

SELLAS Life Sciences Announces Expedited Development Path for Galinpepimut-S (GPS) in Acute Myeloid Leukemia (AML) Following Feedback from FDA

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- Agreement on new open-label randomized registrational Phase 3 study in patients in second complete remission (CR2) poised to reduce sample size, time to primary endpoint and costs
- Fast-Track and Orphan Drug designations for GPS in AML continue to apply

NEW YORK, Nov. 28, 2018 (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 provided an update on its late-stage clinical development program for the Company's proprietary galinpepimut-S (GPS) in patients with acute myeloid leukemia (AML).

Following a clinical and regulatory strategy defining Type C dialogue with the U.S. Food and Drug Administration (FDA), the Company plans to proceed with a clinical study design and biostatistical plan to support a Phase 3 registrational study for maintenance therapy for AML patients who have achieved complete remission after second line (salvage) antileukemic therapy, or CR2. This study will be used as the basis for a Biologics License Application (BLA) submission, subject to results that are both statistically significant and reflective of an effect of sufficient magnitude to be clinically meaningful.

"Following discussion with the FDA, we are embarking upon a revised Phase 3 study for GPS in the monotherapy maintenance setting for AML patients who have achieved CR2. The new design is expected to streamline sample

size, time to accrual completion, primary endpoint readout and potential time to market, as well as costs. We believe this new study design provides SELLAS with a quicker path to approval, provided the study is positive," said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "In addition to a statistical analysis plan which we believe accords a viable pathway for meeting the primary endpoint, we have built in an adaptive design, thus further enhancing the probability of a positive study."

GPS was previously given fast track and orphan drug designations in AML by the FDA.

The planned Phase 3 registrational study will be a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators' choice best available treatment (BAT) in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation.

The study is expected to enroll approximately 116 patients at around 50 clinical sites in the United States and Europe. It is powered at 90% to show a statistically significant difference in the primary endpoint of overall survival (OS) from the time of study entry. Secondary endpoints to be measured include leukemia-free survival, antigen-specific T-cell immune response dynamics, measurable residual disease by multigene array, and assessments of AML clonal evolution and inflammasome molecular signatures in the tumor microenvironment in bone marrow biopsy samples. The study will have a planned interim analysis for safety and futility after 80 events.

This streamlined CR2 study design, as compared to the previously planned study in AML patients who achieved complete remission following first-line antileukemic therapy (CR1), substantially reduces the study size (116 patients in CR2 vs. 390 patients in CR1) and time until topline data (up to 2.5 years in CR2 vs. 4.5 years in CR1) which will result in corresponding significant cost savings. A Phase 2a study of GPS in the AML CR2 setting conducted at the Moffitt Cancer Center previously demonstrated a clinically meaningful and statistically significant three-fold OS prolongation in patients receiving GPS when compared to a comparable group of contemporaneously assessed unvaccinated patients with a median OS of 16.3 months vs 5.4 months and a p-value of 0.0175, respectively, with treatment-related adverse events primarily comprised of grade 1 or 2 local injection site reactions and only one grade 3 (transient leukopenia) adverse event. A prior Phase 2 study of GPS in AML patients who achieved CR1 also met its primary endpoint with an OS rate at 3 years from first vaccination of 47%.

"We are excited to begin this late-stage Phase 3 program with GPS in AML. Earlier studies have positioned this agent to be a potentially effective approach in prolonging survival by delaying or preventing recurrence in patients in complete remission, most of whom harbor measurable residual disease and have a poor prognosis if they are unable to undergo allotransplant. We are hopeful that this new immunotherapeutic vaccine approach will improve outcomes in this patient population, which is at a very high risk of leukemic relapse," said Hagop M. Kantarjian, MD, Professor and Chair of the Department of Leukemia at the University of Texas MD Anderson Cancer Center, and

principal investigator of the upcoming Phase 3 AML clinical development program.

About SELLAS Life Sciences Group, Inc.

SELLAS is a clinical-stage 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 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 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 (or Medicinal Product) designations for GPS from both the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) for AML, MPM, and MM. GPS 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+, 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 further development of galinpepimut-S (GPS) for acute myeloid leukemia, including the timing of clinical results, the cost of clinical trials, the accrual of patients in a clinical trial, the potential time to market for GPS and the potential results from a clinical trial. 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 Exhibit 99.1 in its Current Report on Form 8-K filed on July 18, 2018 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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