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### **ANTI-CANCER VACCINE DOUBLES TIME-TO-DISEASE PROGRESSION AND INCREASES SURVIVAL IN PHASE I BRAIN CANCER TRIAL**

*--Study Conducted by Duke University Researchers Wins Clinical Science Award at Society for Neuro-Oncology Meeting--*

**November 19, 2004, Toronto, Canada.** A Phase I study presented today at the Society for Neuro-Oncology meeting using a therapeutic vaccine against malignant glioma demonstrated a doubling of time-to-disease progression and an increase in patient survival compared to historical controls. The study was conducted by researchers at the Brain Tumor Center at the Duke Comprehensive Cancer Center and funded by the National Institutes of Health. Glioma is a devastating brain cancer that typically results in death in about a year. Patients have few treatment options and nearly all available therapies have had minimal impact on survival. John Sampson, M.D., Ph.D., Associate Professor of Neurosurgery at Duke was the Principal Investigator for the trial. The data are being presented by Gary Archer, Ph.D., Assistant Research Professor at Duke and lead author of the study presentation. This abstract was awarded the Society for Neuro-Oncology's Clinical Science Award.

This vaccine is based on a peptide technology licensed to Alteris Therapeutics, Inc. targeting EGFRvIII, a tumor-specific splice variant of the epidermal growth factor receptor. Splice variants result when sections of a gene are shuffled to create alternative forms of proteins. EGFRvIII, which stimulates the growth of cancer as a result of its ability to enhance tumor cell survival, proliferation, invasion and growth of new tumor blood vessels, is found in more than half of all malignant gliomas. The peptide used in the vaccine is designed to recruit immune system defenses targeting EGFRvIII to stop or slow the growth of cancer cells. Because EGFRvIII has only rarely been observed in normal human tissues, it is a highly specific target for cancer therapy, which is particularly critical for gliomas, where off-target effects can cause devastating inflammation of the brain.

"These early data showing good evidence of efficacy in malignant glioma are encouraging news in a field where therapeutic advances have been very limited," said Dr. Sampson. "We have been eager to test whether novel approaches targeting this EGFR splice variant might have utility in brain cancer, and these positive data support the recent decision to proceed with a version of this vaccine into Phase II studies."

In the Phase I study, 16 patients with malignant gliomas received three vaccines at two-week intervals. More than one-quarter of the treated patients did not experience any disease progression during the study and median overall time to progression was 314 days, compared to 124 days for historical controls. The median survival time was over 596 days (about 20 months) which compares favorably to the 11 to 13 months of survival historically recorded for malignant glioma patients. The two patients with residual tumor after surgery showed nearly complete remission after vaccination. The vaccine therapy was well-tolerated.

“As one of the pioneers focused on harnessing the potential of splice variants for improved cancer treatments, we are very pleased that this Phase I study strongly supports the therapeutic promise of this vaccine in glioma, a disease that has proven resistant to most new therapies,” said Albert Wong, M.D., founder of Alteris. “Now that we have this first confirmation of clinical utility in humans, we intend to pursue trials of splice variant vaccines in glioma and other major cancers.” The splice variant EGFRvIII was originally discovered in brain tumors by Dr. Wong, Dr. Bert Vogelstein (Johns Hopkins University) and Dorell Bigner (Duke University) and was shown to be effective as an anti-cancer therapeutic vaccine in animal models by Dr. Wong. EGFRvIII has now been found in the majority of breast and ovarian cancers and in virtually all metastatic prostate cancers.

Duke University researchers constructed the study vaccine by loading dendritic cells harvested from patients with a peptide targeting EGFRvIII, which they combined with an immunostimulatory molecule. The glioma vaccine is currently in Phase II trials being conducted by Duke University and the MD Anderson Cancer Center under a grant from the National Institutes of Health. The current version of the vaccine includes the EGFRvIII peptide, but without the dendritic cells used in the Phase I study.

Alteris Therapeutics holds an exclusive worldwide license from Duke University and Johns Hopkins University for certain rights to the EGFRvIII technology and a license from Thomas Jefferson University for its use as a therapeutic vaccine.

### **About Duke Comprehensive Cancer Center**

Duke Comprehensive Cancer Center was one of the nation's first cancer centers to be established with the December 1971 passage of the National Cancer Act, in which Congress authorized federal funding to build 15 cancer centers nationwide and expand the programs of four existing cancer centers. Today, the Duke is one of only 38 centers designated by the National Cancer Institute as a "comprehensive cancer center," a recognition which allows it to receive an additional \$5 million annual to enhance career related research activities at Duke. The Duke Comprehensive Cancer Center was ranked seventh among the nation's best cancer treatment hospitals in 2003 by US News & World Report. According to US News & World Report, Duke had the fourth largest number of patient hospital admissions -- 7,600 -- for cancer care in 2002. Thirty percent of those patients came from outside of North Carolina.

### **About Alteris Therapeutics**

Founded in 2002, Alteris Therapeutics, Inc. is an emerging biopharmaceutical company focused on the discovery and development of therapeutics and vaccines based on alternative gene splice forms unique to cancer. The company's proprietary peptide compound, ALT-II0, a therapeutic vaccine against the splice variant growth factor EGFRvIII, is currently being tested in Phase I and Phase II trials for several cancers. Alteris also has a drug discovery program for a second proprietary target it has identified. These initial targets have been implicated in a wide variety of tumors, including breast, colon, lung, ovarian and central nervous system cancers. Alteris currently is developing its proprietary RIAS discovery platform, which it is using to create a robust pipeline of specific tumor targets and to develop therapeutics or vaccines against the most promising candidates. The company received seed financing from BioAdvance and Ben Franklin Technology Partners in 2003. For more information, visit the company's website at [www.alteristhera.com](http://www.alteristhera.com).