



NEWS RELEASE

# SELLAS Announces Completion of Enrollment in Randomized Phase 2 VADIS Trial of Nelipepimut-S (NPS) in Women with Ductal Carcinoma In Situ (DCIS) of the Breast

8/5/2019

Initial Data Expected by end of 2019

NEW YORK, Aug. 05, 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 completion of enrollment in a Phase 2 randomized investigator-sponsored trial (IST) of nelipepimut-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 announce completion of enrollment in the Phase 2 VADIS trial, an important milestone for our NPS clinical program. The premise of the VADIS study is quite innovative, as it will provide valuable data and give us the opportunity to gauge in a controlled, randomized setting whether NPS can effectively induce an antitumor immune response in DCIS patients. We believe NPS could serve as an earlier stage treatment for women with breast cancer and hope to gain through this study further insights on the immunobiological mechanism underlying the clinical activity of NPS. The VADIS results could inform us as to potential synergies between NPS and standard therapies in women with DCIS. We are excited to move NPS another step closer to our goal of improving the therapeutic options for breast cancer patients by potentially serving as an early stage treatment for patients with DCIS. We look forward to seeing the initial data by the end of 2019," said Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

"We are delighted to have completed enrollment in the VADIS study, which will test for an array of sophisticated

histologic, immunodynamic and molecular markers of immune responses following treatment with NPS, including induction of HER2-specific cytotoxic T lymphocyte (CTL) and epitope spreading, the latter being the herald of clinical efficacy for a successful peptide vaccine,” 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 2 VADIS trial. “VADIS is poised to inform us on the design of future treatment strategies for DCIS, which remains an unmet medical need, including combinations of NPS with standard therapies in a broad population,” concluded Dr. Mittendorf.

#### 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. Initial data from this trial are expected by the end of 2019.

#### 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 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 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 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, including the timing thereof. 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 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.

#### 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