



NEWS RELEASE

SELLAS Life Sciences Announces Positive Interim Data from Phase 2b NeuVax™ (nelipepimut-S) Clinical Trial in Combination with Herceptin® in HER2 1+/2+ Breast Cancer Patients

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Clinically meaningful activity in favor of investigational nelipepimut-S (NeuVax) + Herceptin arm

Clinically and statistically significant efficacy in triple negative breast cancer (TNBC) cohort; p=0.023

NEW YORK, April 02, 2018 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group Inc., (Nasdaq:SLS) (SELLAS), a clinical-stage biopharmaceutical company focused on novel cancer immunotherapies for a broad range of cancer indications, today announced positive interim data from the prospective, randomized, single-blinded, controlled Phase 2b independent investigator-sponsored clinical trial (IST) of trastuzumab (Herceptin®) +/- nelipepimut-S (NeuVax™) in HER2 1+/2+ breast cancer patients in the adjuvant setting to prevent recurrences.

A pre-specified interim analysis, conducted by an independent Data Safety Monitoring Board (DSMB) of the efficacy and safety data for the study in an overall population of 275 patients as well as the two primary study target patient populations (node-positive and TNBC) after a median follow-up of 19 months, demonstrated a clinically meaningful difference in median disease-free survival (DFS) in favor of the active arm (NeuVax + Herceptin), a primary endpoint of the study, with hazard ratios of 0.67 and 0.61 in the intent to treat (ITT) and modified ITT (mITT) populations (i.e., those who received at least one dose of vaccine or control) as well as a 34.9% and 39.5% reduction in relative risk of recurrence in the active versus control arms in the ITT and mITT populations, respectively.

A clinically meaningful and also statistically significant difference was found between the two arms in the cohort of patients (n= 98) with triple-negative breast cancer (TNBC), with a hazard ratio of 0.26 and a p-value of 0.023 in favor of the NeuVax + Herceptin combination with a 70.4% reduction in relative risk of recurrence in the active arm versus control. Similarly, a clinically meaningful and statistically significant difference was found between the two

arms in favor of the combination in the cohort of patients not receiving hormonal therapy (n = 110), with a hazard ratio of 0.24 and a p-value of 0.009 with a 74.1% reduction in relative risk of recurrence in the active arm versus control. This pre-specified interim analysis also showed an adverse event profile with no notable differences between treatment arms. The addition of NeuVax to Herceptin did not result in any additional cardiotoxicity compared to Herceptin alone.

“We are indeed excited about these compelling results and believe NeuVax + Herceptin has the potential to become an important therapeutic option for TNBC patients. The positive NeuVax phase 2b data underscores the innovative science and approach we have taken to investigate this agent’s potential to address this persistent therapeutic challenge. We plan to immediately engage with the FDA and EMA, as per the recommendation of the DSMB, to identify the optimal path forward in this particular patient group, while advancing the drug through a partnership or other strategic collaboration,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “These are indeed unique and exciting clinical data for TNBC patients, and I would like to extend my sincere gratitude to all patients who have participated in this clinical trial, as well as the study teams.”

The NeuVax + Herceptin combination was found to be generally well-tolerated. The majority of treatment-emergent adverse events (TEAE) were of mild or moderate (G1/G2) severity and the majority of G3 systemic TEAEs were unrelated to NeuVax. Treatment-related adverse events consisted primarily of manageable local injection site reactions, skin induration, pruritus and fatigue.

Additionally, in the NeuVax + Herceptin arm, in vivo HER2-specific T-cell immune responses (IRs), assessed by delayed type hypersensitivity (DTH) skin testing, showed a time-dependent increase in IR potency compared to the earliest tested datapoint ($p=0.000023$), while no such increase was observed in the control arm.

Based on the results above, the DSMB has recommended to expeditiously seek regulatory guidance by the FDA for further development of the combination of NeuVax + Herceptin in TNBC, considering the statistically significant benefit of the combination therapy seen in this population with large unmet medical need.

“We are very pleased with these findings, which suggest that NeuVax + Herceptin may provide a clinically meaningful benefit to breast cancer patients with low-to-intermediate HER2-expression, especially given the recent report of the NSABP B-47 trial showing no benefit in these patients with Herceptin alone. Furthermore, our trial has shown a significantly improved disease-free survival in women with TNBC. The favorable findings for this cohort are particularly promising, given the limited treatment options for these patients with high risk of recurrence and death,” commented COL (ret) George E. Peoples, MD, FACS, the study director and sponsor-investigator of the IST. “We look forward to presenting these data at an upcoming major medical conference and to supporting SELLAS in the regulatory and developmental pathway for NeuVax.”

Herceptin® is a registered trademark of Genentech, Inc. and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

About the NeuVax + Herceptin study

This Phase 2b trial is a multi-center, randomized, single-blinded, placebo-controlled trial in 275 HER2 1+/2+ breast cancer patients with positive nodes and/or TNBC. The study combines NeuVax and trastuzumab (Herceptin) in the adjuvant setting aiming to prevent recurrence or death. Tumors in these women show low levels of expression of HER2, as measured by immunohistochemistry (IHC), i.e., at a level of either 1+ or 2+ and, hence, these patients are not considered candidates for Herceptin. Patients who are hormone receptor-negative and HER2 1+/2+ by IHC are currently defined as 'triple-negative' breast cancer (TNBC) patients. NeuVax (nelipepimut-S) is a potentially first-in-class, HER2-directed cancer immunotherapy and is the immunodominant peptide derived from the extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast carcinoma. The nelipepimut-S sequence stimulates specific CD8+ cytotoxic T lymphocytes (CTLs) following binding to specific HLA molecules on antigen presenting cells (APC) and destroy HER2 expressing cancer cells.

About SELLAS Life Sciences Group

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 Phase 3 clinical trials planned (pending funding availability) for GPS in two indications, acute myeloid leukemia (AML) and malignant pleural mesothelioma (MPM) and is also developing GPS as a potential treatment for multiple myeloma and ovarian cancer. SELLAS plans to study GPS in up to four additional indications. SELLAS has received Orphan Drug designations from the U.S. Food & Drug Administration (FDA), as well as the European Medicines Agency, for GPS in AML and MPM; GPS also received Fast Track designation for AML and MPM from the FDA.

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

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the results of clinical studies and as to further development of nelipepimut-S (NeuVax) for breast cancer. 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, uncertainties related to timing and ability to obtain needed shareholder consent in a timely manner, the uncertainty of regulatory approval, the uncertainty of partnering its clinical assets, and other risks and uncertainties affecting SELLAS and its development programs. 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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