Patient Population
See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years, Karnofsky PS ≥ 60, and adequate lab values
- Histologically proven intracranial glioblastoma or gliosarcoma at initial surgery; patients will be eligible if the original histology was low-grade glioma and a subsequent diagnosis of glioblastoma/gliosarcoma is made
- Women must not be pregnant or breast-feeding
- Progression of disease assessed by local site using RANO criteria, with plan to administer bevacizumab either as single therapy or with other chemotherapeutic regimens, in order to treat tumor progression/recurrence; patients receiving bevacizumab primarily for reduction of edema are excluded
- Must not have previously received a bevacizumab-containing regimen
- Must not have planned treatment with immunotherapies (vaccines, checkpoint inhibitors, T-cells)
- For patients with intratumoral hemorrhage, there must be at least 10 x 10 x 10 mm “measurable enhancement” that is not obscured/distorted by magnetic susceptibility blooming artifact
- Progressive enhancement on MRI within 28 days of registration, and ≥ 42 days since completion of standard radiation/temozolomide therapy
- Must be cleared for bevacizumab administration with respect to recent surgeries, and post-surgical scans must confirm the presence of measurable residual disease
- Must be able to tolerate brain MRI scans with dynamic intravenous gadolinium-based contrast agent injections per protocol
- Must be scheduled to receive treatment with a bevacizumab-containing chemotherapy regimen; may also be receiving treatment with Optune

Treatment Plan
See Sections 5.0 and 9.0 for Complete Treatment Details

- Patient is registration occurs per protocol, then baseline DSC-MRI is performed prior to bevacizumab initiation (within 3 days), preferably on same day for patient convenience
- Initial dose of bevacizumab is given
- Patient returns for follow-up DSC-MRI before the 2nd dose of bevacizumab; the DSC-MRI can occur between 12-25 days after the initial bevacizumab infusion
- Second dose of bevacizumab is given
- All patients are followed for 1-5 years

Notes:
- If the routine imaging performed by the local site includes EAF151 DSC-MRI protocol + standard brain tumor imaging protocol (BTIP), then this satisfies the baseline perfusion imaging requirement and no additional baseline imaging is needed (see Section 9)
- If a patient with normal/near normal renal function has consented to participate in the exploratory test-retest study, and there is adequate time before bevacizumab initiation, a second baseline DSC-MRI will be performed with identical protocol and preferably on the same scanner at least 48 hours apart from the first baseline DSC-MRI
- Sites will be required to undergo scanner qualification prior to subject enrollment
  ◊ The use of contrast media on qualification scans is recommended, but not mandatory
  ◊ 1.5T or 3T scanner (excluding low-field and 7T scanners) can be used

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN), https://open.ctsu.org

Protocol Information

Please Enroll Your Eligible Patients!
EAF151 Available Through ECOG-ACRIN Cancer Research Group

Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma

Schema

Patients with:
- Histologically proven GBM or gliosarcoma identified by local site to have progressed by RANO criteria

1. Requirements for recurrent GBM: a) any progression in a patient who has not previously received a bevacizumab containing regimen, b) imaging upon which local site decision is made must be recent (within 28 days of registration) and demonstrate progressive contrast enhancement (>25% increase from nodir in contrast enhancing volume or new measurable contrast enhancing lesion remote from the primary site) with measurable enhancement defined as two perpendicular in-plane diameters of at least 10 mm and at least 10 mm in the 3rd orthogonal direction.

2. SI DSC-MRI can be completed 12-25 days after initial dose of bevacizumab and before the 2nd dose of bevacizumab is given to the patient.

3. All patients will be followed for a minimum of 1 year and up to 5 years every 3 months. Follow-up on all patients will continue until the last patient’s 1 year follow-up is completed.