

Gene therapy doubles survival in recurrent glioblastoma

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An experimental gene therapy essentially doubled the overall survival of patients with recurrent glioblastoma compared to the current standard of care, a researcher said Oct. 1 at the Cancer Therapy & Research Center (CTRC) at The University of Texas Health Science Center at San Antonio. Glioblastoma is an aggressive brain cancer that kills two-thirds of patients within five years. A patient's outlook with recurrence of the disease is considered to be weeks or months.

CTRC medical oncologist Andrew J. Brenner, M.D., Ph.D., associate professor in medicine, neurology and neurosurgery at the UT Health Science Center School of Medicine, presented final results of a Phase 2 clinical research study that evaluated the gene therapy, called VB-111, in continuous and intermittent doses and in comparison to the treatment standard, the chemotherapy Avastin. Patients receiving VB-111 survived 15 months on average, compared to 8 months on average for patients receiving Avastin alone. The CTRC and three other centers enrolled 62 patients with recurrent glioblastoma for the studies.

"These are the patients with the most serious cases, whose glioblastoma has recurred after surgery and who, as a result, have a very short life expectancy," Dr. Brenner said.

Dr. Brenner, principal investigator for the studies, presented the results this week at the European Cancer Congress meeting in Vienna, Austria. "In addition to the benefit in overall survival, VB-111 was safe and well-tolerated in the patients, and proved to be effective both as a single



therapy for recurrent glioblastoma and in combination with Avastin," he said.

VB-111 effectively starves the tumor by blocking its ability to grow new blood vessels, Dr. Brenner said. Tumors themselves begin the process by secreting a factor that activates the VB-111 drug. "This drug outsmarts the cancer," Dr. Brenner said.

VB-111 is administered by intravenous infusion once every two months, which is convenient for patients and families, he said. VB-111 has orphan drug status in the U.S. and Europe.

The most frequent side effect in the study was fever, lasting one to two days following the infusion. This suggests an immune system response to the drug, which may play a role in its effectiveness, Dr. Brenner said.

The improvement in overall survival is clinically significant. "These numbers compare favorably to any current benchmark in recurrent glioblastoma and may change the treatment paradigm for these patients," Dr. Brenner said.

"I am very proud of the work of Dr. Brenner and his team who are setting the stage for breakthrough advances in the treatment of brain cancer here at the CTRC," said Ian Thompson Jr., M.D., CTRC director. "We are also especially thankful that Dr. Brenner is helping lead the large team of scientists and physicians who are developing next-generation cancer treatments at our <u>cancer</u> center."

Phase 2 studies, conducted after first-in-human studies, add detail about the effectiveness and safety of experimental treatments for disease. VBL Therapeutics of Tel Aviv, Israel, maker of VB-111, recently launched a Phase 3 clinical research study of the drug to provide more detail.



The CTRC is currently the only site open for the Phase 3 trial, with the first <u>patients</u> enrolled here in San Antonio. Approximately 50 more sites in North America, Israel and Canada will be added in November 2015.

Provided by University of Texas Health Science Center at San Antonio

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