

epigenomics

Epigenomics AG Presents Colorectal Cancer Blood Test at ESMO Conference

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mSEPT9 biomarker facilitates innovative blood test for colorectal cancer

PRESEPT Study for colorectal cancer screening with mSEPT9 well on track

First European diagnostic laboratory to offer mSEPT9 testing on 1st July

Press release, Berlin, Germany, and Seattle, WA, USA, June 25, 2009 - 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, will report on the development status and performance of its blood-based test for colorectal cancer in a poster presentation during this year's European Society for Medical Oncology (ESMO) Conference: 11th World Congress on Gastrointestinal Cancer, in Barcelona, Spain. The European Society for Medical Oncology (ESMO) is the leading European non-profit, professional organization for medical oncology with a focus on promoting multidisciplinary cancer treatment around the world.

Epigenomics' test, which is able to detect colorectal cancer in a simple blood draw, is based on the patented biomarker mSEPT9. The biomarker, which has previously been successfully tested in several case-control studies with more than 3,000 participants in total, is currently being evaluated for its utility in population wide colorectal cancer screening in the ongoing prospective PRESEPT Study.

In her presentation, Dr. Catherine Lofton-Day, Vice President Molecular Biology and project manager of the PRESEPT Study at Epigenomics, will give an overview on the extensive validation work for the mSEPT9 biomarker. In particular she will be focusing on results from two clinical case control studies with several hundred patients successfully completed in 2008 that demonstrate the performance of the mSEPT9 biomarker in detecting colorectal cancer in blood samples. The study results have recently been published in a peer-reviewed publication in *Clinical Chemistry* titled "Circulating Methylated Septin 9 DNA in Plasma is a Biomarker for Colorectal Cancer" (1).

„These two case control studies now published are the latest in a series of seven published studies with over 3,000 cancer patients and controls in which we demonstrated the underlying principle of the test, that our mSEPT9 assay reliably detects DNA derived from colorectal tumors in blood samples, thereby indicating the presence of colorectal cancer of all stages”, explained Dr. Lofton-Day.

Furthermore Dr. Lofton-Day will be focusing on the progress of the PRESEPT Study that is sponsored by Epigenomics. PRESEPT is a multi-center, multinational clinical study to prospectively evaluate the clinical utility of mSEPT9 testing for population-wide colorectal cancer screening. The study includes individuals at average to increased risk for colorectal cancer who have been scheduled for a screening colonoscopy. The study population of about 7,500 individuals is expected to harbor about 50 cases with undetected colorectal cancer. The results of the mSEPT9 blood testing, which will be performed in independent laboratories, will be compared to the results of colonoscopy - the gold standard in colorectal cancer diagnosis - to demonstrate the utility of this innovative test in colorectal cancer screening. The performance characteristics determined in the PRESEPT Study will also provide input for a health economic evaluation of mSEPT9 blood testing for population-wide colorectal cancer screening. It is one of the first studies ever to evaluate the performance of a non-invasive test using a standard blood draw to indicate the presence of colorectal cancer in a cohort representing the colorectal cancer screening population.

“To date we have made great progress in our PRESEPT Study and we are confident the original schedule will be kept with first results presented by the end of this year”, explained Dr. Lofton-Day. According to Dr. Lofton-Day more than 4,600 individuals have been enrolled into the study and two thirds of the 50 expected cases with previously undetected colorectal cancers have been identified.

It is anticipated that a positive outcome of the PRESEPT Study would promote rapid acceptance of this novel diagnostic method among primary care physicians and gastroenterologists as an aid in detecting early stage colorectal cancer. Epigenomics and its partners intend to launch both an in vitro diagnostic ^mSEPT9-based blood test in Europe, and laboratory developed test (LDT) in the U.S. in 2009. From July 1st 2009 onwards the European laboratory network, Switzerland based Viollier AG, will be the first clinical laboratory to begin offering ^mSEPT9-testing to patients, primary care physicians and gastroenterologists in Europe.

2009 ESMO Conference: 11th World Congress on Gastrointestinal Cancer Presentation Details

The poster, titled “Clinical Studies verify performance of the Blood-based Septin 9 DNA Methylation Assay for the Detection of Colorectal Cancer” by, Catherine Lofton-Day, Theo de Vos, Matthias Schuster, Andrew Sledziewski, Michael Wandell and Thomas Rösch will be presented at the ESMO Conference: 11th World Congress on Gastrointestinal Cancer in Barcelona, Spain on Friday, June 26, 2009, 6.15 pm – 6.45 pm at the CCIB, Exhibit Hall, by Dr. Catherine Lofton-Day, Vice President Molecular Biology and Project Manager of PRESEPT at Epigenomics.

(1) Article published online in April 2009: www.clinicalchemistry.org

A printed version will be published in Clinical Chemistry, on July 1st, 2009, Issue: 55 (7), p. 1337. Author: De Vos, T. et al; Title: “Circulating Methylated Septin 9 DNA in Plasma is a Biomarker for Colorectal Cancer”.

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 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 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 multiple clinical studies with in total more than 3,000 individuals tested. A large prospective clinical study – PRESEPT – for evaluation of ^mSEPT9 in a screening population is currently under way (www.presept.net).

For development and global commercialization of in vitro diagnostic test products, Epigenomics pursues a non-exclusive partnering strategy. Strategic diagnostics industry partners include Abbott Molecular, Philips, Sysmex Corporation and Quest Diagnostics Incorporated 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 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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