



Epigenomics AG: First Blood Test for Colorectal Cancer Available in Germany

Date: Monday, 21.09.2009

First diagnostic laboratories start offering testing based on Epigenomics' Septin9 biomarker on October 1st

Test is able to detect colorectal cancer in a simple blood draw

Company hosts press conference at ECCO/ESMO Congress in Berlin today

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 in vitro diagnostic products for cancer, today announced that several German laboratories will start offering laboratory-developed colorectal cancer blood tests based on Epigenomics' proprietary biomarker ^mSEPT9 on October 1st, 2009. Among the first laboratories offering ^mSEPT9 testing for colorectal cancer to gastroenterologists, general practitioners, and patients in Germany will be Labor Krone (Bad Salzflen), Labor Limbach (Heidelberg), MVZ Dr. Stein (Mönchengladbach), and MVZ Dr. Eberhard & Partner (Dortmund). The launch in Germany follows the introduction of ^mSEPT9 testing in Switzerland by the Swiss laboratory network Viollier AG on July 1st, 2009.

Epigenomics today will host a press conference on the medical utility of the ^mSEPT9 biomarker for colorectal cancer blood testing and how it may help to overcome key challenges in colorectal cancer screening effectiveness at this year's joint Multidisciplinary Congress of ECCO – the European Cancer Organisation and ESMO – the European Society for Medical Oncology in Berlin, Germany.

In numerous clinical studies with a total of more than 3,000 subjects Epigenomics has shown that methylated DNA of the Septin9 gene (^mSEPT9) in blood plasma is a strong indicator, or biomarker, for the presence of colorectal cancer. This has opened the way to developing tests for the early detection of colorectal cancer in a simple blood-draw addressing the most challenging hurdles in colorectal screening - patient compliance. Colorectal cancer screening in Germany is recommended and reimbursed under the public health care scheme from the age of 50. Fecal Occult Blood Testing (FOBT), a test that detects invisible blood in stool, is recommended to patients once a year. From 55 years and onwards ambulant colonoscopy is recommended that should be repeated after ten years. Individuals not willing to agree to a colonoscopy are recommended to continue FOBT testing on a biannual schedule. Despite these recommendations the majority of Germans over the age of 50 are not screened at all and as a consequence colorectal cancer is mostly detected in symptomatic stages significantly lowering their chances of survival. Lack of convenience and reservations against invasive methods are among the reasons most often cited for this lack of compliance. Other countries with comparable screening guidelines including, the U.S., face similar challenges.

A blood test for colorectal cancer early detection that is easily integrated into an annual health check-up and does not require patient involvement is believed to be more acceptable to doctors and patients and has the potential to greatly increase the effectiveness of national screening programs. If tested positive in such an easy to use blood test, patients would be referred to a gastroenterologist for colonoscopy to confirm the diagnosis and initiate early treatment.

"Most people in Germany by now know that cancer screening is offered and also believe that this is useful and beneficial. The dilemma is that they don't make use of it themselves", stated Prof. Jürgen Rieman, M.D., chairman of the board of Stiftung Lebensblicke, a non-profit organization advocating colorectal cancer screening in Germany for more than ten years. "With a new and easy to use blood test we could achieve our goal of substantially increasing acceptance of and participation in colorectal cancer screening. Patients tested positive would be followed up by colonoscopy", he continued.

“As a diagnostic laboratory with a focus on innovative molecular diagnostics, we will offer mSEPT9 testing to general practitioners and gastroenterologists in our network”, explained Angelika Vogel, responsible laboratory physician for molecular diagnostic testing at Labor Krone. “This test requires a standard blood draw and no further invasive procedures or patient involvement. All other steps are performed in the quality controlled environment of a professional diagnostics laboratory ensuring the highest quality and reliability of the results to the benefit of the patients and as a basis for further counseling.”

Septin9 testing is initially offered to self-payors and privately insured patients. A large prospective clinical study, PRESEPT, is underway to demonstrate the medical utility and in particular also health economic benefit in population-wide colorectal screening with the Septin9 test. The data is expected to be instrumental in achieving cancer screening guideline inclusion and eventually coverage by public health care schemes in Germany and other European countries as well as the U.S.

To ensure widespread availability of blood-based colorectal cancer early detection, Epigenomics is working with partners in the diagnostics industry, including Abbott Molecular, Chicago, IL, U.S.A. and Quest Diagnostics, Giralda Farms, NJ, U.S.A., that are expected to start offering their Septin9 tests in Europe and the U.S.A., respectively, in the fourth quarter of 2009. Further partners include ARUP Laboratories, Salt Lake City, UT, U.S.A., and Sysmex Corporation, Kobe, Japan.

Press Conference Details

The press conference titled: “A milestone in colorectal cancer screening: The detection of the biomarker mSEPT9 in a simple blood draw”, with presentations by Prof. Juergen Riemann, M.D., Chairman of the Board of Stiftung Lebensblicke, Dr. Achim Plum, Senior Vice President Corporate Development at Epigenomics AG and Angelika Vogel, Laboratory Physician at Labor Krone, will take place today, Monday, September 21st 2009, from 6:30 pm to 8:00 pm, at the ICC Berlin, Neue Kantstrasse/ Ecke Messedamm, conference room 28/29.

Poster Presentation Details

A poster presentation titled “A New Duplex Real-time PCR Assay for Detection of the mSEPT9 Biomarker for Colorectal Cancer Screening Using Blood Plasma” (Poster number 180) will be presented by Dr. Gunter Weiss, Vice President Product Development at Epigenomics AG, on September 22nd 2009, from 9 to 12 am, at ICC Berlin, Hall 13, booth A-21.

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 (adenoma) inside the colon and that over the time forms 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 lungs (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 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 ¹⁸SEPT9 for the early detection of colorectal cancer in a simple blood sample has continuously demonstrated the highest performance in multiple clinical studies with blood samples from in total more than 3,000 individuals. A large prospective clinical study – PRESEPT – for evaluation of ¹⁸SEPT9 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, Quest Diagnostics, Inc., and ARUP Laboratories, Inc. for diagnostic 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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