

## **PRESS RELEASE**

# OncoMethylome Sciences Performs MGMT Testing in Cilengitide Studies for Glioblastoma

OncoMethylome's Technology is being used in Merck KGaA's Clinical Trial Program with Cilengitide

Liege (Belgium) – March 16, 2009, 09:00 AM CET - OncoMethylome Sciences (Euronext Brussels: ONCOB, Euronext Amsterdam: ONCOA) announced today that it has begun MGMT gene promoter methylation testing in a recently started Phase II clinical trial (CORE trial) for cilengitide (Merck KGaA) in newly diagnosed brain tumors (glioblastoma). In addition, testing is also being performed in a Phase III clinical trial (CENTRIC trial) in newly diagnosed glioblastoma that has been running since last year. For these trials, OncoMethylome will provide MGMT gene promoter methylation testing services. Patient selection for those trials is based on the MGMT gene promoter methylation status of their tumor tissue.

Prior studies demonstrated activity of cilengitide in combination with temozolomide and radiation therapy, the standard therapy for newly diagnosed glioblastoma. The goal of the CENTRIC trial is to demonstrate improvements in overall survival in patients with methylated MGMT gene promoter being treated with the combination therapy versus temozolomide/radiation therapy. Now in a companion trial of CENTRIC, patients with unmethylated gene promoter also are being enrolled in the phase II CORE trial in which they are treated with an alternative cilengitide dosing schedule.

In a prior agreement with OncoMethylome, the German global pharmaceutical and chemical group Merck KGaA received a worldwide, non-exclusive license to use the results of the OncoMethylome MGMT gene promoter methylation assay for optimizing glioblastoma multiforme (GBM) treatment with cilengitide. OncoMethylome will receive fees from Merck KGaA for performing the testing services.

Herman Spolders, CEO of OncoMethylome commented, "We are very pleased that Merck KGaA has determined that testing for MGMT gene promoter methylation is a very important component for selecting patients to demonstrate effectiveness of cilengitide in this GBM patient population. The CENTRIC and CORE trials represent another milestone in our efforts to establish the clinical value of MGMT methylation for aiding physicians in optimizing the treatment decision-making process for patients with advanced brain tumors and confirms market interest in our research and development of companion diagnostics."

To download this press release as a PDF, click here: Press Release PDF

#### **About GBM Brain Cancer**

GBM is the most aggressive and malignant form of glioma, a type of primary brain cancer. The annual incidence of GBM is four to five cases per 100,000 persons, with 25,000 to 28,000 new cases diagnosed each year in North America and Europe.

#### **About OncoMethylome Sciences' MGMT Assay**

The use of OncoMethylome's MGMT assay is based on studies that have shown that methylation (silencing) of the MGMT gene promoter may help to identify brain tumors more likely to respond to standard chemotherapeutic agents. Following treatment, GBM patients whose tumors are positive for MGMT gene promoter methylation have demonstrated improved overall survival when compared to patients with unmethylated or normally functioning MGMT. The MGMT assay was used in a retrospective analysis of a subset of GBM patients in a study published in The New England Journal of Medicine in March 2005 (N Engl J Med 2005; 532; 997-1003). Prospective confirmation of the predictive value of MGMT gene promoter methylation for the treatment with radiotherapy and temozolomide is currently ongoing within a large randomized international Phase III trial (Radiation Therapy Oncology Group [RTOG] 0525-EORTC26052-22053).

# **About Cilengitide**

Cilengitide is currently being developed by Merck KGaA. Cilengitide is the first in a new class of investigational anticancer therapies called integrin inhibitors to reach Phase III of development; it is currently being investigated for the treatment of glioblastoma, SCCHN and NSCLC. Integrin inhibitors are thought to work by targeting the tumor and its vasculature.

Integrins are cell surface receptors that are improperly regulated in many cancer types. This lack of regulation enables them to enhance tumor growth, survival and invasiveness. Integrins are fundamental in the process of angiogenesis (blood vessel growth) – a process that is essential for tumors as it enables them to grow past a finite size.

In addition to the Merck-sponsored studies, the U.S. National Cancer Institute (NCI) is sponsoring a number of clinical trials under a Cooperative Research and Development Agreement (CRADA) with Merck KGaA for the development of cilengitide.

# **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 consisting of over ten products 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, Qiagen, Schering-Plough Corp., GlaxoSmithKline Biologicals, Abbott, Millipore Corporation's BioScience Division, EXACT Sciences Corp., 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).

## For more information please contact:

Philip Devine
Tel. +32-479-801-902
ir@oncomethylome.com
www.oncomethylome.com