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EANS-News: Epigenomics AG: PRESEPT Study Subject Enrollment Successfully Completed

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7,852 subjects prospectively enrolled including more than 50 cancer cases Blood samples selected for testing by independent biostatistics group Septin9 testing in three independent laboratories on track; majority of samples tested Completion of PRESEPT Study and reporting of top-line results expected for early 2010

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----- Company Information/Molecular diagnostics/Products

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Press release, Berlin, Germany, and Seattle, WA, U.S.A., December 17, 2009 (euro adhoc) - Epigenomics AG (Frankfurt Prime Standard: ECX), a cancer molecular diagnostics company and sponsor of the PRESEPT Study reports that the enrollment of subjects was successfully completed. By December 16, total prospective enrollment has reached 7,852 study subjects at 32 clinical sites in the U.S.A. and Germany. In this representative screening population a total of 52 potential invasive colorectal adenocarcinoma cases have been identified by colonoscopy until that day exceeding the originally targeted number of 50 cases. To date 49 have been confirmed by pathological examination of tissue obtained by biopsy or surgical resection. Epigenomics expects the remaining colorectal cancer cases to be confirmed following scheduled surgeries during December 2009.

PRESEPT is a prospective multi-center clinical research study started in 2008 to evaluate the performance characteristics and health economic benefit of colorectal cancer screening using Epigenomics' Septin9 blood test in an asymptomatic screening population. Once completed, the PRESEPT Study will likely be the largest privately sponsored colorectal cancer screening studies ever conducted. The PRESEPT screening study follows the successful clinical validation of the Septin9 biomarker as an aid in the diagnosis of colorectal cancer in eight case control studies with in total more than 3,300 colorectal cancer patients and controls conducted by Epigenomics between 2005 and 2009.

With PRESEPT, Septin9 blood testing will be benchmarked against colonoscopy, the gold standard in colorectal cancer diagnosis, to determine the sensitivity and specificity of the Septin9 test for colorectal cancer and different classes of precancerous polyps (adenomas) when applied in its intended use population. Following a predefined statistical analysis plan a subset of about 1,500 of the PRESEPT blood plasma samples were independently selected and are being tested for Septin9. This subset includes blood samples from all confirmed invasive colorectal carcinoma cases, 55 cases with carcinomas in situ, a subset of cases with other advanced adenomas, approximately two hundred randomly selected cases with polyps less than 10 mm and a random selection of about one thousand colonoscopy-verified subjects with no apparent colon disease. The plasma samples to be tested were selected by an independent biostatistics team at the University of Minnesota and subject code and clinical status are masked to the testing laboratories. Following the Septin9 testing of the plasma samples, the test results are sent by the testing laboratories directly to the biostatistics team at the University of Minnesota, where the sample identities will be unmasked and the Septin9 testing data compared to the colonoscopy results and the histopathological findings.

The PRESEPT blood samples are tested in three independent high-profile laboratories, namely Quest Diagnostics Incorporated headquartered in Madison, NJ, U.S.A., ARUP Laboratories, Salt Lake City, UT, U.S.A. and the Institute of Laboratory Medicine and Pathobiochemistry of Charité - Universitätsmedizin Berlin, Germany. The laboratories use Epigenomics' recently launched CE-marked Epi proColon test kit to detect the Septin9 biomarker. Testing has been ongoing since October 2009 and is in the final stages of completion. After unmasking of the sample identities and data analysis, the Study Principal Investigator, Dr. Timothy Church, University of Minnesota, along with the independent PRESEPT Clinical Study Steering Committee, chaired by Prof. David Ransohoff, University of North Carolina, will report the results of the PRESEPT Study according to all applicable standards of scientific and

clinical research.

Epigenomics expects to provide initial results in early 2010 demonstrating whether Septin9 testing using the Epi proColon assay meets the requirements put forth in current US colorectal cancer screening guidelines in detecting "the majority of prevalent or incident cancers at the time of testing". The detailed data analysis will subsequently be submitted to a top-tier journal for peer review and will be presented at major medical conferences beginning in the first half of 2010.

"With the last subject enrolled we took an amazing step forward on our way to finishing the PRESEPT Study," stated Cathy Lofton-Day, PhD, Project Manager of PRESEPT at Epigenomics, Inc., Seattle. "A focused effort by our study management staff and devotion to the PRESEPT Study by our many clinical sites allowed us to reach our targeted enrollment numbers and maintain our timeline", she added.

"We would not have been able to get this far in completing a prospective study of this magnitude and medical importance without the support of our Medical Advisory Board and the PRESEPT Clinical Study Steering Committee", Michael Wandell, PharmD, PRESEPT Study Director, Epigenomics Inc., Seattle remarked. "We benefited enormously from their guidance and confidence in our design and execution of the study."

