Sensei Biotherapeutics Provides Corporate Update and Highlights Key Upcoming Milestones

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- Solnerstotug (SNS-101) dose expansion arm anticipated to be fully enrolled by end of Q1 2025 -

- Clinical data update expected in Q2 2025 -

BOSTON, Jan. 08, 2025 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical stage biotechnology company focused on the discovery and development of next-generation therapeutics for cancer patients, today provided corporate updates on its lead program, solnerstotug (SNS-101) and upcoming milestones.

“2024 was a noteworthy year for Sensei and our pioneering lead program, solnerstotug. We demonstrated that solnerstotug can overcome the safety and pharmacological hurdles associated with first-generation antibodies targeting the immune checkpoint VISTA, positioning it as the first program in its class with potential to demonstrate clinically meaningful antitumor responses. Moreover, despite enrolling a predominantly ‘cold’ tumor patient population that was unlikely to respond to immunotherapy, solnerstotug demonstrated promising early signs of activity,” said John Celebi, President and Chief Executive Officer. “Looking ahead, 2025 is set to be a pivotal year as we seek to share our first significant efficacy data at optimal doses that include a ‘hot’ tumor patient population more likely to respond to immunotherapy that nonetheless has primary or acquired resistance to PD-1 inhibitors. With cash runway into the second quarter of 2026, we are positioned to advance solnerstotug through the completion of the Phase 1 portion of this study.”

Highlights and Milestones

Solnerstotug (SNS-101)

Solnerstotug is a conditionally active antibody designed to selectively target the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation) within the tumor microenvironment. 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 solnerstotug (SNS-101) as both a monotherapy and in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced solid tumors. Key findings and updates as of January 1, 2025 include:

- A total of 45 patients have been enrolled in the dose expansion portion of the Phase 1/2 clinical trial.
- The majority of the “hot” tumor patients enrolled in the combination dose expansion to date have progressed on a prior anti-PD-1 therapy or are PD-L1 negative, making it highly unlikely that these patients would respond upon re-challenge with anti-PD-1 alone.
- Sensei expects to complete enrollment of the dose expansion with approximately 60 patients by the end of Q1 2025.
- The Company expects to report data from evaluable patients in Q2 2025. Patient follow-up data from the dose escalation cohorts will also be presented.
- Solnerstotug continues to be well tolerated with a best-in-class pharmacokinetic profile.
- Dose optimization is now focused on dose levels of 3 and 15 mg/kg Q3W to support the Phase 2 doses in several patient populations under consideration.
- Efforts are ongoing to explore biomarker correlates of clinical benefit using peripheral immunophenotyping and tumor genomic and transcriptomic analyses.

About Sensei Biotherapeutics
Sensei Biotherapeutics (Nasdaq: SNSE) is a clinical stage biotechnology 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 product candidate is solnerstotug, 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. For more information, please visit www.senseibio.com, and follow the company on X @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 solnerstotug (SNS-101), including reporting of data therefrom, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations into the second quarter of 2026. 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 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 November 14, 2024 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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