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UC Brain Tumor Center researchers test experimental brain cancer vaccine for glioblastoma multiforme

Novel approach seeks to harness body's own immune system in Phase II clinical trial at University Hospital

CINCINNATI – Researchers at the University of Cincinnati (UC) Brain Tumor Center have joined a national study to help determine whether a vaccine is capable of combating glioblastoma multiforme, a highly aggressive brain tumor.

In the Phase II, multi-center trial, researchers will create a vaccine by combining brain tumor tissue that has been removed during surgery at University Hospital with the patient's white blood cells. The experimental immunotherapy will be administered via 10 injections over a three-year period.

The Phase II trial is currently enrolling newly diagnosed glioblastoma patients through the UC Brain Tumor Center, a center of excellence at The Neuroscience Institute at UC and University Hospital. The trial's primary objective is to compare survival, without disease progression, of patients treated with the vaccine, radiation and chemotherapy to those given radiation, chemotherapy and a placebo. The trial also will evaluate overall survival of the two groups while further assessing the vaccine's safety.

"We will be using the patient's own tumor to create the vaccine," says Margie Gerena Lewis, M.D., Assistant Professor of Oncology/ Hematology at UC and principal investigator in the UC portion of the study. "We are hoping to wake up the immune system and cause it to reject the glioblastoma cells that remain in the brain after surgery and radiation."

"The underlying hypothesis is that the vaccine will safely delay time to disease progression, increase survival, and induce anti-tumor immunity when administered as a series of injections," adds Ronald Warnick, M.D., Director of the UC Brain Tumor Center and Chairman of the Mayfield Clinic.

Standard therapy for newly diagnosed glioblastoma consists of maximal surgical removal of the tumor, followed by radiation and chemotherapy. Even with this aggressive therapy, the average survival for glioblastoma is only one year.

The glioblastoma vaccine is a dendritic-cell-based immunotherapy manufactured by Northwest Biotherapeutics, Inc., as DC Vax®-Brain. It combines the patient's tumor lysate (a solution of dissolved tumor cells) with dendritic cells isolated from the patient's white blood cells. The role of dendritic cells is to kick-start the immune system, the way the ignition starts an automobile engine.

Preliminary research performed at UCLA, has shown that an immune response can be generated. In preliminary Phase I and II studies, which involved 19 patients, the median survival and time to tumor progression in patients who received the vaccine as well as standard care (radiation and chemotherapy) were more than twice as long compared to patients who received standard care only.

The current study, which will run through December 2009, is designed as a randomized, placebo-controlled, double-blinded trial. It will enroll approximately 240 patients with newly diagnosed glioblastoma. Approximately 160 of these patients will be randomly selected for the treatment group, and 80 will be randomly placed in the placebo group.

Patients in the placebo group whose cancer progresses will have the option of receiving the vaccine. Those who exercise this "crossover option" will become part of an informational arm of the study.

At a minimum, all patients will receive standard treatment comprising surgical resection, external-beam radiation with concurrent chemotherapy, followed by additional 28-day cycles of Temodar chemotherapy.

To qualify for the trial, patients must have a tumor that can be at least 80 percent removed during surgery. In order to develop the tumor lysate, the tumor must be processed at University Hospital and shipped to the manufacturer the same day of the surgery. The patient's white blood cells are later harvested at Hoxworth Blood Center, in a process called leukapheresis, and shipped to the manufacturer in order to develop the vaccine.

The study is one of four clinical trials for glioblastoma currently underway at the UC Brain Tumor Center. For information about this and other studies that are currently enrolling patients, please visit: <http://www.tnicincinnati.com/tumorsResearch.html>

In addition to Drs. Lewis and Warnick, study co-investigators include John Breneman, M.D., Professor of Radiology; Patricia Carey, M.D., Associate Professor of Clinical Transfusion medicine; Ady Kendler, Assistant Professor of Pathology; Christopher McPherson, M.D., Assistant Professor of Neurosurgery; and Apurva Mehta, M.D., Assistant Professor of Internal Medicine.

For additional information about the clinical trial, please contact Amy Stevens, Brain Tumor Clinical Trials Manager, at (513) 584-0763 or amy.stevens@healthall.com.

The UC Brain Tumor Center is a center of excellence within The Neuroscience Institute at University Hospital and the UC College of Medicine. It is closely affiliated with the UC Barrett Cancer Center at University Hospital and Cincinnati Children's Hospital Medical Center. The center offers hope, compassion, expertise and the world's most advanced technologies to adult and pediatric patients from across the region and around the world.