

epigenomics

First Subjects Enrolled in Epigenomics sponsored PRESEPT Colorectal Cancer Screening Study

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Multi-center study in U.S. and Germany enrolling up to 7,500 individuals aims at demonstrating the benefits of colorectal cancer population screening with Epigenomics' Septin 9 blood test

Press Release, Berlin, Germany and Seattle, WA, U.S.A.

Epigenomics AG (Frankfurt Prime Standard: ECX), a molecular diagnostics company focusing on the development and commercialization of products for cancer detection based on DNA methylation, today announced the enrollment of the first subjects in the PRESEPT study.

"We are excited that our PRESEPT study is now well under way as scheduled. PRESEPT is a unique endeavor: It is one of the largest colorectal cancer screening studies ever, and is the first to prospectively evaluate a molecular marker for blood-based colorectal cancer screening", commented Geert Nygaard, Chief Executive Officer of Epigenomics. "The study will support the imminent clinical validation and commercial launch of our partners' diagnostics tests based on our biomarker and technology. The PRESEPT study is a great leap forward in the realization of our vision of detecting cancers based on DNA methylation patterns with a standard blood test."

PRESEPT is a multi-center, multi-national clinical study sponsored by Epigenomics prospectively evaluating the clinical performance of Epigenomics' proprietary biomarker, Septin 9, for colorectal cancer population wide screening of guideline-eligible individuals. With the data generated in the PRESEPT study, Epigenomics intends to demonstrate that colorectal cancer early detection with a blood test based on Septin 9 will meet the requirements of current U.S. screening guidelines for non-invasive screening tests. To support future coverage by health insurers, the performance characteristics established in PRESEPT will be used to determine the potential health economic benefit of blood based colorectal cancer screening using a validated model developed by Uri Ladabaum, M.D., M.S., University of California, San Francisco, CA. Further, Epigenomics will provide industry partners developing Septin 9 IVD tests access to the PRESEPT samples and data to perform pivotal clinical trials necessary to obtain regulatory approvals.

The study is planned to enroll up to 7,500 asymptomatic subjects with average to increased risk for colorectal cancer aged 50 or older that are scheduled for a regular screening colonoscopy at 12 to 14 clinical sites in the U.S. and Germany. This population is expected to harbor about 50 cases of undetected colorectal cancer. For each subject, blood samples are collected prior to bowel prep for colonoscopy and analyzed for methylated Septin 9 DNA by Epigenomics' partner Quest Diagnostics. The results of Septin 9 testing are compared to the data obtained by colonoscopy, the gold standard for definitive colorectal cancer diagnosis.

For the cases where polyps or cancerous lesions are identified during colonoscopy, further clinical and pathological data will be included in the classification of disease.

As a first site participating in PRESEPT, the Regional Gastroenterology Associates, Lancaster, PA, with site principal investigator Dr. Raymond Foley, began enrolling subjects last week. Further sites in the U.S. and Germany are planned to be initiated in the next few weeks. Enrollment is scheduled to ramp up to yield sufficient subjects for an interim analysis in Q1 2009. The final results of PRESEPT are expected during H2 2009.

In accordance with FDA guidance, Epigenomics established a Clinical Study Steering Committee to oversee the study and assure that it is conducted according to all applicable ethical and quality standards. The committee is chaired by David Ransohoff, M.D., University of North Carolina School of Medicine, Chapel Hill, NC. Other members of the committee include Neal K. Osborn, M.D., M.Sc., and Timothy R. Church, Ph.D., principal investigators for PRESEPT at Atlanta Gastroenterology, Atlanta, GA and the University of Minnesota, Minneapolis, MN, respectively, and Robert W. Day, M.D., Ph.D. President Emeritus of The Fred Hutchinson Cancer Research Center, Seattle, WA. Also, Brent Blumenstein, Ph.D., of Trial Architecture Consulting, Seattle, WA, was assigned as independent biostatistician. Epigenomics will be represented on the committee by the PRESEPT Study Director, Michael Wandell, Pharm.D., Senior Vice President Regulatory & Quality, and Cathy Lofton-Day, Ph.D., Vice President Molecular Biology and PRESEPT Project Manager.

"Adherence to current colorectal cancer screening options poses one of the greatest challenges to colorectal cancer detection and treatment. An effective colorectal cancer blood test that could be integrated into the routine physical examination by the primary care physician could greatly increase disease detection in asymptomatic patients. The performance demonstrated for the Septin 9 biomarker in previous case control studies warrants a thorough, in depth, and independent analysis of its potential as screening biomarker, and Epigenomics is putting in motion the elements to make this happen", explained Prof. David Ransohoff, M.D., PRESEPT Clinical Study Steering Committee Chair.

