epigenomics

Press release

Epigenomics receives FDA approval for Epi proColon®

-First and only blood-based colorectal cancer screening test approved by the FDA

-Innovative, convenient and effective screening option for millions of eligible Americans

-Commercialization initiated with partner Polymedco

Berlin (Germany) and Germantown, MD (U.S.A.), April 13, 2016 – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's lead product, Epi proColon®, the first and only FDA-approved blood-based colorectal cancer screening test.

Epi proColon® will be made available in the United States under a joint commercialization agreement with the Company's strategic partner Polymedco, a leader in non-invasive colorectal cancer screening technology.

"We are excited by the FDA's decision to approve Epi proColon® as the first and only blood-based colorectal cancer screening test," said Dr. Thomas Taapken, CEO/CFO of Epigenomics. "While colorectal cancer remains the second-leading cause of cancer death in the United States, one out of three eligible Americans still does not undergo colorectal cancer screening. Given the significant benefits for patients, healthcare professionals and payors, Epi proColon® could help to meet the objective of 80% screening compliance of the eligible U.S. population as pursued by U.S. guideline bodies such as the American Cancer Society."

"Epi proColon® has the potential to become an important opportunity for laboratories across the country to join the fight on colorectal cancer," said Drew Cervasio, President and CEO of Polymedco. "We are very much looking forward to bringing this new, highly innovative blood-based test to the U.S. market."

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).

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.

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.

As typically required by the FDA for new screening products, the Company will initiate a post-approval study to show the long-term benefit of blood-based colorectal cancer screening using Epi proColon®.

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® 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®, is a blood-based screening test for the early detection 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. For more information, visit 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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