epigenomics

Press release

ARUP Laboratories to Offer Epi proColon®, Epigenomics' Blood-Based Colorectal Cancer Screening Test

Berlin (Germany) and Germantown, MD (U.S.A.), November 8, 2016 – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), announced that ARUP Laboratories (Salt Lake City, Utah) is the next major U.S. laboratory to offer Epi proColon®, the first and only FDA-approved blood-based test for colorectal cancer screening.

"I am excited about the inclusion of our FDA-approved cancer screening test Epi proColon into ARUP's comprehensive test menu," said Greg Hamilton, CEO of Epigenomics AG. "With its broad experience in blood-based cancer testing and its strong client network, ARUP Laboratories will continue to play an important role in the fight against colorectal cancer in the United States. While colorectal cancer is one of the most preventable forms of cancer, still 1 in 3 Americans are not regularly screened. Driving patient access to our blood-based test has the potential to significantly increase participation rates in colorectal cancer screening."

"ARUP Laboratories is delighted to offer the Epi proColon test for colorectal cancer screening to our patients," said Dr. Edgar Braendle, ARUP President and CEO. "In 2010, ARUP was one of the first two labs to offer blood-based testing for colorectal cancer based on the Septin 9 biomarker. We were eager to have the opportunity to transition our testing to the newly FDA approved test. Blood-based colorectal cancer testing has the capability of reaching those patients who have been offered and declined other screening methods. Unlike stool-based testing, the Epi proColon test utilizes a routine blood specimen collected in the physician's office."

1 in 3, or approximately 23 million Americans remain unscreened for colorectal cancer. A blood test is an acceptable testing method in healthcare. A blood test mitigates the typical screening barriers such as patient preparation and medication modifications associated with colonoscopy and handling of stool sample. Epi proColon is intended for the unscreened patient population who are unwilling or unable to complete typical screening methods (colonoscopy or stool tests).

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 simple 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 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 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. Additionally, in the ADMIT (Adherence to Minimally Invasive Testing) trial, it was demonstrated that blood-based testing with Epi proColon has the potential to increase compliance with colorectal cancer screening, compared to FIT stool-based testing. In the ADMIT trial, Epi proColon reached an adherence rate of 99.5% among previously screening resistant participants.

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

About ARUP Laboratories

Founded in 1984, ARUP Laboratories is a leading national reference laboratory and a nonprofit enterprise of the University of Utah and its Department of Pathology. ARUP offers more than 3,000 tests and test combinations, ranging from routine screening tests to esoteric molecular and genetic assays. ARUP serves clients across the United States, including many of the nation's top university teaching hospitals and children's hospitals, as well as multihospital groups, major commercial laboratories, group purchasing organizations, military and other government facilities, and major clinics. In addition, ARUP is a worldwide leader in innovative laboratory research and development, led by the efforts of the ARUP Institute for Clinical and Experimental Pathology®.

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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