

Press release

## **Epigenomics announces commercial launch of Epi proColon® in the U.S.**

*Berlin (Germany) and Germantown, MD (U.S.A.), April 26, 2016* – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, announced today that Epi proColon®, its blood-based test for colorectal cancer screening, has now been made commercially available in the U.S. under a joint commercialization agreement with Polymedco, Inc.

Epi proColon® was recently approved by the U.S. Food and Drug Administration (FDA) for colorectal cancer screening in average-risk patients who are non-compliant to other screening tests such as colonoscopy and FIT.

For patients, the test only requires a simple blood sample to be drawn as part of routine healthcare provider visits. There are no dietary restrictions or alterations in medication required for the test. The sample will be analyzed at a local or regional diagnostic laboratory.

“We are very excited to be able to start the commercialization of Epi proColon® as the first and only approved blood-based colorectal cancer screening test just two weeks after its approval by the US FDA,” said Dr. Thomas Taapken, CEO/CFO of Epigenomics. “I would like to thank our employees and our partners at Polymedco for their commitment and hard work to make this happen so quickly. We look forward to making Epi proColon® available through laboratories nationwide.”

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® is indicated for colorectal cancer screening in average-risk patients who choose not to undergo colorectal cancer screening by guideline-recommended methods such as colonoscopy and stool-based fecal immunochemical tests (FIT).

Epi proColon® has received FDA approval based on demonstration of safety and efficacy as established in three major clinical studies. The test has also demonstrated its potential to significantly increase participation rates in colorectal cancer screening.

Epi proColon® 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 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<sup>®</sup>, is a blood-based screening test for the early detection of colorectal cancer. Epi proColon<sup>®</sup> has recently received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in Europe, China and selected other countries. For more information, visit [www.epigenomics.com](http://www.epigenomics.com).

## **About Polymedco**

Since 1980, Polymedco has evolved into a leading manufacturer, marketer, and distributor in the clinical laboratory marketplace. Polymedco supplies clinical diagnostic test kits that are specialized in hematology and cancer screening. The Company is a world leader in non-invasive colorectal cancer screening technology.

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