NEWS RELEASE

SELLAS Announces Positive Follow-up Data from the Randomized Phase 2 VADIS Trial of Nelipepimut-S (NPS) in Women with Ductal Carcinoma In-Situ of the Breast

12/11/2020

– Immune Stimulation Augmented by +1,300% at 6-months Post-NPS Treatment –

– Statistically Significant Difference of Duration of Immune Response of NPS vs. Control: p=0.000094 -

– Data to be Presented Today at the San Antonio Breast Cancer Symposium -

NEW YORK, Dec. 11, 2020 (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, announced today final data with up to 6 months follow-up from a Phase 2 randomized trial (the VADIS study) of the Company's 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. This investigator-sponsored trial randomized patients to receive, prior to surgery, either GM-CSF followed by NPS two weeks later or GM-CSF alone.

Preliminary data previously reported showed that treatment with even a single dose of NPS was capable of newly inducing NPS-specific cytotoxic T-lymphocytes (CTLs) in peripheral blood in DCIS patients. The updated data, based on a 6-month follow-up, demonstrate that CD8+ T-cell responses persist long-term post-NPS treatment, with treated patients retaining and modestly enhancing their antigen-specific immune response. When compared to baseline (BL, prior to investigational agent administration), the relative frequency of NPS-specific CD8 CTLs as a

percentage (NPS-CLT%) in peripheral blood at the 1-month and 6-month post-operative time-points increased in the NPS+GM-CSF group (n=9) by 11- and 14-fold: 0.01+0.02% [BL] vs. 0.11+0.12% [1-mo] and 0.14+0.12% [6-mo], respectively, while in the GM-CSF alone group (n=4) the NPS-CLT% in peripheral blood increased by only 2.25- and 3.75-fold: 0.04+0.07% [BL] vs. 0.09+0.15% [1-mo] and 0.15+0.03% [6-mo], respectively.

For the NPS+GM-CSF group, the differences in absolute NPS-CTL% mean values between baseline and 1- or 6-months post-vaccination were statistically significant, with p-values of 0.039 and 0.0125, respectively. The relative change in NPS-CTL% mean values at 6 months post-vaccination was +1,300+450% for the NPS+GM-CSF group vs. 250+150% in the GM-CSF alone group, which was highly statistically significant in favor of the NPS+GM-CSF group: p=0.000094.

“These data confirm that NPS confers long-term immune response in DCIS patients, with continued, and in fact slightly augmented, antigen-specific T-cell response for up to 6 months post-vaccination in a randomized setting,” said Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “One of the main limitations of cancer vaccines has traditionally been the short duration of the immune response, especially for CD8+ T-cells. With these new data, we believe that a single course of NPS treatment can result in robust and lasting immunity to HER2-expressing breast cancer. In the VADIS study, immune responses emerged and were sustained even in DCIS patients with low levels of HER (IHC 1+ or 2+) expression. These data further support our belief that NPS, by preferentially inducing adaptive immunity and through its potential synergy with trastuzumab, enhances cell killing.”

The VADIS study enrolled 13 patients, with nine patients receiving NPS plus GM-CSF and four patients receiving GM-CSF only. The NPS-CLT% 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), as well as at 30 (+7) and 180 (+7) days after surgery. Further data from additional analyses of select histologic and molecular biomarkers will be presented in a future scientific meeting.

There were no drug-related unexpected serious adverse reactions in the study. The overall adverse event profile of the NPS+GM-CSF combination was similar to the adverse event profile seen with GM-CSF alone. Almost all patients in both arms experienced at least Grade 1 toxicities, and the incidence of Grade 2 toxicities was 6.7% in the GPS+GM-CSF arm and 10.7% in the GM-CSF only arm.

“These results further support the case for continued development of NPS in HER2-expressing breast cancer, as well as potentially other HER2-bearing cancers,” 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 VADIS trial. “In patients with DCIS, a single inoculation with NPS+GM-CSF can induce in

vivo immunity and a continued antigen-specific T-cell response. These data provide support for further testing of NPS+GM-CSF in the neoadjuvant and adjuvant settings in an attempt to prevent invasive recurrence in DCIS," added Dr. Mittendorf.

About the VADIS spotlight poster presentation (PD11-09)

The VADIS data will be presented today, December 11, at the Virtual 2020 Annual San Antonio Breast Cancer Symposium (SABCS)
Title: Vadis trial: phase II trial of Nelipepimut-S peptide vaccine in women with DCIS of the breast.
Authors: O'Shea AE, Clifton GT, Qiao N, Heckman-Stoddard B, Wojtowicz M, Dimond E, Bedrosian I, Weber D, Husband A, Pastorello R, Vornik L, Peoples G, Mittendorf EA.
Presenter: Anne E. O'Shea, MD
Poster Discussion No.: PD11-09
Session Date – Time: Friday, December 11, 2020: 2:15 pm – 3:30 pm CST
Website: **www.sabcs.org**

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**.

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, and the potential for NPS as a drug development candidate. 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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