



NEWS RELEASE

# SELLAS Life Sciences Group and World-Renowned Cancer Center to Study Galinpepimut-S (GPS) in Combination with Nivolumab in Patients with Malignant Pleural Mesothelioma (MPM)

4/4/2019

Initiation of Phase 1 Clinical Trial in Relapsed or Refractory MPM Expected in the Second Quarter of 2019

Previous Combination Study of GPS and Nivolumab Given After Salvage Chemotherapy in Ovarian Cancer Patients Showed 1-year Progression-Free Survival Rate of 70% and Induction of WT1 Antigen-Specific Immunoglobulin G of 86%

NEW YORK, April 04, 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 agreement with Memorial Sloan Kettering Cancer Center (MSK) for the conduct of an investigator-sponsored clinical trial of SELLAS' Wilms tumor-1 (WT1)-targeting peptide immunotherapeutic agent, galinpepimut-S (GPS), in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab, in patients with malignant pleural mesothelioma (MPM). The Phase 1 open-label clinical study will enroll patients with MPM who harbor relapsed or refractory disease after having received frontline standard of care multimodality therapy with study drug provided by both SELLAS and Bristol-Myers Squibb. The principal investigator for the study will be Dr. Marjorie G. Zauderer, MD, Co-Director, Mesothelioma Program, Team Lead, Thoracic Disease Management Team, and Assistant Attending Physician in the Division of Thoracic Oncology, Department of Medicine at MSK.

The purpose of the trial is to determine if the administration of GPS in combination with nivolumab has the potential to demonstrate antitumor immune responses and meaningful clinical activity in the presence of

macroscopic disease in MPM patients. The study will also investigate the tolerability of the combination, evaluate the immunogenicity of the two agents administered together, by CD4+ and CD8+ T-lymphocytes (both peripherally and at the tumor site), and gauge the degree of clinical benefit by assessment of the overall response rate with the combination in comparison with that reported with nivolumab alone in historical comparable patient populations. In a randomized, controlled, blinded Phase 2 clinical trial in MPM patients completed in 2017, GPS monotherapy, given as maintenance after first line tumor-debulking multimodality treatment, demonstrated meaningful clinical activity with median survival of 22.8 months vs. 18.3 months in the control group (N=41) and with associated sustained immune responses (both CD4+ and CD8+) against the WT1 antigen while adverse events were mainly comprised of low grade reactions at the site of the injection.

"SELLAS is excited to embark upon this trial, as we look to expand the utility of GPS in combination with PD-1 inhibitors, and specifically nivolumab. The nivolumab/GPS immunotherapy combination is well positioned to exploit the unique features of each of these two agents through potential synergistic immune-based mechanisms of antitumor action. If positive, this clinical effort will allow us to consider advancing the clinical development of the combination of GPS and nivolumab in relapsed or refractory MPM as a potentially promising approach to treat patients with this recalcitrant thoracic malignancy," stated Dr. Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

"The rationale for this innovative clinical effort is based upon the presumed immunobiologic and pharmacodynamic synergy between the two investigational agents. We hypothesize that the negative influence of tumor microenvironment factors on the immune response is mitigated by nivolumab, thus providing the opportunity for the patients' own immune cells to invade and destroy cancerous growth deposits specifically sensitized against WT1 by GPS. WT1 is both a densely and frequently expressed tumor-associated antigen in MPM, and we believe it represents the optimal target for directly immunizing, vaccine-type therapies such as GPS against this tumor type," commented Dr. Nicholas J. Sarlis, MD, PhD, Chief Medical Officer and Executive Vice President of SELLAS.

Data from a Phase 1 open-label clinical study of patients with WT1+ ovarian cancer in second or greater remission suggested clinical activity for the combination of GPS plus nivolumab, with a progression-free survival (PFS) rate of 70% at one year among patients who received at least three doses of GPS in combination with nivolumab (7/10), while historical 1-year PFS rates with best standard treatment do not exceed 50% in this disease setting.

GPS is also currently being studied in combination with Merck's anti-PD-1 therapy, pembrolizumab, in patients with measurable tumor burden in the context of a Phase 1/2 open-label, non-comparative, multicenter, multi-arm 'basket'-type clinical study in five indications.

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, GPS, is licensed from MSK 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 has a Phase 3 clinical trial planned (pending funding availability) 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 U.S. Food and Drug Administration (FDA) and the European Medicines Agency for AML, MPM, and multiple myeloma (MM); GPS has also received Fast Track designation for AML, MPM and MM from the FDA. SELLAS' second product candidate, nelipepimut-S (NPS, NeuVax™), 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.

#### 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 results of clinical studies and as to further development of GPS in various indications. 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, the uncertainty of finding potential partners for product candidate development, 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.

For more information on SELLAS, please visit [www.sellaslifesciences.com](http://www.sellaslifesciences.com).

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