Sensei Biotherapeutics Announces Clinical Supply Agreement with Regeneron for Phase 1/2 Clinical Trial Evaluating SNS-101, a Conditionally Active VISTA-blocking Antibody, in Combination with Libtayo® (cemiplimab) in Solid Tumors

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BOSTON, Jan. 05, 2023 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), an immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer, today announced a clinical supply agreement with Regeneron for its anti-PD1 therapy Libtayo® (cemiplimab). The supply agreement supports the evaluation of SNS-101, a conditionally active VISTA-blocking antibody, in combination with Libtayo® in a Phase 1/2 trial in solid tumors. Sensei is on track to submit an Investigational New Drug application for SNS-101 in or before April 2023 and the trial is expected to commence in 2023 pending regulatory clearance.

“We are excited for the opportunity to work with Regeneron on our planned clinical trial of SNS-101, which has demonstrated strong anti-tumor activity in combination with PD-1 inhibition in preclinical studies. We look forward to exploring the potential of SNS-101 to inhibit tumor growth across a range of indications,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “We have built a robust preclinical data package supporting the biological rationale for our pH-sensitive approach, which we believe offers both safety and efficacy advantages over pH-independent VISTA antibodies, including the potential to avoid poor pharmacokinetics from target-mediated drug disposition and lower the risk of cytokine release syndrome.”

Under the terms of the agreement, Sensei will sponsor and fund the planned clinical trial and Regeneron will provide Libtayo®. Sensei will maintain global development and commercial rights to SNS-101. Regeneron develops and commercializes Libtayo® globally.

SNS-101 is currently under preclinical development, and the safety and efficacy of SNS-101 or its administration with Libtayo® have not been reviewed by any regulatory authorities.

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 checkpoints and other immunosuppressive 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 of Sensei’s product candidates, including SNS-101; the timing of an IND submission for SNS-101 to the FDA; the timing of commencement of the planned clinical trial for SNS-101; and the potential benefits of SNS-101 in combination with Libtayo®. 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 described in this press release, 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 Regeneron for the supply of Libtayo® and other 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 November 8, 2022 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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