Press release

Epigenomics AG Provides Update on Regulatory Status and Information on Additional Clinical Study for Epi proColon® in the U.S.

Berlin (Germany), Germantown, MD (U.S.A.), July 1, 2014 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, reports on the status of its Pre-Market Approval (PMA) application with the U.S. Food and Drug Administration (FDA) and provides information regarding the design and objectives of an additional clinical study requested by the FDA for regulatory approval of Epi proColon®, the Company's blood-based colorectal cancer (CRC) screening test in the U.S.

In a recently held meeting between the Company and the FDA, detailed discussions were held to specify the details regarding the design of this clinical study. Epigenomics proposed to conduct a study to demonstrate that Epi proColon® will increase participation in CRC screening in patients being offered the blood-based test as compared to those being offered a FIT stool-based test. The trial is intended to be conducted in a population that is non-compliant to CRC screening according to current screening guidelines and may include patients actively managed by CRC screening programs within healthcare systems. Discussions with several healthcare organizations to participate in such a study are already underway. While a decision on the final study plan has not yet been taken, an adaptive study design could allow early completion of the study if statistical significance is clearly met. Based on these initial assumptions Epigenomics foresees that conducting the study can likely be done with a reasonable number of patients that could be enrolled in a matter of a few months. However, additional time will need to be allocated for study initiation and logistics. Once the study has been completed, a PMA amendment with study results will be filed within a reasonable period of time.

The study's secondary objectives will include a measurement of compliance to colonoscopy in those patients with positive test results with Epi proColon® or FIT. For this endpoint, the results will be descriptive and will not be reported with statistical significance in the premarket setting. The Company remains committed to study the performance of its blood-based test in a programmatic setting after potential approval in the context of a post-marketing study as previously proposed in its PMA application. Based on initial estimates, Epigenomics expects additional costs for the study to be in the range of less than EUR 1.0 million.

Dr. Thomas Taapken, CEO/CFO of Epigenomics, commented: "After a productive dialogue with the FDA, we now have a better understanding of the issues and background of the agency's assessment. We are confident that we can complete the requested clinical study within a reasonable period of time. Although Epigenomics is currently able to fund these additional activities, we are constantly evaluating various options to maintain the Company's financial flexibility and to allow for the preparation of commercialization in the U.S. in order to rapidly enter the market post approval."

The discussed clinical study was requested as part of the FDA response letter in relation to Epigenomics' PMA application for the Company's blood-based colorectal cancer screening test Epi proColon® the Company received at the beginning of June 2014.

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Contact Epigenomics AG

Antje Zeise, Manager IR | PR
Epigenomics AG
Kleine Praesidentenstrasse 1
10178 Berlin
Tel +49 (0) 30 24345 386
ir@epigenomics.com
www.epigenomics.com

For U.S. press inquiries:

Epigenomics, Inc.
20271 Goldenrod Lane, Suite 2027
Germantown, Maryland 20876
pr@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 under regulatory review by the FDA for the U.S.A. and the Chinese Food and Drug Administration for China. 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.

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