NEWS RELEASE

SELLAS Life Sciences Provides Regulatory Update for Nelipepimut-S (NPS) for Triple Negative Breast Cancer (TNBC) Following FDA Feedback

2/14/2020

Regulatory clarity on registration-enabling Phase 3 study design of NPS in combination with trastuzumab in TNBC patients in the adjuvant setting enhances business development efforts

NEW YORK, Feb. 14, 2020 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today announced feedback from a Type C review with the U.S. Food and Drug Administration (FDA) regarding its clinical development program for nelipepimut-S (NPS) in patients with triple negative breast cancer (TNBC). Based on written feedback from the FDA and on the totality of clinical, safety and translational NPS data presented to date, the Company has finalized the design and plan for a Phase 3 registration-enabling study of NPS in combination with trastuzumab for the treatment of patients with TNBC in the adjuvant setting after standard treatment. If successful, this study may be considered as the basis for a Biologics License Application (BLA) submission to the FDA.

"We are indeed pleased with the feedback and final outcome from our discussions with the Agency, after extended interaction with them, on the optimal and mutually acceptable design of a potential registration-enabling Phase 3 clinical trial for NPS in combination with trastuzumab. Importantly, we believe we have established an appropriate and expedient pathway to potentially bring NPS in combination with trastuzumab to patients in need as quickly as possible," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We believe this regulatory clarity will enhance our business development efforts to seek out-licensing opportunities to fund and conduct the future clinical development of NPS in order to maximize the potential of the program as we continue to focus all of our resources on the development of our lead asset, galinpepimut-S, which recently entered a registrational Phase 3 study in acute myeloid leukemia."

The planned Phase 3 study will be a 1:1 randomized, blinded two-arm study to evaluate the efficacy and safety of the NPS vaccine (NPS plus granulocyte macrophage-colony stimulating factor (GM-CSF)) in combination with trastuzumab vs. GM-CSF alone as maintenance treatment in the adjuvant setting following standard-of-care therapy in patients with TNBC, defined as hormone receptor-negative, HER2 1+/2+ tumors (as assessed by immunohistochemistry tumors), at high risk of recurrence. The FDA indicated in its feedback that there is adequate safety information to support the use of NPS in combination with trastuzumab.

SELLAS previously reported the final efficacy and safety results from a Phase 2b study of NPS in combination with trastuzumab in TNBC patients (n=97). The disease-free survival (DFS) rate at 24 months was 92.6% for the combination arm vs. 70.2% for the trastuzumab alone arm, a clinically meaningful and statistically significant improvement in favor of the combination therapy (p=0.01). This was associated with a statistically significant reduction of 71.9% (p=0.01) in the frequency of clinically detected recurrences also in favor of the combination arm. Immune response analysis showed that non-recurrent TNBC patients mounted both vigorous NPS-specific clonal CD8+ cytotoxic T-lymphocyte expansion and enhanced in vivo post-antigen challenge cutaneous delayed type hypersensitivity. Most treatment-emergent adverse events were mild or moderate and consisted of manageable local injection site reactions, skin induration, pruritus, and fatigue.

“TNBC is an aggressive type of breast cancer with limited treatment options and poor prognosis, as it is associated with high levels of refractoriness and relapse not only in the metastatic setting, which is true for all types of breast cancer, but also at an early stage. Indeed, following standard frontline chemotherapy, TNBC can relapse as early as within 1−3 years, often with a pattern including visceral metastases. Therefore, optimizing relapse-mitigating approaches in women with TNBC following initial standard therapy (surgery + radiotherapy + chemotherapy) with further safe and effective adjuvant therapy is paramount,” said Elizabeth A. Mittendorf, MD, PhD, Rob and Karen Hale Distinguished Chair in Surgical Oncology, Director of Research, Breast Surgical Oncology Brigham and Women’s Hospital, Director, Breast Immuno-Oncology Program Dana-Farber/Brigham and Women’s Cancer Center, and the Principal Investigator of this planned Phase 3 study. “A Phase 3 study investigating the potential clinical benefit accorded by NPS with trastuzumab, an easily-administered maintenance therapy with a generally manageable toxicity profile, has the potential, assuming positive results, to be practice-changing in the treatment of TNBC, by introducing the first peptide vaccine-based immunotherapy in the therapeutic choices for women with this aggressive malignancy.”

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapeutics for a broad range of cancer indications. SELLAS’ lead product candidate, galinpepimut-S (GPS), is licensed from Memorial Sloan Kettering Cancer Center and targets the Wilms Tumor 1 (WT1) protein, which is

present in an array of tumor types. GPS has potential as a monotherapy or in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipepimut-S (NPS), is a HER2-directed cancer immunotherapy with potential for the treatment of patients with early stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes triple negative breast cancer patients, following standard of care.

For more information on SELLAS, please visit **www.sellaslifesciences.com**.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements" for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995, including those relating to future events. In some cases, forward-looking statements can be identified by terminology such as "plan," "expect," "anticipate," "may," "might," "will," "should," "project," "believe," "estimate," "predict," "potential," "intend," or "continue" and other words or terms of similar meaning. These statements include, without limitation, statements related to plans for further development of and regulatory plans for NPS, statements about the use of the Phase 3 study as described as a potential registration-enabling study, statements regarding the outcome of discussions with the FDA regarding NPS and statements about the Company's strategy and plans for out-licensing NPS. These forward-looking statements are based on current plans, objectives, estimates, expectations and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with immune-oncology product development and clinical success thereof, risks related to the initiation and the progress of such development programs and clinical trials, including safety risks, risks related to the availability of data from these programs, and other risks and uncertainties affecting SELLAS and its development programs as well as risks relating to the out-licensing and partnering efforts, as set forth under the caption "Risk Factors" in SELLAS' Annual Report on Form 10-K filed on March 22, 2019 and in its other SEC filings. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS' forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof. SELLAS undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

Investor Contacts
Will O'Connor
Stern Investor Relations, Inc.

212-362-1200
ir@sellaslife.com

Investor Relations
SELLAS Life Sciences Group, Inc.
917-438-4353
info@sellaslife.com

Source: SELLAS Life Sciences Group