Sensei Biotherapeutics Reports Early Data from Phase 1/2 Clinical Trial of SNS-301 in Combination with Pembrolizumab in Advanced Head and Neck Cancer Patients at ESMO 2020

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SNS-301 demonstrated early signals of anti-tumor activity correlated with immune response and tumor infiltration

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BOSTON & GAITHERSBURG, Md.--(BUSINESS WIRE)--Sensei Biotherapeutics, Inc., a clinical-stage biopharmaceutical company developing personalized yet off the shelf immunotherapies for cancer and infectious diseases, announced today results from the Phase 1/2 clinical trial evaluating the safety, efficacy, and immunogenicity of SNS-301, a first-in-class bio-engineered, inactivated bacteriophage, in patients with Locally Advanced Unresectable or Metastatic/Recurrent Squamous Cell Carcinoma of the Head and Neck (SCCHN). The data were presented in a poster discussion session at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

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Patients with SCCHN often present with immune desert or excluded tumors and only 13-16% of the patients respond to anti PD-1/PDL-1 therapy. Data from the KEYNOTE-012 clinical trial demonstrated that SCCHN patients receiving pembrolizumab alone as 2nd line treatment or later have an objective response rate of 18%, median overall survival of 8 months, and progression-free survival of 2 months. Only 6% of patients with PD-L1 negative disease achieve an objective response to pembrolizumab.

“The efficacy of anti-PD-1/PD-L1 is attributed to the presence of infiltrating antigen-specific CD8+ T-cells. Combining anti-PD-1/PD-L1 with agents that generate or expand anti-tumor T-cells, such as vaccines, is critical to increase overall survival of SCCHN patients,” said Marie-Louise Fjaellskog, M.D., Ph.D., Chief Medical Officer of Sensei Biotherapeutics. “To date, we have observed promising clinical activity that is correlated with immune response for SNS-301, including a partial response in a patient with PD-L1-negative disease. This initial data from 9 patients provides us with the rationale to continue exploring its safety and efficacy in 1st and 2nd line SCCHN patients.”

“We are excited by the emerging translational data for SNS-301, including - in a patient with a confirmed response - a clear conversion from a poorly inflamed tumor into an inflamed microenvironment, characterized by significant T cell infiltration, and upregulation of PD-L1,” said Robert Pierce, M.D., Chief Scientific Officer of Sensei Biotherapeutics. “Based on these early promising results, we plan to expand our Immunophage platform to include additional tumor associated antigens and to combine these into bespoke vaccine cocktails based on a patient tumor’s genetic profile.”

The ongoing multi-center Phase 1/2 clinical trial of SNS-301 in combination pembrolizumab is designed to assess the safety, efficacy and immunogenicity of SNS-301 in SCCHN patients that had received anti-PD1/PD-L1 therapy for at least 3 months prior to enrollment with stable disease or unconfirmed progressive disease as their best response upon entry into the study.

Highlights of the Safety, Efficacy and Immunogenicity Data as of July 23, 2020 include:

- SNS-301 in combination with pembrolizumab was well tolerated with a favorable safety profile. No dose-limiting toxicities were observed during the safety run-in, and reported adverse events were mostly of Grade 1-2 and considered unrelated to study treatment.
- Of the 9 patients evaluable as of the publication date, 6 remain on study. Of these:
  - One patient with PD-L1 negative disease and stable disease on pembrolizumab upon study entry was converted to a partial response with a tumor reduction of 43%.
  - One patient with progressive disease upon study entry was converted to stable disease.
  - Four patients with stable disease upon study entry remain stable, with 2 of these patients on study for 8 months or more.
- Immunohistochemical staining of paired pre- and on-treatment biopsies (12 weeks) from the responding patient’s tumor demonstrate a conversion from a PD-L1-negative, poorly inflamed phenotype into an inflamed, PD-L1-positive tumor, characterized by tumor necrosis, and abundant infiltrating immune cells, including CD4, CD8 T cells and macrophages. This patient also demonstrated a significant serological response to SNS-301.
- All 29 patients screened for the study were highly positive for the ASPH.

Based on these data, Sensei plans to enroll all 30 patients for this study. An additional study in neoadjuvant SCCHN patients is planned to begin early next year in combination with Imfimzi® (durvalumab).

About SNS-301

SNS-301 is a first-in-class cancer immunotherapy designed to overcome immune tolerance and induce robust and durable antigen-specific humoral and cellular responses. It is a bio-engineered, inactivated bacteriophage virus expressing a fusion protein of native bacteriophage GPD

(Glyceraldehyde-3-phosphate dehydrogenase) protein and a selected domain of aspartate β-hydroxylase (ASPH). Expression of ASPH is uniquely upregulated in more than 20 different types of cancer and expression levels in various tumors are generally inversely correlated with disease prognosis ASPH signaling is related to cancer cell growth, cell motility and invasiveness, occurs through the Notch pathway, and is implicated in the epithelial to mesenchymal transition (EMT).

About Sensei Biotherapeutics

Sensei Biotherapeutics is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of precision immunotherapies. The company has developed a unique phage-based platform, *ImmunoPhage*™, that enables the generation of immune activating agents that fully engage the immune system. Its most advanced program, SNS-301, is currently enrolling patients in Phase 2 clinical trials. The company brings together scientific leaders in biology, immunology, and oncology along with a highly experienced management team and scientific advisors. For more information, please visit www.senseibio.com.

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