



## **Sensei Biotherapeutics Reports Results from Phase 1 Clinical Trial of SNS-301, a First-in-class Cancer Immunotherapy Targeting ASPH, a Novel Tumor-specific Antigen**

*SNS-301 demonstrated a favorable safety profile, improvements in disease parameters, and robust antigen-specific immune responses*

*Clinical results presented in Poster Discussion session at ESMO 2018*

*Company to initiate Phase 2 study of SNS-301 in multiple solid tumor indications and hematological malignancies in early 2019*

**GAITHERSBURG, MD – October 19, 2018** – [Sensei Biotherapeutics, Inc.](#), a clinical-stage biopharmaceutical company developing precision immuno-oncology therapies, announced today the results of the Phase 1 clinical trial evaluating the safety and immunogenicity of SNS-301 in patients with biochemically recurrent prostate cancer (BRPC). Patients in the clinical trial were antigen-positive for human aspartate  $\beta$ -hydroxylase (ASPH), a novel tumor-specific embryonic antigen, and selected using Sensei's proprietary companion diagnostic. SNS-301, a first-in-class immunotherapy candidate targeting ASPH, is the lead clinical candidate in Sensei's pipeline of innovative cancer immunotherapies [created using Sensei's SPIRIT platform](#). Results from the Phase 1 study of SNS-301 will be presented at a Poster Discussion session at the European Society for Medical Oncology (ESMO) 2018 Congress, taking place October 19-23, 2018, in Munich, Germany.

"The principal outcomes from this study further energize our strategy of pursuing next-generation targets, such as ASPH, combined with visionary bioengineering and precision medicine," said [John Celebi](#), President and Chief Executive Officer of Sensei Biotherapeutics. "Based on these positive results, we plan to initiate a Phase 2 trial for SNS-301 in various hematological malignancies and solid tumors in early 2019. We also plan to accelerate the development of our cell therapy programs targeting ASPH and other novel tumor-specific antigens."

"SNS-301's strong anti-tumor immune activity was shown through increases in both ASPH-specific CD8<sup>+</sup> T-cells and ASPH-specific B-cell responses," said [Ildiko Csiki](#), M.D., Ph.D., Chief Medical Officer of Sensei Biotherapeutics. "Based on these compelling early data showing anti-tumor immune response, coupled with a favorable safety profile, we believe SNS-301 has the potential to benefit patients with ASPH-expressing tumors. In a Phase 2 setting, we plan to focus on head and neck cancer, myelodysplastic syndrome, and additional solid tumor indications."

In the multi-center Phase 1 clinical trial, SNS-301 was administered every 21 days via intradermal injection to BRPC patients using a fixed dose-escalation schema to establish the recommended Phase 2 dose. The clinical trial enrolled 12 patients who were confirmed to express ASPH using Sensei's proprietary serum-based companion diagnostic test. Patients received between 8 to 23 doses of SNS-301 (with an average of 10 doses per patient) at the three different doses in the study, with the cohort of low-dose patients progressing through to the high dose, and the cohort of mid-dose patients escalating successfully to the high dose.

Data from the Phase 1 trial demonstrated a favorable safety profile, improvements in disease-related parameters, and ASPH-specific immune responses. Highlights of the safety and immunogenicity data presented at ESMO include:

- At all three dose levels in the Phase 1 trial ( $2 \times 10^{10}$ ,  $1 \times 10^{11}$ ,  $3 \times 10^{11}$  particles), SNS-301 was well tolerated with a favorable safety profile. No dose-limiting toxicities or grade 4-5 adverse events were observed in the trial.
- Eight out of the 12 patients (67%) achieved improvements in PSA doubling time and/or absolute PSA level, leading to decreased PSA velocity and suggesting a disease stabilizing effect of SNS-301.
- An average 8-to-10-fold increase in the percentage of ASPH-specific CD8<sup>+</sup> T-cells was observed post-treatment, compared to baseline measurements. Peak antigen-specific T-cell levels were observed between 43 and 85 days from initial treatment. All seven patients that were evaluable for immune responses showed increases in ASPH-specific T-cells.
- An average 5-to-7-fold increase in the percentage of ASPH-specific B-cell responses was observed post-treatment, compared to baseline measurements. Peak antigen-specific B-cell levels were observed between 64 and 106 days from initial treatment. All 12 patients enrolled had increases in ASPH-specific B-cells.
- A strong corresponding increase in anti-ASPH antibody titers across patients correlated with B-cell response and a subsequent reduction in serum-based ASPH was observed.
- The recommended Phase 2 dose was identified as the mid-dose ( $1 \times 10^{11}$  particles) in the Phase 1 trial based on immunogenicity and PSA results of the three evaluated doses.

Sensei's planned Phase 2 program will evaluate SNS-301 as monotherapy in hematological malignancies and as combination therapy with checkpoint inhibitors in multiple solid tumors, with clinical trials to be initiated in 2019.

### **About SNS-301**

SNS-301 is a first-in-class cancer immunotherapy targeting human aspartate  $\beta$ -hydroxylase (ASPH), a cell surface enzyme that is normally expressed during embryonic development. Following embryonic development, the protein is no longer expressed in healthy adults. Expression of ASPH is uniquely upregulated in more than 20 different types of cancer and is related to cancer cell growth, cell motility and invasiveness. ASPH signaling occurs through the Notch pathway and expression levels in various tumors are inversely correlated with disease prognosis. SNS-301 is a bio-engineered, inactivated bacteriophage virus expressing a fusion protein of native bacteriophage gpD (gene product D) protein and a selected domain of ASPH. SNS-301 is designed to overcome immune tolerance and induce robust and durable ASPH-specific humoral and cellular responses. SNS-301 is paired with a companion diagnostic to ensure appropriate patient selection and is delivered easily through an intradermal injection to aid in generating robust immune response.

### **About Sensei Biotherapeutics**

[Sensei Biotherapeutics](#) is a clinical-stage biopharmaceutical company developing precision immuno-oncology therapies to transform the cancer treatment landscape. The company is using its [proprietary drug discovery platform, called SPIRIT](#), to discover and develop both vaccines

and T-cell therapies, including SNS-301, its clinical stage cancer vaccine for the treatment of head and neck cancer and myelodysplastic syndrome, as well as other solid tumors and hematological cancers. SNS-301 targets a novel embryonic antigen and has successfully completed a Phase 1 clinical study. Sensei's precision medicine approach in immuno-oncology includes the use of companion diagnostics to select patients who are most likely to respond to its tumor-specific antigen therapies. Sensei Biotherapeutics is located in Gaithersburg, MD. For more information, please visit [www.senseibio.com](http://www.senseibio.com).

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