More Information on the PRESEPT Study

For more information on the PRESEPT Study, please visit { www.presept.net } [HYPERLINK: <http://www.presept.net>] and { www.clinicaltrials.gov } [HYPERLINK: <http://www.clinicaltrials.gov>] (Identifier: NCT00855348).

About the Septin9 test

The Septin9 test was specifically developed for the convenient detection of invasive colorectal carcinomas of all stages and all locations using a blood sample obtained by a routine blood draw. The test concept is based on detecting aberrant DNA methylation of a specific region of the Septin9 gene. Specific Cytosine residues of the DNA in this region become methylated in colorectal cancer tissue but not in normal colon mucosa. This aberrant methylation can be detected by specific amplification of DNA shed into the blood stream by tumor cells. Detection of colorectal cancer DNA in blood samples by testing for methylated Septin9 DNA has been demonstrated in multiple case control studies with more than 3,300 colorectal cancer patients and controls to be a strong indicator (biomarker) for the presence of colorectal cancer. To make Septin9 testing broadly available to doctors and patients, Epigenomics pursues a dual strategy of direct commercialization of the Septin9 test and non-exclusive licensing of the Septin9 biomarker to IVD industry players with broad market access. Licensees include Abbott Molecular, Sysmex Corporation, Quest Diagnostics Incorporated, and ARUP Laboratories, Inc.

About Epi proColon®

Epi proColon® is Epigenomics' CE-marked, in vitro diagnostic real-time PCR test kit for the qualitative detection of Septin9 gene methylation in cell-free bisulfite converted DNA isolated from human plasma samples. Presence of methylated Septin9 DNA is associated with, and may aid in, the detection of invasive colorectal adenocarcinoma.

For more information on the Epi proColon test and its availability in Europe please visit { www.epiprocolon.com } [HYPERLINK: <http://www.epiprocolon.com>] or contact Epigenomics directly by Email { sales@products.epigenomics.com } [HYPERLINK: <mailto:sales@products.epigenomics.com>] or phone +49 30 24345 111. Epi proColon is not for sale in the United States of America. The analytical and clinical performance characteristics of the product have not been evaluated by the US Food and Drug Administration. The product is CE-marked in compliance with the European IVD Directive 98/79/EC.

About Colorectal Cancer

Colorectal cancer (or colorectal carcinoma) refers to a malignant growth of the colorectal mucosa. Colorectal cancer develops usually in several phases and over many years, beginning with abnormal cell proliferation inside the colon that over the time forms adenomas that, depending on their shape are often referred to as polyps or flat lesions. These benign precursors can become tumors which are initially localized (stage I or II), but over the course of the disease spread into lymph nodes (stage III) and finally metastasize to distant organs such as the liver, bones or lung (stage IV). The development from a small polyp or a flat lesion to a cancer takes an average of 5 to 10 years.

In the U.S. approximately 147,000 people are estimated to be diagnosed with colorectal cancer in 2009. In Europe, including Germany, 413,000 cases were diagnosed in 2006. The five-year survival rate for patients is about 90% if the cancer is diagnosed at an early stage while it is still localized but drops to below 10% in stage IV. Accordingly, effective population-wide screening aiming at catching the cancer in early, still asymptomatic stages

is considered key in lowering the mortality from this disease.

About Epigenomics

Epigenomics is a molecular diagnostics company with a focus on the development of novel products for cancer. Using DNA methylation biomarkers, Epigenomics' tests on the market and in development aim at diagnosing cancer at an early stage before symptoms occur and thereby may reduce mortality from this dreaded disease.

Epigenomics' product portfolio contains the CE-marked IVD test Epi proColon®, the world's first regulatory cleared molecular diagnostic test for the detection of colorectal cancer in blood that is based on the biomarker Septin9, and further proprietary DNA methylation biomarkers and IVD products at various stages of development for colorectal, lung and prostate cancer. For development and global commercialization of IVD test products, Epigenomics pursues a dual business strategy in which direct commercialization of proprietary diagnostic test products is combined with non-exclusive licensing to diagnostic industry players with broad customer access. Strategic diagnostics industry partners include Abbott Molecular, Philips, Sysmex Corporation, Quest Diagnostics Incorporated, and ARUP Laboratories, Inc. for diagnostics test products and services, and QIAGEN N.V. for sample preparation solutions and research products. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary, Epigenomics Inc., in Seattle, WA, U.S.A. For more information, please visit Epigenomics' website at { www.epigenomics.com } [HYPERLINK: <http://www.epigenomics.com>]

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