

Press release

## **Epigenomics AG: Blood test shows promise in the detection of liver cancer**

- *Results from two clinical studies demonstrate high sensitivity and specificity of mSEPT9 blood test*
- *mSEPT9 test exhibited higher diagnostic accuracy than currently established diagnostic marker*
- *Further independent, prospective clinical study with 440 patients initiated*

**Berlin (Germany) and Germantown, MD (U.S.A.), April 19, 2018** - Epigenomics AG (FSE: ECX, OTCQX: EPGNY) today announced promising results from two clinical studies published in *EBioMedicine* supported by *Cell Press* and *The Lancet*, demonstrating high accuracy of Epigenomics' proprietary epigenetic circulating biomarker *mSEPT9* in detecting liver cancer among patients with cirrhosis.

The two independent clinical studies (observational/case-control) included 289 cirrhosis patients with or without liver cancer from France (initial study) and Germany (replication study). Overall, the *mSEPT9* test demonstrated high sensitivity of 90.6 percent at a specificity of 87.2 percent (using the "2 out of 3" algorithm). Importantly, a triple-negative *mSEPT9* test had the highest negative predictive value for excluding liver cancer (97.2 percent), whereas a triple-positive *mSEPT9* test had the highest positive predictive value for retaining a diagnosis of liver cancer (91.5 percent).

The results from the replication study were consistent with those of the initial study with regard to all diagnostic accuracy measures. Furthermore, the *mSEPT9* blood test exhibited higher diagnostic accuracy compared to alpha-fetoprotein (AFP), which has been widely used as a diagnostic marker for liver cancer.

"The detection of liver cancer, one of the deadliest cancer types worldwide, still represents a high medical need," said Abderrahim Oussalah MD, PhD, Department of Molecular Medicine at the University Hospital of Nancy (France). "Findings from two independent clinical studies reveal that the *mSEPT9* test constitutes a promising opportunity in this respect. As more clinical evidence is needed, we have initiated a further, prospective clinical study with 440 patients in order to confirm the diagnostic accuracy of *mSEPT9* in the diagnosis of liver cancer (SEPT9-CROSS study, ClinicalTrials ID: NCT03311152). Future prospective studies should assess the *mSEPT9* test in a screening algorithm for patients with cirrhosis to improve risk prediction and the personalized therapeutic management of liver cancer."

According to the World Health Organization, liver cancer is the fifth most common cancer in men and the seventh in women, and ranks second in annual cancer mortality rates worldwide, with liver cancer diagnosed in more than 700,000 people annually. Major risk factors for liver cancer include cirrhosis, infection with hepatitis B or C virus, alcoholic liver disease, and non-alcoholic fatty liver disease.

"We are very excited about the promising clinical results of our *mSEPT9* blood test in the diagnosis of liver cancer", said Jorge Garces, President & Chief Scientific Officer of Epigenomics AG. "In the future, an accurate blood test could offer the opportunity to closely monitor patients at high risk for developing liver cancer."

The full-length paper is available here: [http://www.ebiomedicine.com/article/S2352-3964\(18\)30116-6/pdf](http://www.ebiomedicine.com/article/S2352-3964(18)30116-6/pdf)

**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).

**Contact:**

Epigenomics AG, Investor Relations, Peter Vogt, Geneststrasse 5, 10829 Berlin, Tel +49 (0) 30 24345 386, Fax +49 (0) 30 24345 555, E-Mail: [ir@epigenomics.com](mailto:ir@epigenomics.com)

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