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EANS-Adhoc: Epigenomics AG: PRESEPT Academic Research Study Meets Its

Primary

Objective

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Company Information/Molecular diagnostics/Studies

08.03.2010

Berlin, March 8, 2010 - Epigenomics AG (ISIN: DE000A0BVT96), a cancer molecular diagnostics company, reports updated top-line PRESEPT Study data showing that the Septin9 biomarker in this research study detected colorectal cancer cases with a sensitivity of approximately 63% based on 32 colorectal cancer (CRC) cases correctly identified out of 51 cancer cases with valid measurements of Septin9 in blood plasma samples. With this performance the PRESEPT Study has met its objective of detecting the majority of prevalent and incident cancers in a screening cohort, a requirement for noninvasive screening tests set forth in current joint guidelines by the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (1). With a specificity of around 89% the Septin9 testing result meets the targeted specificity range of 85% to 90%, which based on an initial health economic analysis, should support public and private payer coverage and reimbursement.

As originally foreseen in the study protocol, the study results were updated upon testing of samples determined to be invalid along with testing of a small number of additional cancer cases identified after the previous testing was initiated. Furthermore, investigative actions were implemented after a preliminary data analysis in January 15, 2010 had indicated that one of the three laboratories performing the Septin9 testing had reported a cancer detection rate that deviated from findings in the other PRESEPT Study testing laboratories and all previous studies. An investigation into these results led to retesting potentially affected samples by the other two labs. In addition a remainder of material leftover from processing of the samples measured in the study was also tested for Septin9 at each of the three independent laboratories and included into the analysis. The combined results from all of the above testing activities contributed to the improved test performance reported.

Epigenomics can now report that the additional testing directed by the PRESEPT Clinical Study Steering Committee (CSSC) has been completed, and the Committee has reported to Epigenomics that the primary objective of the study of identifying the majority of colorectal cancer cases has been successfully met. Although histopathological review and further detailed statistical analysis remain to be completed, the CSSC concludes the results are not inconsistent with case-control studies previously reported (2-4) and that the data indicate that Septin9 testing may be a useful tool to detect the presence of occult colorectal cancer in a standard plasma specimen obtained from average risk individuals eligible for colorectal cancer screening. Later this year the CSSC will submit the PRESEPT Study results for presentation at a major medical meeting and peer-reviewed publication in a major scientific journal.

A simple blood test for colorectal cancer, which can be made available to the large group of patients who are eligible for colorectal cancer screening, but are unwilling or unable to use other available methods, has the potential to address the lack of compliance with today's screening approaches (5). Based on the Septin9 performance data and the prevalence of CRC observed in the PRESEPT Study cohort, a primary care physician informing a patient of a Septin9 test result that is negative for colorectal cancer, can do so with the certainty of it being correct 99.7% of the time (Negative Predictive Value).

PRESEPT is a prospective multi-center clinical research study started in 2008 to evaluate the performance characteristics and health economic benefit of colorectal cancer screening using Epigenomics' Septin9 blood test in a screening population. The PRESEPT Study is one of the largest commercially sponsored colorectal cancer screening clinical studies ever conducted. Between June 2008 and December 2009, in total 7,941 screening eligible average risk subjects were enrolled into the PRESEPT Study at 32 clinical sites in the U.S. and Germany. This study population contained 53 cases of previously unsuspected colorectal cancer that were identified by screening colonoscopies performed on all study participants. Over two-thirds of the 53 colorectal cancer cases identified in the cohort were early stage disease (Stages I and II) with a large proportion of the stage I colorectal cancer cases being very early stage disease (so-called pT1) as determined by pathology.

End of Ad Hoc Announcement References

1. Levin B, et al., Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. Gastroenterology 2008; 134(5): 1570-95. 2. Lofton-Day C, et al. DNA methylation biomarkers for blood-based colorectal cancer screening. Clin Chem. 2008; 54(2):414-23. 3. Grützmann R, et al. Sensitive detection of colorectal cancer in peripheral blood by mSEPT9 DNA methylation assay. PLoS One. 2008;3(11):e3759. 4. deVos T, et al. Circulating methylated SEPT9 DNA in plasma is a biomarker for colorectal cancer. Clin Chem. 2009; 55(7):1337-46. 5. The Centers for Disease Control and Prevention (CDC) e.g. estimates that 40% of the eligible population of adults 50 years of age or older –the age group at greatest risk of developing colorectal cancer– in the USA has not been screened appropriately. {
<http://www.cdc.gov/cancer/colorectal/sfl/>}[HYPERLINK:
<http://www.cdc.gov/cancer/colorectal/sfl/>]

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