

Early Safety and Efficacy of a Phase 1/2 Multi-Center Trial of SNS-301 Added to Pembrolizumab in Patients with Advanced Squamous Cell Carcinoma of the Head and Neck

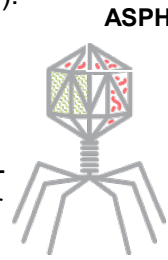
Alain Algazi¹, William Smith², Timothy Panella³, Dong M. Shin⁴, Ann Gramza⁵, Marie-Louise Fjaellskog⁶, John Celebi⁶, Alice Drumheller⁶, Jean S. Campbell⁶, Robert H. Pierce⁶, Steve Fuller⁶, Michael Guarino⁷

¹Department of Medicine, UCSF, San Francisco, CA; ²New Orleans Clinical Research Center, New Orleans, LA; ³Department of Medical Oncology, University of Tennessee, Knoxville, TN; ⁴Winship Cancer Institute, Emory University, Atlanta GA; ⁵Georgetown University Hospital, Washington, DC; ⁶Sensei Biotherapeutics, Gaithersburg, MD; ⁷Department of Medical Oncology, Christiana Hospital, Newark, DE

Abstract
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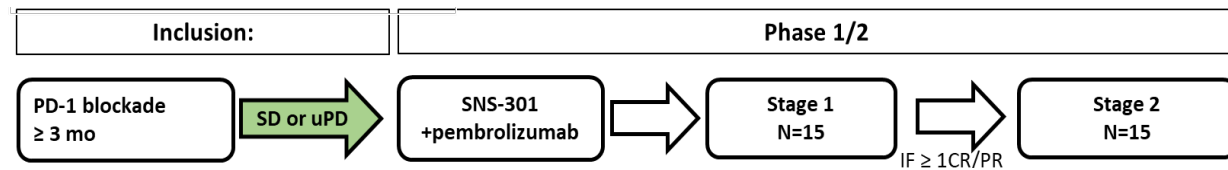
BACKGROUND

- The absence of infiltrating antigen-specific CD8+ T-cells at baseline is associated with low response rates to anti-PD1/PDL1 antibodies. SCCHN tumors often exclude effector T cells, and 1st/2nd line response rates in SCCHN are low (13 to 18%).
- Highly immunogenic, antigen specific antitumor vaccines may expand intratumoral CD8+ T cells, potentially increasing durable response rates to anti-PD1 antibodies.
- SNS-301 is a first-in-class and self-adjuvanted bacteriophage-base immune-activating vaccine targeting human aspartate β-hydroxylase (ASPH), a tumor associated antigen commonly overexpressed in cancer.



METHODS

Study Design



Study Objectives

To evaluate safety, tolerability and anti-tumor activity as well as immune response and tumor/immune biomarkers.

RESULTS – SNS-301 + PEMBROLIZUMAB

Patient Characteristics

Characteristics	% (N=11)
Age median (range)	62 (57-69)
Male/Female	82/18
ECOG 0/1	18/82
HPV	
pos	36
neg	36
unknown	18
PD-L1	
pos	36
neg	9
unknown	54
Prior lines systemic tx	
1	45
2	27
≥3	27
Ongoing anti-PD-1/PDL1 tx median (range)	37 weeks (20-101)

