Sensei Biotherapeutics Reports Favorable Clinical Data for SNS-101 at 2023 SITC Annual Meeting

November 3, 2023

- Clinical dose escalation data for SNS-101 monotherapy show well tolerated safety profile, potentially best-in-class pharmacokinetics, and encouraging cytokine release profile across multiple dose cohorts -

- First VISTA-blocking antibody administered at a dose anticipated to be therapeutically relevant without eliciting dose-limiting toxicity -

- Monotherapy data from Phase 1/2 study to be presented in a late-breaking poster presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting -

BOSTON, Nov. 03, 2023 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients, today reported initial data from the monotherapy dose-escalation portion of its Phase 1/2 clinical trial for SNS-101, a conditionally active, human monoclonal antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation). The data, to be presented in a late-breaker poster presentation at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting, suggest a potential best-in-class safety and pharmacokinetic profile among VISTA blocking antibodies and the potential to overcome long-standing pharmacological challenges encountered by first generation approaches to blocking VISTA.

“We are pleased to report favorable clinical data for SNS-101, a pioneering VISTA-blocking antibody that provides validation of our conditionally active approach. The data support that this highly innovative antibody is well tolerated across dose levels tested to date, shows linear, dose-dependent pharmacokinetics predicted preclinically to elicit immune-mediated anti-tumor activity, and a cytokine profile consistent with an absence of cytokine release syndrome,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “Data from this clinical study to date provides important initial evidence that SNS-101 can provide clinically meaningful and mechanistic differentiation from first generation anti-VISTA approaches, as indicated by SNS-101 dose levels that are at least 10 times higher than the first clinical study of a competitor VISTA antibody that was prematurely halted due to cytokine release syndrome and poor pharmacokinetics. We believe this represents a foundational clinical achievement in the pursuit of a transformational VISTA-blocking antibody, and we look forward to building on this success with additional data readouts, including efficacy analysis, expected next year.”

The multi-center Phase 1/2 clinical trial is a dose escalation study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of SNS-101 as both a monotherapy and in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced solid tumors.

Summary of reported data (as of the October 3, 2023 cutoff date):

- A total of 13 patients were enrolled in the study.
  - In the monotherapy dose escalation arm, ten patients were enrolled across four dosing cohorts receiving SNS-101 treatment at 0.3, 1, 3, or 10 mg/kg.
  - In the combination arm, three patients were enrolled at the first dose level of 3.0 mg/kg of SNS-101 plus 350 mg of Libtayo® (cemiplimab).
- Safety, cytokine expression and pharmacokinetic data were presented for seven patients from the first three monotherapy cohorts, all of which have cleared the dose-limiting toxicity assessment period.
  - A total of 11 adverse events (including one serious adverse event not considered related to SNS-101) was reported in five patients, with no dose-limiting toxicities observed. Only one adverse event (Grade 2 dermatitis acneiform) was considered related to SNS-101.
  - There were no instances of cytokine release syndrome and no significant changes in key inflammatory cytokines over time, consistent with preclinical studies.
  - Pharmacokinetic data demonstrate dose-proportional exposure consistent with lack of target mediated drug disposition, no notable accumulation with repeat dosing, and linear elimination kinetics of SNS-101, in concordance with preclinical data.

“Too many patients remain underserved by existing immunotherapies. SNS-101 highlights the potential of targeting VISTA through an innovative concept, thoughtful approach and a well-executed study as Sensei has done,” said Shiraj Sen, M.D., Ph.D., a medical oncologist at NEXT Oncology and investigator on the Phase 1/2 SNS-101 clinical trial. “I’m encouraged by the patient experience so far in the SNS-101 trial, including a potentially

best-in-class safety profile and an every-three-week dosing schedule that helps alleviate the logistical burden imposed on patients by agents requiring more frequent administration due to their unfavorable PK profiles."

Sensei expects to report initial safety and pharmacokinetic combination data in Q1 2024, with topline monotherapy data in Q2 2024, and topline combination data in 2024.

Presentation at SITC:

Title: A phase 1/2 study of safety, tolerability and pharmacokinetics of SNS-101, a pH-sensitive anti-VISTA mAb, as monotherapy and in combination with cemiplimab in patients with advanced solid tumors
Presentation type: Poster (late breaking abstract)
Abstract Number: 1532
Date and time: Saturday, November 4, 2023, at 9 a.m. PT – 8:30 p.m. PT
Location: Exhibit Halls A and B1 – San Diego Convention Center
Lead authors: Shiraj Sen, M.D., Ph.D. and F. Donelson Smith, Ph.D.

A copy of the presentation materials will be added to the "Events & Presentations" section of the Company's Investor Relations website at www.senseibio.com.

About Sensei Biotherapeutics:
Sensei Biotherapeutics (Nasdaq: SNSE) is a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients. Through its TMAb™ (Tumor Microenvironment Activated biologics) platform, Sensei develops conditionally active therapeutics designed to disable immunosuppressive signals or activate immunostimulatory signals selectively in the tumor microenvironment to unleash T cells against tumors. Sensei's lead investigational candidate is SNS-101, a conditionally active antibody designed to block the V-domain Ig suppressor of T cell activation (VISTA) checkpoint selectively within the low pH tumor microenvironment, where VISTA acts as a suppressor of T cells by binding the receptor PSGL-1. The company is also developing SNS-102, a conditional binding monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSIG-4), as well as SNS-103, also a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39. For more information, please visit www.senseibio.com, and follow the company on Twitter @SenseiBio and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "believe", "designed to," "expect", "may", "plan", "potential", "will", and similar expressions, and are based on Sensei's current beliefs and expectations. These forward-looking statements include expectations regarding the development and potential therapeutic benefits of Sensei's product candidates, as well as the timing of Sensei's Phase 1/2 clinical trial of SNS-101, including reporting of data therefrom. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the development of therapeutic product candidates, such as the risk that any one or more of Sensei's product candidates will not be successfully developed or commercialized; the risk of delay or cessation of any planned clinical trials of Sensei's product candidates; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Sensei's product candidates; the risk that Sensei's product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that we anticipate; risks associated with Sensei's dependence on third-party suppliers and manufacturers, including sole source suppliers, over which we may not always have full control; risks regarding the accuracy of our estimates of expenses, capital requirements and needs for additional financing; and other risks and uncertainties that are described in Sensei's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on or about August 3, 2023 and Sensei's other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Sensei as of the date of this release, and Sensei assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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