Testing the Addition of an Anti-cancer Drug, Selinexor, to the Usual Chemotherapy Treatment (Temozolomide) for Brain Tumors That Have Returned After Previous Treatment

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically confirmed glioblastoma (IDH wild-type, MGMT promoter methylated) that has undergone resection or biopsy upon first recurrence. Recurrence at site of prior involvement is defined by histopathological evidence of viable neoplastic cells associated with any of the following: mitotic activity, increased proliferation rate, micro-endothelial proliferation, or pseudo-palisading necrosis * Prior to resection or biopsy, patients must have measurable disease, defined as at least one bi-dimensional contrast-enhancing lesion with clearly defined margins, with 2 perpendicular diameters of at least 10 mm, visible on \>= 2 axial slices * Patients must have received first-line treatment of temozolomide plus radiotherapy * Patients must not have received any prior therapy aside from resection or biopsy for their recurrent disease * Age \>= 18 years. Because no dosing or adverse event data are currently available on the use of selinexor (KPT-330) in combination with temozolomide in patients \< 18 years of age, children are excluded from this study * Karnofsky performance status \>= 60% (Eastern Cooperative Oncology Group \[ECOG\] =\< 2) * Absolute neutrophil count \>= 1,500/mcL * Platelets \>= 100,000/mcL * Hemoglobin \>= 10 g/dL * Total bilirubin =\< 2 x institutional upper limit of normal (ULN) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\])/alanine transaminase (ALT) (serum glutamic-pyruvic transaminase \[SGPT\]) =\< 3 x institutional ULN * Glomerular filtration rate (GFR) \>= 30 mL/min/1.73 m\^2 * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Patients with a 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 for this trial * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * The effects of selinexor (KPT-330) and temozolomide on the developing human fetus are unknown. For this reason and because selective nuclear export inhibitors as well as deoxyribonucleic acid (DNA) alkylating agents are known to be teratogenic, women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation, and for 180 days after the last dose of temozolomide. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 90 days after completion of study treatment administration * Ability to understand and the willingness to sign a written informed consent document. Participants with impaired decision-making capacity who have a legally-authorized representative (LAR) and/or family member available will also be eligible

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Exclusion Criteria:

* Patients who have had chemotherapy must have full recovery of organ and marrow function following the nadir of the last chemotherapy cycle * Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities \> grade 1) with the exception of alopecia * Patients who are receiving any other investigational agents * Patients who have previously received bevacizumab * History of allergic reactions attributed to compounds of similar chemical or biologic composition to selinexor (KPT-330) or temozolomide * History of hypersensitivity to dacarbazine (DTIC), since both dacarbazine and temozolomide are metabolized to 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC) * Patients with uncontrolled intercurrent illness * Pregnant women are excluded from this study because selinexor (KPT-330) is a selective inhibitor of nuclear export with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with selinexor (KPT-330), breastfeeding is not allowed for mothers during treatment with selinexor (KPT-330) and for 7 days after the last dose. These potential risks may also apply to other agents used in this study * Hospitalized patients with severe coronavirus disease of 2019 (COVID-19) who are \>= 75 years old, or with a high-risk COVID-GRAM score, or with lactate dehydrogenase (LDH) \> 370 (U/L) AND D-Dimer \> 600 mcg/L FEU should not receive low-dose selinexor (KPT-330) pending additional results

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, PROCEDURE: Magnetic Resonance Imaging, DRUG: Placebo Administration, DRUG: Selinexor, DRUG: Temozolomide
Conditions:
Recurrent Glioblastoma, IDH-Wildtype, Recurrent MGMT-Methylated Glioblastoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
IRB
Number:
System ID: NCT05432804
