epigenomics

Press release

Epigenomics Reaches 99.5 % Adherence for Epi proColon® in ADMIT Study

Berlin, Germany, May 8, 2015 - Epigenomics AG (Frankfurt Prime Standard: ECX; ISIN: DE000A11QW50) announces results from the ADMIT trial (ADherence to Minimally Invasive Testing - NCT02251782) for its non-invasive blood-based test for colorectal cancer (CRC) screening, Epi proColon®. The study demonstrated a 99.5% rate of adherence to CRC screening using Epi proColon®, while the fecal immunochemical test (FIT) showed an adherence rate of 88.1%. These numbers contrast to a baseline adherence to standard of care CRC screening of less than 25%, as measured in a passive control arm in which previously non-compliant patients were offered CRC screening tests (FIT or colonoscopy) as part of their standard of care.

Adherence to Epi proColon® was significantly greater than adherence to FIT, with an observed difference of 11.4% ($p<0.0001$).

The study was designed to determine whether the adherence to Epi proColon® was significantly greater than to FIT plus a margin of 8.2%. This margin was determined before the study based on a projected FIT adherence rate. While adherence to Epi proColon® ultimately was higher than the FIT adherence plus 8.2%, the comparison fell just short of statistical significance ($p=0.059$). However, given the difference in the observed FIT adherence rate in the study from the projected one, demonstrating an adherence to Epi proColon® equaling the FIT adherence rate plus a margin of 3.2% would have been sufficient to prove superiority. In this scenario, the observed difference in adherence (11.4%) met statistical significance ($p<0.0001$).

“We are convinced that these study results will support our pre-market approval (PMA) application for Epi proColon®. Seeing adherence with Epi proColon® approaching 100% clearly confirms our assumption that blood-based CRC screening has the potential to significantly lower the barrier for patients that have been historically non-compliant to participate in CRC screening programs,” said Dr. Thomas Taapken, CEO of Epigenomics. “We plan to submit the data as part of our PMA application and further discuss the study results with the U.S. Food and Drug Administration (FDA) over the next few weeks.”

The ADMIT trial was requested by the FDA in the context of Epigenomics’ PMA application for Epi proColon®.

The study was originally designed to investigate CRC screening participation for average risk, screening eligible study subjects that were historically non-compliant to offered guideline-recommended screening methods (colonoscopy or FIT testing) and included 413 eligible subjects identified by Epigenomics’ clinical trial partners, Kaiser Permanente and Geisinger Health Systems. Study subjects were randomized to either a FIT test kit for home use or a

blood draw for the Epi proColon® test. Rates of adherence were compared between those that accepted and completed the blood test and those that accepted and completed the FIT test.

An observational secondary objective of the study aims to demonstrate the number of patients who completed colonoscopy after positive test results with Epi proColon® or FIT. This data will be reported to the FDA once the study is formally completed within the next few weeks, i.e. up to six weeks after the last positive test result of a study subject was obtained.

Further Information

For further information please refer to the press release issued today by Epigenomics AG at www.epigenomics.com.

Conference call for press and analysts

Epigenomics' management will host a conference call at 3pm CET/9 am ET today, Friday 8th May 2015.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 69 247 501 895

Dial-in number (within the UK): +44 203 367 92 16

Dial-in number (within the U.S.): +1 408 9169 838

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

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

About Epigenomics

Epigenomics (www.epigenomics.com) is a molecular diagnostics company developing and commercializing innovative 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, has received approval by the Chinese Food and Drug Administration for China and is under regulatory review by the U.S. Food and Drug Administration (FDA). Additionally, the Company markets its tissue assay for use in lung cancer diagnosis, Epi proLung®, in Europe. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies and testing laboratories. Epigenomics is an international company with operations in Europe and the U.S.A.

Contact Epigenomics AG

Antje Zeise, Manager IR | PR
Epigenomics AG
Geneststraße 5
10829 Berlin

epigenomics

Phone +49 (0) 30 24345 386
ir@epigenomics.com
www.epigenomics.com

For US press inquiries:

Epigenomics, Inc.
20271 Goldenrod Lane, Suite 2027
Germantown, Maryland 20876
pr@epigenomics.com

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