epigenomics

Press release

Journal of "Cancer Treatment and Research Communications" Publishes Results of Study with Blood Test Epi proColon®

ADMIT Study Results Demonstrate Higher Uptake of a Colorectal Cancer Screening Blood Test Compared to a Fecal Test

Berlin (Germany) and Germantown, MD (U.S.A.), January 11, 2017 – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), announced that the results of the ADMIT study have been published in the peer-reviewed journal *Cancer Treatment and Research Communications.* Study results confirm that a blood-based colorectal cancer screening test has the potential to increase the participation in colorectal cancer screening compared to a fecal test.

The study demonstrated a 99.5% rate of adherence to CRC screening using Epi proColon, while the fecal immunochemical test (FIT) showed an adherence rate of 88.1%. These numbers contrast to a baseline adherence to standard of care CRC screening of about 20%, as measured in a passive control arm in which previously non-compliant patients were offered CRC screening tests (FIT or colonoscopy) as part of their standard of care.

Nicholas Potter, PhD., Executive Vice-President of Clinical Affairs, Molecular Pathology Laboratory Network and co-author of the ADMIT study, commented: "Colorectal cancer is one of the most preventable forms of cancer, but still 1 in 3 or almost 23 million Americans are not up-to-date with their screenings. The ADMIT study demonstrated that in this underscreened population, a blood test could become the new "conversation starter" between patient and practitioner for achieving the desired outcome of getting more people screened."

Raymond Nungesser, M.D., Family Medicine Practitioner, Geisinger Health System and co-author of the study, added: "Colorectal cancer screening rates have been stagnant over the last decade due to the preparation and sampling barriers. A blood test for colorectal cancer screening mitigates these barriers and provides healthcare professionals with a new tool to not only significantly increase the number of individuals screened but that will also save lives."

Greg Hamilton, Chief Executive Officer of Epigenomics AG, said: "Higher participation in screening is essential in the fight against colorectal cancer, which is the second leading cause of cancer death in the United States. With demonstrated participation rates of 99.5% in the ADMIT study, the Epi proColon blood test has the potential to reach the under screened patients thereby saving thousands of lives and millions in healthcare dollars."

Epi proColon is nationally available in the United States. For patients, the test only requires a blood sample 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 national or regional diagnostic laboratory.

The full study, "Uptake of a Colorectal Cancer Screening Blood Test is Higher than a Fecal Test Offered in Clinic: A Randomized Trial" can be accessed on the following website:
http://www.sciencedirect.com/science/article/pii/S2468294216300181

About colorectal cancer (CRC)

The American Cancer Society projects there will 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. While the 5-year survival rate for early colorectal cancer (stage I) is 90%, only four-out-of-ten cases are diagnosed at this early stage. According to the American Cancer Society, this is in part due to the underuse of screening.

About Epi proColon

Epi proColon is indicated for colorectal cancer screening in average-risk patients who are unwilling or unable to perform colorectal cancer screening by colonoscopy and stool-based methods.

For patients, the test only requires a blood sample 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 national or regional diagnostic laboratory.

Epi proColon is an in-vitro PCR (polymerase chain reaction) assay for the qualitative detection of Septin 9 gene methylation in DNA isolated from the patient's plasma. Cytosine residues of the Septin 9 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 Septin 9 methylation biomarker was demonstrated in multiple clinical studies, to be a reliable indicator of the presence of colorectal cancer.

Clinical evidence of Epi proColon

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

The approval was based on multiple trials. In the performance evaluation trial using the PRESEPT prospective collection from 7.941 average risk patients (NCT00855348), samples from all patients with colorectal cancer or advanced adenomas, and a stratified random collection of patients with small polyps or no evidence of disease were blinded, randomized to batches and tested at independent laboratories. In this study, the test detected 68% of all cancer cases at 80% specificity. In a second study, conducted head-to-head against FIT, it was shown that Epi proColon is statistically non-inferior to FIT, a USPSTF recommended method in detecting colorectal cancer.

For more information on Epi proColon, visit www.epiprocolon.com.

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, and China and selected other countries. Epigenomics' second product, Epi proLung®, is in development as a blood-based test for lung cancer detection.

For more information, visit www.epigenomics.com.

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