



# sensei<sup>TM</sup> BIO

## Sensei Biotherapeutics Provides Corporate Update and Highlights Key Upcoming Milestones

January 4, 2024

*- Completed SNS-101 monotherapy dose escalation through 15 mg/kg with no dose limiting toxicities -*

*- Expands patient cohort in specific tumor types -*

*- Multiple clinical milestones expected in 2024 -*

*- Strong balance sheet with cash runway extended into the fourth quarter of 2025 -*

BOSTON, Jan. 04, 2024 (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 provided corporate updates on its research and development programs and upcoming milestones.

"In 2023, we significantly advanced our lead clinical asset while prudently maintaining our strong balance sheet," said John Celebi, President and Chief Executive Officer. "We believe SNS-101, which has demonstrated potentially best-in-class pharmacokinetics and tolerability at clinical doses far beyond other VISTA-targeted immunotherapies, has strong potential as a transformative option in multiple cancer indications. Given the favorable data thus far, we are expanding the SNS-101 Phase 1/2 clinical trial to include additional patients in a more focused set of indications as an intermediate stage to further optimize the Phase 2 study design with additional patient data while we prepare for an anticipated end of Phase 1 meeting with FDA by Q4 2024. As a result, we are dedicating additional resources to support this expanded clinical program while pausing the IND-enabling studies originally planned for our next TMAb product candidate. We expect these adjustments to extend our cash runway into the fourth quarter of 2025."

### Highlights and Milestones

#### SNS-101

SNS-101 is a conditionally active antibody harnessing the acidic tumor microenvironment to target the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation). VISTA is implicated in numerous cancer indications and its expression correlates with low survival rates. Sensei is conducting a multi-center Phase 1/2 clinical trial 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. Recent updates include:

- As of January 2, 2024:
  - A total of 25 patients have been treated with SNS-101 across various dose levels, with 16 patients in the monotherapy arm and nine patients in the combination arm. There have been no dose limiting toxicities (DLT) observed across both the monotherapy arm and the combination arm.
  - In the monotherapy dose escalation arm, patients have cleared all planned dosing cohorts of 0.3, 1, 3, 10 and 15 mg/kg.
  - In the combination dose escalation arm, six patients have been enrolled in the first cohort and have cleared the DLT period at a dose level of 3.0 mg/kg SNS-101 + Libtayo. The second cohort at a dose level of 10.0 mg/kg SNS-101 + Libtayo has been enrolled and is pending clearance of the DLT period as determined by the study safety monitoring committee.
- Following completion of dose escalation and prior to initiating the Phase 2 portion, the Company plans to enroll up to 40 additional patients in both monotherapy and in combination with Libtayo in specific tumor types to further optimize the design of the Phase 2 trial.
  - In the monotherapy dose expansion arm, Sensei plans to enroll up to 10 patients with microsatellite stable (MSS) colorectal cancer (CRC) at a dose level of 15 mg/kg.
  - In the combination dose expansion arm, Sensei plans to enroll up to 30 patients with MSS CRC, head and neck cancer (H&N), non-small cell lung cancer (NSCLC), and melanoma. The dose level will be determined following completion of the combination dose escalation phase of the study.
  - The solid tumor types were selected to focus the cancer indications on a basket of more commonly occurring histologies, including both "hot" (NSCLC, H&N, Melanoma) and "cold" (CRC) tumors where we believe SNS-101

has potential to provide clinical benefit based on VISTA biology and supporting preclinical data. All patients with “hot” tumors enrolling into the expansion arm are expected to have been previously treated with a PD1/L1 checkpoint inhibitor. Additional tumor types and doses may be considered for both the monotherapy and combination expansion arms.

- Sensei expects to open enrollment in the monotherapy expansion arm later this month. The combination expansion arm will begin following completion of the combination dose escalation phase of this study.

Anticipated milestones for the SNS-101 Phase 1/2 clinical trial include:

- Initial safety and pharmacokinetic data for the combination dose escalation arm of SNS-101 and Libtayo in Q1 2024
- Topline data for the SNS-101 monotherapy dose escalation arm in Q2 2024
- Topline data for the combination dose escalation arm of SNS-101 and Libtayo in Q3 2024
- Initial data for the SNS-101 dose expansion cohorts by the end of 2024

#### Additional Corporate Updates

- Sensei announces that Ron Weitzman, M.D., F.A.C.P., has joined Sensei as part-time Chief Medical Officer. Dr. Weitzman joined Sensei as a consultant in August 2022 and has been instrumental in the design and implementation of the ongoing Phase 1/2 clinical trial. Dr. Weitzman brings over 25 years experience leading oncology clinical studies ranging from early to late-stage clinical development, including a pivotal study for cabozantinib that led to its FDA approval. Dr. Weitzman has held leadership roles at various global biopharmaceutical companies, including Exelixis, Genentech and Novartis, and has served as a consulting CMO to various biotechnology companies for nearly a decade. Dr. Weitzman is board-certified by the American Board of Internal Medicine in Medical Oncology and is an active member of the American College of Physicians.
- Sensei has decided to realign its resources to fully support the Phase 1/2 clinical trial of SNS-101. As a result, Sensei will pause IND-enabling work on its preclinical-stage TMAb programs, including SNS-102 (VSI4), SNS-103 (CD39) and SNS-201 (VISTAxCD28). During this time, preclinical work to characterize selected lead antibodies, including their mechanisms of action, and target biology is expected to continue.
  - In 2023, Sensei selected lead candidates for both SNS-102 and SNS-201. SNS-102 is a conditionally active antibody targeting VSI4 that is 585-fold more selective for VSI4 at low pH conditions. SNS-201 is a bispecific antibody incorporating a CD28 agonist arm and a pH-sensitive anti-VISTA arm designed to conditionally activate CD28 under low pH conditions, such as those found in the tumor microenvironment, leading to T cell activation in the tumor while minimizing off-tumor toxicity.
- This realignment of resources is expected to extend cash runway into the fourth quarter of 2025.

#### **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. 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 conditionally active monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSI4); SNS-103, a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39; and SNS-201, a conditionally active VISTAxCD28 bispecific antibody consisting of a CD28 agonist arm and a pH-sensitive anti-VISTA arm. For more information, please visit [www.senseibio.com](http://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, the timing of Sensei's Phase 1/2 clinical trial of SNS-101, including reporting of data therefrom, the expansion of the Phase 1 clinical trial to include additional patients with specific tumor types, the expected timing of an end of Phase 1 meeting with the FDA for SNS-101, preclinical activities related to the Company's preclinical TMAb product candidates, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the fourth quarter of 2025. 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 and early results from the clinical trial of SNS-101, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Sensei's product candidates, including SNS-101; the risk that Sensei's product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that Sensei anticipates; risks associated with Sensei's dependence on third-party suppliers and manufacturers, including sole source suppliers, over which Sensei may not always have full control; risks regarding the accuracy of Sensei's 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 November 7, 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.

**Investor Contact:**

Michael Biega  
Senior Director, Investor Relations  
Sensei Biotherapeutics  
[mbiega@senseibio.com](mailto:mbiega@senseibio.com)

**Media Contact:**

Joyce Allaire  
LifeSci Advisors  
[Jallaire@lifesciadvisors.com](mailto:Jallaire@lifesciadvisors.com)