



## MAXINE DUNITZ NEUROSURGICAL INSTITUTE

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### **PHASE II STUDY OF AZIXA (MPC-6827) FOR THE TREATMENT OF PATIENTS WITH RECURRENT GLIOBLASTOMA MULTIFORME (IRB #18170)**

Gliomas account for 40-70% of all primary brain tumors. Glioblastoma multiforme (GBM) represents the most malignant of these tumors. Conventional treatment for primary disease includes surgery, radiotherapy, and chemotherapy. However, despite these various treatments, patients suffering from glioblastoma multiforme have a poor prognosis with a median survival time of 12-15 months. Treatment of patients with recurrent primary brain tumors is limited.

Glioblastoma multiforme is one of the most highly vascularized tumors, meaning these tumors are heavily supplied with blood that enables them to grow at a fast rate. The area containing the tumor can also be abnormal, defined by increased interstitial pressure that may contribute to the ineffectiveness of chemotherapy. These abnormal vessels offer an opportunity to interfere with glioblastoma multiforme growth by agents that selectively disrupt tumor vasculature, the network of blood vessels surrounding the tumor.

The study drug, MPC-6827, has at least two mechanisms of action. It is cytotoxic (meaning it is toxic to cells) in a wide range of tumor types and it is a vascular disrupting agent that interferes with blood vessel formation. MPC-6827 kills tumor cells by reducing the blood supply to the tumor.

This is an open label trial in patients with glioblastoma multiforme following first or second recurrence. Patients will be placed in one of two groups according to their previous treatment experience. The purpose of this study is to evaluate the safety and effectiveness of the MPC-6827. The primary endpoint for this study is the 6-month progression free survival (the proportion of patients who remain alive and free of any progression at 6 months). Subjects will be treated with Azixa™ (MPC-6827) 3.3 mg/m<sup>2</sup> once weekly for 3 consecutive weeks every 4 weeks (1 cycle = 4 weeks). Treatment will continue until disease progression or unacceptable toxicity. Blood samples will be collected 4 times during the course of the main study and sent to the Sponsor for future research.

Approximately 68 patients will participate in this study around the country—10 patients will be recruited at Cedars-Sinai Medical Center.

MRIs are performed once every 4-8 weeks as part of subjects' standard of care (one time every other cycle). There are two possible MRIs during the course of the study that may be considered research-related: the baseline and the end of study MRIs. However, the end of study MRI may be considered standard of care if the subjects last study visit occurs on a regularly scheduled standard of care MRI date.

CSMC will not be participating in the Urine PK sub-study.

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