

SELLAS Life Sciences Announces Presentation of Final Data Analysis from Phase 2b Study of Nelipepimut-S Plus Trastuzumab at the 2019 ASCO-SITC Clinical Immuno-Oncology Meeting

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NEW YORK, March 04, 2019 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today announced final results from the efficacy and safety data analysis of the prospective, randomized, single-blinded, controlled Phase 2b independent investigator-sponsored clinical trial of the combination of trastuzumab (Herceptin®) +/- nelipepimut-S (NeuVax™, NPS) targeting HER2 low-expressing breast cancer patient cohorts, including triple-negative breast cancer (TNBC) patients, which were presented at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium in San Francisco, CA.

The comprehensive findings are based on the final analysis of the full data-set from the clinical trial, and at a median follow-up of 25.7 months from the time of randomization. In the clinical trial, 275 patients were randomized to either placebo with granulocyte-macrophage colony-stimulating factor (GM-CSF) (n=139) or NPS with GM-CSF (n=136), while all received trastuzumab every 3 weeks for one year. No safety-related statistically significant differences were seen between the treatment and control arms in the rate of grade 1-3 adverse events of either local or systemic nature, while no grade 4/5 toxicities were observed in either arm. Also, there was no statistically significant difference between the treatment arms in the cardiac ejection fraction measured at baseline, as well as at four additional time-points up to 24 months post-randomization.

In the intent-to-treat (ITT) population (all HER2 low-expressing breast cancer patients; n=275), and over the 24-month post-randomization follow-up period, the disease-free survival (DFS) landmark rate was in favor of the combination (NPS plus trastuzumab) arm (89.8%) versus trastuzumab alone (83.8%), as shown in the graph below:

In the 97-patient TNBC cohort, the DFS landmark rate at 24 months for patients treated with NPS plus trastuzumab (n=53) was 92.6% compared to 70.2% for those treated with trastuzumab alone (n=44), a clinically and statistically significant improvement, as shown in the graph below:

In the TNBC cohort, there was a statistically significant reduction of 71.9% ($p=0.01$) in the frequency of clinically detected recurrences in those patients treated with the combination (NPS plus trastuzumab) versus trastuzumab alone.

“This final analysis of the study database establishes a clinically meaningful and statistically significant prolongation in DFS, a validated surrogate marker of overall survival for TNBC - by both hazard ratios and 24-month event rates - and a meaningful decrease in the frequency of relapses identified by standard clinical follow-up in favor of NPS plus trastuzumab given in the adjuvant setting in TNBC patients,” commented 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 the Phase 2b study.

Nicholas J. Sarlis, MD, PhD, Executive Vice President and Chief Medical Officer of SELLAS, further commented that “These definitive results provide us with an enhanced understanding of the clinical effect and safety profile of the combination therapy in this trial, with positive efficacy outcomes being essentially confined to TNBC patients, and continue to encourage us and support our ongoing discussions with the U.S. Food and Drug Administration on the most appropriate registration-enabling development path for NPS in TNBC.”

The abstract text can be accessed at: <https://meetinglibrary.asco.org/record/170408/abstract>.

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About SELLAS Life Sciences Group, Inc.

SELLAS is a clinical-stage biopharmaceutical company focused on 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 has a Phase 3 clinical trial planned (pending funding availability) for GPS in acute myeloid leukemia (AML) and is also studying GPS in combination with pembrolizumab in multiple indications. SELLAS has received Orphan Drug designations for GPS from the U.S. Food & Drug Administration (FDA) and the

European Medicines Agency (EMA) for AML, malignant pleural mesothelioma (MPM), and multiple myeloma (MM); GPS has also received Fast Track designation for AML, MPM and MM from the FDA. SELLAS' second product candidate, nelipepimut-S (NeuVax™, NPS), is a HER2-directed cancer immunotherapy being investigated for the prevention of the recurrence of breast cancer after standard of care treatment in the adjuvant setting. NPS has received Fast Track status designation by FDA 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 (TNBC) patients, following standard of care.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," 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 the results of clinical studies and as to further development of NPS for breast cancer and interactions with the U.S. Food and Drug Administration. 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, the uncertainty of regulatory approval, the uncertainty of finding potential partners for product candidate development, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption "Risk Factors" in Exhibit 99.1 in its Current Report on Form 8-K filed on July 18, 2018 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.

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

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