The design of the PRESEPT study was developed in close collaboration with Epigenomics' Medical Advisory Board for Colorectal Cancer Screening that represents a cross section of primary care physicians and gastroenterologists with particular expertise in colonoscopy, colorectal cancer screening, evidence-based medicine, outcomes research, and health economic analysis.

About Colorectal Cancer Screening

Colorectal cancer is the second leading cause of cancer related death in the U.S. with an estimated direct medical treatment cost of \$8.3 billion in 2007. With a cure rate over 90% if diagnosed in early stages in the United States, there is now general agreement that average-risk adults aged 50 and older should be screened for colorectal cancer. If detected early, individual treatment costs for colon cancer are estimated at \$30,000 per

patient, whereas treatment for a patient who has developed late stage disease is estimated at \$120,000. However, less than 50% of the screening population has had a recent test. Given today's treatment options for colorectal cancer, patient outcomes could potentially be greatly improved if more cancers were detected in early stages.

From a public health as well as a health economics perspective, the poor adoption of current screening options limits the effectiveness of colorectal cancer screening initiatives; Current colorectal cancer screening guidelines include two types of tests, those that detect polyps and cancer such as colonoscopy and virtual colonoscopy and those that detect cancer such as the non-invasive stool based tests. Non-invasive screening is most often conducted using FOBT, which while inexpensive, exhibits a low compliance rate (around 14% in the US) due to its use restrictions, perceived inconvenience and lack of consumer acceptance. The gold standard procedure for colorectal cancer detection is colonoscopy; it exhibits excellent performance characteristics, but has a limited utility as a first line screen due to its high cost, healthcare delivery resource limitations, and inadequate patient acceptance. It is believed a non-invasive, convenient, blood-based screening assay capable of detecting individuals with colorectal disease, confirmed by colonoscopy, would have greater utility for population screening.

About the Septin 9 Biomarker

The Septin 9 gene encodes a protein involved in cell division and is thought to play a role in the onset of cancer. Epigenomics has demonstrated in multiple clinical case control studies with over 3,500 samples from colorectal cancer patients, healthy controls, and patients with non-cancerous colon diseases that methylated DNA of the Septin 9 gene shed by tumors into the blood stream can serve as a biomarker for the sensitive and specific detection of colorectal cancer. As a first strategic partner, Abbott Molecular, Inc. licensed the worldwide non-exclusive IVD rights to Epigenomics' proprietary Septin 9 biomarker for colorectal cancer. In addition, Quest Diagnostics Inc., the leading provider of diagnostic testing, information and services, obtained the license to commercialize a laboratory-developed test (LDT) for Septin 9 in the U.S.

About DNA Methylation

DNA methylation is a natural and tightly controlled biological process that serves the regulation of genes and the stability of the human genome. Cytosine, one of the four bases in DNA, can be modified by the covalent addition of a methyl group. DNA methylation in gene regulatory regions (i.e. gene promoters) helps control gene activity. Every cell type has its unique DNA methylation "fingerprint" that changes in various normal biological processes and in many diseases, in particular cancer. DNA methylation thus provides a rich source for highly specific biomarkers for organ-specific disease diagnosis, classification and prediction for therapeutic intervention.

About Epigenomics AG

Epigenomics is a molecular diagnostics company with a focus on the

development of novel products for cancer. Using DNA methylation biomarkers, Epigenomics' tests in development aim at diagnosing cancer at an early stage before symptoms occur and thereby may reduce mortality from this dreaded disease.

Epigenomics' product pipeline contains a validated biomarker for the early detection of colorectal cancer in blood plasma, and further proprietary DNA methylation biomarkers at various stages of development for prostate and lung cancer detection in body fluids. Epigenomics' biomarker Septin 9 for the early detection of colorectal cancer in a simple blood sample demonstrated continuously highest performance in multiple clinical studies with in total more than 3,500 individuals tested.

For development and global commercialization as in vitro diagnostic test kits, Epigenomics pursues a non-exclusive partnering strategy with diagnostics industry companies. As a first strategic partner, Abbott Molecular Inc. licensed the worldwide non-exclusive IVD rights to Epigenomics' proprietary Septin 9 biomarker for colorectal cancer. Epigenomics also aims at giving patients and doctors early access to these biomarkers through reference laboratory testing services. As a first reference laboratory partner, Quest Diagnostics Inc., the leading provider of diagnostic testing, information and services, obtained the license to commercialize a laboratory-developed test (LDT) for Septin 9 in the U.S.

Partners in the health care industry and the biomedical research community can access Epigenomics' portfolio of proprietary DNA methylation technologies and biomarkers protected by more than 150 patent families 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.

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