

Epigenomics AG Initiates Testing of Blood Plasma Samples from PRESEPT Study in Three Independent Clinical Laboratories

PRESEPT Study evaluates clinical performance and health economic benefit of colorectal cancer screening with ^mSEPT9 blood test

Quest Diagnostics, ARUP Laboratories, and Charité - Universitätsmedizin Berlin selected to test ^mSEPT9 biomarker in blood plasma samples from PRESEPT Study subjects

Laboratories to use recently launched Epi proColon CE Marked IVD test products for the testing of the PRESEPT medical research study samples

Selection of about 1,500 masked blood samples to be tested in several batches - data analysis after last sample of last batch is tested

PRESEPT enrollment now exceeds 6,400 subjects with more than three quarters of targeted 50 colorectal cancer cases accrued

Laboratories to start testing in October – completion expected late 2009 or early 2010

Press release, Berlin, Germany, and Seattle, WA, USA, October 08, 2009 - Epigenomics AG (Frankfurt Prime Standard: ECX), a molecular diagnostics company focusing on the development and commercialization of in vitro diagnostic (IVD) products for early cancer detection, today announced that it has initiated the testing of the biomarker ^mSEPT9 in plasma samples collected in the PRESEPT Study. Subject enrollment into the study at 32 clinical sites is ongoing and progressing well.

PRESEPT is a prospective multi-center, multi-national clinical research study to evaluate the performance characteristics and health economic benefit of colorectal cancer screening using the ^mSEPT9 blood test in a representative asymptomatic screening eligible population. Once completed, the PRESEPT Study will be the largest commercially sponsored colorectal cancer screening studies ever conducted.

Enrollment as of early October already exceeded 6,400 subjects among which more than three quarters of the targeted 50 colorectal cancer cases have been identified by colonoscopy. Epigenomics expects to reach its original enrollment target of around 7,500 subjects during Q4 of 2009 but will continue enrolling until the study population comprises 50 colorectal cancer cases, a target expected to be reached either in late 2009 or early 2010.

^mSEPT9 testing will be performed by three independent high-profile laboratories, namely Quest Diagnostics Incorporated headquartered in Madison, NJ, U.S.A., ARUP Laboratories, Salt Lake City, UT, USA and the Institute of Laboratory Medicine and Pathobiochemistry of Charité – Universitätsmedizin Berlin, Germany. Each has passed a rigorous quality audit as well as extensive training and qualification with the ^mSEPT9 assay procedure before being selected for the study. The laboratories will use the

recently launched CE-marked Epi *pro*Colon test kit to detect the ¹³¹CpG SEPT9 biomarker in the PRESEPT blood samples for this research study. The contracted laboratories will measure the ¹³¹CpG SEPT9 biomarker in a combined total of about 1,500 blood plasma samples collected in the PRESEPT Study. Following a predefined statistical analysis plan this subset of the about 7,500 PRESEPT blood plasma samples will include all 50 CRC cases, several hundred cases with polyps and a random selection of about 900-1000 colonoscopy-verified subjects with no evidence of disease as controls. Following the processing of all samples, the results of ¹³¹CpG SEPT9 testing will be compared to the findings by colonoscopy plus the histopathology of the polyps and cancer cases by an independent biostatistical group at the University of Minnesota.

The plasma samples to be tested are being selected by the Study Principal Investigator and subject identity or clinical status are masked to the testing laboratories. Thus, throughout ¹³¹CpG SEPT9 testing neither Epigenomics nor its laboratory partners will know the identity of the subjects corresponding to the samples or the colonoscopy results of the respective subjects. The biostatistical group will unmask the samples and compare the results of ¹³¹CpG SEPT9 testing with the findings in colonoscopy after all of the ~ 1,500 blood samples are analyzed for the ¹³¹CpG SEPT9 biomarker.

The blood plasma samples will be processed in several batches, the first of which will be tested in the first half of October with further batches scheduled for later in October, November, and December. Testing of the last batch will commence once the 50th cancer subject is identified. Each batch will contain randomized, masked samples from cancer and polyp cases, and control subjects with no evidence of disease. After unmasking and data analysis, the Study Principal Investigator along with the PRESEPT Study independent oversight group, the Clinical Study Steering Committee, will accurately report the results of the PRESEPT Study according to the highest standards of scientific and clinical research.

