



NEWS RELEASE

# SELLAS Commences Pivotal Phase 3 REGAL Study of Galinpepimut-S (GPS) in Patients with Acute Myeloid Leukemia (AML)

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-- Study Open for Enrollment and Patient Screening Underway --

NEW YORK, Jan. 08, 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 that it has started patient screening for its pivotal Phase 3 REGAL clinical trial of its lead clinical candidate, galinpepimut-S (GPS), in patients with acute myeloid leukemia (AML) who have achieved complete remission after second-line anti-leukemic therapy (CR2). The study is expected to enroll approximately 116 patients across approximately 50 clinical sites in the U.S. and Europe. GPS was previously granted Fast Track designation and orphan drug designation in AML by the U.S. Food and Drug Administration (FDA) and orphan drug designation by the European Medicines Agency (EMA).

"The commencement of our Phase 3 clinical trial marks an important milestone for SELLAS, and reflects our continued commitment to developing GPS as a potential first-in-class WT1-targeting cancer vaccine for patients with AML. We are indeed excited that patient screening is underway for our REGAL study," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "In previous Phase 2 studies in patients with AML, GPS has demonstrated a clinically meaningful and statistically significant prolonging of survival by delaying or preventing recurrence in patients in complete remission, who often are at very high risk of relapse. Of particular note, our Phase 2 AML CR2 study, which is the indication for our Phase 3 study, showed a 10.9 months survival benefit with a p-value of 0.0175. We remain focused on expeditiously enrolling our Phase 3 study. The results from the REGAL study, if positive, will be used as the basis for a Biologics License Application (BLA) submission to the FDA."

The REGAL study is 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 overall survival (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. The Company anticipates interim analysis for safety and futility in the fourth quarter of 2021.

In a previous Phase 2a study in AML patients in the CR2 setting, GPS demonstrated a clinically meaningful and statistically significant median OS of 16.3 months in AML CR2 patients vs. 5.4 months in contemporaneously assessed unvaccinated patients ( $p = 0.0175$ ). Treatment-related adverse events were primarily comprised of Grade 1 or 2 local injection site reactions and one Grade 3 (transient leukopenia) adverse event. A second previous Phase 2 study of GPS in AML patients who achieved first complete remission (CR1) also met its primary endpoint with an OS rate at 3 years from first vaccination of 47%.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical 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' 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](http://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. 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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