

Press release

## **China FDA names Epigenomics' blood-based Septin9 colorectal cancer test a most innovative medical product for 2015**

- *Only 9 out of 7530 approved medical devices in 2015 were named “innovative medical product” by the Chinese regulators*
- *Epigenomics innovative blood-based Septin9 test Epi proColon® for early detection of colorectal cancer (CRC) is approved in the U.S., China and Europe*
- *CRC is a rapidly growing medical problem in China, about 290 million people are currently eligible for screening*

**Berlin (Germany) and Germantown, MD (U.S.A.), May 2, 2016** – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, announced today that the China Food and Drug Administration (CFDA) has named the blood-based Septin9 test an “innovative medical product.” In the recently published “2015 Medical Device Registration Annual Report,” only nine out of 7530 approved medical devices were granted this label by the Chinese regulators. The CFDA recognizes the domestic initiative and significant clinical value of Septin9 tests. Epigenomics’ strategic development and commercialization partner BioChain Institute Inc. and its affiliate BioChain (Beijing) Science and Technology Corp., have developed the aforementioned product for the China market based on Epigenomics’ technologies. Septin9 was approved by the CFDA for detection of colorectal cancer in 2015.

“This is excellent news and recognizes the potentially huge contribution we can make to early colorectal cancer detection in China with our proprietary biomarker Septin9,” commented Dr. Thomas Taapken, CEO/CFO of Epigenomics. “We are proud that, together with our strategic partner BioChain, we will be able to give the Chinese population access to this innovative screening opportunity.”

“We are delighted to receive this official recommendation by the Chinese regulator,” Grace Tian, CEO of BioChain, added. “This gives us even more confidence that our emphasis on early cancer detection is immensely valuable to our society. We are excited about bringing blood-based Septin9 tests to the market in China as a truly joint effort between our two companies and we look forward to an even more fruitful collaboration going forward.”

In 2013, BioChain and Epigenomics entered into a license agreement for the development and commercialization of a Septin9-based colorectal cancer blood-test in China. In 2015, BioChain successfully introduced the test into the Chinese market. Shortly after this, the companies reported that CRC testing, based on Epigenomics’ proprietary Septin9 biomarker, was included in the Chinese Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer (CRC).

Epigenomics’ blood-based Septin9 test Epi proColon® is the first CE-marked, FDA and CFDA-approved blood-based colorectal cancer detection diagnostic. It is strongly protected by patents in multiple global jurisdictions, including China, where both the marker itself and the detection

technology are widely protected by granted and pending patents. Both parties, BioChain and Epigenomics remain highly committed to take all necessary steps to enforce these IP rights that will protect and strengthen BioChain's market exclusivity in China.

In March 2016 the collaboration between the two partners was extended for a strategic license agreement on the development and commercialization of a novel, blood-based lung cancer test for China.

## **About Colorectal Cancer in China**

In accordance with various international guidelines, about 290 million people are currently eligible for CRC screening in China and effective testing methods that are accepted by patients will be vital to significantly reduce CRC deaths. CRC is a rapidly growing medical problem. In a recently published report, the independent market research firm Decision Resources estimates that the number of incident cases of CRC in urban areas of China will almost double between 2012 and 2022. This is demanding for better, simple to use and affordable screening methods. Hence, the Chinese government has elected CRC screening as one of its key focus areas in cancer prevention.

## **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® has recently received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in Europe, China and selected other countries. For more information, visit [www.epigenomics.com](http://www.epigenomics.com).

## **About BioChain**

BioChain ([www.biochain.com](http://www.biochain.com), [www.biochainbj.com](http://www.biochainbj.com)) is a 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).

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