NEWS RELEASE

SELLAS Life Sciences Provides Update on Pivotal Phase 3 REGAL Trial of Galinpepimut-S (GPS) in Acute Myeloid Leukemia (AML)

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- Contract Research Organization for the REGAL trial has informed the Company that 72 events have occurred in the trial as of December 26, 2025; SELLAS remains blinded to trial outcomes
- Timing of the final analysis is event-driven, and SELLAS will announce the occurrence of the 80th event

NEW YORK, Dec. 29, 2025 (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 therapies for a broad range of cancer indications, today provided an update on the ongoing Phase 3 REGAL trial evaluating GPS as a potential maintenance therapy in patients with AML after second complete remission (CR2).

Following the Independent Data Monitoring Committee (IDMC) recommendation in August 2025 that the Phase 3 REGAL trial continue without modification, it was expected that the 80th event (death) required to trigger the final analysis would occur before year-end. The REGAL trial is an overall survival study, and per the statistical analysis plan, the final analysis will be triggered once 80 events (deaths) have occurred.

SELLAS was informed by its contract research organization managing the REGAL trial that the pooled number of events was 72 as of December 26, 2025. SELLAS remains blinded to all efficacy and survival data outcomes and, as no outcomes analyses were performed and no statistical penalty has been incurred, this one-time update on the aggregate number of events does not impact future statistical analyses. Because the final analysis is event-driven, and the timing of studies with overall survival as an endpoint can vary, SELLAS will announce the 80th event when it occurs.

“We appreciate the continued dedication of the patients, families, and investigators participating in the pivotal Phase 3 REGAL trial where survival times, fortunately for patients and caregivers, appear longer than expected,”

said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “While the 80th event has not yet occurred, and we remain fully blinded, every passing month may increase the probability of a successful study as highlighted by key opinion leaders in our recent R&D event. Conclusive data will follow the unblinding and analyses of the study results. We remain steadfast in our commitment to advancing breakthrough therapies, such as GPS, that possess the potential to significantly improve the lives of patients with AML.”

“The REGAL study represents a meaningful effort to evaluate GPS as a novel therapeutic approach in an AML population with significant unmet need,” said Dr. Yair Levy, Director of Hematologic Malignancies Research at Texas Oncology Baylor University Medical Center, and a member of the REGAL Steering Committee. “For patients who are unable to undergo transplant, as in the REGAL study, their treatment usually consists of a combination of hypomethylating agents and/or a BCL-2 inhibitor, with an expected median overall survival of around eight months. We hope to see an extended survival benefit, with a tolerable safety profile, as observed in previous GPS studies.”

SELLAS Life Sciences Virtual R&D Day – October 29, 2025: Advancing Novel Therapies in Acute Myeloid Leukemia (AML): An Overview of the Ongoing Phase 3 REGAL Trial of Galinpepimut-S (GPS) and SLS009 Program Update. To access a replay of the R&D Day, please click here.

About Phase 3 REGAL Trial

REGAL **(NCT04229979)** is a Phase 3 randomized registrational clinical trial for GPS in AML patients who have achieved complete remission following second-line salvage therapy (CR2 patients). The primary endpoint is overall survival. The IDMC is an independent group of medical, scientific, and biostatistics experts who are responsible for reviewing and evaluating patient safety and efficacy data for REGAL, and for monitoring quality and overall conduct to ensure the validity, scientific and clinical merits of the study. The IDMC charter provides for periodic reviews of safety, efficacy, and futility in addition to the interim and final analyses.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics 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 the potential as a monotherapy and combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing SLS009 (tambiciclib) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. 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 GPS clinical development program, including the REGAL study and the timing of future milestones related thereto. 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 with 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 20, 2025 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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