Press release

Epigenomics announces initiation of PMA filing for Epi proColon, provides update on regulatory timeline

Berlin, Germany, and Seattle, WA, U.S.A., January 4, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, is pleased to announce that it has submitted the first module of its premarket approval (PMA) submission to the US Food and Drug Administration (FDA) on December 30, 2011.

On December 30, 2011 Epigenomics has initiated the process of gaining US regulatory approval of its colorectal cancer (CRC) screening test Epi proColon® by submitting the first module of its modular PMA approval submission to the FDA. The first module of the submission includes all required documentation on the manufacturing and quality controls section in relation to the product. Further modules are scheduled to be submitted throughout the first and second quarters of 2012 and the final module, including all clinical data is scheduled for submission in the second half of 2012. Under the FDA's modular PMA submission protocol, in its guidance document "Guidance for Industry and FDA staff – Premarket Approval Application Modular Review", the FDA provides for a 90 day review period by the agency for each individual module.

As previously announced, a head-to-head comparative study with the goal of demonstrating non-inferiority of Epi proColon® to fecal immunochemical testing (FIT) will be an integral part of the clinical module. The design of the clinical study has been discussed with the FDA and upon finalizing of the study protocol, it will be initiated in the coming months. The clinical module of the PMA submission will encompass the results of the head-to-head comparative study, 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®.

Geert Nygaard, CEO of Epigenomics commented: "We are pleased that we have initiated the regulatory process for our CRC screening test Epi proColon® with the FDA. We intend to initiate the additional head-to-head study of our product against FIT as soon as possible, which would be required to meet our ambitious timeline for the completion of our submission in the second half of 2012."

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Further Information

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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 *pro*Colon®, 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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