epigenomics

Press release

FDA Issues Response Letter for Epigenomics' Colorectal Cancer Screening Blood Test Epi proColon® Requesting Further Data Pre-Approval

- **Meeting to discuss next steps with FDA scheduled in June**
- **FDA decision has no impact on commercialization of Septin9-based tests by LDT partners or existing commercial arrangements for Epi proColon® in other regions**
- **Company remains committed to offer highly efficient and convenient alternative for CRC screening**

Berlin (Germany) and Germantown, MD (U.S.A.), June 2, 2014 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced that it has received a response letter from the U.S. Food and Drug Administration (FDA) in relation to its premarket approval (PMA) application for the Company's blood-based colorectal cancer (CRC) screening test Epi proColon®.

In its letter, the FDA determined that while the studies performed so far have established the clinical performance characteristics of the test, the PMA application does not yet contain sufficient evidence to warrant an approval for Epi proColon®. However, the FDA provided helpful guidance on how to amend the PMA to make it approvable. The main item stressed in their response letter revolves around the need for additional data demonstrating that the blood-based Epi proColon® test 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. Since Epigenomics' originally conducted clinical studies were performed in patients who had agreed to a routine screening colonoscopy, the FDA is requesting Epigenomics to demonstrate whether patients in the targeted population can be turned compliant to CRC screening by Epi proColon®.

Epigenomics has scheduled a meeting with the FDA at the end of June in order to discuss next steps and how to best address the outstanding questions. It is expected that an additional study to demonstrate increased compliance and adherence of patients to blood-based CRC testing will be needed to address FDA's outstanding requests. Details around this study will be determined in dialog with the FDA.

"We were surprised with FDA's assessment of our PMA submission. While this is not what we expected, we remain fully committed to offering people who are unwilling or unable to undergo recommended CRC screening a highly efficient and convenient alternative for CRC screening," said Dr. Thomas Taapken, CEO/CFO of Epigenomics. "We will continue the dialog with the FDA to learn more about the background of the agency's assessment and will work diligently to amend our PMA application accordingly in order to determine an appropriate path forward towards US market approval."

Formally, a "Not Approvable Letter" is issued when the FDA determines that a PMA submission lacks significant information for approval at the time of review. FDA will identify what is necessary to make the PMA approvable. Epigenomics has 180 days to respond and amend the PMA, or request an extension of time with an estimate when the requested information will be submitted.

Epi proColon® is approved for marketing in Europe since 2012. The Septin9 marker has been incorporated into laboratory developed tests (LDTs) in the United States. In addition, Epigenomics' strategic partner BioChain has officially submitted an application to the China Food and Drug Administration (CFDA) in April for the approval of Epi proColon® in the Chinese market. Both companies expect commercialization of the test in China to start in 2015. The FDA decision will have no impact on the commercialization of Septin9 assays by LDT partners and on the existing commercial arrangements for Epi proColon® in other regions.

Conference call

Epigenomics' management will host a conference call at 4:30 pm CET/10:30 am EST on Tuesday, June 3rd, 2014.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): + 49 69 247501895

Dial-in number (within the UK): + 44 203 3679216

Dial-in number (within the U.S.): + 1 408 9169838

Participants are kindly requested to dial in 10 minutes prior to the start of the call.

A replay of the conference call will be provided on Epigenomics' website subsequently:
http://www.epigenomics.com/en/news-investors.html

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About Epi proColon®

The Epi proColon® test is a qualitative assay for the detection of methylated Septin9 DNA (SEPT9) in human blood plasma using real-time PCR, a common method being routinely used in most diagnostic laboratories. Analysis of Septin9 DNA-methylation in plasma represents a straightforward, minimally invasive method to detect all stages of CRC. Septin9 testing is dedicated to serve as an attractive alternative to existing CRC screening methods including fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), and flexible sigmoidoscopy in patient populations where sufficient compliance to CRC screening programs is not achieved.

About Colorectal Cancer (CRC)

Today, CRC is the third most common cancer diagnosed in men and women in the U.S. and the second leading cause of death from cancer among adults. According to the American Cancer Society, it is estimated that there will be around 96,830 new cases of colon cancer and roughly 40,000 new cases of rectal cancer being diagnosed in the U.S. in 2014. In the same period, approximately 50,310 patients will die from this disease. However, routine screening programs could dramatically increase chances of survival.

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.

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