An Open-label, Phase 2 Basket Study of SEA-CD40 Combination Therapies in Advanced Malignancies

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:
• Histologically or cytologically confirmed unresectable malignancy defined as one of the following:
  • Cohort 1: Relapsed and/or refractory metastatic melanoma
  • Uveal/ocular melanoma is excluded
  • Must have progressed on treatment with an anti-PD-(L)1 mAb. PD-(L)1 treatment progression is defined as meeting all of the following criteria:
    • Has received at least 2 doses of an approved anti-PD-(L)1 mAb
    • Has demonstrated disease progression after PD-(L)1 as defined by RECIST v1.1.
    • Progressive disease has been documented within 12 weeks from the last dose of anti-PD-(L)1 mAb
    • Last dose of anti-PD-(L)1 must have been within 90 days prior to enrollment
  • Participants with a targetable BRAF mutation must have been treated with, been intolerant of, or declined treatment with BRAF/MEK targeted therapy prior to study entry
  • Cohort 2: Metastatic uveal melanoma
    • Must not have received prior treatment for advanced or metastatic disease except for prior adjuvant/neoadjuvant immunotherapy
    • No prior liver-directed therapy
  • Cohort 3: Metastatic PD-(L)1-naive melanoma
    • Uveal/ocular melanoma is excluded
    • Must not have received prior treatment for advanced or metastatic disease except for prior adjuvant/neoadjuvant immunotherapy.
    • For participants with a targetable BRAF mutation, prior BRAF/MEK targeted therapy is allowed if completed 4 weeks prior to first dose of study treatment.
  • Cohorts 4 and 5: Non-squamous NSCLC
    • Participants must have stage IV disease per AJCC 8th edition
    • No known driver mutations/alterations mutation for which targeted therapy is available
    • Must have non-squamous histology.
    • No prior therapy for metastatic disease
    • No prior treatment with anti-PD-(L)1 or PD-L2 agent or an antibody targeting other immuno-regulatory receptors or mechanisms
    • Able to provide archival tumor tissue from locations not radiated prior to biopsy. If archival tumor sample is not available a fresh baseline biopsy is required.
    • Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1
    • Measurable disease per RECIST v1.1 at baseline

Exclusion Criteria:
• History of another malignancy within 3 years of first dose of study drug
• Active central nervous system (CNS) metastases and/or carcinomatous meningitis.
• Previous exposure to CD40-targeted therapy
• Currently on chronic systemic steroids in excess of physiologic replacement
• Has had an allogeneic tissue/solid organ transplant.
• History of autoimmune disease that has required systemic treatment in the past 2 years

Conditions & Interventions

Interventions:

Conditions:
Melanoma, Carcinoma, Non-Small-Cell Lung

Keywords:
Relapsed melanoma, Refractory melanoma, Metastatic uveal melanoma, Metastatic PD-(L)1-naive melanoma, Non-squamous NSCLC, NSCLC, Non-small cell lung cancer, Seattle Genetics, Clinics and Surgery Center (CSC)

More Information

Description: This is a phase 2, global, open-label, multicenter trial designed to assess the activity, safety, and tolerability of SEA-CD40 in combination with standard-of-care therapies in adults with selected solid tumors. The study will include multiple indication-specific cohorts. Up to approximately 200 subjects may be enrolled in this study.

Contact(s): Evidio Domingo Musibay - musib024@umn.edu
Principal Investigator: Evidio Domingo Musibay
Phase: Phase 2
IRB Number: STUDY00014590
System ID: NCT04993677

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.