

# SELLAS Announces Positive Antigen-Specific Immune Response Data for Nelopepimut-S (NPS) in Women with Ductal Carcinoma In Situ (DCIS) of the Breast from Phase 2 VADIS Study

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Preliminary data show 11-fold increase in CD8 cytotoxic T-lymphocytes immune response in patients who received single dose of NPS compared to baseline

NEW YORK, March 18, 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 preliminary antigen-specific immune response data from a Phase 2 randomized investigator-sponsored trial (IST) of nelopepimut-S (NPS) in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) in women with ductal carcinoma in situ (DCIS) of the breast who are HLA-A2+ or A3+ positive, express HER2 at IHC 1+, 2+, or 3+ levels, and are pre- or post-menopausal.

"We are pleased to report preliminary results from the National Cancer Institute-sponsored Phase 2 VADIS trial, showing NPS is capable of inducing an antigen-specific antitumor immune response in DCIS patients even after a single vaccination, which is particularly encouraging," said Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Based on the immunobiological mechanism of action of NPS, we believe that NPS could be synergistic with standard therapies or novel immunotherapeutic approaches in women with DCIS. Moreover, these data correlate to previous findings of NPS in patients with invasive (non-DCIS) breast cancer. Given NPS' low toxicity burden and high antigen-specific immune response, further clinical study of NPS as a therapeutic which could address the medical need of women with DCIS at an early stage of their therapeutic journey is likely warranted and these data further support 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.”

The study enrolled 13 patients, with nine patients receiving NPS plus GM-CSF and four patients receiving GM-CSF only. The relative frequency of NPS-specific CD8 cytotoxic T-lymphocytes as a percentage (NPS-CTL%) was twice as large in the NPS-treated patients. The NPS-CTL% was measured in the peripheral blood by a sensitive and specific assay using dextramer staining followed by flow cytometry, both at baseline (before vaccination or GM-CSF) and at 30 (+/-7) days after surgery. The mean difference in NPS-CTL% increase between the active and control groups was +0.10% vs +0.05%. The relative magnitude of change in NPS-CTL% mean values in NPS-treated patients over time was an 11-fold increase, from 0.01% at baseline to 0.11% after surgery, indicating a continued antigen-specific T-cell response post-NPS vaccination. NPS was generally well-tolerated in the study with no drug-related unexpected serious adverse reactions. The overall adverse event profile was consistent with previous safety data.

The final data is being further analyzed by the National Institute of Health, MD Anderson Cancer Center and the study principal investigator, Dr. Elizabeth Mittendorf, MD, PhD of the Dana-Farber/Brigham and Women’s Cancer Center, and will be presented at an upcoming medical conference.

“The preliminary data from the VADIS study showing a doubling of the difference in increase in antigen-specific CD8 cytotoxic T-lymphocytes in NPS-treated patients vs. controls, even with a single NPS inoculation, indicate in vivo immunogenicity of this cancer vaccine in DCIS. These data, as well as the previously reported clinical effects of NPS in the adjuvant setting after frontline therapy for invasive breast cancer, provide support for the possibility that NPS may be able to decrease the rate of recurrences in earlier-stage disease, such as DCIS, which I believe should be studied formally in future clinical studies,” said Dr. Mittendorf. “While additional analyses of certain histologic and molecular markers of the patients’ immune responses against the NPS and other HER2 antigenic epitopes are currently ongoing, these initial immunobiological results from the VADIS study are encouraging.”

#### About the Phase 2 VADIS Trial

This Phase 2 randomized trial is sponsored and operationalized by the National Cancer Institute (NCI) to study NPS’ potential clinical effects in earlier-stage disease. Patients are randomized to receive, prior to surgery, either GM-CSF followed by NPS two weeks later or GM-CSF alone. The primary endpoint of the trial is the difference in the frequency of newly induced NPS-cytotoxic T lymphocytes (CTL; CD8+ T-cell) in peripheral blood between the two arms of the study, using a dextramer assay. Secondary endpoints to be compared between the two arms include the nature and incidence of adverse events and in vivo immune response to NPS, in addition to other select histologic and molecular biomarkers.

#### About DCIS

DCIS is defined by the NCI as a noninvasive condition in which abnormal cells are found in the lining of a breast duct and have not spread outside the duct to other tissues in the breast. DCIS is the most common type of breast neoplasm with malignant potential. In some cases, DCIS may become invasive cancer and spread to other tissues and, currently, it is not possible to know which lesions could become invasive. Current treatment options for DCIS include breast-conserving surgery and radiation therapy with or without tamoxifen, breast-conserving surgery without radiation therapy, or total mastectomy with or without tamoxifen. Tamoxifen is given in cases with hormone receptor positivity only. No targeted or immune therapies have shown any definitive clinical activity in DCIS to date. The current standard treatment aims at forestalling the progression of DCIS to invasive cancer. In approximately 15-25% of cases progression does occur. DCIS is diagnosed in more than 60,000 women each year in the United States, comprising 1 in 5 newly diagnosed cases of breast cancer.

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 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, 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](http://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," 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 clinical development of NPS for breast cancer, including DCIS, the potential for NPS as a drug development candidate, and the Company's plans for seeking out-licensing opportunities for the further development of 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, the uncertainty

of regulatory approval, 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 13, 2020 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.

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