Epigenomics expects that preliminary results will be available either late in 2009 or early 2010. The detailed results of the PRESEPT Study will subsequently be submitted for publication in a top-tier peer-reviewed journal and presented at major medical conferences in the first half of 2010.

“With the start of blood plasma sample testing we have reached an important milestone in the PRESEPT clinical study and have entered the home stretch for completion,” stated Cathy Lofton-Day, PhD, Project Manager of PRESEPT at Epigenomics, Inc., Seattle. “We believe that all three laboratories are excellent choices for testing the samples and generating data for ¹³¹CpG SEPT9 biomarker performance in the PRESEPT cohort,” she added.

“Choosing to go with high-quality external clinical laboratories will add significant credibility to the PRESEPT Study results and should demonstrate the robustness of our assay in routine clinical laboratory settings,” Michael Wandell, PharmD, Study Director

PRESEPT, Epigenomics Inc., Seattle remarked. “We are using our Epi *pro*Colon kit to measure the PRESEPT samples. This kit has recently been CE marked and is commercially available to clinical laboratories as an IVD test kit in Europe through Epigenomics’ direct marketing and sales organization.”

Geert Nygaard, CEO of Epigenomics AG, further stated: “Demonstrating the performance of our Epi *pro*Colon IVD blood test in this prospective screening cohort will be of tremendous value to our marketing efforts in Europe and in making the Septin9 blood test a widely accepted additional option for colorectal cancer screening.”

Further Information

For further information on PRESEPT, please visit www.presept.net or clinicaltrials.gov (Identifier: NCT00855348).

More information on the partner laboratories can be found on their respective web sites:

Quest Diagnostics: www.questdiagnostics.com

ARUP Laboratories: www.aruplab.com

ZLP, Charité – Universitätsmedizin Berlin: zlp.charite.de (German)

About Epi *pro*Colon

Epi *pro*Colon is a CE-marked, in vitro diagnostic real-time PCR test kit for the qualitative detection of SEPT9 gene methylation (^mSEPT9) in cell-free bisulfite converted DNA isolated from human plasma samples. Presence of ^mSEPT9 is associated with, and may aid in, the detection of invasive colorectal adenocarcinoma.

The ^mSEPT9 assay is based on detecting aberrant DNA methylation of the v2 region of the Septin9 gene. Cytosine residues in the v2 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 using the ^mSEPT9 biomarker has been demonstrated in multiple case control studies with plasma specimens from colorectal cancer patients and colonoscopy-verified negative controls to be a strong indicator of the presence of colorectal cancer.

For more information on Epi *pro*Colon test and its availability in Europe visit www.epiprocolon.com or contact Epigenomics directly by Email (sales@products.epigenomics.com) or phone (+49 30 24345 111).

Epi proColon is not for sale in the United States of America.

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 Epi proColon, a CE-marked IVD blood test for the early detection of colorectal cancer based on the validated biomarker mSEPT9, and further proprietary DNA methylation biomarkers at various stages of development for colorectal, prostate and lung cancer detection in urine, blood and bronchial lavage specimens. Epigenomics' biomarker mSEPT9 for the early detection of colorectal cancer in a simple blood sample has demonstrated continuously highest performance in eight clinical case-control studies with in total more than 3,250 individuals tested. A large prospective clinical study – PRESEPT – to evaluate the performance characteristics and the health economic benefit of colorectal cancer screening with the mSEPT9 biomarker in a representative screening population currently under way (www.presept.net). Once completed, the PRESEPT Study will be one of the largest commercially sponsored colorectal cancer screening clinical studies ever conducted. The clinical performance and health economic analysis results are expected to support future coverage of mSEPT9 testing by public and private health insurers worldwide. Epigenomics' partners developing IVD test kits for the mSEPT9 biomarker can co-fund and access the PRESEPT sample collection to conduct clinical trials for regulatory filings in the U.S.

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.

Partners in the health care industry and the biomedical research community can access Epigenomics' portfolio of proprietary DNA methylation technologies and biomarkers through research products, Biomarker Services, IVD Development Collaborations, and Licensing. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary in Seattle, WA, U.S.A. For more information, please visit Epigenomics' website at www.epigenomics.com.

Epigenomics legal disclaimers. This communication expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Epigenomics AG to

be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Epigenomics AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on this technology is currently available for sale in the United States. The analytical and clinical performance characteristics of any product based on this technology which may be sold at some future time in the U.S. have not been established.