

Press release

## **Epigenomics' Epi proColon<sup>®</sup> Included in Newly Issued USPSTF Guidelines for Colorectal Cancer Screening**

- *USPSTF recognizes Epi proColon as the only blood-based colorectal cancer screening test*
- *Convenient and minimal-invasive blood-based testing contributes to USPSTF's goal of higher screening participation*
- *USPSTF guidelines expected to support adoption of Epi proColon by patients, physicians and insurers*

**Berlin (Germany) and Germantown, MD (U.S.A.), June 16, 2016** – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, announced today that the United States Preventive Task Force (USPSTF) has included Epi proColon<sup>®</sup> in its new recommendation statement for colorectal cancer screening, published in the Journal of the American Medical Association (JAMA). USPSTF is the first U.S. guideline body to recognize this novel colorectal cancer screening test after its recent FDA approval.

In its statement, the USPSTF highlights that there is convincing evidence that colorectal cancer screening substantially reduces deaths from the disease and that not enough people in the United States are using screening tests.

In the recommendation, the USPSTF names Epi proColon (“SEPT9 DNA test”) as one of several screening tests for the detection of early-stage colorectal cancer. The use of screening tests such as Epi proColon is recommended in the population of adults between 50 to 75 years.

The USPSTF also acknowledges that there is no “one size fits all” approach to colorectal cancer screening. As a consequence, instead of emphasizing specific screening approaches, the new guideline rather focuses on the importance of patient participation in CRC screening, without recommending for or against any particular method. However, only methods with substantial scientific evidence were included in their review of available tests.

Epigenomics expects that the new USPSTF recommendation will contribute to higher CRC screening rates, which have been stagnant over the past years. The American Cancer Society and other medical guideline bodies pursue a colorectal cancer screening goal of 80% of eligible patients.

“We are excited about the inclusion of Epi proColon in the new USPSTF recommendation, which recognizes the potential role of our novel blood-based test in colorectal cancer screening, especially in driving patient compliance in individuals who are reluctant to collect stool samples or undergo colonoscopy” said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “This recommendation emphasizes the need for additional screening options and will help to drive medical adoption and support reimbursement coverage of Epi proColon in U.S. market.”

### **About USPSTF**

The United States Preventive Services Task Force (USPSTF) is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. The task force, a panel of primary care physicians and epidemiologists, is funded, staffed, and appointed by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (Source: Wikipedia).

## **About Colorectal Cancer**

According to the American Cancer Society, there are projected to be over 134,000 new diagnosed cases of colorectal cancer and almost 50,000 deaths from colorectal cancer in 2016 in the United States. Colorectal cancer remains the second-leading cause of cancer death in the United States. Although screening and early detection of colorectal cancer can save lives, about 35 percent of eligible U.S. patients are not being regularly screened.

## **About Epi proColon**

Epi proColon<sup>®</sup> is an *in-vitro* PCR (polymerase chain reaction) assay for the qualitative detection of Septin9 gene methylation in DNA isolated from the patient's plasma. Cytosine residues of the Septin9 gene are methylated in colorectal cancer tissue, but not in normal colon mucosa. This tumor-specific methylation pattern can be used to detect cell-free DNA shed into the blood stream by tumor cells. Detection of colorectal cancer-derived DNA in blood plasma using the Septin9 methylation biomarker has been demonstrated in multiple clinical studies to be a reliable indicator of the presence of colorectal cancer.

Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, China and selected other countries.

## **About Epigenomics**

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, China and selected other countries. Epigenomics' second product, Epi proLung<sup>®</sup>, is in development as a blood-based test for lung cancer detection.

For more information, visit [www.epigenomics.com](http://www.epigenomics.com).

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