

# SELLAS Life Sciences Presents Interim Phase 1 Clinical Data of Galinpepimut-S (GPS) in Combination with Nivolumab to Treat Wilms Tumor 1 Positive (WT1+) Ovarian Cancer Patients at ASCO 2018

6/4/2018

1-year progression-free survival (PFS) rate of 70% with induction of serum levels of WT1 Antigen-Specific Immunoglobulin G (IgG) in 86% of patients treated with GPS in combination with programmed cell death protein-1 (PD-1) inhibition

No serious adverse events observed

Data support continued development of GPS in combination with PD-1 inhibitors

NEW YORK, June 04, 2018 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (NASDAQ:SLS) ("SELLAS" or "the Company") today announces interim Phase 1 data of GPS in combination with nivolumab in patients with WT1+ ovarian cancer in second or third remission after salvage chemotherapy at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentation, "A phase I study of concomitant galinpepimut-S (GPS) in combination with nivolumab (nivo) in patients (pts) with WT1+ ovarian cancer (OC) in second or third remission," is being delivered by Roisin E. O’Cearbhaill, M.D., Gynecologic Medical Oncology Service, Memorial Sloan Kettering Cancer Center, during the "Gynecologic Cancer" session from 1:15 to 4:45 p.m. CT. The primary endpoint of the study is safety and assessment of toxicity, and treatment is continued until disease progression or toxicity. The secondary endpoint is immune response, and the exploratory endpoints include landmark 1-year PFS rate compared to historical controls and correlative analyses between clinical and immune responses.

Exploratory efficacy interim data from this open-label Phase 1 investigator-sponsored trial showed that GPS, when

combined with a PD-1 inhibitor, demonstrated PFS of 64% at one year in an intent to treat (ITT) group of 11 evaluable patients with WT1+ ovarian cancer in second or greater remission. Among patients who received at least three doses of GPS in combination with nivolumab, PFS at one year was 70% (7/10). The historical rates with best standard treatment do not exceed 50% in this disease setting. The most common adverse events were Grade 1 or 2, including fatigue and injection site reactions. Dose limiting toxicity was observed in one patient, following the second dose of the combination. No additional adverse event burden was observed for the combination as compared to nivolumab monotherapy. WT1 is a tumor antigen that is expressed in about half of ovarian cancers. The combination induced a high frequency of T- and B-cell immune responses.

Based on these safety, clinical activity and immunogenicity data, SELLAS expects to initiate a Phase 1/2 clinical study of GPS in combination with the PD-1 inhibitor pembrolizumab in a variety of tumor types, including WT1+ ovarian cancer in the third quarter of 2018.

“Patients with advanced relapsed ovarian cancer, in which WT1 is highly expressed, have few treatment options with limited efficacy,” said Angelos Stergiou, MD, ScD h.c., President & Chief Executive Officer of SELLAS. “The interim data being presented today further support the therapeutic potential of GPS in high-risk cancer populations, including ovarian cancer. In this Phase 1 trial, the combination of GPS and nivolumab showed promising clinical and immune response activity with no additional adverse event burden as compared to nivolumab monotherapy, warranting further evaluation. These data bolster our commitment to developing GPS, alone and in combination, across a wide range of cancers, and we look forward to initiating our Phase 1/2 basket trial investigating the combination of GPS with pembrolizumab in five WT1+ tumor types, including ovarian, small cell lung, colorectal and triple negative breast cancer and acute myeloid leukemia.”

Of the 11 patients evaluated:

- 7 patients were in second remission and 4 patients were in third remission
- 10 patients received six total doses of GPS (800 mcg) over 12 weeks in combination with seven infusions of I.V. nivolumab (3 mg/kg) over 14 weeks
- all underwent toxicity assessments with each dose of GPS, and three weeks after the completion of therapy at Week 15. Non-progressors at Week 15 were permitted to receive four additional GPS doses, administered every eight weeks.

With regard to clinical and immune responses:

- in 11 evaluable patients, the landmark 1-year PFS rate was 64% in the ITT group and 70% in the ten patients who received at least three doses of GPS + nivolumab. Historical rates do not exceed 50% in this disease setting

- serum levels of antigen-specific IgG, against both individual WT1 peptides within GPS and the full-length WT1 protein, were induced in 86% of patients
- achievement of high titers of WT1-specific IgG post-GPS results from Immunoglobulin (Ig) M to IgG class switching, the latter being a surrogate marker of induction of activated T-helper (Th) cells after vaccination
- antigen-specific T-cell responses to individual WT1 peptides were observed between Weeks 6-15, primarily CD4 T-cells and, to a smaller extent, CD8 T-cells

“Effective consolidation or maintenance strategies are needed to prevent further recurrence or to prolong remission in patients with ovarian cancer after successful salvage from a previous relapse. In this setting, immune-directed therapy with a combination of blocker nivolumab and GPS, a multivalent, heteroclitic peptide vaccine targeting WT1, an antigen expressed in about half of ovarian cancers, led to high rates of antigen-specific immunization. We anticipate that this enhanced immunogenicity will translate into a reduction in relapses in larger studies,” mentioned Dr. O’Cearbhaill. She added “these encouraging interim data suggest that the combination of GPS plus PD-1 inhibitors deserves further study in WT1+ ovarian cancer.”

#### About Galinpepimut-S (GPS):

GPS is a heteroclitic multivalent, multi-peptide cancer immunotherapeutic agent composed of four peptides, addressing over 20 epitopes, and derived from the WT1 protein, which has been ranked by the National Cancer Institute as a top priority among cancer antigens for immunotherapy. Importantly, because the WT1 antigen is overexpressed in many malignancies, and is not found in most normal tissues, GPS has the potential to be a broad immunotherapy, effective across a multitude of diverse cancer types and patient populations.

#### About SELLAS:

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 (MM) and ovarian cancer. SELLAS plans to study GPS in up to four additional indications. SELLAS has received Orphan Drug designations for GPS from the U.S. Food & Drug Administration (FDA) for AML, MPM, and MM, as well as from the European Medicines Agency, for AML and MPM; GPS also received Fast Track designation for AML and MPM from the FDA. SELLAS’ second product candidate, NeuVax™ (nelipepimut-S), 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. NeuVax™ 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+, 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, including, but not limited to, statements related to the results of clinical studies and as to further development of GPS for ovarian cancer as well as for a broad range of cancer indications, including the timing of clinical trials. 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. These risks and uncertainties are described more fully in SELLAS' Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS' forward-looking statements. 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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Source: SELLAS Life Sciences Group