



**Epigenomics AG Launches its Epi proColon Product in Europe - the First Ever In Vitro Diagnostic Blood Test for Colorectal Cancer Early Detection**

**Date:** Tuesday, 06.10.2009

***Epi proColon is the first CE-marked test in accordance with European IVD regulations for the early detection of colorectal cancer in a simple blood draw***

***Epi proColon finds two thirds of cancers at early, curable disease stages in final performance evaluation study***

***Epi proColon will now be made available to molecular diagnostics laboratories, patients, and doctors in Europe***

***Epigenomics to commercialize Epi proColon through direct marketing and sales in Germany, Switzerland, Austria and via distributors in the rest of Europe***

***Epigenomics commercial strategy evolves to a dual business model combining direct commercialization and non-exclusive licensing partnerships***

***Press release, Berlin, Germany, and Seattle, WA, USA,***

Epigenomics AG (Frankfurt Prime Standard: ECX), a molecular diagnostics company focusing on the development and commercialization of in vitro diagnostic (IVD) products for cancer, today launched the world's first in vitro diagnostic blood test for early detection of colorectal cancer. Epi *proColon* is an innovative molecular diagnostic test that can detect tumor derived methylated DNA of the Septin9 gene (*mSEPT9*) in blood plasma as a reliable indicator, or biomarker, for colorectal cancer.

In a performance evaluation study, the final step of Epigenomics' IVD product development, analyzing blood samples from about 260 patients with colorectal cancer or without any evidence of colorectal cancer, the Epi *proColon* test detected two thirds of the cancer cases in early, still localized disease stages. When colorectal cancer is still localized, i.e. has not spread to lymph nodes or distant organs, about 90% of the patients can be cured from the disease (90% 5-year survival rate).

Preceding the performance evaluation study and the launch of Epi *proColon*, Epigenomics had shown in seven clinical studies between 2005 and 2008 with a total of more than 3,000 subjects that *mSEPT9* in blood plasma is a strong biomarker for the presence of colorectal cancer. In these studies *mSEPT9* testing detected about 70% of the cancers across all disease stages (i.e. early as well as later stages) with about 90% specificity, results that were confirmed in the most recent performance evaluation study for the Epi *proColon* test.

Early detection of colorectal cancer in a simple blood draw has the potential to overcome the most challenging hurdles in colorectal screening - patient compliance.

Colorectal cancer screening in Germany is recommended by national guidelines. Under this scheme annual screening with guaiac Fecal Occult Blood Test (FOBT), a test that detects invisible blood in stool, is recommended from the age of 50 years. From 55 years and onwards an

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 every other year. Both, guaiac FOBT and colonoscopy are reimbursed by the public healthcare scheme in Germany. Despite these recommendations the vast majority of Germans over the age of 50 are not screened at all and as a consequence colorectal cancer is mostly detected in symptomatic later stages significantly lowering the patients' chances of survival. Lack of convenience and reservations against invasive methods are among the reasons most often cited for this lack of compliance. Other European countries and the U.S. that have comparable screening guidelines all face similar challenges. A blood test for colorectal cancer early detection that can easily be 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 by increasing overall screening compliance. 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.

“The big issue in colorectal cancer screening remains that far too few people make use of it. Stool tests and colonoscopy are still not sufficiently accepted by patients”, explained Dr. Thomas Roesch, Professor for Endoscopy at the University Medical Center Hamburg-Eppendorf. “In this situation a simple blood test makes a lot of sense as it is easy to use for the patients and quickly done. And who wouldn't accept to undergo colonoscopy if the blood test already indicated a high risk of having colorectal cancer?”

The Epi *proColon* blood test does not only have the chance to gain better acceptance in the target group for colorectal cancer screening. With a cancer detection rate of about 70% it also significantly outperforms guaiac FOBTs, that are the currently most widely used stool tests used for screening but only find 30-40% of the cancer cases.

Epi *proColon* is the first CE-marked in vitro diagnostics product that Epigenomics markets directly to molecular diagnostic laboratories in Europe. Septin9 testing is currently being offered by selected innovative early adopter laboratories including Viollier AG in Switzerland and the German laboratories Krone, Limbach, MVZ Dr. Stein, and MVZ Dr. Eberhard & Partner. These labs have established and validated laboratory developed tests for the *m*SEPT9 biomarker. With the availability of Epi *proColon* that has been fully validated and CE-marked by Epigenomics as an aid in the detection of colorectal cancer, Septin9 testing can now be implemented in a much broader range of clinical laboratories with molecular diagnostics capabilities across Europe. Epigenomics aims at serving the home market in Germany, Austria and Switzerland through direct marketing and sales, while initially commercializing through distributors in other European markets.

