epigenomics

Press release

Epigenomics AG Announces Publication of Results of Two U.S. Clinical Studies with its Blood-based Epi proColon® CRC Screening Test

Berlin (Germany), Germantown, MD (U.S.A.), June 24, 2014 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced that results from its U.S. clinical validation study for its blood-based colorectal cancer (CRC) detection test Epi proColon® as well as from its head-to-head comparative study with fecal immunochemical occult blood testing (FIT) have been published in renowned scientific journals. Both clinical studies are part of the required data package to seek regulatory approval of Epi proColon® in the U.S.

The peer-reviewed article, "Validation of a Real-Time PCR-Based Qualitative Assay for the Detection of Methylated Sept9 DNA in Human Plasma", discussing the data of Epigenomics' U.S. pivotal clinical validation study has been published online on Clinical Chemistry (www.clinchem.org) and will subsequently appear in the journal's print issue.

Based on prospectively collected plasma samples from a cohort of approximately 8,000 average risk individuals, the study was designed to measure the clinical performance of Epi proColon® for the detection of CRC in comparison to colonoscopy. The data published in Clinical Chemistry elaborates on top-line data Epigenomics announced in December 2011. In this clinical study Epi proColon® detected 68% of colorectal cancer cases (sensitivity) while correctly identifying 80% of the patients free of disease (specificity). The study results establish the clinical performance of Epi proColon® and suggest that under the assumption that choice drives improvement in CRC screening participation, this novel test has the potential to reach the otherwise non-compliant patients.

In addition, the peer-reviewed publication, "Plasma Septin9 versus Fecal Immunochemical Testing for Colorectal Cancer Screening: A Prospective Multicenter Study", discussing the top-line data of the head-to-head comparative study of Epi proColon® versus FIT has recently been published online on PLOS ONE (www.plosone.org).

The study was designed to demonstrate the non-inferiority of Epi proColon® in detection of CRC in comparison to one of the most commonly used FIT products in the U.S. market and was performed at 61 clinical sites across the U.S. The published data elaborate on the top-line data Epigenomics announced in December 2012. Sensitivity of Epi proColon® in detecting patients with CRC was 73% versus 68% for FIT. Specificity of Epi proColon® was 82% versus 97% for FIT. The study results confirm the performance of the assay and

indicated that Epi proColon® met the critically important endpoint of non-inferiority with respect to sensitivity to the state-of-the-art FIT test in detecting CRC.

"We are very pleased to see that the clinical results of these U.S. studies with our blood-based Epi proColon® CRC screening test now have been made publicly available. This is of particular importance as payors, policymakers, medical societies and guideline bodies will rely on this information for their decision-making process," explained Dr. Thomas Taapken, CEO/CFO of Epigenomics. "Since participation in CRC screening programs remains suboptimal, we are convinced that a blood-based test like Epi proColon® could significantly increase participation rates, considering that blood-testing is routine and well accepted for many other health conditions."

The Company initially completed the PMA filing for Epi proColon® approval in early 2013 and received a response letter from the U.S. Food and Drug Administration (FDA) in June 2014. The main item stressed in the response letter revolved around the need for additional data clearly demonstrating that Epi proColon® will increase compliance to CRC screening in the intended use population, i.e. in those patients who today do not undergo CRC screening by guideline recommended methods such as colonoscopy or FIT. The Company is currently in dialog with the FDA to learn more about the background of the agency's assessment and will work diligently to amend the PMA application accordingly in order to ensure an appropriate path forward towards U.S. market approval.

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About Epigenomics

Epigenomics (www.epigenomics.com) is a molecular diagnostics company developing and commercializing a pipeline of proprietary products for cancer. The Company's products enable doctors to diagnose cancer earlier and more accurately, leading to improved outcomes for patients. Epigenomics' lead product, Epi proColon®, is a blood-based test for the early detection of colorectal cancer, which is currently marketed in Europe and is under regulatory review by the FDA for the U.S.A. and the Chinese Food and Drug Administration for China. Additionally, the Company markets its tissue assay for use in lung cancer diagnosis, Epi proLung®, in Europe. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies and testing laboratories. Epigenomics is an international company with operations in Europe and the U.S.A.