EAF223/GABLE

For Patients with Newly Diagnosed Glioblastoma

EAF223 Available Through the ECOG-ACRIN Cancer Research Group

Phase II Glioblastoma Accelerated Biomarkers Learning Environment Trial (GABLE)

Patient Population
See Section 3 for Complete Eligibility Details

- ≥ 18 years of age
- Karnofsky Performance Status ≥ 60%
- Must have newly diagnosed glioblastoma (GBM) (must be IDH wild type), with pathologic proof, based on WHO 2021 criteria
- Must be planning to receive standard-of-care treatment for newly diagnosed GBM
  - Patients who are planning to receive radiotherapy: protons, stereotactic radiosurgery, or abbreviated hypofractionated regimens are not eligible
- Must have completed an MRI prior to the diagnostic surgery for GBM and have images available for upload into TRIAD
- Must have diagnostic surgery for GBM within 7 weeks prior to registration
- Must not have any additional planned surgery for GBM prior to initiating RT/TMZ
- Must have O6-Methylguanine-DNA Methyltransferase (MGMT) methylation status ordered at time of registration
- Must have a post-op MRI completed within 3 weeks after diagnostic surgery for GBM and have images available for TRIAD
- No contraindications to MRI, including injection of gadolinium-based contrast agents, and demonstrated ability to tolerate MRI on pre-surgical imaging
- No allergies to agents that may potentially be used for non-standard of care imaging (18F-fluciclovine, MR contrast)
- Not pregnant or breast-feeding
- Patients with prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible

Treatment Plan
See Section 5 for Complete Treatment Details

- Patients with newly diagnosed GBM will be registered within 7 weeks after diagnostic surgery and prior to the start of treatment
- EAF223 treatment: Concomitant temozolomide and radiation followed by maintenance temozolomide, with or without Optune
  - Standard treatment includes radiotherapy administered at 1.8-2.0 Gy per day to a total dose of 59.4-60 Gy (+/- 5%)
  - Temozolomide will be 75 mg/m²/day or per institutional guidelines
- Only patients with 3DCRT/IMRT will be evaluable for the biomarker evaluation endpoints
- MRI imaging must be completed at the following times:
  - Pre-operative (prior to diagnostic surgery)
  - Post-operative (within 3 weeks after diagnostic surgery)
  - Time point 1: 4 (+/- 2) weeks after completing radiation
  - Time point 2: 12 (+/- 2) weeks after completing radiation
  - Time point 3: 12-22 weeks after completing radiation
- Patients showing progressive enhancement by central review will be scheduled for a single non-standard-of-care imaging study (1st cohort is 18F-fluciclovine PET, 2nd cohort is MR spectroscopy)
- Neurological Assessment in Neuro-Oncology (NANO) will require completion by a clinician at the clinical visit corresponding to/closest to time point 1 and 2 MRI, and any unscheduled MRI within 12 weeks post-XRT. Then, for patients with progressive enhancement, every clinical visit thereafter

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

Protocol Information

Please Enroll Your Eligible Patients!