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Press release

Epigenomics AG: FDA Advisory Committee Provides Recommendations for Epigenomics' Colorectal Cancer Screening Blood Test

FDA Advisory Committee votes favorably that the benefits of Epi proColon® outweigh the risks

Berlin (Germany) and Germantown, MD (U.S.A.), March 27, 2014 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced the outcome of a meeting of the Molecular and Clinical Genetics Panel of FDA's Medical Devices Advisory Committee held in conjunction with its premarket approval (PMA) for its blood-based colorectal cancer (CRC) screening test Epi proColon®. After deliberations, the members of the Medical Devices Advisory Committee voted positively that the benefits of Epi proColon® outweigh the risks for use in patients who meet the criteria.

In addition to reviewing the Company's clinical data and the performance of Epi proColon®, the Advisory Committee discussed data presented by the FDA as well as testimonies shared during the public comment session. The committee also discussed risk mitigation strategies that should be considered in addition to the current proposed labeling. The panel voted on three questions. The Advisory Committee members voted 9 to 0 favorably, with one abstention, in assessing whether there is reasonable assurance for safe use of the product in the intended population. The Advisory Committee members were split 5 to 5 in the vote assessing the effectiveness for use of the product in the intended population, with a negative vote from the Panel Chairperson to break the tie. Finally, the panel voted on the question of whether for patients who meet the criteria specified in the proposed intended use, the benefits outweigh the risks for use of Epi proColon®. The Advisory Committee members voted 5 to 4 favorably, with one abstention, supporting the view that the product's benefits outweigh its risks. While recommendations of the Advisory Committee are not binding, they will be considered in FDA's review process.

The panel expressed concerns about the lack of long-term data in a programmatic use of the product under the proposed intended use. As part of the intention to establish Epi proColon® as a CRC screening alternative for patients currently not

compliant to existing methods such as colonoscopy or stool-based tests, Epigenomics proposes to perform a post-approval study. More specifically, Epigenomics intends to investigate longitudinal performance of the test in a screening situation, in order to assess the long-term benefits of CRC screening utilizing Epi proColon®. The Company believes this will address the panel's concern.

The Company will meet with the PMA review team of the FDA to discuss a product labeling, that is addressing the concerns, as well as the design of the proposed post-approval study. After this meeting, Epigenomics will provide a detailed update about its planned next steps and expectations around the regulatory timeline. It is currently expected that such a meeting will be held within the next four to six weeks.

"We thank the Committee members for their thorough considerations and the insightful discussion", said Dr. Thomas Taapken, CEO/CFO of Epigenomics. "We are pleased with the outcome of today's meeting and appreciate the support expressed by the CRC community. We look forward to working with FDA and the community to continue the fight against CRC. As the only blood-based test for the early detection of CRC, the potential launch of Epi proColon® will help to significantly increase the number of people being tested early for CRC and help meet the objective of 80% screening compliance of the U.S. population, as pursued by U.S. guideline bodies."

The Company had completed the PMA filing for Epi proColon® for U.S. approval with the FDA in early 2013, which was subsequently accepted and granted priority review status by the FDA in February 2013.

The meeting of the Molecular and Clinical Genetics Panel of FDA's Medical Devices Advisory Committee was held on March 26, 2014 in Gaithersburg, MD and was convened by FDA as part of the PMA review process for Epi proColon®. Of note, this was the first time this panel was convened to discuss a PMA. The Committee discussed and evaluated the effectiveness, safety, and the benefit-risk profile of Epi proColon® in order to make appropriate recommendations regarding the safe and effective use of the test to FDA.

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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. 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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