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Epigenomics AG Releases Preliminary PRESEPT Study Data

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Company Information/Molecular diagnostics

15.01.2010

Berlin, January 15, 2010 - Epigenomics AG (ISIN: DE000A0BVT96), a cancer molecular diagnostics company, informs on preliminary data from the prospective multi-center clinical PRESEPT Colorectal Cancer Screening Study (clinicaltrials.gov; identifier: NCT00855348) sponsored by the company. The primary study objective is to demonstrate that the Septin9 biomarker satisfies the requirements 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. (Ref. 1) The results of this preliminary data analysis were reported by Timothy R. Church, Ph.D., University of Minnesota, Minneapolis, MN, U.S.A., Principle Investigator of the PRESEPT Study on behalf of the PRESEPT Clinical Study Steering Committee, chaired by Professor David Ransohoff, M.D. University of North Carolina School of Medicine, Chapel Hill, NC, U.S.A.

This preliminary analysis indicates that two of the three testing laboratories performing the Septin9 testing on blood plasma samples from PRESEPT Study subjects achieved cancer detection rates of 62.5% each, that were within expectations from previously published clinical studies (Refs 2-4) taking into account the higher proportion of early stage cancers in the PRESEPT Study cohort. The third laboratory reported a cancer detection rate of 28% deviating from findings in the other PRESEPT Study testing laboratories and all previous studies. The overall cancer detection rate based on results from all three laboratories combined added up to 50%. Specificity as measured on colonoscopy verified subjects without any apparent colon disease was at 91% confirming the high specificity rates seen in previous clinical studies.

The Clinical Study Steering Committee, which includes the Principal Investigator representing the independent University of Minnesota biostatistics team, charged with analyzing the PRESEPT data, intends to conduct a failure investigation to identify the potential causes for the outlier results observed in the one of the laboratory before reporting final results of the study, that may deviate from the reported preliminary results of the study.

Between June 2008 and December 2009, 7,914 average risk, CRC screening eligible subjects were enrolled into the PRESEPT Study at 32 clinical sites, of which 22 sites were located in the U.S. and 10 sites were located in Germany. This study population contained 50 confirmed cases of previously unsuspected colorectal cancer that were identified by screening colonoscopies performed on all study participants.

Final and detailed study results will be presented at upcoming medical conferences and will also be submitted to a scientific journal for peer-review and publication once available.

End of Ad Hoc

Further information

Conference Calls

Epigenomics' management scheduled conference calls for Monday, January 18, 2010 at 15:00 CET (German language) and 17:00 CET/11:00 am EST (English language) to inform on the preliminary results and potential further actions as well as answering questions from investors and media. Dial-in details will be published on Epigenomics website www.epigenomics.com prior to the calls.

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.

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