epigenomics

Press release

Epigenomics AG Completes U.S. Clinical Validation Study for Colorectal Cancer Blood Test Epi proColon; Provides Update on U.S. Regulatory Plans

Conference Call Scheduled for today, 9th December 2011 at 4 pm CET

Berlin, Germany, and Seattle, WA, U.S.A., December 9, 2011 - Epigenomics AG (Frankfurt Prime Standard: ECX), the cancer molecular diagnostic company, today reports the completion of the clinical validation study for its second-generation colorectal cancer blood test Epi proColon in the U.S. The study was designed to measure the clinical performance of Epi proColon for the detection of colorectal cancer in comparison to colonoscopy and is part of the required data package to seek regulatory approval of the product in the U.S. In the reported study, Epi proColon detected 68% of the colorectal cancer cases (sensitivity) while correctly identifying 80% of the patients free of disease (specificity). While the results of the study represent the lower end of the expected performance data, the findings of the study confirm the results obtained in a previously conducted clinical study with the first generation of the company's Epi proColon test in the same cohort of patients.

Study subjects tested were selected from a prospectively collected cohort of 7.940 individuals, defined as being at average risk for colorectal cancer by current screening guidelines and who underwent colonoscopy for colorectal cancer screening. The tested study cohort included 45 cancer cases. All plasma samples selected were blinded, randomized, and tested with Epi proColon at three independent laboratories in the U.S.

After consultation with the U.S. Food and Drug Administration (FDA), the company confirmed that the clinical data would be assessed as part of the regular Premarket Approval (PMA) review process. The Company will begin the regulatory process with the FDA by submitting the first module of its PMA this month. In addition to the clinical validation study data, Epigenomics will also perform a head-to-head comparative study for colorectal cancer detection through comparison with fecal immunochemical testing (FIT) for the purpose of demonstrating non-inferiority of Epi proColon to FIT. This study will also become an integral part of the PMA submission to the FDA and is anticipated to be completed in 2012.

Conference Call for Investors and Media

Epigenomics' management will host a conference call to discuss the study results and to inform about the further process of the FDA submission at 4 pm CET (10 am EST) today, December 9, 2011. The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 69 247 501 899

Dial-in number (within U.K.): +44 203 147 4861

Dial-in number (within the US): +1 212 444 0297

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

A recording 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 *pro*Colon®, 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.

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