OVERLOOK HOSPITAL OFFERS GROUND BREAKING BRAIN TUMOR VACCINE TRIAL
Brain cancer patients receive DCVax®-Brain personalized vaccine therapy

May 20, 2008, Summit, NJ — Michael Gruber, MD, medical director of The Brain Tumor Center of New Jersey, located at Overlook Hospital’s Atlantic Neuroscience Institute is enrolling patients in a phase II clinical trial of the personalized cancer vaccine, DCVax®-Brain sponsored by Northwest Biotherapeutics, Inc. (OTCBB: NWBO). Dr. Gruber is the only lead investigator in the tri-state area currently enrolling patients in this trial. This trial is designed and powered as a pivotal trial and has been cleared by the FDA.

In two phase I clinical trials carried out between 2001 and 2006, clinical data showed that patients survived more than twice as long with DCVax-Brain as with either of the two therapeutics approved by the U.S. Food and Drug Administration (FDA) for Glioblastoma multiforme (GBM), the most aggressive form of brain cancer.

Patients with newly diagnosed GBM, which affects between 18,000 and 20,000 Americans each year, will be enrolled in the phase II trial. Beyond surgery to remove the brain tumor and radiation therapy, there are only two treatments for GBM currently approved by the FDA which have not been able to demonstrate significant delays in disease progression and extension of overall survival.

In contrast, in the DCVax-Brain phase I clinical trial conducted at the University of California at Los Angeles (UCLA) and currently continuing under the support of Northwest Biotherapeutics, patients experienced much longer extensions of survival, and longer periods before tumor recurrence. To date, the clinical data have shown a median survival of 33.8 months (and continuing) for DCVax®-Brain treated patients, with nine of 19 patients surviving from 12 to 82 months after initial surgery. Most of these patients have no evidence of tumor recurrence. Four of these patients have survival times without progression or recurrence of their cancer that now extends to four years.

The DCVax-Brain personalized therapeutics vaccine in clinical development is a type of immunotherapy designed to stimulate a patient’s own immune system to fight cancer. DCVax-Brain is a simple injection made up of the patient’s own dendritic cells that have been "educated" to recognize and kill cancer cells bearing the biomarkers of the patient’s tumor.

"Each of these patients has undergone tumor removal at surgery as part of the current standard of care. We use some of those tumor cells, and the dendritic cells drawn from a sample of the patient's blood, to teach the immune system to recognize the tumor cells as harmful so the body can work to eradicate them," said lead investigator, Michael Gruber, MD, medical director, The Brain Tumor Center of New Jersey, Overlook Hospital, Summit, NJ.

The primary objective of the phase II study is to compare progression free survival between patients treated with DCVax-Brain and control patients. The secondary objective is to compare overall survival between DCVax-Brain treated and control patients, including time to progression of disease, survival rates, safety and evaluation of immune responses induced by DCVax-Brain.

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Following primary therapy, 141 eligible patients 18 to 65 years old with newly diagnosed GBM will be randomized at a ratio of 2:1 to the DCVax-Brain trial and be treated over a period of three years. Patients will receive two injections of DCVax-Brain at zero, two, four weeks and at two, four, eight, 12, 18, 24, and 30 months. Disease progression is assessed every two months by brain MRI. Five sites in the United States currently participate in this trial.

**Brain Tumor Facts**

Brain cancer is diagnosed in about 200,000 patients per year with approximately 40,000 being primary brain cancer, and the remainder the result of metastasis from other distant primary cancers such as breast, lung and colon. Approximately 60% of brain cancers are diagnosed as astrocytoma of which there are four forms, grade I through IV. Glioblastoma multiforme (GBM) is the most aggressive and lethal form of astrocytoma and is classified as grade IV. Brain tumors are the leading cause of solid tumor cancer death in children under the age of 20.

Glioblastoma multiforme represents about 50% of the astrocytoma, and is the most lethal form of brain cancer for which there are currently few treatment options that significantly influence disease outcome. In the United States, the incidence of GBM is about 10,000 -12,000 cases per year, prevalence is approximately 25,000, and there is no gender or age bias as well. Worldwide, the incidence and prevalence is approximately double that number. Survival at one year is about 28%, at two years 8% and at five years < 3%.

**About the Medical Director**

Michael Gruber, MD, neuro-oncologist and medical director of the Brain Tumor Center of New Jersey, is a nationally recognized leader in the specialized field of neuro-oncology. Dr. Gruber graduated from Temple University School of Medicine and completed his neurological residency at the Neurological Institute at Columbia Presbyterian Medical Center and a fellowship in Neuro-Oncology at Massachusetts General Hospital. Dr. Gruber is a clinical professor of Neurology and Neurosurgery at the New York University School of Medicine.

**About the Brain Tumor Center of New Jersey**

Located in Summit, New Jersey, the Brain Tumor Center of New Jersey, part of Atlantic Health’s Overlook Hospital and Atlantic Neuroscience Institute atlantichealth.org, offers the safest, most efficient treatments available today to decrease pain, lessen risk and speed recovery for patients with brain tumors. Some of the groundbreaking technology now in use at Overlook includes: the revolutionary CyberKnife® to treat inoperable brain tumors with the newest generation in radiosurgery technology using robotics, rather than a headframe, to create pinpoint accuracy. Overlook is the most experienced center in the tri-state region using this modality. Another technology is the Siemens Neurostar – the only dedicated biplane neuro-angiography suite in the area. The Neurostar provides images of the brain from multiple angles at the same time. Overlook’s neuro-radiology division offers the latest diagnostics in brain 3T-MRI, CT and PET/CT. The Brain Tumor Center of New Jersey also offers patients the newest medications and treatments by participating in clinical trials and is supported by Overlook’s state-of-the-art inpatient neuroscience unit and dedicated neuro-intensive care unit.

For more information, or to make an appointment, call 908-522-5914.

**About Northwest Biotherapeutics**

Northwest Biotherapeutics (OTCBB: NWBO) is a biotechnology company focused on developing immunotherapy products that treat cancers more effectively than current treatments, without toxicity, on a cost-effective basis. The company has two broad platform technologies: dendritic cell-based vaccines, and therapeutic antibodies. Northwest Biotherapeutics’ three lead product candidates are: DCVax®-Brain, a personalized dendritic cell vaccine for the treatment of Glioblastoma multiforme, which has entered into a large Phase II pivotal clinical trials cleared by the FDA; DCVax®-Prostate, a personalized dendritic cell vaccine for treatment of hormone independent non-metastatic prostate cancer, which is ready to enter a Phase III clinical trial cleared by the FDA; and monoclonal antibodies to CXCR4, which are in late pre-clinical development for the treatment of multiple cancers. For further information, go to www.nwbio.com.

The company also has a robust pipeline of additional products cleared by the FDA for early stage clinical trials in multiple other cancers.

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