



Swiss Viollier AG First Laboratory in Europe to offer Epigenomics' Colorectal Cancer Blood Test

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The Swiss private diagnostic laboratory will launch ^mSEPT9 blood testing service for colorectal cancer early detection on July 1, 2009

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 products for cancer detection based on DNA methylation, today reports that its blood-based test for colorectal cancer will be available for the first time to patients in Europe starting from July 1, 2009. The test, which is able to detect colorectal cancer in a simple blood draw, is based on Epigenomics' patented biomarker ^mSEPT9 and is the first blood test ever for colorectal cancer detection offered in Europe. As the first laboratory network Swiss Viollier AG will offer the test to patients, general practitioners and gastroenterologists. Viollier AG, headquartered in the Basel area, is one of Switzerland's largest private diagnostic laboratories and an innovative leader in laboratory diagnostics.

"We are excited to be the first laboratory to work with the ^mSEPT9 test. This test is a true innovation in early cancer detection", commented Edouard H. Viollier, MD, chairman, board of directors Viollier AG. "Blood sampling is easy and convenient for both the patient and the doctor and this test is performed in our professional laboratory under highest quality standards that ensure reliable results. We believe that this could be the future of non-invasive colorectal cancer screening and key to increasing compliance to screening programs."

With approximately 149,000 and 300,000 newly diagnosed individuals each year in the U.S. and Europe, respectively, colorectal cancer is the most frequent gastrointestinal tumor and second in cancer mortality each year in the U.S. and Europe. With approximately 4,100 new cases every year Switzerland is the country with the highest colorectal cancer incidence in Europe. In total 10.4% of all cancer-related deaths in Switzerland are caused by colorectal cancer.

The majority of colorectal cancers are diagnosed in advanced stages, limiting the chances for curative treatment. To improve prognosis for this disease the cancer must be detected in early stages. More than 90% of all patients could be cured if the cancer was diagnosed at an early, still localized stage.

Many countries including the U.S. and Germany introduced colonoscopy - typically in ten year intervals - as a screening modality for colorectal cancer. In Switzerland, although no national colorectal cancer screening program was introduced yet, colonoscopy is recommended from the age of 50 by private and public cancer prevention initiatives. By these screening programs and initiatives, the detection of colorectal cancer in early disease stages was expected to improve considerably. However, only a minority of the target population complies with screening recommendations, hence limiting the success of these approaches. Time requirements, invasiveness and fear of complications prevent most individuals from undergoing this sensible screening procedure. Besides colonoscopy, non-invasive tests for the detection of blood in stool samples (Fecal Occult Blood Test – FOBT) are currently recommended as a screening modality. However, they are not well accepted by patients because they have to be performed by the patients themselves and certain nutritional recommendations have to be followed. A blood-based test, detecting early stages of colorectal cancer because of its convenience for patients and doctors could encourage people, who reject colonoscopy and stool tests, to participate in colorectal cancer screening programs. An endoscopic examination would be strongly recommended particularly to those patients with a positive finding in the blood test.

"Compliance is the biggest hurdle in colorectal cancer screening. Although there are procedures like colonoscopy and FOBT that have been established as screening modalities for several years now, there still is very little acceptance and poor compliance by the

patients”, Prof. Peter Bauerfeind, of the Division of Gastroenterology & Hepatology of the University Hospital Zurich, Switzerland, commented the launch of the test. “A blood-based test fits into doctors’ daily routine and requires almost no patient involvement. Such a test for colorectal cancer screening could find much better acceptance among patients and drive compliance.”

The ^mSEPT9 colorectal cancer blood test is designed to be as convenient and patient friendly as possible. All it takes for the patient is giving a blood sample in the doctor’s office as part of their regular check-up. The sample is shipped to a local or regional diagnostic laboratory where it is tested for the ^mSEPT9 biomarker. The test result is provided to the doctor who can discuss it with the patient within a few days after the blood sample was taken. If the test were positive, a colonoscopy would typically be performed to confirm the test result and localize the tumor as a first step towards cancer therapy. Epigenomics has shown in a series of seven published case control studies with over 3,000 patient-samples and controls, that the ^mSEPT9 assay reliably detects cell-free DNA derived from colorectal tumors in blood samples and thereby indicates the presence of colorectal cancer of all stages.

Epigenomics expects further diagnostic laboratories in Europe to introduce ^mSEPT9 testing in due course. In addition, Epigenomics’ non-exclusively licenses the ^mSEPT9 biomarker and its technologies to partners in the diagnostics industry for global commercialization of in vitro diagnostic blood tests for colorectal cancer based on ^mSEPT9. A first IVD test kit for ^mSEPT9 testing is expected to be launched in Europe by the end of 2009. In the U.S., ^mSEPT9 testing is expected to be offered initially by Quest Diagnostics, a leader in diagnostic testing, information and services in the U.S. Quest Diagnostics is currently in the process of establishing a laboratory-developed test for ^mSEPT9 under license from Epigenomics. FDA approved IVD products through Epigenomics’ current and future IVD partners will follow.

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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