epigenomics

Press release

Epigenomics AG Reports Non-Inferiority of Blood-based Epi proColon® against Fecal Immunochemical Testing in Detection of Colorectal Cancer in a Head-to-Head Comparative Study

Berlin, Germany, and Seattle, WA, U.S.A., December 04, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today announced top-line results from a head-to-head comparative study between its blood-based colorectal cancer (*CRC*) detection test Epi proColon® and fecal immunochemical testing (*FIT*) to demonstrate the non-inferiority of Epi proColon® in detection of CRC.

Dr. Thomas Taapken, Chief Financial Officer and acting Chief Executive Officer of Epigenomics, commented: "Based on the achieved non-inferiority in CRC detection, we believe that Epi proColon® has demonstrated its value to be a convenient non-invasive test alternative for CRC detection. Bringing a blood-based non-invasive product like Epi proColon® to the market will significantly drive awareness for colorectal cancer screening among individuals that would otherwise be noncompliant, since current compliance to FIT testing remains at low levels."

In the reported trial, Epi proColon® detected 73 in a total of 103 evaluable samples from patients with colorectal cancer, which represents a sensitivity of 71%. The FIT comparator used in the study, one of the most commonly used FIT products in the US market, detected 66 out of 98 cancer cases for which stool samples were provided, translating into a sensitivity of 67%. Based on Epigenomics' analysis of the data, which was confirmed by an external party, the Company met the critically important endpoint of non-inferiority with respect to sensitivity of Epi proColon® to FIT. These results represent an important milestone for Epigenomics and will be part of the final module of the Premarket Approval (*PMA*) submission expected to be filed with the U.S. Food and Drug Administration (*FDA*) before the end of this year.

The double blind study was performed at 70 clinical trial sites across the US and comprised two arms. The first arm included a total of 103 asymptomatic, average risk individuals without family history or previous incidences of CRC, who were diagnosed and confirmed as having colorectal cancer during a screening colonoscopy. Matched blood and stool samples from these patients were collected at least 10 days after colonoscopy but before surgical intervention. The second arm of the study included 198 individuals selected according to the same criteria, but whose blood and stool samples were collected before the colonoscopy. This study arm included three cancer cases as

well as advanced adenomas, polyps and individuals with no evidence of disease. Based on all non-CRC samples from the second arm, specificity for Epi proColon® was determined at 81% and for FIT at 98%. These findings are in line both with previous studies on Epi proColon® and published data for FIT. In summary, Epigenomics met the critically important sensitivity endpoint, which provides the potential to discover more CRC patients. The difference in specificity was anticipated and in the Company's opinion is less vital, since patients will undergo a colonoscopy –the currently recommended screening procedure– as a result of a positive test result. Testing of all samples was performed strictly according to the instructions for use by the respective manufacturers of both tests at an independent third party testing laboratory in the US, which was blinded to the samples analyzed.

Dr. Uwe Staub, Chief Operating Officer of Epigenomics, commented: "These positive study results confirm the performance of our assay and indicate that Epi proColon® is non-inferior to FIT in the detection of CRC. We look forward to an active dialogue with the agency upon completion of our PMA filing before the end of this year."

The company plans to submit detailed study results for presentation at a medical meeting and for peer-reviewed publications in the near future.

Conference call for press and analysts

Epigenomics' management will host a conference call and an audio webcast at 5pm CET/11am ET today, Tuesday 4th December 2012.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): + 49 69 247501899

Dial-in number (within the UK): + 44 203 1474861

Dial-in number (within the U.S.): + 1 212 4440297

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

The presentation accompanying the conference call and dial-in details for the audio webcast will be available on Epigenomics' website:
http://www.epigenomics.com/en/news-investors.html

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

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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 in development for the U.S.A. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

Epigenomics legal disclaimer