



Dr. Kurt Jaeckle to Lead Phase III Clinical Trial of Novel Drug VAL-083 for Late-Stage Glioblastoma

Atlantic Health System's Gerald J. Glasser Brain Tumor Center, one of four study sites in the country, opens Phase III study of first-in-class cancer drug.

SUMMIT, NJ, USA, January 13, 2018 /EINPresswire.com/ -- The Gerald J. Glasser Brain Tumor Center of Overlook Medical Center's Atlantic Neuroscience Institute and Carol G. Simon Cancer Center is one of four sites in the country to begin a Phase III clinical trial of the novel drug VAL-083 for patients whose glioblastoma multiforme or gliosarcoma has progressed during or after treatment with the standard of care chemo-radiation therapy. Other study locations are: Kaiser Permanente Los Angeles Medical Center; University of California, San Francisco; and Dent Neurosciences Research Center, Amherst, NY.

The goal of the new study, which will be randomized to include a group that receives the experimental drug and a much smaller group that receives standard treatment for late-stage glioblastoma, will be to see if VAL-083 increases survival beyond what current therapies can deliver. The study is sponsored by DelMar Pharmaceuticals Ltd.

[Kurt Jaeckle, MD](#), will serve as Principal Investigator for the local arm of the study. A neuro-oncologist, Dr. Jaeckle is co-medical director, with neurosurgeon [Yaron Moshel, MD](#), PhD, of the Gerald J. Glasser Brain Tumor Center.

"Glioblastoma is very difficult to treat, and I am encouraged by previously reported results with VAL-083," said Dr. Jaeckle. "I am also happy that some of the most innovative pharmaceutical companies are looking to Atlantic Health System when they seek to test new types of treatments for brain tumors. The availability of this and other neuro-oncology clinical trials provides a benefit to our patients, and gives me hope for the future.

Glioblastoma is the most common and most aggressive type of brain cancer, with typical survival of 14-20 months for newly diagnosed patients. Standard treatment includes surgery to remove as much of the tumor as is safely possible, followed by radiation therapy and chemotherapy with temozolomide. Nearly all glioblastoma patients will relapse. Gliosarcoma, which is also being studied in this clinical trial, is a rare and equally aggressive form of glioblastoma.

This study is an adaptive (trial design can be changed once it starts), randomized controlled, Phase III clinical trial in adult patients with diagnoses of glioblastoma multiforme or gliosarcoma confirmed histologically (through microscopic examination of tumor cells) at initial diagnosis, who have been previously treated with surgery (if appropriate), standard of care chemo-radiation with temozolomide, with or without adjuvant temozolomide, and bevacizumab.

Eligible participants must have progressive, recurrent disease. Patients with prior low-grade glioma or anaplastic glioma are eligible, if histologic assessment demonstrates transformation to glioblastoma or gliosarcoma. Eligible patients will be randomized to receive either VAL-083 or the researcher's

choice of chemotherapy. Twice as many patients will receive the VAL-083. To learn more about study inclusion and exclusion criteria, go to: research.atlantichealth.org/VAL_083.

About VAL-083

VAL-083 is a first-in-class small molecule chemotherapy drug. This means that the molecular structure of VAL-083 is not similar in chemical structure (an analogue) or derivative of other small molecule chemotherapeutics approved for the treatment of cancer. VAL-083 is unique in that it has been shown to overcome cancer cells' resistance to MGMT, a DNA-repair mechanism that causes recurrent glioblastoma to resist treatment with temozolomide. Many glioblastoma tumors express large amounts of MGMT, making them difficult to treat with currently available chemotherapies.

According to DelMar Pharmaceuticals, VAL-083 has been assessed in 42 Phase I and Phase II clinical trials sponsored by the National Cancer Institute as a treatment against various cancers. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types, including lung, brain, cervical, ovarian tumors and hematologic (blood) cancers. Earlier clinical trials have shown that VAL-083 is comparable or superior to other chemotherapies in treating glioblastoma.

About Dr. Jaeckle

Dr. Jaeckle recently joined the Gerald J. Glasser Brain Tumor Center after 16 years at the world-renowned Mayo Clinic in Jacksonville, Florida, and seven years at MD Anderson Cancer Center before that. Dr. Jaeckle has served as principal and co-investigator on several national and international Phase I-III clinical therapeutic trials, which have evaluated new chemotherapeutic and novel molecular targeted agents for the treatment of brain tumors.

About the Gerald J. Glasser Brain Tumor Center

Specialists at the Gerald J. Glasser Brain Tumor Center treat a variety of brain tumors and related conditions, including acoustic neuromas and schwannomas; anaplastic astrocytomas, oligodendrogliomas and low-grade gliomas; brain, epidural and leptomeningeal metastases; ependymomas; glioblastomas; low-grade astrocytomas; lymphomas; meningiomas; medulloblastomas; peripheral nerve, pineal and pituitary tumors; rare glial and neuronal tumors; sarcomas; and spinal cord tumors. The center features a multidisciplinary panel of experts who specialize in neurosurgery, skull base surgery, neuroradiology, radiation oncology, neuro-oncology, medical oncology, neurology, neuropathology and social work. Overlook Medical Center also has the largest CyberKnife (R) program in the tri-state area for the treatment of brain tumors. The brain tumor center recently moved into its own space on the main level of Overlook Medical Center, in order to foster an optimal, convenient patient-centered experience.

Dr. Jaeckle sees patients at the new Gerald J. Glasser Brain Tumor Center of Overlook Medical Center's Atlantic Neuroscience Institute and Carol G. Simon Cancer Center, 99 Beauvoir Avenue, Summit, NJ. He and other members of the Gerald J. Glasser Brain Tumor Center can be reached at (908) 516-2941. For more information on this clinical trial or other studies, please call the Atlantic Research Center at (973) 971-5235.

About Atlantic Health System

Atlantic Health System, headquartered in Morristown, N.J., is an integrated health care delivery system powered by a workforce of 16,000 team members dedicated to building healthier communities. The system is comprised of 350 sites of care, including six hospitals: Morristown

Medical Center, Overlook Medical Center, Newton Medical Center, Chilton Medical Center, Hackettstown Medical Center and Goryeb Children's Hospital. Atlantic Health System also supports communities through Atlantic Medical Group, Atlantic Rehabilitation, Atlantic Home Care and Hospice, and its subsidiary, Atlantic Ambulance Corporation. Atlantic Health System sponsors the Atlantic Accountable Care Organization, one of the larger ACOs in the nation, and Optimus Healthcare Partners.

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