epigenomics

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

Epigenomics receives FDA notification about status of pending approval decision for Epi proColon®

Berlin, Germany, January 8, 2016 - Epigenomics AG, Berlin, Germany, (Frankfurt Prime Standard: ECX; ISIN: DE000A11QW50) the German-American cancer molecular diagnostics company, today announced that the U.S. Food and Drug Administration (FDA) has informed the Company that the already submitted and available data for Epigenomics' blood-based colorectal cancer (CRC) screening test Epi proColon® would allow the agency to come to a final determination on its safety and effectiveness. Given that no new data would be required before reaching a final decision on the premarket approval ("PMA") submission, FDA would expect that final stages of the review process would be completed in the near future.

According to the FDA, final approval of the Company's application is subject to the resolution of minor outstanding topics, such as the use of appropriate language in the product labeling.

Epigenomics will work closely with the FDA to reach the final approval decision within the next few months.

Upon approval, Epi proColon® would be the first and only FDA-approved blood-based test for the detection of colorectal cancer. Epi proColon® will be made available in the United States jointly with the Company's strategic commercialization partner Polymedco.

– End of Ad hoc –

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this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on this technology is currently available for sale by Epigenomics in the United States or Canada. The analytical and clinical performance characteristics of any Epigenomics product based on this technology which may be sold at some future time in the U.S. have not been established.