“With the launch of Epi *proColon* we follow the request by our customers to offer a CE-marked version of our Septin9 test that can easily be implemented and takes away the burden of validation from the laboratory“, explained Geert Nygaard, Chief Executive Officer of Epigenomics. “It

also marks a great leap forward in the execution of our commercial strategy to become a leading molecular diagnostics company. With Epi proColon we are the world's first company offering a regulated IVD product for the early detection of colorectal cancer using a simple blood draw. This test has the potential to be used for population-wide colorectal cancer screening. With several hundred million people world-wide being eligible for colorectal cancer screening, our test has the potential to save many lives and at the same time addresses one of the most attractive future markets in molecular diagnostics."

To ensure the broadest possible availability of blood-based colorectal cancer early detection, Epigenomics also pursues a non-exclusive licensing strategy and 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.

"With the decision for direct commercialization of Epi proColon in addition to our partnering strategy, Epigenomics will take a much more active role in building the colorectal cancer blood testing market. We intend to leverage the know-how we have gathered in colorectal cancer screening over the years as we developed the test with some of the most influential opinion leaders in the field", Nygaard explained Epigenomics' strategic move. "However, we continue to be fully committed to our non-exclusive partnering strategy for *m*SEPT9 and strongly believe in the synergies created by several diagnostics players advocating colorectal cancer blood testing as an alternative to current stool tests for screening and offering the test on multiple diagnostic platforms. To this end we will continue to support our current and future partners in their development and commercialization efforts for colorectal cancer blood tests based on *m*SEPT9 to the extent permitted and possible."

Epigenomics will introduce the Epi proColon test to German laboratory physicians at the upcoming 6th Annual Conference German Society of Clinical Chemistry and Laboratory Medicine (DGKL) in Leipzig, Germany, on October 7-10, 2009 and to a broader European audience at GASTRO 2009 in London, UK, on November 21-25, 2009.

### **Conference Call for Investors and Media**

Epigenomics' management will host a conference call on the Epi proColon launch and its strategy going forward at 4pm CET today, Tuesday October 6, 2009. The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 (0)69 247 501 891

Dial-in number (within the US): +1 212 444 0297

Participants are kindly requested to dial in 10 minutes prior to the start of the call.

The presentation accompanying the conference call will be available at 3 pm for download on the Epigenomics website:

[http://www.epigenomics.com/en/downloads/corporate\\_material/](http://www.epigenomics.com/en/downloads/corporate_material/)

A recording of the conference call will be provided on Epigenomics' website subsequently:

[http://www.epigenomics.com/en/downloads/corporate\\_material/](http://www.epigenomics.com/en/downloads/corporate_material/)

### **Epigenomics at the DGKL and GASTRO Conferences**

Epigenomics will be represented at the DGKL (German Society for Clinical Chemistry and Laboratory Medicine) Conference 2009 in Leipzig, Germany, from October 7th to 10th 2009, with a booth in the Congress Center Leipzig, Hall 1, booth number 17+18.

A poster presentation reporting the first experiences with the Septin9 test in daily laboratory routine will be presented by Dr. Lothar Kruska, Head of Molecular biology laboratory at MVZ Dr. Stein, Moenchengladbach, Germany, on October 8th 2009, from 3:30pm to 4:30 pm, at the Congress Center Leipzig, Hall 1, booth number 17+18.

Epigenomics will be represented at the GASTRO 2009 congress at ExCel London, UK, One Western Gateway Royal Victoria Dock, from November 21st to 25th 2009, at the industry exhibition, booth number 90.

A poster presentation titled "Clinical Performance of a blood-based test for detection of the Septin9 biomarker for colorectal cancer screening" (Poster number P0964) will be presented during the poster session "Colonic and Anorectal disorders II", by Dr. Gunter Weiss, Vice President Product Development at Epigenomics AG, on Tuesday, November 24th, 2009, from 9 am to 5 pm, at ExCel London, Hall S10.

### **About Epi proColon**

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

The *m*SEPT9 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 *m*SEPT9 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](http://www.epiprocolon.com) or contact Epigenomics directly by Email ([sales@products.epigenomics.com](mailto:sales@products.epigenomics.com)) or phone (+49 30 24345 111).

### **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 *pro*Colon, a CE-marked IVD blood test for the early detection of colorectal cancer based on the validated biomarker *m*SEPT9, 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 *m*SEPT9 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 *m*SEPT9 in a screening population is currently under way ([www.presept.net](http://www.presept.net)).

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](http://www.epigenomics.com).

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