Press release

Epigenomics AG submits the third module in its PMA filing with FDA for Epi proColon®

Berlin, Germany, and Seattle, WA, U.S.A., June 12, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, announced today that it has submitted the third module of its Premarket Approval (PMA) application to the United States Food & Drug Administration (FDA) for its blood-based colorectal cancer screening test Epi proColon®.

Module three describes the analytical performance of Epi proColon® in terms of accuracy, precision and stability. Reproducibility and validation of the analytical performance were assessed through testing at three external laboratories. The first two modules of the PMA are related to design control, manufacturing, quality management, and software validation. The fourth and last module is planned for submission in the second half of 2012 and will include the results of a head-to-head comparative study with the goal of demonstrating non-inferiority of Epi proColon® to fecal immunochemical testing (FIT), which is currently underway and enrolling study subjects according to plan. Furthermore, it will include previously announced data from a clinical validation study in a cohort of prospectively collected samples, and other clinical study results generated during the development of Epi proColon®.

Under the FDA's modular PMA submission guidance, the complete contents of a PMA is broken down into well-delineated modules, such as non-clinical, clinical, and manufacturing, that together become a complete application. The FDA reviews each module separately as it is received, allowing companies to receive timely feedback during the review process. The FDA guides that it will take 90 days to complete its review of each module as stated in "Guidance for Industry and FDA staff – Premarket Approval Application Modular Review" as posted on FDA's homepage.

Geert Nygaard, Chief Executive Officer of Epigenomics commented: "The submission of the third module concludes a significant part of our PMA filing. We look forward to successfully finishing the ongoing clinical trial and subsequently completing our PMA submission to FDA by year end. Our team has been working expeditiously to finalize our first US market application and we remain committed and focused on introducing Epi proColon® as the first FDA approved blood-based test for the early detection of colorectal cancer in the US. We firmly believe that the test will help drive screening compliance and make a difference in detecting cancers in patients who would otherwise avoid being tested for colorectal cancer."

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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 in development for the U.S.A. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

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