epigenomics

Ad Hoc Announcement pursuant to Sec. 15 WpHG (German Securities Trading Act)

# Epigenomics AG appeals recent FDA request for additional information

***Berlin, Germany, November 25, 2015*** - Epigenomics AG, Berlin, Germany, (Frankfurt Prime Standard: ECX; ISIN: DE000A11QW50) the German-American cancer molecular diagnostics company, today announced that after discussions with FDA in relation to its premarket approval (PMA) application for the Company's blood-based colorectal cancer (CRC) screening test Epi proColon®, it is appealing the agency's decision on additional data requirements. Epigenomics is requesting a supervisory review of the recent decision to require additional clinical data to support PMA approval.

Epigenomics believes that an approval for the intended use of Epi proColon® is warranted based on the data that has been submitted to date. The Company has provided an extensive amount of data under its PMA application and received a favorable recommendation by the FDA Medical Device Advisory Committee in March 2014. Furthermore, in its appeal, Epigenomics has highlighted the difficulties to measure adherence in the intended use population under the existing regulatory framework along with a willingness to work with FDA to design an appropriate post-approval study.

FDA regulations provide several mechanisms to applicants for further review of the agency's actions. A request for supervisory review is directed to the next organizational level above the level at which the decision was made. Based on respective guidelines and following discussions with FDA, Epigenomics believes the supervisory review will be completed in Q1 2016.

Any decision on the company's appeal does not affect to the right of Epigenomics to amend its PMA application in the future.

- End of Ad hoc –

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