

SELLAS Announces Immune Response Data in Triple Negative Breast Cancer Patients from Phase 2b Study of Nelipepimut-S (NPS) Plus Trastuzumab Presented at ASCO 2019

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NPS-Specific Cytotoxic T-Lymphocyte Mean Frequencies Increased by 2.86-fold Compared to Baseline at 30 months

Notable Correlation Between Progressive Increase of NPS-Specific Cytotoxic T-Lymphocyte in NPS Plus Trastuzumab Patient Cohort and Remaining Clinically Relapse-Free Over Time

NEW YORK, June 03, 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 results from a preplanned analysis of immunologic responses in the cohort of patients with triple negative breast cancer (TNBC) from the prospective, randomized, single-blinded, controlled Phase 2b independent investigator-sponsored clinical trial of nelipepimut-S (NPS) +/- trastuzumab (Herceptin®) targeting HER2 low-expressing breast cancer patients. This analysis was presented on June 2, 2019 at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

"Effective adjuvant/maintenance therapy strategies are urgently needed to prevent recurrence or to prolong remission in patients with TNBC after successful frontline standard therapy for early-stage disease. In this setting, immune-directed therapy with NPS, a peptide vaccine targeting HER2, a protein expressed at low levels in TNBC, along with trastuzumab, led to high rates of antigen-specific immunization by both ex vivo and in vivo validated measures, corroborating the immunobiological synergy between these two agents," 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 the Phase 2b study.

"These ex vivo and in vivo results in TNBC patients, particularly the newly discovered correlation between mounting an immune response and remaining clinically relapse-free over time, provide a solid mechanistic rationale for the previously observed clinically meaningful and statistically significant prolongation in disease-free survival (DFS), and the significant decrease in the frequency of relapses identified by standard clinical follow-up, in favor of NPS plus trastuzumab," said Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

"As we continue discussions with potential partners and the U.S. Food and Drug Administration (FDA) on this promising program, we remain excited with these data demonstrated in the TNBC population," added Dr. Stergiou.

The Phase 2b study enrolled patients with HER2-low expressing breast cancer who remained clinically disease-free after completion of frontline standard of care therapy. Patients were selected to harbor node-positive disease and/or TNBC, as well as expressing human leukocyte antigen (HLA) types indicated for NPS administration (A2, A3, A24/26; pertinent to approx. 85% of the global population). Patients were randomized to placebo with granulocyte-macrophage colony-stimulating factor (GM-CSF) (n=139) or NPS with GM-CSF (n=136), while they all received trastuzumab every 3 weeks for one year. The Company previously reported results of the final analysis of efficacy and safety outcomes in the cohort of patients whose tumors did not express hormone receptors, TNBC (n=97). DFS of patients treated with NPS plus trastuzumab (n=53) was 92.6% compared to 70.2% for those treated with trastuzumab alone (n=44) and represented a clinically meaningful and a statistically significant improvement with the combination therapy, p=0.01. This was associated with a statistically significant reduction by 71.9% (p=0.01) in the frequency of clinically detected recurrences in favor of the combination in the TNBC cohort.

Ninety-one of the 97 TNBC patients in this clinical study were analyzed for immune responses (IR) at five timepoints, 51 of whom received the combination therapy. IR were evaluated ex vivo by clonal expansion of antigen NPS-specific cytotoxic T-lymphocytes (CTL) by dextramer-staining/flow cytometry at predefined time points over three years. In vivo IR were assessed by cutaneous delayed type hypersensitivity (DTH) reactions periodically, by measuring the diameter of skin induration (in mm) post intradermal NPS treatment.

NPS plus trastuzumab-treated TNBC patients exhibited increases in CTL frequencies compared with baseline by 1.1-, 1.73-, and 2.86-fold at 18, 24 and 30 months, respectively. The mean CTL frequencies in these patients increased from 29 ± 0.1 per 10^{-4} at baseline to $112 \pm 2.6\%$ at 30 months, a 2.86-fold difference that was highly clinically indicative (p = 0.058), as compared with patients receiving trastuzumab only, whereby CTL frequencies were 20 ± 0.1 per 10^{-4} at baseline compared with 52 ± 1.6 per 10^{-4} at 30 months, a 1.6-fold non-significant difference (p=0.70). Three patients in the combination arm recurred (5.9%) as compared with 12 (30%) in the trastuzumab-alone arm. TNBC patients treated with NPS plus trastuzumab whose disease recurred did not mount an IR by ex

vivo assessment (absolute CTL frequency change) or by in vivo DTH (no change in skin induration), while non-recurrent patients mounted both vigorous NPS-specific clonal CTL expansion and enhanced in vivo DTH.

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 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, 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 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 FDA. 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 the Company's 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 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.

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

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Investor Contacts

Will O'Connor

Stern Investor Relations, Inc.

212-362-1200

ir@sellaslife.com

David Moser, JD

SELLAS Life Sciences Group

813-864-2571

info@sellaslife.com

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