ABTC 1301: Pilot Study of MLN0128 in Preoperative Recurrent Glioblastoma (GBM) Patients

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 prior histologically proven glioblastoma or gliosarcoma that is progressive or recurrent following radiation therapy and/or chemotherapy?	YES	NO	
Q.4	Patients must have measurable, supratentorial contrast-enhancing progressive or recurrent glioblastoma or gliosarcoma by MRI imaging within 21 days of starting treatment	YES	NO	
Q.5	Date of Baseline MRI	YES	NO	
Q.6	How many prior relapses has the patient been treated for?			
Q.7	Has patient fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study?	YES	NO	
Q.8	Have the required intervals passed since the end of any applicable protocol-specified prior therapies?	YES	NO	
Q.9	Is the patient undergoing repeat surgery that is clinically indicated as determined by their care providers?	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 of childbearing or child fathering potential agreed to use medically acceptable forms of contraception for the duration of study participation?	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	No prior invasive malignancy, unless disease-free for >= 5 years (Exceptions: non-melanoma skin cancer, in-situ cancers)	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?	YES	NO	
Q.19	Does the patient have a history of allergic reactions to any of the study drugs?	YES	NO	
Q.20	Has the patient had prior therapy with PI3K inhibitors, AKT inhibitors and/or mTor inhibitors?	YES	NO	
Q.21	Has the patient received prior treatment with Bevacizumab/VEGFR inhibitors?	YES	NO	
Q.22	Is patient receiving enzyme-inducing anticonvulsant drugs?	YES	NO	
Q.23	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.24	Does the patient have significant hematologic, renal, or hepatic dysfunction?	YES	NO	
Q.25	Does the patient have evidence of significant intracranial hemorrhage?	YES	NO	
Q.26	Does the patient have a history of any of the protocol-specified conditions?	YES	NO	
Q.27	Does the patient have clinically significant cardiovascular disease?	YES	NO	
Q.28	Does the patient have clinically significant pulmonary disease?	YES	NO	
Q.29	Does the patient have congenital long QT syndrome or baseline QTc greater than 480 ms?	YES	NO	
Q.30	QTc Date	DD/MMM/YYYY		
Q.31	QTc Interval			
Q.32	Does the patient have poorly controlled diabetes?	YES	NO	
Q.33	Has the patient started receiving bisphosphonates less than 30 days prior to the first administration study drug?	YES	NO	
Q.34	Does the patient have malabsorption syndrome	YES	NO	
Q.35	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.36	Has patient agreed to stop breastfeeding?	YES	NO	N/A
Q.37	Is the patient HIV positive on combination antiretroviral therapy?	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	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
Partial Prothromboplastin Time			sec		
Activated Partial Prothromboplastin Time			sec		

Phase I Arm 1 Eligibility Criteria:

Q.37	Does the surgeon expect to resect at least 350 mg of tumor from enhancing tumor and at least 350 mg from non-enhancing tumor with low risk of inducing neurological injury?	YES	NO	

Phase I Arm 2 Eligibility Criteria:

Q.38	Does the surgeon expect to resect at least 1000 mg of tumor from enhancing tumor and at least 350 mg from non-enhancing tumor with low risk of inducing neurological injury?	YES	NO	
Q.39	Does the patient have at least 20 (preferably 40) slides of archival tumor tissue from a prior surgery demonstrating GBM?	YES	NO	

Weekly Dose Eligibility Criteria:

Q.40	Is the participant currently on a PPI?	YES	NO	