



NEWS RELEASE

SELLAS Reports Promising Updated Clinical Data and Initial Immune Response Profiles from Ongoing Phase 1/2 Study of Galinpepimut-S (GPS) Combined with Keytruda for Treating WT1+ Advanced Ovarian Cancer

6/30/2021

Updated Data Shows 100 Percent of Patients Alive and 45.5 Percent Continuing Investigational Therapy as of the Latest Follow-Up

Immune Data Shows GPS Induced WT1-Specific Immune Responses with a Substantial Increase in Antigen-Reactive T-Lymphocytes Averaging +242% for CD8+ and +80.5% for CD4+ T-Cells from Baseline to 18 Weeks Post Treatment

NEW YORK, June 30, 2021 (GLOBE NEWSWIRE) -- **SELLAS Life Sciences Group, Inc.** (NASDAQ: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapies for a broad range of indications, today announced promising updated clinical data and initial immunobiological data from its Phase 1/2 clinical trial with its lead asset, galinpepimut-S (GPS), the Company's Wilms Tumor-1 (WT1)-targeting peptide immunotherapeutic, in combination with the checkpoint inhibitor pembrolizumab (Keytruda®).

Conducted under a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Kenilworth, N.J. USA (known as MSD outside of the United States and Canada), the study is investigating the combination of GPS and pembrolizumab in treating patients diagnosed with second- or third-line WT1(+) relapsed or refractory platinum-resistant, advanced metastatic ovarian cancer. The WT1 antigen is one of the most widely expressed cancer antigens in multiple malignancies and has been ranked by the National Cancer Institute as the top priority among cancer antigens for immunotherapy.

The study details are as follows:

- Eleven patients (median age: 63 years) who received at least three GPS doses, the last of which was combined with pembrolizumab, were evaluated for clinical responses and three of those patients were also evaluated for immune responses.
- 66.7 percent of evaluable patients were refractory to or had failed their second-line therapies, and 33.3 percent failed third-line therapy or later.
- All enrolled patients (100 percent) were resistant to the standard of care platinum-based therapy. Expected overall survival for patients receiving standard of care platinum-based therapy is nine to 12 months.
- Median overall survival among the patients in this trial is not yet known as all patients are still alive at the time of the analysis, which period of time exceeds nine months.

Disease Control Rate

An ad hoc analysis of clinical outcomes in the cohort of 11 patients shows a disease control rate (DCR), the sum of overall response rate and rate of stable disease, of 63.6 percent, with a median follow-up of 15.4 weeks. In December 2020, the Company reported initial data showing a DCR of 87.5 percent in eight patients, with a median follow-up of 9.4 weeks. In this very difficult treatment-resistant patient population, at the time of the follow-up analysis, median progression-free survival (PFS) was 11.8 weeks. The landmark PFS rate by log-rank analysis at six months (26 weeks) was 33 percent.

Analysis of the updated data, using a validated immunohistochemistry assay during the eligibility screening period, shows that the rate of WT1 ovarian tumor positivity in this patient population remained high at approximately 63.6 percent. As of the time of this analysis, all patients are alive, and five patients (45.5 percent) are continuing to receive investigational therapy. Enrollment for this study is ongoing, with a target of approximately 20 total evaluable patients.

The safety profile of the GPS-pembrolizumab combination was similar to that seen with pembrolizumab alone, with the addition of only low-grade, temporary local reactions at the GPS injection site, consistent with previously performed clinical studies with GPS.

Immunobiological Data

CD8+ and CD4+ T-lymphocytes were isolated from peripheral blood mononuclear cells from three patients from whom samples had been collected both at baseline and at the time of the sixth GPS dose (i.e., 18 weeks after starting investigational therapy). The T-cells were assayed ex-vivo for immune responses against the pool of the four peptides that comprise GPS using the validated assay intracellular cytokine staining with fluorescence-activated single cell sorting (ICS-FACS) (Scorpion Biological Services, San Antonio, Texas), with appropriate positive and negative controls.

A total of five cytokine “channels” were used for the analysis (i.e., interferon-g, TNF-a, interleukin-2, CD107a and MIP-1b). The peptide re-challenge incubation period was seven days. At the 18-week time point versus pre-vaccination baseline, the assay demonstrated a relative increase in WT1-specific T-lymphocyte frequencies in peripheral blood averaging +242 percent (range: +104 to +385 percent across five cytokines) for CD8+ and +80.5 percent (range: +1 to +174 percent) for CD4+. There was also evidence of polyfunctional T-cell activation (increases in secretion of >2 cytokines) in two out of three patients (66 percent).

“Considering the overall poor prognosis in this particular clinical setting and based on the observed median PFS, overall survival and DCR in this study, combining GPS with the PD1 inhibitor pembrolizumab appears to be clinically promising as compared to bevacizumab-free salvage chemotherapy regimens and without the toxicity burden associated with the latter,” said Angelos Stergiou, M.D., Sc.D. h.c., President and CEO, SELLAS. “Patients treated with GPS plus pembrolizumab also appear to maintain a considerable degree of stable disease, as evidenced by the median DCR of 63.6 percent – all evaluable patients are alive. Continuing to review the clinical data will help us determine the fundamental value of the combination approach to fighting this disease. The initial trends are promising, and further maturity of the data and studying additional patients will allow us to draw more definitive conclusions regarding the clinical benefit. We expect to perform another set of similar ad hoc clinical and immunobiological analyses over the next six months as the study progresses.”

“Based on this early data, it is encouraging to see the induction of WT1-specific T-cell immune responses with the administration of GPS in combination with pembrolizumab with a validated complex ex-vivo immune response assay on peripheral blood from patients with platinum-refractory metastatic ovarian cancer who had undergone numerous prior therapies,” added Jeffrey S. Weber, M.D., Ph.D.; Deputy Director of the Perlmutter Cancer Center at New York University (NYU)-Langone Health; Co-Director of its Melanoma Research Program Center; and Chair of SELLAS’ Scientific Advisory Board. “Expansion of these results with data from additional patients, as well as at time points longer than 18 weeks (when such patient samples become available for testing), will be key in getting a more comprehensive picture of the combination immunotherapy’s biological effect.”

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic malignancies and the fifth most frequent cause of cancer death in women in the United States. Over 22,000 cases are diagnosed annually, and there are an estimated 15,500 deaths per year. The majority of patients have widespread disease at presentation. The five-year survival for the advanced-stage disease remains less than 30 percent. Combining GPS with the checkpoint inhibitor pembrolizumab, which beneficially and profoundly alters the tumor microenvironment (TME), is hypothesized to increase the proportion of patients who develop an immune response against their cancer and potentially improve their clinical outcome over pembrolizumab monotherapy, without the burden of additional toxicities in

macroscopically measurable malignancies.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapeutics for a broad range of indications. SELLAS' lead product candidate, 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 both as a monotherapy and in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipepimut-S (NPS), is a HER2-directed cancer immunotherapy with potential to treat 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 the standard of care.

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

Keytruda® is a registered trademark of Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

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 GPS for ovarian cancer, and the potential for GPS 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 the COVID-19 pandemic and its impact on the Company's clinical plans, 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 23, 2021 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

Valter Pinto / Allison Soss

KCSA Strategic Communications

Email: **SELLAS@kcsa.com**

Phone: 914.907.2675 / 215.272.2707

Media Contacts

Caitlin Kasunich / Raquel Cona

KCSA Strategic Communications

Email: **SELLAS@kcsa.com**

Phone: 212.896.1241 / 212.896.1276

Source: SELLAS Life Sciences Group, Inc.