Testing Ipilimumab and Nivolumab Combination With or Without Cabozantinib in People >= 18 Years Old With Advanced Soft Tissue Sarcoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically or cytologically confirmed metastatic STS, specifically undifferentiated pleomorphic sarcoma (UPS), extraskeletal myxoid chondrosarcoma (EMC), liposarcoma (LPS) or non-uterine leiomyosarcoma (LMS) that are locally advanced and surgically unresectable * Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded for non-nodal lesions and short axis for nodal lesions) as \>= 20 mm (\>= 2 cm) by chest x-ray or as \>= 10 mm (\>= 1 cm) with CT scan, MRI, or calipers by clinical exam. Disease will be measured by RECISTv1.1 * Patients with prior treatment with MET or VEGFR inhibitors are allowed. However, prior cabozantinib-treated patients will not be allowed. Prior ipilimumab in combination with nivolumab-treated patients will not be allowed * Age \>= 18 years * Eastern Cooperative Oncology Group (ECOG) performance status =\< 2 (Karnofsky \>= 60%) * Absolute neutrophil count \>= 1,000/mcL * Platelets \>= 75,000/mcL * Total bilirubin =\< 1.5 x institutional upper limit of normal (ULN) * Aspartate aminotransferase (AST)(serum glutamic oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT)(serum glutamate pyruvate transaminase \[SGPT\]) =\< 3 x institutional ULN * Creatinine =\< 1.5 x institutional ULN OR glomerular filtration rate (GFR) \>= 50 mL/min/1.73 m\^2 * Serum albumin \>= 2.8g/dL * Lipase \< 2.0 x ULN and no radiologic or clinical evidence of pancreatitis * Urine protein/creatinine ratio (UPCR) =\< 1 mg/mg * 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 have undetectable HCV viral load 12 or more weeks after treatment completion. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression \>= 1 month after treatment of the brain metastases. Patients with new or progressive brain metastases (active brain metastases) or leptomeningeal disease are eligible if the treating physician determines that immediate CNS specific treatment is not required and is unlikely to be required during the first 2 cycles of therapy * 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 * Patients must be willing to provide blood specimens and undergo biopsies for research purposes * Patients with baseline blood pressure (BP) lower than 140 mmHg (systolic) and 90 mmHg (diastolic). Patients on \> 2 anti-hypertensive agents will be excluded * Human immunodeficiency virus (HIV)-infected patients on effective combination antiretroviral therapy are eligible as long as HIV is well-controlled and there is undetectable viral load within 6 months. For these patients, an HIV viral load test must be completed within 28 days prior to enrollment * The effects of nivolumab, ipilimumab, and cabozantinib on the developing human fetus are unknown. For this reason and because other therapeutic agents used in this trial are known to be teratogenic, women of child-bearing potential (WOCBP) 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. WOCBP (defined as any female who has experienced menarche and who has not undergone surgical sterilization \[hysterectomy or bilateral oophorectomy\] or who is not postmenopausal) should use an adequate method to avoid pregnancy for 5 months after the last dose of investigational drug. Women of childbearing potential must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotropin \[HCG\]) at the time of enrollment and within 8 days prior to each cycle. Women must not be breastfeeding * Men who are sexually active with women of child-bearing potential (WOCBP) must use any contraceptive method with a failure rate of less than 1% per year. Men receiving cabozantinib and who are sexually active with WOCBP will be instructed to adhere to contraception for a period of 5 months after the last dose of investigational product. Women who are not of childbearing potential (i.e., who are postmenopausal or surgically sterile) as well as azoospermic men do not require contraception * Ability to understand and the willingness to sign a written informed consent document

---

Exclusion Criteria:

* 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, stable hyperthyroidism on replacement therapy, type-1 diabetes, well-controlled on insulin, and non-clinically significant toxicities at the discretion of the study Principal Investigator * Patients who are receiving any other investigational agents * Eligibility of subjects receiving any medications or substances known to affect or with the potential to affect the activity of cabozantinib will be determined following review of their cases by the Principal Investigator. Patients who are taking enzyme-inducing anticonvulsant agents are not eligible * History of allergic reactions attributed to compounds of similar chemical or biologic composition to cabozantinib, nivolumab, or ipilimumab * Patients receiving any medications or substances that are strong inhibitors or inducers of CYP3A4 are ineligible. Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, and St. John's Wort) are not allowed for this study. Because the lists of these agents are constantly changing, frequently updated lists available at http://medicine.iupui.edu/clinpharm/ddis/table.asp or other reliable resources will be consulted. Patients who need to come off CYP3A4 inhibitors/inducers should adhere to a washout period of at least 5 times the half-life of the CYP3A4 inhibitors and 14 days of CYP3A4 inducers * Patients with any other significant condition(s) that would make this protocol unreasonably hazardous are ineligible. Patients with uncontrolled intercurrent illness or clinical evidence of an active infection at the time of enrollment are ineligible * Pregnant women are excluded from this study because cabozantinib is a receptor kinase inhibitor agent 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 cabozantinib in combination with nivolumab and ipilimumab, breastfeeding should be discontinued if the mother is treated with cabozantinib. These potential risks may also apply to other immunotherapeutic agents (ipilimumab and nivolumab) used in this study * Patients with any of the following within 12 weeks prior to the first dose of cabozantinib: gastrointestinal bleeding, hemoptysis or pulmonary hemorrhage, radiographic evidence of cavitating pulmonary lesion(s), evidence of tumor invasion of the gastrointestinal (GI) tract (esophagus, stomach, small or large bowel, rectum, or anus), or any evidence of endotracheal or endobronchial tumor or encasement of any major blood vessels are ineligible * The patient is unable to swallow tablets * The patient has a corrected QT interval calculated by the Fridericia formula (QTcF) \>= 470 ms within 28 days before enrollment * Patients with a requirement for steroid or immunosuppressive treatment should be excluded if they have a condition requiring systemic treatment with either corticosteroids (\> 10 mg daily prednisone equivalents) or other immunosuppressive medications within 14 days of study drug administration. Inhaled or topical steroids and adrenal replacement doses \> 10 mg daily prednisone equivalents are permitted in the absence of active autoimmune disease

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy, PROCEDURE: Biospecimen Collection, DRUG: Cabozantinib, PROCEDURE: Computed Tomography, BIOLOGICAL: Ipilimumab, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Nivolumab

Conditions:

Locally Advanced Extraskeletal Myxoid Chondrosarcoma, Locally Advanced Leiomyosarcoma, Locally Advanced Liposarcoma, Locally Advanced Undifferentiated

Locally Advanced Extraskeletal Myxoid Chondrosarcoma, Locally Advanced Leiomyosarcoma, Locally Advanced Liposarcoma, Locally Advanced Undifferentiated Pleomorphic Sarcoma, Locally Advanced Unresectable Soft Tissue Sarcoma, Metastatic Soft Tissue Sarcoma, Metastatic Undifferentiated Pleomorphic Sarcoma, Unresectable Leiomyosarcoma, Unresectable Liposarcoma, Unresectable Undifferentiated Pleomorphic Sarcoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT05836571

Thank you for choosing StudyFinder. Please visit http://studyfinder.cctr.vcu.edu to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.