Acceptable Safety Profile

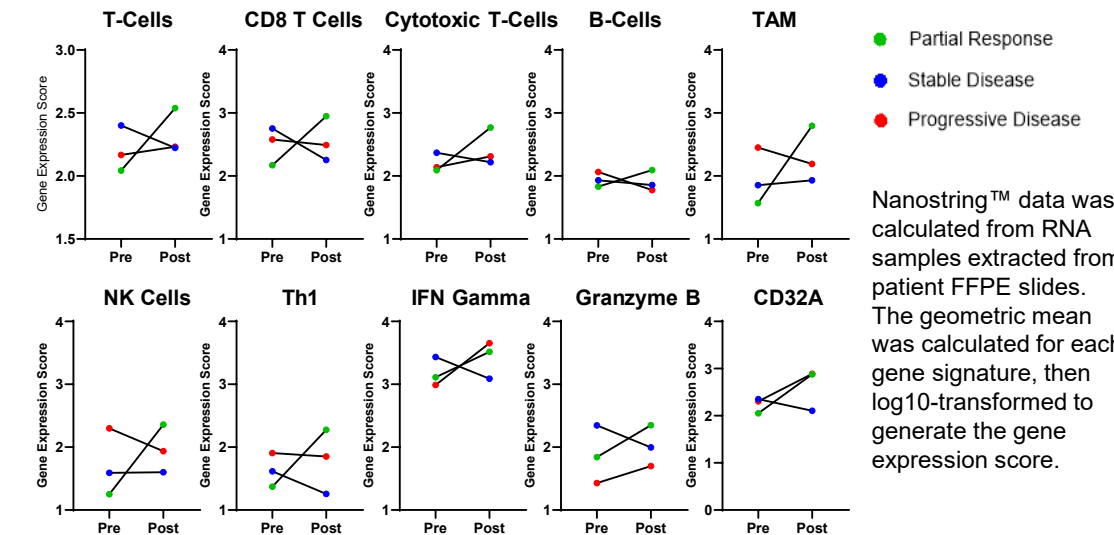
Related Events	Overall (N=11)	
	All Grades n(%)	Grade 3-4 n(%)
Decreased appetite	2 (18.2)	-
Fatigue	2 (18.2)	-
Pruritus	2 (18.2)	-
Back pain	1 (9.1)	-
Constipation	1 (9.1)	-
Dehydration	1 (9.1)	1 (9.1)
Diarrhea	1 (9.1)	-
Dizziness	1 (9.1)	-
Electrocardiogram QT prolonged	1 (9.1)	1 (9.1)
Erythema	1 (9.1)	-
Headache	1 (9.1)	-
Injection site pain	1 (9.1)	-
Nausea	1 (9.1)	-
Non-cardiac chest pain	1 (9.1)	-
Urine output decreased	1 (9.1)	-
Weight decreased	1 (9.1)	-

- No DLTs and mostly Grade 1-2 unrelated adverse events (AE).

Contact Information:
Marie-Louise Fjaellskog (Medical Monitor):
mfjaellskog@sensebio.com
Cell: +1 617 959 7208

