epigenomics

Press release

Epigenomics Provides Additional Data on the Outcome of its Head-to-Head Comparison Study of Epi proColon® to FIT

Berlin, Germany, and Seattle, WA, U.S.A., December 19, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today provided detailed results from a head-to-head comparative study between its blood-based colorectal cancer (CRC) detection test Epi proColon® and fecal immunochemical testing (FIT) for which it recently reported top-line results. This trial was designed to evaluate non-inferiority of the blood based Epi proColon® assay performance in comparison to FIT.

The subjects included in the first arm of the study were average risk, asymptomatic screening patients with no history (own or familial) of CRC. These patients were identified as CRC patients in the context of screening colonoscopies performed from April-November 2012 across 70 sites in the US.

As previously reported, in this study, Epi proColon® was able to detect 73 out of 103 cancer cases, demonstrating an overall sensitivity of 71%. Clinical staging information of the disease was available for 71 of the 103 cases.

Further analysis of the data shows that Epi proColon® was able to demonstrate 61% sensitivity for 23 cases in stages 0 and 1 (FIT 61% sensitivity), 75% for 16 cases in stage 2 (FIT 75% sensitivity), 70% for 20 cases in stage 3 (FIT 85% sensitivity) and 92% in 12 stage 4 cases (FIT 64% sensitivity). In the 32 cases of unknown clinical staging, the sensitivity was 69% (57% sensitivity for FIT).

The correspondence of the blood and stool based test methods was 62%, whereby Epi proColon® was able to identify 20 cases that could not be identified by FIT, while FIT identified 17 CRC cases, which were not found through Epi proColon®.

The second arm of the study comprised 198 average risk individuals, which were prospectively enrolled (i.e. before colonoscopy). Among these, 3 CRC cases were identified by colonoscopy. Both, Epi proColon® and FIT were able to find 2 out of these three CRC cases. At the same time, of the 24 advanced adenomas included in the second arm, neither method detected a significant number of these. The adenoma detection for Epi proColon®, as shown in previous studies, was low. Surprisingly, the finding was the same for FIT, although it was previously believed to be a distinct advantage of this method.

Overall reported specificities for Epi proColon® and FIT were at 81% and 98% respectively. While the point estimate of 81% specificity for Epi proColon® was still above the pre-defined non-inferiority margin, this result was statistically non-significant. The difference in specificity is less vital in the Company's opinion, as patients will undergo a colonoscopy – the currently recommended screening procedure – as a result of a positive test result. In addition to this it is noteworthy that the Company's CE marked version of the product, optimized for specificity and launched in Europe earlier this year, has a specificity for CRC detection of 99%. This could open additional possibilities to address the US market in the future.

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Contact Epigenomics AG

Antje Zeise
Manager IR | PR
Epigenomics AG
Tel +49 (0) 30 24345 368
ir@epigenomics.com
www.epigenomics.com

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.

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