Safety and Tolerability Study of GIM-531 in Advanced Solid Tumors

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Written informed consent * Cytologically or histologically confirmed locally advanced or metastatic solid tumor that has progressed on standard therapy or for which no standard therapy exist; or be intolerant of standard therapy * Have not received an experimental drug within 4 weeks or 5 half-lives (whichever is shorter) of study drug treatment or already be enrolled in a clinical study * ECOG performance status 0-1 * Laboratory and ECG assessments within 28 days of enrollment including acceptable cardiac, renal, and hepatic functions * Agree to baseline core needle biopsy or archival (within 12 months of screening) tumor submission; Note: Participants whose only site(s) of disease are in areas considered moderate or high risk for biopsy complications may be enrolled without a fresh biopsy upon Sponsor approval. * Non pregnant participants; female participants of child bearing potential with non-sterile partners agree to use an effective form of contraception from the time of first dose of study drug (or 14 days prior to first dose for oral contraception) until 7 months after the last dose of study drug. Effective forms of contraception include hormonal (injection or oral), double barrier method, or intrauterine device. Non-sterile male participants with sexual partners of childbearing potential agree to use a barrier contraception method and agree to not donate sperm from the time of first dose of study drug until 4 months after the last dose of study drug. * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) version (v)1.1 Phase 1 Expansion Cohorts Specific Inclusion Criteria (in addition to above inclusion criteria): * NSCLC: Participants must have locally advanced/unresectable or metastatic NSCLC. Participants must have received no more than 3 prior lines of therapy in the advanced/metastatic setting. * TNBC: Participants must have locally advanced unresectable, recurrent, or metastatic TNBC. Participants must have received no more than 3 prior lines of therapy in the advanced/metastatic setting. * Ovarian Cancer: Participants must have locally advanced unresectable, recurrent, or metastatic ovarian cancer. Participants must have platinum-resistant ovarian cancer defined as disease recurrence or within 6 months after the last administration of platinum-based chemotherapy. Participants must have received no more than 1 line of therapy after development of platinum resistance. Maintenance treatment with Poly(ADP-ribose) polymerase inhibitors (PARPi) or bevacizumab are not counted as separate lines of therapy. * Tumors with AKT3 mutation/amplification: Participants must have a locally advanced unresectable, recurrent, or metastatic solid malignancy. Participants with known AKT3 mutation/amplification based on next generation sequencing (NGS) performed per local standard of care. Phase 2 Specific Inclusion Criteria (in addition to above inclusion criteria): * Have confirmed unresectable Stage III or metastatic Stage IV cutaneous melanoma, NSCLC, or RCC that has radiographically progressed (as confirmed by imaging assessed by the Investigator) on an approved single-agent or combination anti-PD-1 therapy * Must have received the anti-PD-1 therapy containing regimen as the latest line of treatment and be eligible to restart or to continue anti-PD-1 therapy in combination with GIM-531 * BRAF wild-type melanoma or RCC: Participants must have received no more than 2 prior lines of therapy in the advanced/metastatic setting * BRAF (V600) mutant melanoma or NSCLC: Participants must have received no more than 3 prior lines of therapy in the advanced/metastatic setting. Key

---

Exclusion Criteria:

* Ongoing \>Grade 1 toxicity from prior therapy according to Common Terminology Criteria for Adverse Events v5.0 (Note: Grade 2 alopecia and Grade 2 sensory neuropathy are not exclusionary) * Has known leptomeningeal disease, spinal cord compression, or brain metastases, except participants with the following: * Brain metastases that have been treated and are clinically stable for at least 4 weeks prior to the first administration of study drug; Note: Participants receiving steroids for brain metastases must be either off steroids or on a stable, or decreasing dose, of \<10 mg daily of prednisone (or equivalent) in order to be eligible for enrollment; and * No ongoing neurological symptoms related to the anatomic location of the brain metastases. Note: Neurological symptoms that are considered sequelae to treatment for brain metastases are allowed. * Has known structural cardiac disease * Has known serious arrythmia, serious dysrhythmia, history of long QT syndrome, or clinically relevant cardiac conduction abnormalities * Has an active autoimmune disease that has required systemic treatment in the past 12 months (ie, with use of disease modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed. * At time of screening, is receiving systemic steroid therapy (greater than or equal to 10 mg/day of prednisone or equivalent) or is taking any immunosuppressive therapy; Note: Use of topical, inhaled, nasal, or ophthalmic steroids is allowed. * Has active and clinically significant bacterial, fungal, or viral infection, including known hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) * Has a history of, or currently has, an acquired or primary (congenital) immunodeficiency; * Has had prior anti-cancer treatment with chemotherapeutic agents or immune modulating agents within \<4 weeks or 5 half-lives, whichever is shorter, prior to the first dose of study drug. * Has received a live vaccine within 30 days of first dose of study drug; * Has had or has planned major surgery within 2 weeks of the first dose of study drug; * Inability to swallow an oral dose of a medication (eg, oral capsules) * Is taking medications that are considered strong inducers or inhibitors of CYP2C8 or CYP3A4/5, P-glycoprotein (P-gp), breast cancer resistant protein (BCRP), or sensitive substrates of P-gp and BCRP (Appendix C) that cannot be discontinued at least 1 week prior to first dose of study drug and for the duration of the study. * Is taking drugs that modify gastric pH, such as proton-pump inhibitors (PPIs) or H2 blockers. Antacids such as calcium carbonate or aluminum hydroxide-based products are permitted.

Conditions & Interventions

Interventions:

DRUG: GIM-531, DRUG: Anti-PD-1 monoclonal antibody

Conditions:

Melanoma Stage IV, Solid Tumor

Keywords:

PD-1 resistance, PD-1 resistant/refractory, AKT3

More Information

Contact(s): Jayadev Sureddi, CBCC CRO - jayadev.sureddi@cbcc.global

Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT06425926

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.