

Press release

Epigenomics enters strategic license and development agreement with BioChain on novel, blood-based lung cancer test

- *BioChain to acquire exclusive development and commercial license for China*
- *Initiation of clinical study planned in 2016 with the goal of gaining China Food and Drug Administration (CFDA) approval by BioChain*
- *Epigenomics to receive upfront, milestone and minimum annual payments as well as royalties on future revenues*

Berlin (Germany) and Germantown, MD (U.S.A.), March 30, 2016 – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced that it has entered a strategic license agreement with BioChain on the development and commercialization of a novel, blood-based lung cancer test for China.

BioChain, a leading clinical diagnostics company in cancer and genetic tests in China and the United States, will initiate a clinical trial to validate the lung cancer detection test with the goal to gain market approval by the CFDA. The trial is expected to start in 2016. The product development will be based on Epigenomics' novel panel of blood-based DNA methylation biomarkers that has shown promising results in a clinical validation study.

Under the terms of the agreement, Epigenomics will receive undisclosed upfront, milestone and minimum annual payments as well as mid single-digit royalty on future revenues. In view of the high, rapidly growing prevalence of lung cancer among the Chinese population, the commercialization of a novel, blood-based test represents a major business opportunity for both companies. Epigenomics is entitled to commercialize this product in other markets outside China.

“The agreement with BioChain is a major milestone in our strategy to fully exploit the commercial potential of our innovative, blood-based cancer tests,” commented Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “Lung cancer diagnosis remains challenging worldwide and we are convinced, that blood-based testing has the potential to address the high unmet medical need in this field. Based on the existing successful cooperation with BioChain in the development and commercialization of a colorectal cancer screening test for China, we look forward to extending our partnership on lung cancer going forward.”

In 2013, BioChain and Epigenomics had entered into a license agreement on the development and commercialization of a Septin9-based colorectal cancer blood-test for China. BioChain has successfully introduced the test into the Chinese market in 2015.

About the newly developed blood-based lung cancer test

Epigenomics' new assay is based on a combination of proprietary DNA methylation biomarkers including SHOX2 and PTGER4. Starting from the existing product Epi proLung® BL, which detects the lung cancer biomarker SHOX2 in bronchial fluid, Epigenomics aims to develop an easy-to-use blood-based alternative to existing testing methods, leveraging its vast expertise in the emerging field of liquid biopsies and its strong platform in DNA methylation.

The development is financed by a grant of up to EUR 2.8 million from the European Commission within the framework of the Horizon 2020 program awarded in April 2015. In the first feasibility studies, the DNA methylation panel displayed high sensitivity in detecting lung cancer. Epigenomics is currently initiating further clinical studies for the validation of the test.

About lung cancer

According to the World Health Organization, lung cancer is the leading cause of cancer death worldwide. The vast majority of cases of lung cancer are due to long-term exposure to tobacco smoke. Early detection and treatment of lung cancer can save lives: Survival rates for patients with lung cancer fall as the stage at diagnosis becomes more advanced.

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 early detection of colorectal cancer. Epi proColon® is currently marketed in Europe, China and selected other countries. For more information, visit www.epigenomics.com.

About BioChain

BioChain (www.biochain.com, www.biochainbj.com) is a manufacturer of Life Sciences tools and the pioneer of molecular genetics diagnostics in the US and China. It is also the owner and operator of an independent reference laboratory, equivalent of a CLIA lab, in China – Beijing BioChain Medical Laboratory (BBML). BBML is unique in that it focuses on the application of molecular diagnostics technologies and products. BBML is located in the economic development zone of Beijing, China. Through BBML, BioChain is committed to the application of the cutting edge “omics” technologies in the areas of reproductive health and cancer diagnosis.

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