines, CEO of EKF, commented: "The launch of PrecisionPath™ Colon, at a price under \$1,000 coupled with a 7 day turnaround time, demonstrates EKF's commitment to providing affordable access to world-class diagnostic testing to oncologists treating patients across the US. It remains our goal to secure reimbursement from public and private payers for PrecisionPath[™] and we believe our case is strengthened by our focus on invasive colon cancer and the very clear guidelines that support clinical utility in this area."

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About EKF Diagnostics Holdings plc - <u>www.ekfdiagnostics.com</u>

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 market. 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 Selah Genomics - www.selahgenomics.com

Selah Genomics is a clinical diagnostic specialist supporting healthcare providers and the pharmaceutical industry with advanced molecular and genomic diagnostic services. Selah's services add value to early stage drug development, clinical trials and regulatory processes in the pharmaceutical industry and helps clinicians and healthcare providers treat and monitor patients, thereby improving patient outcomes. With the Power of Precision, Selah Genomics provides the best in molecular diagnostic testing, assay validation and genomic profiling that all leads to one common goal: to provide better outcomes for patients.

About GHS's Research Development Corporation (RDC)

The designated innovation engine for GHS, the RDC focuses on forming strategic collaborations and partnerships with industry (pharmaceutical companies, biotechnology companies, molecular medicine-focused companies, etc.), leading intellectual property and tech transfer strategies for GHS, and in spearheading relevant economic development strategies including the support of high-impact start-ups and early stage innovation companies housed in GHS's unique innovation zone/wet lab space. The RDC also leads business development activities for GHS's world class cancer research institute, "ITOR" (Institute for Translational Oncology Research) - which has one of the top phase 1 clinical research units in the country, and has partnered with more than 50 pharma/biotech companies who continually sponsor phase 1 clinical trials at GHS, including numerous first-in-human studies. ITOR also has a rapidly growing bioinformatics-driven Tissue Bank and Biorepository, a Clinical Genomics Center for onsite molecular profiling and a 30,000 sq ft innovation/research zone with multiple private sector, academic and clinician partners.

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