A Study to Compare Treatment With the Drug Selumetinib Alone Versus Selumetinib and Vinblastine in Patients With Recurrent or Progressive Low-Grade Glioma

Status: RECRUITING

Eligibility Criteria

Age: 2 years to 25 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Feasibility phase: patients must be \>= 2 years and =\< 21 years of age at the time of enrollment * Efficacy phase: patients must be \>= 2 years and =\< 25 years of age at the time of enrollment * All patients \> 21 years of age at the time of enrollment must have had initial diagnosis of low-grade glioma by 21 years of age * Patients must have a body surface area (BSA) of \>= 0.5 m\^2 at enrollment * Patients must have eligibility confirmed by rapid central pathology and central molecular screening reviews performed on APEC14B1 * Non-neurofibromatosis type 1 (non-NF1), non-tuberous sclerosis complex (non-TSC) low-grade glioma (LGG) without a BRAFV600E or IDH1 mutation * Patients must have progressive or recurrent LGG. Note: Biopsy may be at either initial diagnosis or recurrence * Patients must have measurable disease, defined as having a two-dimensional measurable tumor volume of \>= 1 cm\^2 * Tumor size will be measured to include both solid and cystic components of the tumor (whether or not tumor is enhancing) + fluid attenuated inversion recovery (FLAIR) signal * Eligible histologies will include all tumors considered low-grade glioma or low-grade astrocytoma (World Health Organization \[WHO\] grade 1 and II) by the WHO Classification of Tumors of the Central Nervous System

•4th Edition Revised, with the exception of subependymal giant cell astrocytoma * Patients with metastatic disease or multiple independent primary LGGs are eligible * Patients must be progressive or recurrent after having been treated with at least one prior tumor-directed therapy before enrollment * Patients must have fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study * Myelosuppressive chemotherapy: Must not have received within 2 weeks of entry onto this study (4 weeks if prior nitrosourea); * Biologic (anti-neoplastic agent): At least 7 days since the completion of therapy with a biologic agent; * Radiation therapy (RT): \>= 2 weeks (wks) for local palliative RT (small port); \>= 6 months must have elapsed if prior craniospinal RT or if \>= 50% radiation of pelvis; \>= 6 wks must have elapsed if other substantial bone marrow (BM) radiation; * Antibodies: \>= 21 days must have elapsed from infusion of last dose of antibody, and toxicity related to prior antibody therapy must be recovered to =\< grade 1; * MEK inhibitor or vinblastine: Must not have received treatment with a MEK inhibitor or vinblastine within 6 months of study enrollment * Creatinine clearance or radioisotope glomerular filtration rate (GFR) \>= 70 mL/min/1.73 m\^ 2 or a serum creatinine based on age/sex as follows (within 7 days prior to enrollment): * 2 to \< 6 years: 0.8 mg/dL (male) 0.8 mg/dL (female) * 6 to \< 10 years: 1 mg/dL (male) 1 mg/dL (female) * 10 to \< 13 years: 1.2 mg/dL (male) 1.2 mg/dL (female) * 13 to \< 16 years: 1.5 mg/dL (male) 1.4 mg/dL (female) * \>= 16 years: 1.7 mg/dL (male) 1.4 mg/dL (female) * Total bilirubin =\< 1.5 x upper limit of normal (ULN) for age (within 7 days prior to enrollment) (children with a diagnosis of Gilbert's syndrome will be allowed on study regardless of their total and indirect \[unconjugated\] bilirubin levels as long as their direct \[conjugated\] bilirubin is \< 3.1 mg/dL) * Serum glutamic pyruvic transaminase (SGPT) (alanine aminotransferase \[ALT\]) =\< 135 U/L (within 7 days prior to enrollment) * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L * Albumin \>= 2 g/L (within 7 days prior to enrollment) * Left ventricular ejection fraction (LVEF) \>= 53% (or institutional normal; if the LVEF result is given as a range of values, then the upper value of the range will be used) by echocardiogram (within 4 weeks prior to enrollment) * Corrected QT interval (QTc interval) =\< 450 msec by electrocardiogram (EKG) (within 4 weeks prior to enrollment) * Absolute neutrophil count \>= 1,000/uL (unsupported) (within 7 days prior to enrollment) * Platelets \>= 100,000/uL (unsupported) (within 7 days prior to enrollment) * Hemoglobin \>= 8 g/dL (may be supported) (within 7 days prior to enrollment) * Patients with a known seizure disorder should be stable and should not have experienced a significant increase in seizure frequency within 2 weeks prior to enrollment * Stable neurological examination for \>= 1 week * HYPERTENSION: * Patients 2-17 years of age must have a blood pressure that is =\< 95th percentile for age, height, and sex at the time of enrollment (with or without the use of anti-hypertensive medications); * Patients \>= 18 years of age must have a blood pressure =\< 130/80 mmHg at the time of enrollment (with or without the use of anti-hypertensive medications) * Note for patients of all ages: Adequate blood pressure can be achieved using medication for the treatment of hypertension * All patients must have ophthalmology toxicity assessments performed within 4 weeks prior to enrollment * For all patients, an MRI of the brain (with orbital cuts for optic pathway tumors) and/or spine (depending on the site\[s\] of primary disease) with and without contrast must be performed within 4 weeks prior to enrollment * Note: If surgical resection or biopsy is performed at the time of progression or recurrence, a post-operative MRI is required * Patients must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1, or 2. Use Karnofsky for patients \> 16 years of age and Lansky for patients =\< 16 years of age * Patients must have the ability to swallow whole capsules

