Sensei Biotherapeutics Announces IND Clearance by U.S. FDA Enabling Phase 1 Initiation for SNS-101, a Conditionally Active VISTA-Blocking Antibody

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First patient dose in the Phase 1/2 clinical trial expected in mid-2023

BOSTON, April 20, 2023 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), an immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for SNS-101, a conditionally active VISTA-blocking antibody, paving the way for the Company to conduct a Phase 1/2 clinical trial in patients with solid tumors.

“Receiving IND clearance to advance our first conditionally active antibody into a Phase 1/2 clinical trial represents an important milestone for Sensei. We believe that SNS-101 has the potential to make a significant impact in the field and to improve the lives of cancer patients worldwide,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “We are delighted to bring SNS-101 into the clinic and explore its potential as a transformative treatment option for patients with solid tumors.”

The Phase 1/2 clinical trial is designed 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 solid-tumor cancer patients. The Phase 1 dose escalation portion of the clinical trial will be followed by an expansion Phase 2 in selected patient populations once a recommended Phase 2 dose is determined. SNS-101 will be administered as an intravenous infusion once every three weeks. Sensei expects to dose the first patient in mid-2023.

“Based on our preclinical data, we believe SNS-101 will be the first antibody to meaningfully explore the VISTA axis in the immuno-oncology space, with potential to achieve a higher therapeutic index and a more favorable tolerability profile than drugs limited by toxicity and poor pharmacokinetics,” said Edward van der Horst, Ph.D., Chief Scientific Officer of Sensei.

SNS-101 is a conditionally active, human monoclonal IgG1 antibody designed to selectively block the VISTA checkpoint in the tumor microenvironment, which acts as a suppressor of T cells by binding the receptor PSGL-1. Preclinical studies have demonstrated SNS-101’s potential to inhibit tumor growth as monotherapy, significantly enhance the anti-tumor effects of PD-1 blockade, avoid poor pharmacokinetics from target-mediated drug disposition and lower the risk of cytokine release syndrome.

About Sensei Biotherapeutics
Sensei Biotherapeutics (Nasdaq: SNSE) is an 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 timing of the first patient dosing in the planned 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, including the first patient dosing of SNS-101; 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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 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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