

Press release

Epigenomics Updates on Regulatory Status for Epi proColon® in the U.S.A.

Berlin (Germany), Germantown, MD (U.S.A.), April 29, 2014 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today provides an update on the status of its discussions with the Food and Drug Administration (FDA) regarding Epi proColon®, the Company's blood-based colorectal cancer (CRC) screening test, following a recent meeting with the premarket approval (PMA) review team at the FDA. The meeting focused on detailed discussions regarding submitted data, product labeling, design of the proposed post-approval study as well as on topics raised at the recent Medical Devices Advisory Committee ("Advisory Committee") meeting and progress was made in addressing open issues. The post-approval study proposed by Epigenomics is intended to investigate the test's longitudinal performance in a programmatic setting to assess the long-term benefits of CRC screening using Epi proColon®.

Dr. Thomas Taapken, CEO/CFO of Epigenomics, commented: "We look forward to continuing to diligently collaborate with FDA over the weeks to come on the topics discussed. While FDA regulations do not allow Epigenomics to anticipate a decision or decision date, we remain confident that the data submitted supports our PMA application for Epi proColon®."

The Company initially completed the PMA filing for Epi proColon® for FDA approval in early 2013. As part of the PMA review process, an Advisory Committee was convened by the FDA on March 26, 2014 to discuss and evaluate the effectiveness, safety and the benefit-risk profile of Epi proColon®. Members of the Advisory Committee voted positively that the benefits of Epi proColon® outweigh the risks of the test for use in patients who meet its application criteria.

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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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