ABTC 1403: The Effect of IL-7 (CYT107) on CD4 Counts in Patients with High Grade Gliomas and Severe Treatment-related CD4 Lymphopenia After Concurrent Radiation and Temozolomide

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 high grade glioma by pathology (WHO grade III and IV)?	YES	NO	
Q.4	Has the patient's post-operative treatment included at least 80% of standard radiation and concomitant temozolomide?	YES	NO	
Q.5	Has the patient received any other prior chemotherapy, immunotherapy or therapy with biologic agent (including immunotoxins, immunoconjugates, antisense, peptide receptor antagonists, interfereons, interleukins, TIL, LAK or gene therapy or hormonal therapy for their brain tumor other than prior Gliadel Wafers or glucocorticoid therapy?	NO	YES	
Q.6	Did patients have a CD4 count ≤ 200 cells/mm^3 in the last 7 days of standard radiation + temozolomide treatment (58-60 Gy radiation with temozolomide 75 mg/m^2 daily during radiation)?	YES	NO	
Q.7	What is the daily dose of dexamethasone that the patient is receiving?	Dose (mg):		
Q.8	What is the patient's Karnofsky performance score?	KPS:		
Q.9	Does the patient have the ability to understand the written informed consent?	YES	NO	
Q.10	Negative serum pregnancy test date	DD/MMM/YYYY		
Q.11	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.12	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.13	Has the patient had a prior malignancy within the past 5 years?	NO	YES	
Q.14	Is the subject equal to or greater than 18 years of age?	YES	NO	
Q.15	Is the patient receiving any investigational agents?	NO	YES	
Q.16	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?	NO	YES	
Q.17	Has patient agreed to stop breastfeeding?	YES	NO	N/A
Q.18	Does the patient have HIV infection?	NO	YES	
Q.19	QTc Interval			
Q.20	Does the patient require a therapy with a drug known to prolong the QT/QTc interval?	NO	YES	
Q.21	Does the patient have a history of or currently have evidence of autoimmune disease including: myasthenia	NO	YES	

	gravis, Guillian Barre syndrome, systemic lupus erythematosus, multiple sclerosis, scleroderma, ulcerative colitis, Crohn's disease, autoimmune hepatitis, Wegener's, etc?			

Laboratory Eligibility Criteria:

Lab Test	Sample Collection Date	Lab Value	Unit of Measure	Lower Limit Normal	Upper Limit Normal
CD4 Count			{Cells}/ µL	N/A	N/A
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
Partial Prothromboplastin Time			sec		
Activated Partial Prothromboplastin Time			sec		