

SELLAS Announces Positive Follow-Up Phase 1/2 Clinical Data for Galinpepimut-S (GPS) in Acute Myeloid Leukemia (AML)

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- Final analysis shows statistically significant median overall survival of 21 months in patients who received GPS compared to previously reported 5.4 months in the control arm (p-value < 0.02) -

- Data provides additional support for ongoing pivotal Phase 3 REGAL study of GPS in patients with AML -

NEW YORK, Feb. 26, 2020 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today announced final follow-up data for its Phase 1/2 study of GPS in patients with acute myeloid leukemia (AML) in second complete remission (CR2). The final data show a median overall survival (OS) of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS therapy compared to 5.4 months in the AML CR2 patients treated with best standard care, a statistically significant difference (p-value < 0.02). Final analysis also showed that GPS therapy continued to be well-tolerated throughout the study.

"We're extremely pleased with this follow-up data, which show that GPS may have potential as a longer-term therapy for AML patients in CR2, an aggressive disease where the majority of patients typically relapse and have a survival rate of approximately 5 months with best standard therapy," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "The 21-month survival data observed further increases our confidence in the potential of GPS as a maintenance treatment for AML patients in CR2, the same patient population as our pivotal Phase 3 study, known as REGAL."

“These follow-up data build upon the initially published clinical results from the Phase 1/2 study of GPS in AML patients in CR2 and provide further evidence that this novel immunotherapeutic vaccine approach may improve outcomes for patients in this setting, who often harbor measurable residual disease and have a poor prognosis if they are unable to undergo allotransplant,” said Javier Pinilla-Ibarz, MD, PhD, Director of Immunotherapy for Malignant Hematology at the H. Lee Moffitt Cancer Center, and principal investigator of the Phase 1/2 study. “With this persistently positive efficacy signal, low toxicity burden, and CD4+ and CD8+ T cell responses, GPS has significant potential to serve as a maintenance therapy in AML patients in CR2, a patient population at great risk of leukemic relapse.”

The Company previously reported initial data from the Phase 1/2 study of GPS in AML patients in CR2 at a median follow-up of 19.3 months, showing median OS in GPS-treated patients of 16.3 months vs. 5.4 months in a patient cohort contemporaneously treated with best standard therapy ($p = 0.0175$). The final analysis, at a median follow-up of 30.8 months, now shows a median OS of 21 months in the GPS-treated patient cohort.

“Given these results, it is particularly exciting to be involved in the ongoing pivotal Phase 3 REGAL study of GPS in AML patients in CR2,” 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 Phase 3 REGAL study. “We are working to rapidly enroll patients who meet entry criteria for this study and believe these compelling results will enhance the visibility of this novel therapy and encourage broader participation in the pivotal Phase 3 trial. I look forward to initial results from the REGAL study, as I remain supportive of GPS’s potential promise as an immunotherapeutic agent in the AML CR2 setting.”

SELLAS is currently enrolling patients in the ongoing Phase 3 REGAL study, a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators’ choice best available treatment 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 primary endpoint is the OS from the time of study entry. Secondary endpoints 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. SELLAS expects an interim analysis for safety and futility in the fourth quarter of 2021.

For further information on enrolling in the REGAL study, please visit:

<https://www.clinicaltrials.gov/ct2/show/NCT04229979?term=galinpepimut-S&draw=2&rank=3>.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapeutics for a broad range of cancer 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 as a monotherapy or 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 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.

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 Company's plans for further development of and regulatory plans for GPS, including the timing of clinical results, 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 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 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.

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