Sensei Biotherapeutics Announces New Clinical Data from the Ongoing Phase 1/2 Combination Trial of SNS-301 in Patients with Squamous Cell Carcinoma of the Head and Neck

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– Data continue to show that SNS-301 in combination with pembrolizumab is well tolerated –

– One deep (71% tumor reduction) and durable (11 months) partial response and two longstanding (8 and 10 months) stable diseases observed in patients with no response to prior PD-1 blockade –

– Data show potential of company's proprietary ImmunoPhage™ platform to expand and improve current oncology treatments–

BOSTON, May 19, 2021 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, a clinical-stage immunotherapy company focused on the discovery and development of next generation therapeutics for cancer, today announced new data from the ongoing Phase 1/2 clinical trial of SNS-301, an investigational medicine in patients with advanced squamous cell carcinoma of the head and neck (SCCHN), in combination with pembrolizumab. The data will be presented as a poster by Alain Algazi, M.D., from the University of California San Francisco to the medical community at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place virtually June 4 – 8, 2021.

As of the April 14, 2021 cut-off date, 21 patients with locally advanced unresectable or metastatic SCCHN had been enrolled and treated in the study. Twenty of the patients enrolled did not achieve an objective response to prior treatment with PD-1 blockade (Cohort A) and one patient was PD-1 blockade naïve (Cohort B). The safety profile of SNS-301 in combination with pembrolizumab observed from 20 evaluable patients was favorable and consistent with previously reported data. Efficacy data was available from twelve patients in Cohort A. Notably, the efficacy bar was set high by enrolling patients with no objective response to prior PD-1 blockade (median 7.5 months). Data from nine evaluable patients from Cohort A were last reported from this study at the Society for Immunotherapy of Cancer's (SITC) 35 th Annual Meeting.

"These data suggest SNS-301, when combined with PD-1 blockade, has the potential to provide long-term benefit as second and later line treatment for patients with late-stage cancer and few other treatment options," said Marie-Louise Fjallskog, M.D., Ph.D., Chief Medical Officer of Sensei Biotherapeutics. "We expect to report more mature data, including data for SNS-301 combination therapy in the frontline setting, by the end of this year."

"This study continues to enhance our understanding of the broad potential of our ImmunoPhage™ platform," said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. "The information we are gathering is just one aspect of the potential of our ImmunoPhage platform to expand the durability and improve the treatment of many devastating cancers. Our team continues to lead advances in the understanding of bacteriophage through internal research and collaborations with world-class academic laboratories, and we are excited to apply these learnings to our pipeline of ImmunoPhage programs."

Data from Phase 1/2 Trial of SNS-301 SSCCHN As of April 14, 2021

Data highlighted today are part of a poster (#6029), titled: "Update on Safety and Efficacy of a Phase 1/2 Trial of SNS-301 and Pembrolizumab in Patients with Advanced Squamous Cell Carcinoma of the Head and Neck." The abstract and related poster can be downloaded from the ASCO Meeting Library.

Safety Data

As of the data cut-off, a safety analysis conducted in 20 evaluable patients showed that SNS-301 in combination with pembrolizumab continues to have a favorable safety profile.

- The combination of SNS-301 and pembrolizumab was well tolerated. Mostly Grade 1-2, mild to moderate, unrelated adverse events (AE) were observed. Four Grade 3 AEs were reported as treatment-related: dehydration, pruritus, rash and EKG QT prolongation.

Efficacy Data

An analysis of anti-tumor activity was conducted in 12 patients who did not achieve an objective response to prior treatment with PD-1 blockade (Cohort A). No patients were evaluable from Cohort B as of the cut-off date.

- 67% (n=8/12) of patients achieved stable disease (SD) or partial response (PR), including:
  - One patient with PD-L1 negative tumor who achieved a tumor reduction of 71% that is still ongoing after 11 months of therapy. Nanostring™ data for this patient show T-cell increase and T-cell activation.
  - Seven patients achieved SD, including two patients with long-standing SD (8 and 10 months).

