



## **Sensei Biotherapeutics Presents Clinical Trial Data Demonstrating SNS-301 Induces Rapid and Robust Antigen-specific Immune Responses at the Society for Immunotherapy of Cancer's 33<sup>rd</sup> Annual Meeting**

*Dose-dependent, ASPH-specific immune responses observed*

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

**GAITHERSBURG, MD – November 6, 2018** – Sensei Biotherapeutics, Inc., a clinical-stage biopharmaceutical company developing precision immuno-oncology therapies, announced today that clinical and immunological data from the Phase 1 clinical trial of SNS-301 will be highlighted in a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 33<sup>rd</sup> Annual Meeting, to be held November 9-11, 2018 in Washington, D.C. Data showed rapid and significant antigen-specific B-cell and T-cell responses induced by SNS-301, a first-in-class cancer immunotherapy targeting human aspartate  $\beta$ -hydroxylase (ASPH), a novel tumor-specific embryonic antigen.

"These data clinically confirm the immunogenicity and mechanism of action of SNS-301, as we see strong, ASPH-targeted activation of the immune system in patients who received the immunotherapy. Taken together, the data indicate that SNS-301 is capable of overcoming central immune tolerance. We plan to target ASPH with both cancer vaccines and cell therapies to benefit different patient populations," said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. "Based on these encouraging results, we look forward to initiating a Phase 2 trial for SNS-301 in various hematological malignancies and solid tumors in early 2019."

Twelve patients with biochemically recurrent prostate cancer who were screened for ASPH using Sensei's proprietary companion diagnostic were treated with SNS-301 in the Phase 1, multi-center, proof-of-concept study. SNS-301 was administered every 21 days via intradermal injection using a fixed dose-escalation schema through which patients received between 8 and 23 doses at three different dose ranges, and the recommended Phase 2 dose was determined based on the immunogenicity data and changes seen in prostate specific antigen (PSA) doubling times at the three evaluated doses. Highlights of the immunogenicity data from the SNS-301 Phase 1 study presented at SITC include:

- Natural Killer (NK) cell levels in patients treated with SNS-301 were higher than NK cell levels in healthy donors, indicating activation of the innate immune system.
- All patients evaluable for immune profiling experienced dose-dependent, ASPH-specific immune responses including B-cell, T-cell and antibody responses.
- Increases in activated interferon gamma (IFN- $\gamma$ ) releasing T cells were demonstrated, and both ASPH-specific CD4<sup>+</sup> helper T cells and CD8<sup>+</sup> cytotoxic T cells showed dose-dependent activation over the first six cycles of SNS-301 dosing with peak responses often occurring after only three or four doses.
  - An average of eight to ten-fold increase in the percentage of ASPH-specific CD8<sup>+</sup> T cells was observed post-treatment, compared to baseline measurements.



- Anti-ASPH antibody titers increased in a dose-dependent manner over the first four to six cycles (80-120 days) after administration of SNS-301. This increase in antibody response correlated with concomitant increases in the percentages of ASPH-specific B cells, as measured by flow cytometry.
  - An average five to seven-fold increase in the percentage of ASPH-specific B-cell responses was observed post-treatment, compared to baseline measurements.
- Eight out of the twelve 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 SNS301.
- Based on evaluation of the three different dose ranges ( $2 \times 10^{10}$ ,  $1 \times 10^{11}$ ,  $3 \times 10^{11}$  particles), immune responses occurred more rapidly at the two higher doses, as compared to the lower dose. Immunologic efficacy generally correlated with biochemical responses in these patients.

In the Phase 1 study, SNS301 was well tolerated with a favorable safety profile at all three dose levels with no dose-limiting toxicities or grade 4 or 5 adverse events.

### **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 alters signaling that occurs through the Notch pathway and its 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) 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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