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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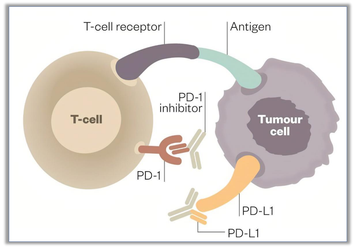
Background

Advanced or metastatic sarcoma is associated with an invariably 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

Three cases with chemo-resistant advanced soft tissue sarcoma 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.

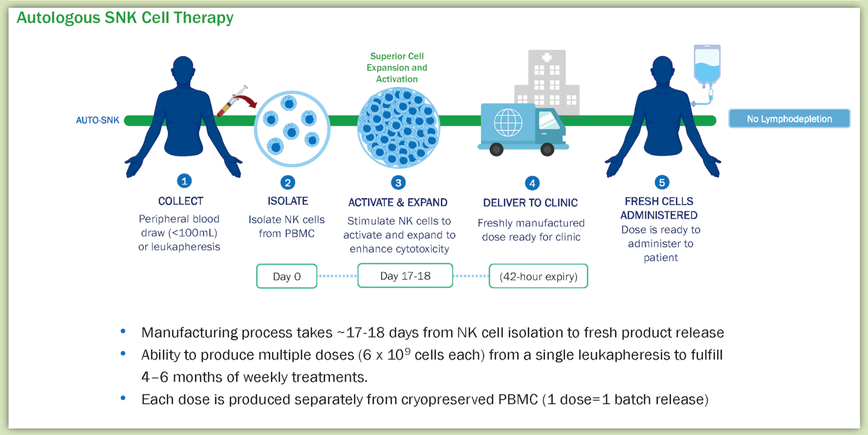
Case #2 (RIC) received SNK01 (4 x 10^9 cells) and pembrolizumab 200 mg i.v. q 3 weeks.

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.

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

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.



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: 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.

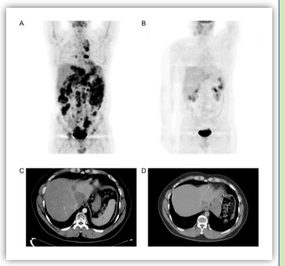


Figure 1: BEFORE treatment PET scan (A) and abdominal scan (C). AFTER treatment PET scan (B) and abdominal scan (D).

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.

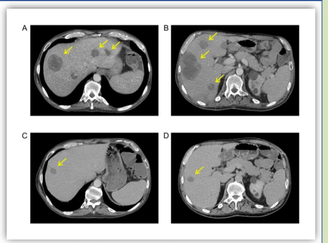


Figure 2: BEFORE treatment abdominal scans (A, B). AFTER treatment abdominal scans (C, D).

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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