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EANS-News: Epigenomics AG: Licensee ARUP Launches Septin9 Colorectal Cancer Blood Test in the United States

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----- New
Products/Molecular diagnostics/Partnerships

Press release Berlin and Seattle, July 21, 2010 (euro adhoc) - Epigenomics AG (Frankfurt Prime Standard: ECX) announced that its licensee ARUP Laboratories, Salt Lake City, UT, U.S.A., has launched a laboratory-developed test for the blood-based detection of colorectal cancer yesterday. The test is based on Epigenomics' proprietary Septin9 biomarker and DNA methylation technologies non-exclusively licensed to ARUP in August 2009.

The launch of ARUP's Septin9 test marks another important milestone in Epigenomics' dual business strategy of direct commercialization and non-exclusive licensing and partnering of its proprietary biomarkers and technologies for cancer molecular diagnostics. Multiple in vitro diagnostic and laboratory-developed blood tests for the early detection of colorectal cancer based on the Septin9 biomarker have been made available since October 2009 in Europe, Asia/Pacific and the U.S. by Epigenomics and its partners Abbott Molecular, Quest Diagnostics, and ARUP Laboratories. Furthermore, Canadian Warnex Laboratories is working on a laboratory-developed test for Septin9 that is expected to be launched later this year.

According to ARUP the independently developed and validated Septin9 test identifies nine out of ten people with previously undetected colorectal cancer, including those with early stage disease.

"The test performance demonstrated by ARUP in the clinical validation of their laboratory-developed test for the Septin9 biomarker underscores the full potential this biomarker has," commented Geert Nygaard, Chief Executive Officer of Epigenomics. "As a single biomarker test it compares very favorably in terms of its clinical performance and economics to competing approaches that often require a handful of biomarkers be tested in stool to more than two hundred biomarkers for blood testing on an array and complex algorithms to get to similar performance levels in sensitivity and specificity," he continued.

ARUP Laboratories' Septin9 blood test, which is now available to physicians and patients in the U.S., is not meant to replace colonoscopy but primarily aims at patients who cannot or will not undergo the established screening methods. The lack of compliance to conventional screening methods such as colonoscopy and stool tests is considered to be the biggest hurdle to effective colorectal cancer screening today. Screening experts believe that a convenient blood test that can be integrated into a regular check-up in the doctor's office may greatly enhance compliance among the more than 80 million US citizens aged 50 years and older for which current guidelines recommend regular colorectal cancer screening.

Prior to and accompanying its introduction into the clinical diagnostics market, the Septin9 biomarker has been evaluated extensively in numerous carefully designed case control studies and a prospective clinical cohort study, of almost 8,000 subjects - PRESEPT - demonstrating its applicability to population-based colorectal cancer screening. Today, Septin9 is likely the most thoroughly and widely tested molecular diagnostic biomarker for colorectal cancer meeting the most stringent requirements of clinical validation.

"The level of clinical validation required to meet regulatory standards as well as the expectations of the medical community to achieve widespread adoption of new diagnostic tests have been steadily increasing over the last couple of years," Nygaard explained. "While we see many research studies with new biomarker combinations for blood based colorectal cancer screening being published, none have so far met the high standards we have set with the systematic clinical validation of Septin9."

Founded in 1984, ARUP Laboratories is a national reference laboratory and an enterprise of the University of Utah and its Department of Pathology. ARUP offers more than 3,000 tests and test combinations, ranging from routine screening tests to esoteric molecular and genetic assays. Clients across the United States include university teaching hospitals, multihospital groups, major commercial laboratories, military and other government facilities, as well as major clinics.

More Information

For more information, please see the press release issued by ARUP Laboratories
<http://www.aruplab.com/AboutARUP/PressRoom/index.jsp> or visit ARUP Consult@,
<http://www.arupconsult.com/Topics/ColorectalCancer.html>

About Epigenomics

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

Epigenomics' product portfolio contains the CE-marked IVD test Epi proColon, the world's first regulatory cleared molecular diagnostic test for the detection of colorectal cancer in blood that is based on the biomarker Septin9, Epi proLung, a CE-marked test kit to aid in the diagnosis of lung cancer, and further proprietary DNA methylation biomarkers and IVD products at various stages of development for colorectal, lung and prostate cancer. For development and global commercialization of IVD test products, Epigenomics pursues a dual business strategy in which direct commercialization of proprietary diagnostic test products is combined with non-exclusive licensing to diagnostic industry players with broad customer access. Strategic diagnostics industry partners include Abbott Molecular, Sysmex Corporation, Quest Diagnostics Incorporated, ARUP Laboratories, and Warnex Inc. for diagnostic test products and services, and QIAGEN N.V. for sample preparation solutions and research products. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary, Epigenomics Inc., in Seattle, WA, U.S.A. For more information, please visit Epigenomics' website at www.epigenomics.com

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