

Press release

## **Epigenomics AG obtains CE Mark for Liquid Biopsy Test for Liver Cancer Detection**

- *CE Mark for liver cancer blood test enables commercialization in Europe*
- *Prospective U.S. trial for FDA submission to be initiated in 2019*
- *Investigating optimal path for CFDA approval in China*

**Berlin (Germany) and San Diego, CA (U.S.A.), October 29, 2018** - Epigenomics AG (FSE: ECX, OTCQX: EPGNY) today announced that it has received CE Mark for its blood test to aid in detecting liver cancer among patients with cirrhosis two months ahead of schedule. The test will be commercialized under the brand name "HCCBloodTest". In 2019, the company plans to initiate a prospective clinical trial in the U.S. for submission to the FDA. Additionally, Epigenomics is evaluating options to expedite CFDA approval in China.

In a recently reported clinical study, the HCCBloodTest demonstrated high sensitivity of 90.6 percent at a specificity of 87.2 percent for the indication of liver cancer. Furthermore, the blood test exhibited higher diagnostic accuracy compared to alpha-fetoprotein (AFP), a widely used serum diagnostic marker for liver cancer.

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 10 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 Euros per year. Epigenomics is currently evaluating the best potential commercial partnership opportunities for the distribution of the product.

"We are very excited about the opportunity to launch the first liquid biopsy IVD test for liver cancer", said Greg Hamilton, CEO of Epigenomics AG. "Detecting liver cancer in cirrhosis patients represents a significant medical need worldwide. Based on the initial performance data of the test, we are moving forward with prospective clinical studies to capitalize on the opportunity to address this deadly disease."

\*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<sup>®</sup>, 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<sup>®</sup>, a blood-based test for lung cancer detection, has received CE mark in Europe.

For more information, visit [www.epigenomics.com](http://www.epigenomics.com).

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