

### PRESS RELEASE

# OncoMethylome presents promising results of a blood-based methylation assay for the detection of colorectal cancer

OncoMethylome's blood test for colorectal cancer screening is being presented at the ECCO – ESMO Congress, Europe's largest cancer conference

**Liege (Belgium) – September 21, 2009, 05h00 AM CET –** OncoMethylome Sciences is announcing today promising results from its on-going evaluation of a blood-based methylation assay for the screening and detection of colorectal cancer (CRC). The results are being presented on Monday, September 21<sup>st</sup> at the 15<sup>th</sup> Congress of the European Cancer Organization and 34<sup>th</sup> Congress of the European Society for Medical Oncology in Berlin, Germany.

In recognition of the positive new clinical data and the importance of OncoMethylome's novel test to the cancer field, the Conference organizers selected OncoMethylome's late-breaking abstract for an oral presentation and are issuing their own press release about OncoMethylome's blood-based colorectal cancer screening test. Data on the method of methylation marker selection, the analytical performance of the test and the first results from a multi-center feasibility study is being presented. The ultimate goal of the program is to provide a sensitive, specific and patient-friendly option for colorectal cancer screening. A copy of the press release of the Conference organizers can be found at <a href="https://www.ecco-org.eu/page.aspx/1671">www.ecco-org.eu/page.aspx/1671</a>

"We optimised the methods of DNA extraction and methylation detection so that we could detect low levels of methylated genes in blood samples of people with colorectal cancer," says Dr. Louwagie, OncoMethylome's VP of Product Development, "and we were able to find a high frequency of two newly reported methylation genes, SYNE1 and FOXE1, in colorectal cancer patients. Equally important, the same methylation genes occurred infrequently in non-cancerous individuals."

"The results are very encouraging and by the end of 2009, we plan to complete enrolment of 7000 people into a prospective colorectal cancer screening study currently being conducted in several German colonoscopy centers. Once validated, the new methylation test could be used as a non-invasive screening option for patients who decline or do not have access to colonoscopy or do not wish to undertake the faecal occult blood test" says Dr. Louwagie.

"DNA methylation of critical genes has been linked to the initiation and progression of tumours, and this assay is detecting changes specifically found in cancerous tissues" commented Dr. Herman Spolders, CEO of OncoMethylome. "This new test will provide a way of screening a large part of the population, in a more patient-friendly and non-invasive manner, so that more cancers are detected early and treated successfully. We are very excited about the progress and are currently talking to several partners about distribution rights."

#### **About Colorectal Cancer**

Colorectal cancer ("CRC") occurs in approximately one in every 17 people during their lifetime and is the second leading cause of cancer-related death in the United States and Europe, where a combined total of about 560,000 people develop the disease each year and 250,000 die from it. CRC typically occurs in adults (over age 50) but, because symptoms are often not present in early-stage disease, less than 40% of patients are diagnosed at an early stage when the disease is most treatable. Due to the high morbidity and mortality of late stage CRC (5-year survival rate is 11% in the US), there have been on-going efforts to provide access to methods for early detection in age-appropriate, non-symptomatic adults. Despite these efforts, it is estimated that over 100 million adults in the US and Europe have not been screened for CRC.

# **About Colorectal Cancer Screening**

Colonoscopy, where the interior of the colon and rectum is examined using a tiny camera mounted on a flexible tube, is the most sensitive test currently available and has the benefit of allowing removal of pre-cancerous polyps. Colonoscopy, however, is invasive, expensive, requires bowel preparation and skilled practitioners, thereby making it inaccessible or unacceptable for many patients.

Faecal occult blood testing (FOBT), where patients give stool samples to be analysed, is less invasive, inexpensive and is used in national screening programmes in some European countries. This test detects the presence of blood in a stool sample, which can be due to CRC but also to other non-cancerous conditions. Due to patients' reluctance to handle stool samples, however, compliance for even the best-organised national screening programs in Europe is often less than 50%. In the US, less than 20% of the targeted population undergoes FOBT screening within a two-year time frame.

# **About Methylation and Methylation Markers**

Methylation is a natural control mechanism that regulates gene expression in DNA. Abnormal methylation of certain genes, such as tumor suppressor genes, can silence gene expression and is associated with cancer development. Genes, whose methylation is linked to cancer, are called methylation markers. OncoMethylome owns proprietary technology that is highly sensitive and capable of detecting methylation markers, and thereby cancer, even in early stages of cancer development.

## **About OncoMethylome Sciences**

OncoMethylome Sciences (Euronext Brussels: ONCOB; Euronext Amsterdam: ONCOA) is a molecular diagnostics company developing gene methylation tests to assist physicians in effectively detecting and treating cancer. Specifically, the company's tests are designed to help the physician (i) accurately detect cancer in early stages of cancer development, (ii) predict a patient's response to drug therapy, and (iii) predict the likelihood of cancer recurrence.

OncoMethylome boasts a broad product development pipeline and a solid partnering record. The company collaborates with leading international molecular oncology research centers, such as The Johns Hopkins University, and has a number of commercial and collaborative partnerships with Veridex LLC, a Johnson & Johnson company, LabCorp, Schering-Plough Corp., GlaxoSmithKline Biologicals, Abbott, Millipore Corporation's BioScience Division,

Merck KGaA and Qiagen. OncoMethylome's products are based on methylation technology invented by Johns Hopkins University (USA).

Established in January 2003, OncoMethylome has offices in Liege and Leuven (Belgium), in Durham, NC (USA), and in Amsterdam (the Netherlands).

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