ABTC 1402: Phase II Study of TRC102 in Combination with Temozolomide for Recurrent Glioblastoma

Eligibility Checklist

Patient Name:

Last_____ First_____

Eligibility Criteria:

Q.1	Projected Start Date of Treatment	DD/MMM/YYYY		
Q.2	Assigned Treatment Arm	Arm:		
Q.3	Does the patient have histologically confirmed glioblastoma that is progressive or recurrent following radiation therapy and temozolomide?	YES	NO	
Q.4	Does the patient have available MGMT methylation status from routinely used methods for MGMT methylation testing?	YES	NO	
Q.5	Is the patient able to undergo MRI scans of the brain with gadolinium?	YES	NO	
Q.6	If patient is on corticosteroids, has the dose been stable or decreasing for at least 5 days prior to enrollment?	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	Have the required intervals passed since the end of any applicable protocol-specified prior therapies?	YES	NO	
Q.9	Has patient fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study?	YES	NO	
Q.10	Is the subject equal to or greater than 18 years of age?	YES	NO	
Q.11	What is the patient's Karnofsky performance score?	KPS:		
Q.12	Does the patient have the ability to understand the written informed consent?	YES	NO	
Q.13	Negative serum pregnancy test date	DD/MMM/YYYY		
Q.14	Has patient agreed to use an effective contraceptive method for the duration of their study participation and for 30 days after the last dose of chemotherapy?	YES	NO	N/A
Q.15	Does the patient have a 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.16	Has the patient had a prior malignancy within the last five years?	YES	NO	
Q.17	Does the patient have the ability to swallow oral medication?	YES	NO	
Q.18	Is the patient receiving any investigational agents?	NO	YES	
Q.19	Does the patient have a known sensitivity to the study drug(s) or any of their formulation excipients?	NO	YES	
Q.20	Is patient receiving enzyme-inducing anticonvulsant drugs?	NO	YES	
Q.21	If the patient is receiving enzyme-inducing anticonvulsant drugs, has the patient been off of them for 10 days prior to study start?	YES	NO	N/A
Q.22	Is the patient on anticoagulation therapy?	NO	YES	
Q.23	Did the patient have prior gastrointestinal surgery or disease that might interfere with absorption of study	NO	YES	

	drug(s)?			
Q.24	Have all prior treatment related toxicities recovered to less than or equal to grade 1 prior to registration?	YES	NO	
Q.25	Does the patient have active brain metastases from a systemic solid tumor?	YES	NO	
Q.26	Has uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, clinically significant cardiac disease, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirement?	NO	YES	
Q.27	Has patient agreed to stop breastfeeding?	YES	NO	N/A
Q.28	Is the patient HIV positive on combination antiretroviral therapy?	NO	YES	

Laboratory Eligibility Criteria:

Lab Test	Sample Collection Date	Lab Value	Unit of Measure	Lower Limit Normal	Upper Limit Normal
Absolute Neutrophil Count			{Cells}/µL	N/A	N/A
Platelets			/µL	N/A	N/A
Hemoglobin			g/dL	N/A	N/A
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
Activated Partial Prothromboplastin Time			sec		
Partial Prothromboplastin Time			sec		

Arm 1 Eligibility Criteria:

Q.29	Date of Baseline MRI	MM/DD/YYYY		
Q.30	Does the patient have measurable contrast-enhancing progressive or recurrent glioblastoma by MRI within 21 days of starting treatment?	YES	NO	
Q.31	Is the patient in the first recurrence of glioblastoma following radiation therapy and temozolomide?	YES	NO	
Q.32	Has the patient received bevacizumab previously?	NO	YES	

Arm 2 Eligibility Criteria:

Q.33	Except for bevacizumab, has the patient received prior antiangiogenesis therapy such as, but not limited to, aflibercept, ramucirumab, cediranib, cabozantinib or XL184?	NO	YES	

Q.34	Has the patient progressed/recurred on bevacizumab as the most recent regimen?	NO	YES	