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.

METHODS

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

SNS-301 is a first-in-class and self-adjuvanted bacteriophage-base immune-activating vaccine targeting ASPH.

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

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

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Schedule of Events

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