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Exclusion Criteria:

* Prior therapy with vinblastine and/or a MEK inhibitor is permitted, with the following exceptions: * Patients must not have had progressive disease while on therapy with vinblastine or a MEK inhibitor; * Patients must not have discontinued vinblastine or selumetinib due to toxicity * Patients with a concurrent malignancy or history of treatment (other than surgery) for another tumor within the last year are ineligible * Patients with diffuse intrinsic pontine tumors as seen on MRI (\> 2/3 of pons involvement on imaging) are not eligible even if biopsy reveals grade I/II histology * Patients may not be receiving any other investigational agents * Patients must not have known hypersensitivity to selumetinib, vinblastine, or similar compounds * CYP3A4 agents: Patients must not have received fluconazole or drugs that are strong inducers or inhibitors of CYP3A4 within 7 days prior to study enrollment * Patients with any serious medical or psychiatric illness/condition, including substance use disorders or ophthalmological conditions, likely in the judgment of the investigator to interfere or limit compliance with study requirements/treatment * Patients who, in the opinion of the investigator, are not able to comply with the study procedures are not eligible * PRE-EXISTING CONDITIONS (CARDIAC): * Known genetic disorder that increases risk for coronary artery disease. Note: The presence of dyslipidemia in a family with a history of myocardial infarction is not in itself an exclusion unless there is a known genetic disorder documented; * Symptomatic heart failure * New York Heart Association (NYHA) class II-IV prior or current cardiomyopathy * Severe valvular heart disease * History of atrial fibrillation * PRE-EXISTING CONDITIONS (OPHTHALMOLOGIC CONDITIONS): * Current or past history of central serous retinopathy * Current or past history of retinal vein occlusion or retinal detachment * Patients with uncontrolled glaucoma * If checking pressure is clinically indicated, patients with intraocular pressure (IOP) \> 22 mmHg or upper limit of normal (ULN) adjusted by age are not eligible * Any multivitamin containing vitamin E must be stopped prior to study enrollment even if it contains less than 100% of the daily recommended dosing for vitamin E * Surgery within 2 weeks prior to enrollment, with the exception of a surgical biopsy, placement of a vascular access device or cerebrospinal fluid (CSF) diverting procedure such as endoscopic third ventriculostomy (ETV) and ventriculoperitoneal (VP) shunt * Note: Patients must have healed from any prior surgery * Patients who have an uncontrolled infection are not eligible * Female patients who are pregnant are not eligible since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential * Lactating females who plan to breastfeed their infants * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation and for 12 weeks after stopping study therapy are not eligible * Note: Women of child-bearing potential and males with sexual partners who are pregnant or who could become pregnant (i.e., women of child-bearing potential) should use effective methods of contraception for the duration of the study and for 12 weeks after stopping study therapy to avoid pregnancy and/or potential adverse effects on the developing embryo * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

Conditions & Interventions

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Interventions:
PROCEDURE: Biospecimen Collection, PROCEDURE: Magnetic Resonance Imaging, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, DRUG: Selumetinib Sulfate, DRUG: Vinblastine Sulfate
Conditions:
Recurrent Low Grade Astrocytoma, Recurrent WHO Grade 2 Glioma, Refractory Low Grade Astrocytoma, Refractory Low Grade Glioma, Refractory WHO Grade 1 Glioma

More Information

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IRB
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