Sensei Biotherapeutics Reports New Data from Phase 1 Clinical Trial of SNS-301

June 5, 2018

SNS-301 demonstrated a strong safety profile and promising immune responses in patients with biochemically recurrent prostate cancer

SNS-301 is a first-in-class immunotherapy candidate emerging from Sensei's SPIRIT platform that targets a novel embryonic antigen found on more than 20 types of cancers

GAITHERSBURG, Md.--(BUSINESS WIRE)--Sensei Biotherapeutics, Inc., a privately-held biopharmaceutical company developing immuno-oncology therapies that teach the immune system to recognize and attack cancer, announced today the publication of data from the company's multi-center Phase 1 clinical trial to assess safety and immunogenicity of SNS-301 (formerly PAN-301) in patients with biochemically recurrent prostate cancer. Data were published in conjunction with the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

> Sensei announced publication of data from its phase 1 clinical trial of SNS-301 in patients with persistent prostate cancer in conjunction with #ASCO2018.
>
> Tweet this

SNS-301 is a first-in-class immunotherapy candidate utilizing a bacteriophage viral vector targeting a novel embryonic antigen called human aspartate β-hydroxylase (ASPH). In adults, ASPH is only expressed on the surface of cancer cells and has been detected in more than 20 different types of cancer. SNS-301 was created using Sensei's SPIRIT platform to optimize for antigen presentation and vaccine immunogenicity.

In the Phase 1 trial, SNS-301 was administered every 21 days via intradermal injection to men with biochemically relapsed prostate cancer, using a fixed dose-escalation schema to establish the recommended Phase 2 dose. A minimum of three doses of SNS-301 were administered to each patient. Fifteen patients who met all other inclusion and exclusion criteria were screened for ASPH expression using a serum-based companion diagnostic test, and 12 of the 15 patients presented the minimum threshold for ASPH expression. These patients received as many as 18 doses of SNS-301 (mean = 10 doses per patient), including a minimum of 3 treatments at the high dose, over the 15-month duration of the study. Highlights of the safety and immunogenicity data published at ASCO include:

- SNS-301 was well tolerated with a favorable safety profile across all dose levels in the Phase 1 study.
- No dose-limiting toxicities were observed at the three dose levels evaluated in the trial.
- All patients in the study experienced dose-dependent, ASPH-specific humoral and cellular immune responses, including ASPH-specific B-cell and T-cell responses.
- 75% (6/8) of evaluable patients achieved improvements in Prostate-Specific Antigen (PSA) doubling time and/or absolute PSA. Improvements in PSA doubling rate are an indicative measure of slowing disease progression.

"We are extremely encouraged by these clinical results from our Phase 1 study of SNS-301 which validate the potential of our proprietary SPIRIT drug development platform to generate novel immuno-oncology therapies," said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. "SNS-301 exemplifies Sensei Biotherapeutics' ability to engineer promising therapeutic candidates designed to teach the immune system to recognize and attack cancer."

This Phase 1 study of SNS-301 was initiated in January 2017 and enrollment of 12 patients was completed in February 2018. SNS-301 is the lead clinical candidate from Sensei Biotherapeutics' proprietary SPIRIT drug development platform. Final results will be presented at a medical meeting in the second half of 2018 and initial enrollment in a Phase 2 efficacy trial is anticipated by the end of the year.

About SNS-301

SNS-301 is a first-in-class immunotherapy candidate utilizing a bacteriophage viral vector that targets human aspartate β-hydroxylase (ASPH), a cell surface enzyme that is normally expressed during fetal development. Following fetal development, the protein is no longer expressed. 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 expression levels are inversely correlated with disease prognosis.

Though enhanced antigen presentation and other engineered immunotherapeutic features, SNS-301 is designed to overcome self-tolerance and induce robust and durable humoral and cellular immune responses that are specific to ASPH. SNS-301 is delivered through intradermal injection and avoids time-consuming and uncomfortable infusions, greatly facilitating ease of use.

About Sensei Biotherapeutics

Sensei Biotherapeutics is a privately-held biopharmaceutical company developing immuno-oncology therapies that stimulate the immune system to 'teach' it to recognize cancer-specific antigens and attack cancer cells. The company's patented and proprietary drug development platform, called SPIRIT, creates novel therapies that target neoantigens or altered self-antigens – which are antigens encoded by tumor-specific mutated genes – and are designed to overcome self- tolerance by eliciting a potent cellular and humoral immune response to eliminate cancer cells. Sensei's precision medicine approach in immuno-oncology includes novel therapies along with companion diagnostics. The company's lead drug candidate, SNS-301, is a first-in-class cancer immunotherapy candidate that targets a novel embryonic antigen and has successfully completed a Phase 1 clinical study. Sensei Biotherapeutics is located in Gaithersburg, MD. For more information, please visit www.senseibio.com.

Contacts

The Yates Network
Kathryn Morris, 914-204-6412
kathryn@theyatesnetwork.com