

Press release

Epigenomics AG Announces Initiation of a Prospective Clinical Study for Liver Cancer Detection

Berlin (Germany) and San Diego, CA (U.S.A.), 20 December, 2018 - Epigenomics AG (FSE: ECX, OTCQX: EPGNY) today announced the initiation of a multi-center validation and development study of its methylated cell free DNA biomarkers to aid in the detection of hepatocellular carcinoma (HCC) in patients with cirrhosis.

As an expansion of its molecular diagnostic product offering, the company recently CE marked the HCCBloodTest for cirrhotic patients at risk for HCC, based on a published clinical study, demonstrating a high sensitivity of 90.6 percent at a specificity of 87.2 percent. Furthermore, the blood test exhibited higher diagnostic accuracy compared to alpha-fetoprotein (AFP), a widely used serum diagnostic marker for liver cancer.

The company is now initiating a cross-sectional, prospective clinical trial at three medical centers to assess its methylated cell free DNA biomarkers and validate the performance of HCCBloodTest for a similar indication in the U.S. population. Key findings from this current study will bridge to a longitudinal study for FDA submission that will initiate in the second half of 2019.

According to the World Health Organization (WHO), liver cancer is the second most common cause of death from cancer worldwide with hepatocellular carcinoma (HCC) accounting for 70-90 percent of primary liver cancers (PLC)*. A major risk factor for developing HCC is liver cirrhosis. Globally, Epigenomics estimates the liver cirrhosis surveillance market to be in excess of ten million tests per year making it more than a three billion euro market opportunity globally.

In Europe, liver cirrhosis is responsible for over 170,000 deaths per year* and Epigenomics estimates approximately three million patients per year in Western Europe are eligible for liver surveillance resulting in a total available market of over one billion euro per year.

“The current methods for diagnosing the progression of liver cancer in cirrhotic patients are not perfect,” said Dr. Edward Mena, Hepatologist and Medical Director of the Pasadena Liver Center, President and CEO of California Liver Research Institute (CLRI), “and, I am optimistic that potential new biomarkers may improve outcomes in these patients.”

“We feel this important cross-sectional, prospective study of cirrhotic patients will further support the applicability of HCCBloodTest in early liver cancer detection”, said Greg Hamilton, CEO of Epigenomics AG. “Reliably detecting liver cancer is a worldwide challenge. Based on the initial performance data of the test, we have made this prospective clinical study a corporate priority.”

*Journal of Hepatology Volume 58, Issue 3 March 2013, Blachier et.al.

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 cirrhotic patients, have received CE mark in Europe.

For more information, visit www.epigenomics.com.

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