

## PRESS RELEASE

# OncoMethylome Sciences to Perform MGMT Testing in RTOG Phase III Study of Avastin for Glioblastoma

OncoMethylome's Technology is being used in RTOG Clinical Trial Program with Avastin

**Liege (Belgium) – April 16, 2009, 08h00 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 III clinical trial for the U.S.-based, Radiotherapy Oncology Group (RTOG) in newly diagnosed brain tumors (glioblastoma [GBM]).

This trial will compare the current standard-of-care therapy, concurrent chemoradiation and adjuvant temozolomide (Temodar®, Schering-Plough) with the standard-of-care and the addition of bevacizumab (Avastin®, Genentech, a wholly-owned member of the Roche Group). All patients will receive standard therapy of radiation and daily temozolomide for three weeks. Patients will then be stratified by MGMT methylation status and molecular profile to receive standard therapy plus bevacizumab or a continuation of their standard therapy plus placebo. OncoMethylome Sciences will receive payments for performing MGMT testing using their patented Methylation-Specific PCR technology.

"Prior studies have shown that patients with methylated MGMT are more likely to respond to temozolomide-based therapy. Since encouraging response rates have been demonstrated in phase II trials of Avastin for treatment in patients with recurrent glioblastoma, we designed this trial as a natural progression to evaluate the benefits of the combination therapy in newly diagnosed GBM," said Mark R. Gilbert, MD, the study's principal investigator and professor of neuro-oncology at the University of Texas M.D. Anderson Cancer Center. "The goal of RTOG 0825 is to demonstrate improvements in progression-free and overall survival in all GBM patients being treated with the combination therapy versus temozolomide/radiation therapy alone."

Herman Spolders, CEO of OncoMethylome commented, "We are very pleased that the RTOG has determined that testing for MGMT gene methylation will play a key role in evaluating patient response to this combination therapy. This trial supports our efforts to establish the clinical value of MGMT methylation for optimizing the treatment decision-making process for patients with advanced brain tumors and confirms market interest in our MGMT assay leading to personalized and more effective treatments."

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## About Glioblastoma Multiforme (GBM) Brain Tumors

GBM is the most aggressive and malignant form of glioma, a type of primary brain tumor. 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 (RTOG 0525-EORTC26052-22053).

### **About the Radiation Therapy Oncology Group (RTOG)**

RTOG is located the American College of Radiology (ACR) Clinical Research Center in Philadelphia, PA. RTOG is a multi-institutional international clinical cooperative group funded primarily by National Cancer Institute grants CA21661 and CA37422. RTOG has 40 years of experience in conducting clinical trials and is comprised of over 300 major research institutions in the United States, Canada, and internationally. The group currently is currently accruing to 40 studies that involve radiation therapy alone or in conjunction with surgery and/or chemotherapeutic drugs or which investigate quality of life issues and their effects on the cancer patient. More information about the groups is available at www.rtog.org

### About Bevacizumab (Avastin®)

Bevacizumab (Avastin®) is a biologic antibody designed to specifically inhibit the vascular endothelial growth factor (VEGF) protein that plays an important role in the development and maintenance of blood vessels, a process known as angiogenesis. Glioblastomas express high levels of VEGF and develop an extensive network of tumor blood vessels. VEGF is a potent activator of angiogenesis throughout the lifecycle of a tumor and is thought to be critical to a tumor's ability to grow beyond a few millimeters.

Avastin is approved for the first- and second-line treatment of metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy and for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer (NSCLC) in combination with carboplatin and paclitaxel. Avastin is also approved, in combination with paclitaxel, for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer. Please visit www.gene.com for full prescribing information, including Boxed WARNINGS, side effects, and important safety information.

## **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, 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).

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