epigenomics

Ad hoc Announcement Pursuant to § 15 WpHG (German Securities Trading Act)

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 (ISIN: DE000A1K0516, OTCQX: EPGNY) 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 during 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.

The Company had completed the PMA filing for Epi proColon® for US 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.

- **End of Ad hoc –**

Contact Epigenomics AG

Antje Zeise CIRO
Manager IR | PR
Epigenomics AG
Phone: +49 (0) 30 24345 386
ir@epigenomics.com
www.epigenomics.com

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