Sensei Biotherapeutics Announces First Patient Dosed in Phase 1/2 Clinical Trial of SNS-101, a Conditionally Active VISTA-blocking Antibody, for the Treatment of Advanced Solid Tumors

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- Topline Phase 1 monotherapy and initial combination data expected in 2024 -

BOSTON, June 01, 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 announced that the first patient has been dosed in its Phase 1/2 clinical trial evaluating SNS-101 for the treatment of advanced solid tumors. SNS-101 is a conditionally active, human monoclonal IgG1 antibody, designed to selectively block the immune checkpoint VISTA in the tumor microenvironment, which acts as a suppressor of T cells by binding the receptor PSGL-1.

“Studying this novel, conditionally active antibody for treating patients with a variety of VISTA-positive solid tumors aligns with our research goals,” said James L. Gulley, M.D., Ph.D., Co-Director of the Center for Immuno-Oncology at the National Cancer Institute, part of the National Institutes of Health. NCI will be a Phase I site for the trial. “The Center for Cancer Research's Center for Immuno-Oncology at the NCI was recently established to explore fundamental questions of cancer immunotherapy through rigorous preclinical studies and translate these findings into clinical trials. The goal is developing novel therapies for a spectrum of cancers with high unmet medical needs.”

“This milestone is the latest in an exciting journey marked by careful study of VISTA’s role in tumor growth and rigorous experimentation by our research and development team,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “We’re excited to bring the promise of Sensei’s approach to VISTA inhibition into the clinical setting, where we believe SNS-101 will be the first drug candidate to effectively test the VISTA axis. We believe clinical validation of SNS-101 and the underlying approach would represent a tremendous advancement for the field and provide a potentially transformative treatment option for patients.”

The multi-center Phase 1/2 clinical trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of SNS-101 as both monotherapy and in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced solid tumors. Preclinical data showing SNS-101’s safety and tolerability profile and linear elimination kinetics support a starting dose of 0.3 mg/kg for the Phase 1 monotherapy dose escalation portion of the trial, substantially higher than other anti-VISTA antibodies. Sensei intends to begin the Phase 1 combination dose escalation portion of the trial, based on emerging clinical data from the monotherapy dose escalation. The Company expects to report topline monotherapy data and initial combination therapy data from Phase 1 in 2024. Once the recommended Phase 2 dose is determined in Phase 1, the Phase 2 cohort expansion portion of the study will begin in selected patient populations. For more information on the clinical trial, visit clinicaltrials.gov, identifier NCT05864144.

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 of Sensei’s product candidates and platforms; the potential safety profile of Sensei’s product candidates, including SNS-101; the potential benefits and efficacy of Sensei’s product candidates, including SNS-101; and the expected timing to report topline monotherapy data and initial combination therapy data in the clinical trial for SNS-101. 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 studies, including the preclinical studies of SNS-101, 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 May 9, 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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