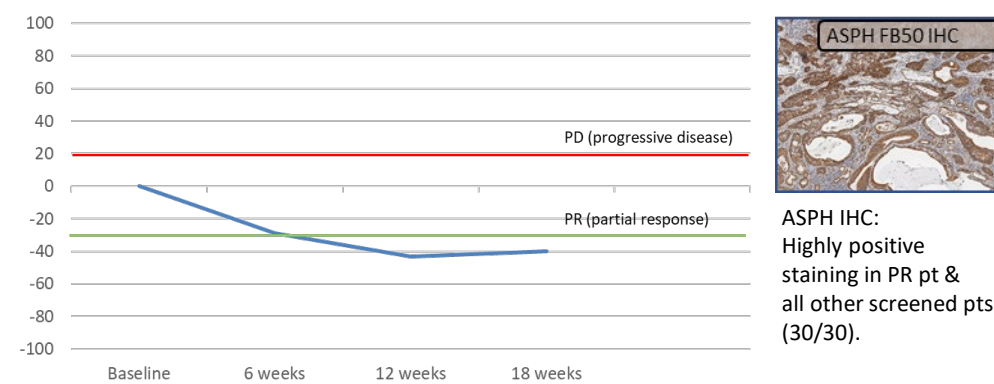
RESULTS – SNS-301 + PEMBROLIZUMAB

SNS-301 Increased Immune Cell Counts in PR Patient

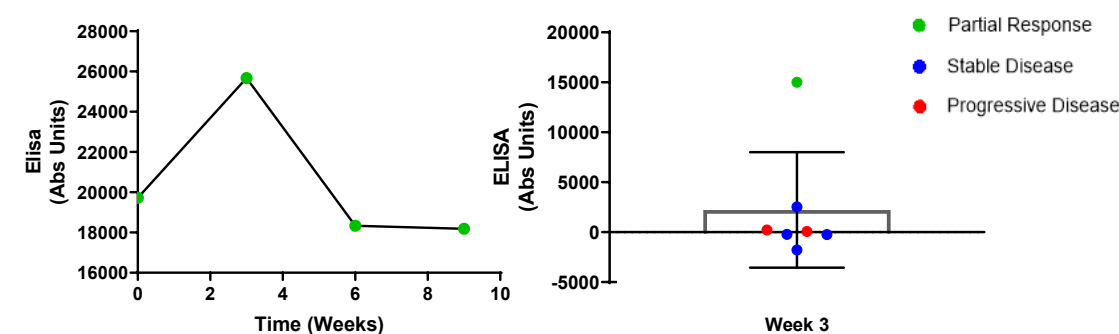


Confirmed PR (-43%) Achieved in Patient with PD-L1^{NEG} Tumor

- 69 yo woman diagnosed with HPV^{NEG} and PD-L1^{NEG} T2N0M0 laryngeal cancer May 2019.
- Cancer therapy: IMRT (2-54 Gy) and carboplatin/paclitaxel (PR).
- At study entry treated with pembrolizumab for > 3 months (SD).

