Abstract Title: PHASE 1 STUDY OF ESCALATING DOSES OF EX VIVO EXPANDED, AUTOLOTOUS NATURAL KILLER CELLS IN PATIENTS WITH PATHOLOGICALLY CONFIRMED CANCER REFRACTORY TO CONVENTIONAL THERAPY [NCT03941262]

ABSTRACT PREVIEW: PHASE 1 STUDY OF ESCALATING DOSES OF EX VIVO EXPANDED, AUTOLOTOUS NATURAL KILLER CELLS IN PATIENTS WITH PATHOLOGICALLY CONFIRMED CANCER REFRACTORY TO CONVENTIONAL THERAPY [NCT03941262]

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Abstract Information

Category

Immunology & Immunotherapy

Permission to Use

- Yes

Attendance

- Yes

Objective

Background and Rationale: SNK01 is an autologous natural killer (NK) cell-derived adopted cellular immunotherapy being developed as a single agent and in combination with targeted therapies to treat advanced and metastatic solid tumors. NK cells are an essential class of innate immune cells that play a critical role in mediating antitumor response. NK cells can directly kill tumor cells and rapidly secrete

proinflammatory cytokines to potentiate the adaptive immune response. SNK01 is the first-in- kind, autologous non-genetically modified NK cell therapy with highly enhanced cytotoxicity and near 100 % expression of CD16, NKG2D, NKp46, and DNAM-1, which can be consistently produced from healthy subjects, and heavily treated cancer patients alike.
Objectives:
Primary : To investigate the safety of SNK01 using NIH CT CAE vs 5.0
Secondary: To asses objective response rate (ORR), progression-free survival (PFS) using RECiST v1,1 and overall survival (OS)

Methods

In this single-arm Phase I study to investigate the safety and potential anti-tumor activity of SNK01, eleven patients (Cohorts 1-3) with refractory metastatic solid tumors were treated in a 3+ 3 monotherapy dose escalation study with five weekly infusions of SNK01 (Dose Level I: 1x10^9, Dose Level 2: 2x10^9, and Dose Level 3: 4x10^9 cells/infusion). After completing the 3 Cohorts of single dose escalation of SNK01, the protocol was amended to include Cohort 4 (n=18) wherein SNK01 is given in combination with an immune checkpoint inhibitor (avelumab or pembrolizumab). Patients with PD-L1 negative or low PD-L1+tumors who have failed conventional therapy and who have measurable disease by RECIST 1.1 are being enrolled to receive either SNK01 (4 X 10^9 cells) + pembrolizumab 200 mg q 3 weeks or avelumab 800 mg q 2 weeks. Patients will be treated until disease progression or unacceptable toxicity. Primary end point is safety. Secondary endpoints are objective response rate (ORR), progression-free survival (PFS) and overall survival (OS). The trial is currently in progress and 16/18 patients have been enrolled to date.

Results

The trial is currently in progress and 16/18 patients have been enrolled to date.

Conclusion

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Disclosure Information

FDA Disclosure
No (List the Manufacturer's Name and Drug or Device in the following question)

Manufacturer's Name and Drugs or Devices
Manufacturer: NKGen Biotech Drug: SNK01 autologous natural killer cells ex vivo expanded

Financial Relationship
No