Press release

CMS accepts Epigenomics' application for NCD review

Berlin (Germany) and San Diego, CA (U.S.A.), May 3, 2019 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY; the "Company") announces that the Centers for Medicare & Medicaid Services (CMS) has accepted the company's application for a National Coverage Determination (NCD) review of Epi proColon, Epigenomics' blood test for colorectal cancer screening. The NCD is one of two options to obtain CMS coverage for Epi proColon, which would represent a major U.S. market breakthrough for the company. With this step, no decision has yet been made on coverage, but CMS has determined that there is a rationale to accept the NCD review at this time.

While CMS has accepted the application, due to the limitation of resources, CMS will not "Open" the NCD review process immediately. Once CMS resources are available the NCD will be "Opened", by initiating a 30-day public comment period and CMS will issue a proposed decision within six months per legal statute. If this proposed coverage decision is positive, another 30-day comment period follows. CMS will publish its final decision within 90 days of the initial proposed decision.

"The acceptance of our NCD application by CMS is a major step forward to achieve reimbursement as we will have a definitive answer within six to nine months of CMS opening the review period", said Greg Hamilton, CEO of Epigenomics AG. "Additionally, we will continue to pursue the legislative path for reimbursement as we believe this option is also a viable solution. Overall, we are optimistic that we will receive a coverage decision for Epi proColon."

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon®, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epi proLung®, a blood-based test for lung cancer detection, and HCCBloodTest, a blood-based test for liver cancer detection in cirrohtic patients, have received CE mark in Europe.

For more information, visit www.epigenomics.com.

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