ABTC 1202: Phase I Study of MK-1775 with Radiation and Temozolomide in Patients with Newly Diagnosed Glioblastoma and Evaluation of Intratumoral Drug Distribution in Patients with Recurrent Glioblastoma

Phase 1 Arm 2 Eligibility Checklist

Patient Name:

Last_____ First_____

Eligibility Criteria:

Q.1	Is subject equal to or greater than 18 years of age?	YES	NO	
Q.2	Date of baseline MRI	DD/MMM/YYYY		
Q.3	What is the patient's Karnofsky performance score?	KPS:		
Q.4	Does the patient have the ability to understand the written informed consent?	YES	NO	
Q.5	No prior invasive malignancy, unless disease-free for >= 5 years (Exceptions: non-melanoma skin cancer, in-situ cancers)	YES	NO	
Q.6	Does the patient have an concurrent malignancy other than curatively treated basal or squamous cell carcinoma of the skin or carcinoma in situ of the cervix, breast, or bladder?	YES	NO	
Q.7	Does the patient have a tumor tissue form indicating availability of archived tissue from initial resection at diagnosis of glioblastoma completed and signed by a pathologist?	YES	NO	
Q.8	Has patient been on a stable or decreasing dose of corticosteroids for the indicated period?	YES	NO	
Q.9	Is patient receiving enzyme-inducing anticonvsulant drugs?	YES	NO	
Q.10	If the patient is receiving enzyme-inducing anticonvsulant drugs, has the patient been off of them for 10 days prior to study start?	YES	NO	N/A
Q.11	Is patient able to swallow capsules?	YES	NO	
Q.12	Is the patient receiving any investigational agents?	YES	NO	
Q.13	Does the patient have known HIV infection?	YES	NO	
Q.14	Has uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirement?	YES	NO	
Q.15	Is the patient receiving anti-coagulants other than low-molecular weight heparin?	YES	NO	
Q.16	Does the patient have a history of allergic reactions to any of the study drugs?	YES	NO	
Q.17	Is the patient on drugs known to be moderate or potent inhibitors/inducers of CYP3A4 or related substrates of CYP3A4?	YES	NO	
Q.18	Women of childbearing potential and men must agree to use an effective method of contraception (hormonal or barrier method of birth control; abstinence) from the time	YES	NO	N/A

	the consent is signed, during the duration of study participation, and 4 months after discontinuation of protocol therapy. If not woman of childbearing potential (check N/A)			
Q.19	Negative serum pregnancy test date	DD/MMM/YYYY		
Q.20	Has patient agreed to stop breastfeeding?	YES	NO	

Laboratory Eligibility Criteria:

Lab Test	Sample Collection Date	Lab Value	Unit of Measure	Lower Limit Normal	Upper Limit Normal
Absolute Neutrophil Count			{Cells}/mL		
Platelets			/µL		
Hemoglobin			g/dL		
Serum Total Bilirubin			mg/dL		
Aspartate Aminotransferase, Serum			u/L		
Alanine Aminotransferase, Serum			u/L		
Serum Creatinine			mg/dL		
Creatinine Clearance			ml/min/1.73m^2	60	N/A
Partial Prothromboplastin Time			sec		

Phase I Arm 2 Eligibility Criteria:

Q.21	Does the patient have a histologically proven glioblastoma?	YES	NO	
Q.22	Has the patient fully recovered from any surgical procedure prior to enrollment?	YES	NO	
Q.23	Has the patient received planned treatment with radiation therapy and concomitant temozolomide at least 28 days but no more than 49 days prior to starting treatment on this study?	YES	NO	
Q.24	Has the patient had prior therapy (including radiation therapy) other than the planned radiation and TMZ, gliadel wafers, or glucocorticoid therapy?	YES	NO	