

# epigenomics

## **Sysmex and Epigenomics AG Announce Strategic R&D Collaboration in Colorectal Cancer Diagnostics**

**Date:** Thursday, 22.01.2009

- ***Focus on detection of methylated DNA in blood using Sysmex instrumentation***
- ***Sysmex assay system to be benchmarked against Epigenomics' mSEPT9 assay***
- ***Parties entered into negotiations for a non-exclusive IVD license to mSEPT9 colorectal cancer blood test***

*Berlin, Germany, and Kobe, Japan*

Sysmex Corporation (HQ: Kobe Japan; President: Hisashi Ietsugu) and Epigenomics AG (Frankfurt Prime Standard: ECX; ISIN: DE000A0BVT96) announced today that they have signed a strategic research and development collaboration agreement in molecular diagnostics.

Under the terms of the agreement, Sysmex and Epigenomics will assess the suitability of Sysmex's molecular diagnostics instrumentation for the detection of DNA methylation cancer biomarkers in blood. As a benchmark for the development of its assay system, Sysmex will use Epigenomics' mSEPT9 Methylation Detection Assay commercially available as a research use only product. If successful, Sysmex intends to develop and commercialize initially in Japan a blood test for the early detection of colorectal cancer based on Epigenomics' proprietary SEPT9 DNA Methylation Biomarker (mSEPT9). Upon entering into this collaboration both parties have started negotiations for a non-exclusive mSEPT9 licensing agreement.

Under the terms of the collaboration agreement, Sysmex gets access to Epigenomics' technologies through R&D licenses and technology transfer and will be supported by Epigenomics in its R&D work. In return, Epigenomics will receive certain license fees, R&D funding and reimbursements and will sell its mSEPT9 research use only product to Sysmex.

"We are committed to the creation of new technologies that will assist in providing individual patients with optimal medical care, through testing and diagnosis. This new joint research agreement will lead to the establishment of early detection technology. This will improve Sysmex's portfolio of diagnostic technology and help to attain the goal of effective disease management ranging from early detection to treatment support and relapse prevention." said Dr. Tameo Iwasaki, head of research and development of Sysmex.

"We are very excited about this partnership with Sysmex, one of the top 10 leading and fastest growing companies in the diagnostics industry. This agreement is another important step towards the commercialization of our mSEPT9 biomarker for colorectal cancer blood testing", commented Geert Nygaard, Chief Executive Officer of Epigenomics. "It validates the clinical utility and the commercial attractiveness of our approach to colorectal cancer diagnostics as well as our non-exclusive partnering strategy. With Sysmex we expect to create a route to the attractive Japanese market for our early cancer detection franchise."

### **About Sysmex**

Since the foundation, Sysmex has remained focused on the diagnostics of human blood, urine, and cells based on our original "technology". Sysmex has provided healthcare professionals the world over with a broad range of products and solutions, including instruments, reagents, software, and after-sales support for diverse testing fields. As the only Asian company among the top 10 leading players in the global diagnostics market, Sysmex is expanding the sales and support network established in Japan onto foreign soils. By combining quality products with maintenance services and academic support to enhance overall added value, Sysmex is striving to increase confidence through enhanced

customer satisfaction.

Healthcare testing will play an increasingly important role in treatment and disease prevention by using medical technology to achieve remarkable breakthroughs. To help fulfill one of our mantras: "To live a longer, healthier life"; a desire cherished by everyone, we are exploring emerging opportunities in the life science field. In order to offer healthcare services optimized to each individual, Sysmex is applying R&D to the creation of high-value-added testing and diagnostic technologies that are innovative and original. Sysmex is leveraging state-of-the-art technologies for gene and protein analysis. Sysmex Corporation is listed in Tokyo Stock Exchange, First Section and the Osaka Securities Exchange, First Section (Securities Code: 6869). For more information about Sysmex, please visit our website at <http://www.sysmex.co.jp/en/>.

### **About Epigenomics AG**

Epigenomics is a molecular diagnostics company with a focus on the development of novel products for cancer. Using DNA methylation biomarkers, Epigenomics' tests in development aim at diagnosing cancer at an early stage before symptoms occur and thereby may reduce mortality from this dreaded disease.

Epigenomics' product pipeline contains a validated biomarker for the early detection of colorectal cancer in blood plasma, and further proprietary DNA methylation biomarkers at various stages of development for prostate and lung cancer detection in urine, blood and bronchial lavage specimens. Epigenomics' biomarker SEPT9 DNA Methylation Biomarker (*mSEPT9*) for the early detection of colorectal cancer in a simple blood sample demonstrated continuously highest performance in multiple clinical studies with in total about 3,500 individuals tested.

For development and global commercialization as in vitro diagnostic test kits, Epigenomics pursues a non-exclusive partnering strategy with diagnostics industry companies. As a first strategic partner, Abbott Molecular Inc. licensed the worldwide non-exclusive IVD rights to Epigenomics' proprietary *mSEPT9* biomarker for colorectal cancer. Epigenomics also aims at giving patients and doctors early access to these biomarkers through reference laboratory testing services. As a first reference laboratory partner, Quest Diagnostics Inc., the leading provider of diagnostic testing, information and services in the U.S., obtained the license to commercialize a laboratory-developed test (LDT) for *mSEPT9* in the U.S.

Partners in the health care industry and the biomedical research community can access Epigenomics' portfolio of proprietary DNA methylation technologies and biomarkers protected by more than 150 patent families through research products, Biomarker Services, IVD Development Collaborations, and Licensing. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary in Seattle, WA, U.S.A. For more information, please visit Epigenomics' website at [www.epigenomics.com](http://www.epigenomics.com).

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