Patient outcomes appear to correlate to post-treatment PD-L1 expression and immune infiltration in tumors.

Analyses of secondary endpoints using ELISA and ELISPOT assays to evaluate SNS-301 specific B and T cell responses in patient samples are ongoing. Sensei expects to report these data as part of the larger dataset planned by the end of 2021. Sensei also plans to add a third cohort by the end of 2021 to evaluate SNS-301 with HPV-specific E6/E7 ImmunoPhage.

About the Phase 1/2 Clinical Study

The multi-center Phase 1/2 clinical trial is designed to evaluate safety, tolerability, and anti-tumor activity of SNS-301 in combination with pembrolizumab, as well as immune response and tumor/immune biomarkers. The study has two cohorts with a total of 60 patients with locally advanced unresectable or metastatic squamous cell carcinoma of the head and neck (SCCHN) who did not achieve a response to prior treatment with PD-1 blockade (Cohort A) or patients who did not receive prior therapy with PD-1 blockade (Cohort B).

About ImmunoPhage™ Platform

Sensei's proprietary ImmunoPhage™ platform enables the delivery of innovative treatments that are personalized to a patient's own tumor specific antigens. Bacteriophages have built-in capabilities that utilize the inherent nature of viruses to elicit the innate and adaptive immune system, supporting a highly immunogenic approach. SNS-301 is a first-in-class and self-adjuvanted bacteriophage-base immune-activating vaccine targeting human aspartate β-hydroxylase (ASPH), a tumor-associated antigen commonly overexpressed in cancer.

About SNS-301

SNS-301 is a first-in-class cancer immunotherapy designed to overcome immune tolerance and induce robust and durable antigen-specific humoral and cellular responses. It is a bio-engineered, inactivated bacteriophage virus expressing a fragment of the tumor-associated antigen, ASPH, as a fusion protein to the bacteriophage lambda capsid decoration protein, gpD. Expression of ASPH is uniquely upregulated in more than 20 different types of cancer and expression levels in various tumors are generally inversely correlated with disease prognosis. ASPH signaling is related to cancer cell growth, cell motility and invasiveness, occurs through the Notch pathway and is implicated in the epithelial to mesenchymal transition (EMT).

About Sensei Biotherapeutics

Sensei Biotherapeutics is a clinical-stage biopharmaceutical company engaged in discovery, development, and delivery of next generation immunotherapies with an initial focus on treatments for cancer. Sensei has developed two unique approaches – its ImmunoPhage platform that leverages bacteriophage to fully engage the immune system, and its monoclonal antibody (mAb) and nanobody platform, which is comprised of unique human monoclonal antibodies and alpaca derived nanobodies that are selectively active in the tumor microenvironment. Using the ImmunoPhage platform, Sensei is developing a library of ImmunoPhage, called Phortress™, to target multiple tumor-associated antigens to create a personalized, yet off-the-shelf cocktail approach for treating cancer patients. The platform enables efficient, scalable and cost-effective manufacturing to support all of Sensei's clinical programs. The company's most advanced immunotherapy, SNS-301, a first-in-class ImmunoPhage targeting the tumor antigen Aspartyl beta Hydroxylase (ASPH), is currently in a Phase 1/2 clinical trial in patients with advanced squamous cell carcinoma of the head and neck. SNS-401 is an ImmunoPhage cocktail in preclinical development for the treatment of Merkel Cell Carcinoma. Using its mAb platform, the company has developed SNS-VISTA, an antibody-based therapeutic in lead generation targeting an immune checkpoint gene that inhibits anti-tumor immune responses called V-domain Ig suppressor of T cell activation (VISTA). 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 such as "believe", "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 clinical development of Sensei's product candidates, including SNS-301, the availability of data from Sensei's clinical trials and the potential benefits of Sensei's product candidates and proprietary ImmunoPhage platform. 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 conduct of clinical trials, Sensei's reliance on third parties over which it may not always have full control, 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 30, 2021 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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