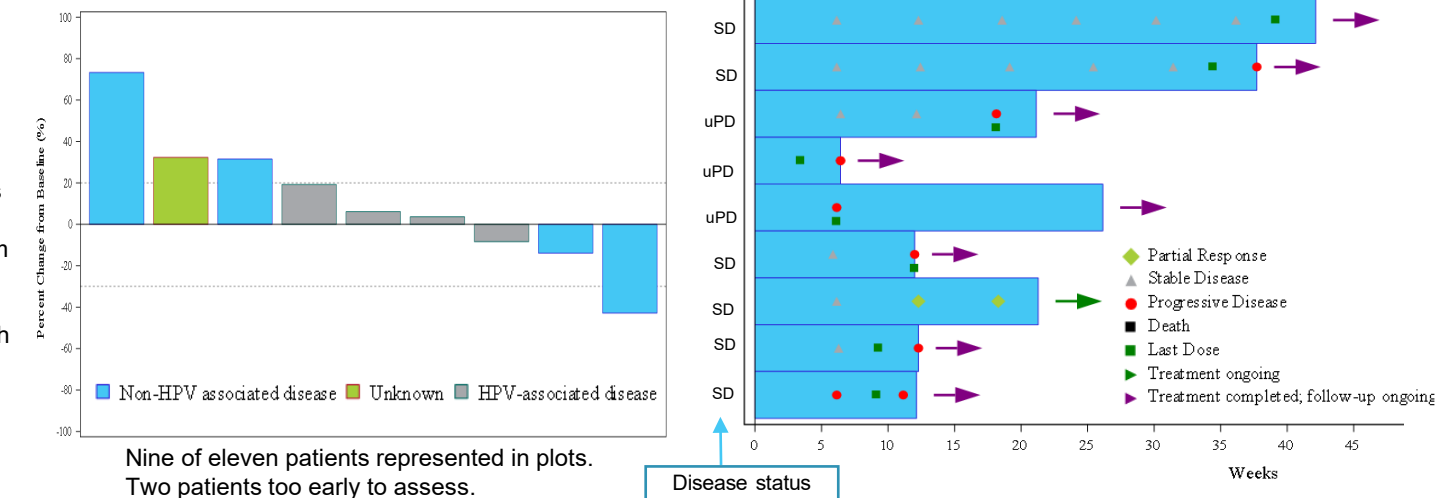


Enhanced Serological Response to SNS-301 in Patient with PR

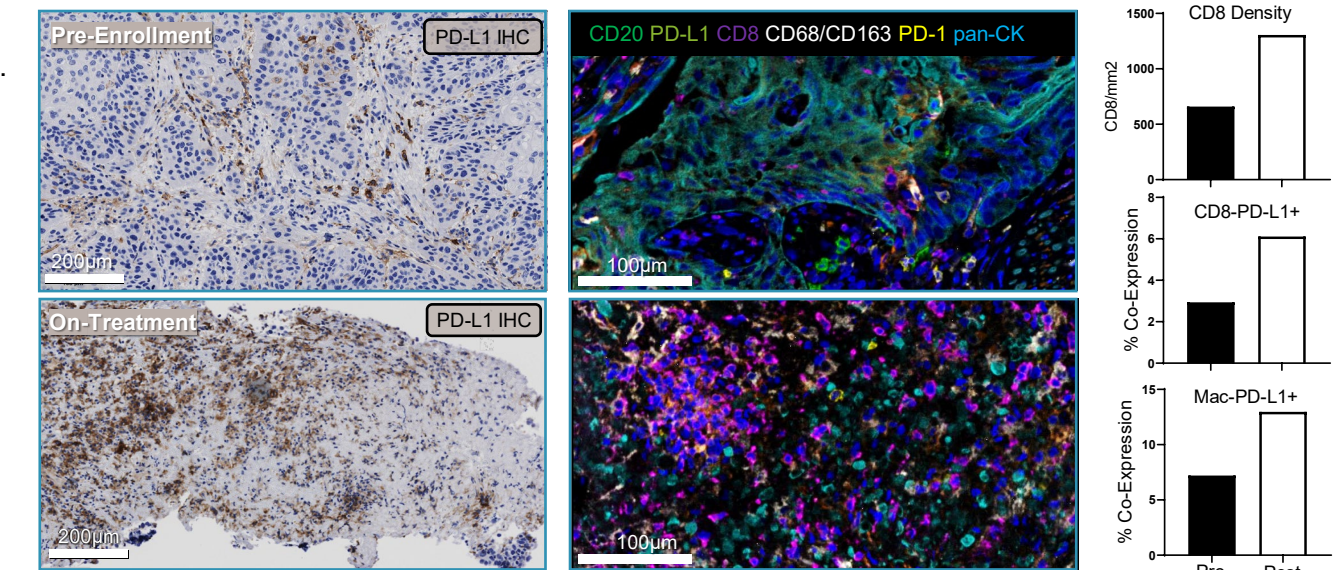


Patient with PR experienced increased SNS-301 response at week 3 (left) which returned to baseline by week 6. PR demonstrated an increased SNS-301 response (normalized as change from parental phage response) at week 3 compared to patients with SD or PD.

Encouraging Clinical Activity in Pts with SD or uPD on Prior PD-1 Blockade



SNS-301 Catalyzes PD-L1^{NEG} Immune Desert Tumor into Inflamed Phenotype



FFPE H&N samples from PR* were stained with anti-PD-L1 (left panels) and sequentially with a 6-component immuno-phenotyping panel (middle) with AE1/AE3, CD8, CD4, PD-1, PD-L1, and CD163 and DAPI as a nuclear counterstain. The number of CD8 T cells and PD-L1 associated T cells and macrophages increased in the treatment group (right).

CONCLUSIONS

- All screened patients stained highly positive for ASPH.
- The combination of SNS-301 and pembrolizumab was well tolerated.
- Encouraging clinical activity was observed with PR in a pt with PD-L1^{NEG} tumor, SD in a pt with uPD at study entry and long-lasting (> 6 month) SD in 2 pts.
- Nanostring™ data was concordant with clinical effect.
- Pt with PR showed an elevated response to SNS-301 phage in serum.
- Translational data suggest cellular and humoral responses to SNS-301, including conversion from poorly to highly inflamed tumor in pt with PR.

