Signature Diagnostics Announces Positive Study Results for Detector C, Its Non-Invasive, Blood-Based IVD Screening Test for Early Detection of Colorectal Cancer

- Study data to be presented on June 6 at the Annual American Society of Clinical Oncology (ASCO)
- Product Launch planned for Q4 2010 - Q1 2011

POTSDAM, Germany, June 4, 2010 - Signature Diagnostics AG announced today positive results from its prospective, multi-center clinical study validating Detector C, its in-vitro diagnostic screening product. Detector C is a non-invasive, blood-based screening test for the early detection of colorectal cancer. The test uses Affymetrix technology to evaluate the expression of 202 genes that are active in white blood cells in response to tumor formation and growth. The test showed a consistently high sensitivity of 90 percent for all four cancer stages (including early stages), and a specificity of 88 percent. The company will present the complete study data at the American Society of Clinical Oncology (ASCO) on June 6, between 2:00 - 6:00 PM, in Hall A2 (Abstract No: 3580).

“Detector C is the safest and most accurate blood-based screening test available, making it particularly well suited for population screening. The unprecedented low number of false negatives warrants its use prior to colonoscopy and as an alternative to inaccurate haemocult II tests,” said André Rosenthal, CEO of Signature Diagnostics AG. “Detector C has the potential to provide an early warning to hundreds of thousands of individuals with early stage colorectal cancer, enabling them to begin treatment while their disease is still curable.”

Detector C has been successfully validated using an independent set of 343 blood samples including 210 samples originating from patients confirmed with all four stages of colorectal cancer and 133 samples from healthy controls over age 55 undergoing colonoscopy for screening purposes. The prospective validation study demonstrated a sensitivity of 0.90 (95% CI: 0.851-0.937) and a specificity of 0.88 (95% CI: 0.812-0.930). The sensitivity results by UICC stage are as follows: stage I: 0.89 (95% CI: 0.774-0.958), stage II: 0.90 (95% CI: 0.788-0.961), stage III: 0.90 (95% CI: 0.805-0.959) and stage IV: 0.93 (95% CI: 0.765-0.991). Detector C also identified high-grade intraepithelial neoplasia with a sensitivity of 0.66.

Multivariate analysis showed no significant effect in relation to stage, age, gender, tumor localization, or RNA quality on correct prediction. Detector C showed an extremely low false
negative rate of only one in 872 tested individuals, which is four times lower than the false negative rates of other blood-based tests. In comparison to Haemocult II (gFOBT), Detector C has a seven times lower rate of false negatives.

About Signature Diagnostics AG

Signature Diagnostics AG is a molecular diagnostics company based in Potsdam, Germany, focusing on the development and commercialization of novel in-vitro diagnostic (IVD) products for the prognosis and early detection (screening) of colorectal cancer. Using its state-of-the-art technologies in tissue and blood sample collection, molecular pathology, genome-wide tumor profiling technologies, data mining, and biostatistics, the company collaborates with many clinical and diagnostic partners. Signature Diagnostics sponsors and conducts large prospective, multicenter clinical trials with more than 25 primary care hospitals and several dozen colonoscopy centers in Germany to discover and validate RNA biomarkers in colorectal cancer and colorectal cancer screening. The company's first products, Predictor C and Detector C, will be launched by the end of 2010 in its own ISO 15189 certified service lab.

About Colorectal Cancer Screening

The EU-5 and US screening population (aged 50 to 79) totals 170 million individuals. Approximately 5.1 million individuals (3 percent) have an undetected colorectal cancer (CRC). Only 396,000 CRC cases (7.8 percent) are presently diagnosed annually (EU-5: 220,000, USA: 176,000). Classical screening methods, including haemocult II (gFOBT) and colonoscopy, detect only 5 percent of these 396,000 CRC patients. In 4.7 million individuals affected with CRC, the asymptomatic cancer remains undetected.

In Germany, 73,000 patients are diagnosed with CRC every year. Due to the risks and inconvenience associated with CRC colonoscopy screening (bleeding events, colon perforations), patient participation is low (3-5 percent per year). Therefore, CRC screening using colonoscopy results in the diagnosis of only 5.400 patients each year. Furthermore, CRC screening, using gFOBT, is declining due to the test's inaccuracy and the difficulties associated with collecting stool samples. There is a great need for a non-invasive in-vitro diagnostic (IVD) that can detect early stage CRC and serve as a reliable screening tool.

For questions, please contact:

Jana Frömke
Corporate Communications
Signature Diagnostics
Hermannswerder 20A
14473 Potsdam, Germany
Tel: +49-331-2000-208
PR@signature-diagnostics.de