A Phase I Study of HCW9218, a Bifunctional TGF-B; Antagonist/IL-15 Protein Complex, in Select Advanced Solid Tumors After Failing at Least Two Prior Therapies

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Histologically or cytologically confirmed advanced/metastatic solid tumor cancer (except pancreatic and primary brain cancers), has failed at least 2 prior lines of therapy given either in the recurrent or metastatic setting and must be refractory to or intolerant of existing therapy(ies) known to provide clinical benefit for their condition.
- Measurable disease per RECIST v 1.1.
- Acute effects of any prior therapy must have resolved to baseline or Grade â‰¥1 NCI CTCAE v5 except for AEs not constituting a safety risk by enrolling Investigator judgment.
- Age 18 years or older at the time of consent.
- ECOG Performance Status 0 or 1.
- Evidence of adequate organ function within 14 days prior to enrollment as defined in Section 4.1.6.
- Adequate pulmonary function with PFTs >50% FEV1 if symptomatic or known impairment.
- Sexually active persons of child-bearing potential or with partners of childbearing potential must agree to use a highly effective form of contraception (refer to Section 4.1.10 for acceptable methods) for at least 28 days after the last dose of HCW9218.
- Provides voluntary written consent prior to the performance of any research related activity.

Exclusion Criteria:

- Pregnant or breastfeeding.
- History of clinically significant vascular disease, including any of the following within 6 months prior to start of study treatment: MI or unstable angina, percutaneous coronary intervention, bypass grafting, ventricular arrhythmia requiring medication, stroke or transient ischemic attack, symptomatic peripheral arterial disease.
- Marked baseline prolongation of QT/QTc interval (e.g., demonstration of a QTc interval greater or equal to 470 milliseconds by Fridericia’s correction).
- Known or suspected untreated CNS metastases.
- Anti-cancer treatment including surgery, radiotherapy, chemotherapy, other immunotherapy, or investigational therapy within 14 days before treatment start.
- Other prior malignancy except for the following: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated Stage I or II cancer from which the subject is currently in complete remission, or any other cancer from which the subject has been disease-free for 3 years after surgical treatment.
- Known hypersensitivity or history of allergic reactions attributed to compounds of similar chemical or biologic composition to the agents used in the study.
- Prior therapy with TGF-Î± antagonist, IL-15 or analogs.
- Concurrent use of St. John’s wort and/or other herbal CYP modulators within 7 days of Day 1. Must agree to not use during study treatment through the end of treatment visit to be eligible.
- Known autoimmune disease requiring active treatment. Persons with a condition requiring systemic treatment with either corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of enrollment. Inhaled or topical steroids, and adrenal replacement steroid doses â‰¥10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease.
- Active systemic infection requiring parenteral antibiotic therapy. All prior infections must have resolved following optimal therapy.
- Active infection from which the subject has been disease-free for 3 years after surgical treatment.
- Known HIV-positive or AIDS.
- Psychiatric illness/social situations that would limit compliance with study requirements.
- Other illness or a medical issue that in the opinion of the Investigator would exclude the subject from participating in this study

Conditions & Interventions

Interventions:
Drug: HCW9218
Conditions:
Solid Tumor
Keywords:
Clinics and Surgery Center (CSC), Phase I Clinic

More Information

Description: This is a single center, Phase I dose finding study of HCW9218 for the treatment of select advanced solid tumor cancers, including, but not limited to breast, ovarian, prostate and colorectal. HCW9218 potently activates natural killer (NK) cells and CD8+ T cells in vitro and in vivo to promote their proliferative and metabolic activities and enhance their cytotoxicity against tumor targets. The fusion complex also exhibits TGF-Î± neutralizing activity in vitro and sequesters plasma TGF-Î± in vivo. It is hypothesized that HCW9218 may serve as a novel therapeutic to simultaneously provide immunostimulation and lessen immunosuppression associated with solid tumors. The primary objective of this study is to determine the maximum tolerated dose (MTD) of HCW9218 as monotherapy in advanced solid tumor cancers except pancreatic cancer and primary brain tumors.

Contact(s): Melissa Geller - geller005@umn.edu
Principal Investigator: Melissa Geller, MD
Phase: Phase 1
IRB Number: STUDY00015102
System ID: NCT05322408

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