Abstract #1136

SNK01 AUTOLOGOUS ENHANCED NATURAL KILLER CELLS AND AN IMMUNE CHECKPOINT INHIBITOR CONTROL TUMOR GROWTH IN RARE CHEMOTHERAPY-RESISTANT ADVANCED SOFT TISSUE SARCOMA

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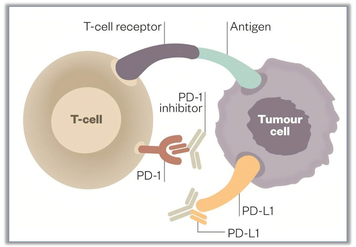
Background

Advanced or metastatic sarcoma is most often associated with a fatal outcome. SNK01 is a first-in-kind, autologous, non-genetically modified natural killer cell therapy with highly enhanced cytotoxicity and over 90% activating receptor expression which can be consistently produced from chemotherapy-treated patients.



Legend: Pembrolizumab is a monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

Methods and Materials

Objective: To report 3 unique rare cases of chemotherapy-resistant advanced STS who achieved durable partial responses and disease control with SNK01 + ICI.

Patients with the following histologic subtypes:

- Desmoplastic small round cell tumor (DSRCT)
- Radiation-induced chondrosarcoma (RIC)
- Undifferentiated spindle cell sarcoma

Case #1 (DSRCT) received SNK01 (2 x 10^9 cells) and pembrolizumab 200 mg i.v. q 3 weeks.

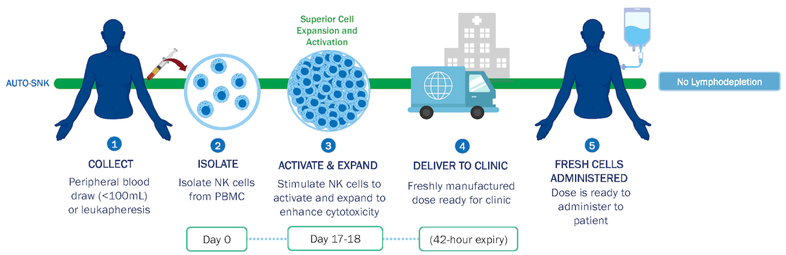
Case #2 (RIC) received SNK01 (4 x 10^9 cells) and pembrolizumab 200 mg i.v. q 3 weeks.

Case #3 with undifferentiated spindle cell sarcoma was enrolled in the SK01-US01 study and received SNK01 (4 x 10^9 cells) i.v. q 2 weeks and avelumab 800 mg i.v. q 2 weeks.

Conclusion

Taken together, these unique case studies demonstrate the potential of SNK01 in controlling tumor growth when combined with an immune check point inhibitor with no added toxicity.

Autologous SNK Cell Therapy



- Manufacturing process takes ~17-18 days from NK cell isolation to fresh product release
- Ability to produce multiple doses (6 x 10^9 cells each) from a single leukapheresis to fulfill 4–6 months of weekly treatments.
- Each dose is produced separately from cryopreserved PBMC (1 dose=1 batch release)

Results: Safety analysis

Grade 3 or greater adverse events include hypothyroidism (n=1), increased ALT (n=1), increased alkaline phosphatase (n=1) and increased GGT (n=1) which were attributed to immune checkpoint inhibitor therapy.

Results: Efficacy Analysis: CASE 1

DSCRT: Patient had a **47%** partial response over one year of treatment. Patient underwent a surgical debulking procedure followed by whole abdominal radiation and intraperitoneal chemotherapy, after which he resumed **SNK01 + pembrolizumab** regimen for **47** cycles over **43** months. His last scan showed no evidence of disease (Figure 1). Patient's ECOG score is 0.

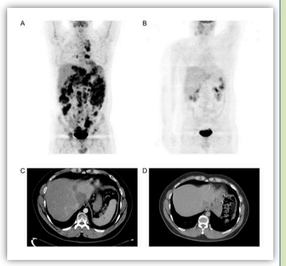


Figure 1: BEFORE treatment PET scan (A) and abdominal scan (C). AFTER treatment PET scan (B) and abdominal scan (D).

Results: CASE 2

RIC: Patient had a **38%** partial response (Figure 2) after **4** months of treatment, underwent debulking surgery but died of post-surgical infection. The patient had received **18** cycles of **SNK01 + pembrolizumab** and survived 12 additional months.

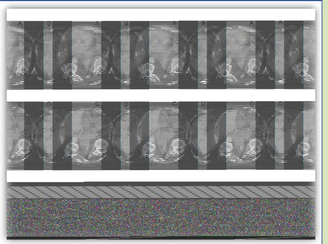


Figure 2: BEFORE treatment abdominal scans (A, B). AFTER treatment abdominal scans (C, D).

Results: CASE 3

Undifferentiated spindle cell sarcoma: The patient had durable disease control (**SD**), has received **41** treatment cycles during the **18**-month treatment period.

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3) Victoria S. Chua, Sant P. Chawla, Erlinda Maria Gordon, Ted T. Kim, Brenda L. Gibson, Paul Y. Chang, Paul Y. Song USFDA Authorized Compassionate Use of SNK01 (Autologous Non-Genetically Modified Natural Killer Cells With Enhanced Cytotoxicity) and Immune Checkpoint Inhibitors in Advanced Heavily Pre-treated Sarcoma. A Promising Regimen. Annals of Oncology (2022) 33 (suppl_7): S331-S355. 10.1016/annonc/annonc1058
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