SOTIO (Sotio)

A Study of SOT101 in Combination With Pembrolizumab to Evaluate the Efficacy and Safety in Patients With Selected Advanced Solid Tumor

This is the trial summary as assessed on clinicaltrials.gov on 08/12//2022.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT05256381.

Trial Design:

ARM	INTERVENTION
Experimental: SOT101 and Pembrolizumab Participants will be treated with 12 µg/kg of SOT101 on Day 1, Day 2, Day 8, and Day 9 of each 3-week cycle in combination with 200 mg pembrolizumab on Day 1 of each 3-week cycle.	SOT101 – SC injection Pembrolizumab – IV infusion

Inclusion criteria:

- Participants with the following histologically or cytologically confirmed solid tumor indications and line of treatment:
    1. Non-small cell lung cancer (NSCLC).
    2. Colorectal cancer.
    3. Cutaneous squamous cell carcinoma (cSCC).
    4. Advanced hepatocellular carcinoma.
    5. mCRPC.
    6. Ovarian cancer.
- Have measurable disease per RECIST 1.1. mCRPC participants with no measurable disease and only widespread bone disease must have a CTC count of >5 cells per 7.5 mL of blood.
- Accessible tumor tissue available for fresh biopsy except for mCRPC with no accessible tumor tissue
- Eastern Cooperative Oncology Group (ECOG) score 0-1.
- Have recovered from all AEs (except alopecia) due to previous therapies to grade ≤1 (excluding alopecia) or have stable grade 2 neuropathy.
- Have adequate organ function as defined below:
    1. Hematology:
        a. Absolute neutrophil count ≥1500/µL.
        b. Platelets ≥100 000/µL.
        c. Hemoglobin ≥9.0 g/dL .
    2. Renal function: Creatinine clearance as measured by glomerular filtration rate ≥30 mL/min using Cockcroft-Gault equation.

3. Hepatic function: Alanine transaminase (ALT)/aspartate transaminase (AST) ≤2.5× upper limit of normal (ULN) and total bilirubin ≤1.5×ULN or direct bilirubin ≤ ULN in participants without liver metastasis. In participants with liver metastasis, ALT/AST ≤5×ULN is allowed but total bilirubin must be ≤2×ULN.
4. Prothrombin time and activated partial thromboplastin time ≤1.5×ULN.

- Participants must not have active hepatitis B or hepatitis C infection.
- Adequate contraception must be applied in all women of childbearing potential (WOCBP) and in male participants.

Exclusion criteria:

- Has received prior therapy with an anti-programmed cell death protein 1 (anti-PD-1), anti-programmed cell death ligand 1 (anti-PD-L1), or anti-programmed cell death ligand 2 (anti-PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor and was discontinued from that treatment due to a grade ≥3 AE.
- Prior exposure to agonists of interleukin (IL)-2 or IL-15.
- Prior systemic anti-cancer therapies, including investigational agents:
    1. Less than 4 weeks for systemic chemotherapy and immuno-oncology therapies; and for tyrosine kinase inhibitors 4 weeks or 5 half-lives (whichever is shorter).
    2. Less than 4 weeks from major surgeries and not recovered adequately.
- Has received prior radiotherapy within 2 weeks.
- NSCLC indication only: Received radiation therapy to the lung >30 Gy within 6 months.
- Has received a live or live-attenuated vaccine within 30 days.
- Clinically significant cardiac abnormalities including prior history of any of the following:
    1. Cardiomyopathy, with left ventricular ejection fraction ≤ 50%.
    2. Congestive heart failure of New York Heart Association grade ≥2.
    3. History of clinically significant artery or coronary heart disease.
    4. Prolongation of QTcF >450 msec .
    5. Clinically significant cardiac arrythmia that cannot be controlled with adequate medication.
- Uncontrolled hypertension defined as systolic blood pressure >160 mmHg, diastolic blood pressure >110 mmHg.
- Prior allogeneic hematopoietic stem cell transplantation within the last 5 years.
- Prior allogeneic tissue/solid organ transplant.
- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy.
- History of or serology positive for human immunodeficiency virus (HIV).
- Has a known additional malignancy that is progressing or has required active treatment within the past 5 years, except for basal cell carcinoma of the skin or carcinoma in situ that have undergone potentially curative therapy are not excluded.
- Has known active central nervous system metastases and/or carcinomatous meningitis, unless stable.
- Had severe hypersensitivity (grade ≥3) to pembrolizumab and/or any of its excipients.
- Has an active autoimmune disease that has required systemic treatment in the past 2 years.
- History of (non-infectious) pneumonitis/interstitial lung disease that required steroids or current pneumonitis/interstitial lung disease.
- Has an active infection requiring systemic therapy.

- Has any condition that might confound the results of the study or interfere with the participant's participation for the full duration of the study.