Phase 1/2 Open-Label, Multi-Center Trial of SNS-301 Added to Pembrolizumab in Patients with Advanced Squamous Cell Carcinoma of the Head & Neck

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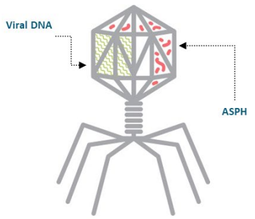
BACKGROUND

- The absence of infiltrating antigen-specific CD8+ T-cells at baseline is associated with low response rates to PD-1 blockade. Squamous Cell Carcinoma of the Head and Neck (SCCHN) tumors often exclude effector T cells, and 1st/2nd line response rates are low (13-18%).
- Highly immunogenic, antigen specific antitumor vaccines may expand intratumoral CD8+ T cells, potentially increasing durable response rates to PD-1 blockade.
- A majority of SCCHN tumors express the tumor associated antigen human aspartate β-hydroxylase (ASPH).
- The study design selects patients with ASPH+ locally advanced/metastatic SCCHN who already received PD-1 blockade for ≥ 3 months. After enrollment, the patients receive a combination of PD-1 blockade and SNS-301 (vaccine targeting ASPH).
- Given that the median time to response with PD-1 blockade is around 2 months, we believe that objective responses observed on combination therapy are likely to be attributable to the addition of SNS-301.

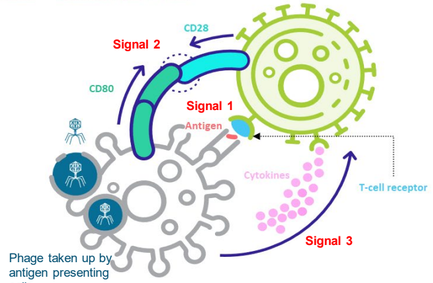
SNS-301

- SNS-301 is a first-in-class and self-adjuvanted bacteriophage-base immune-activating vaccine targeting ASPH.
- SNS-301 is given as an intradermal injection using the 3M® hollow microstructured transdermal system (hMTS) device.

SNS-301 is engineered with both antigen and immune stimulatory viral DNA.



SNS-301 are taken into antigen presenting cells, which present antigen to T and B cells via MHC I and II ang generate the 3 key signals required to generate a strong immune response.



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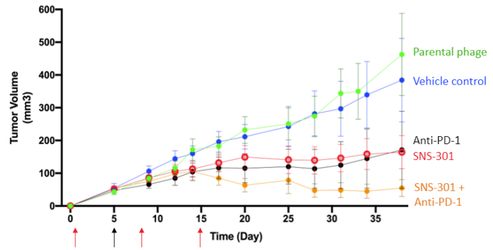
PRECLINICAL RATIONALE

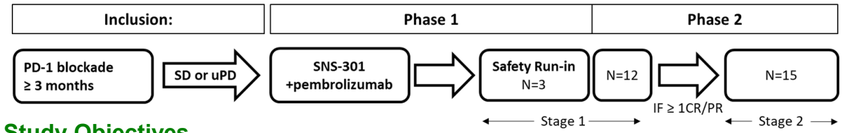
SNS-301 + PD-1 Blockade Seems More Effective Than Either Drug Alone



C57BL/6 mice (n=10) were implanted with a mouse hepatoma cell line, Hepa1-6. Mice received 3 doses of phage (read arrows) at Day 1, 8 and 15 and one dose of anti-PD-1 on day 5.

METHODS

Study Design



Study Objectives

- Evaluate safety, tolerability, anti-tumor activity, immune responses and tumor/immune biomarkers.

Tumor and Blood Analyses

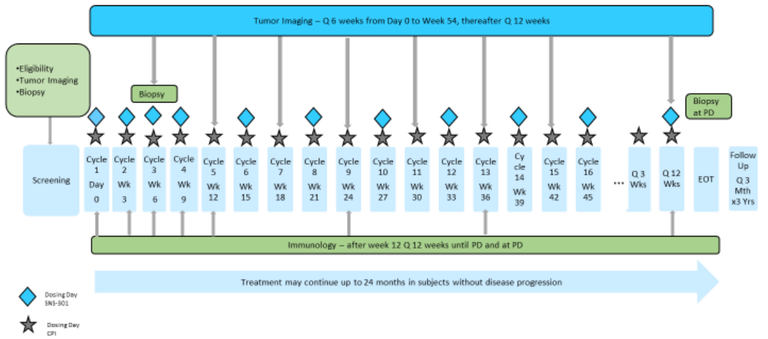
- A CLIA validated assay was developed by Fred Hutchinson Cancer Research Center to determine ASPH expression for patient selection.
- Tumor tissue is provided to characterize the tumor microenvironment using Nanostring™ & multiplex immunohistochemistry.
- Blood samples are collected to evaluate B and T cell responses using ELISA, ELISPOT and flow cytometry.

Eligibility Criteria

- Histologically or cytologically documented locally advanced unresectable or metastatic/recurrent SCCHN
- SD or unconfirmed PD as best response on PD-1 blockade for at least 3 months
- Measurable disease, as defined by RECIST version 1.1
- Willing to provide biopsy sample pre-study, during study and at disease progression
- Patient without evidence of rapid progression

METHODS

Schedule of Events



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