

NEWS RELEASE

SELLAS Life Sciences Announces Positive Pivotal Phase 3 REGAL Trial Data Showing Immunotherapeutic Cancer Vaccine, Galinpepimut-S (GPS), Demonstrated a Statistically Significant and Clinically Meaningful Improvement in Overall Survival in Patients with Acute Myeloid Leukemia

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- REGAL trial met its primary endpoint with GPS demonstrating statistically significant and clinically meaningful reduction in risk of death by 41% with median overall survival of 24.0 months versus 14.7 months for best available treatment, and a hazard ratio of 0.59 (p=0.035) -

- Company plans to meet with the U.S. Food and Drug Administration (FDA) while advancing preparations for a Biologics License Application (BLA) submission for GPS -

- SELLAS to host webcast today, November 17, 2026, at 7:45 a.m. Eastern Time -

NEW YORK, Nov. 17, 2026 (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 announced positive topline results from the pivotal randomized Phase 3 REGAL trial evaluating galinpepimut-S (GPS), an immunotherapeutic cancer vaccine, in patients with acute myeloid leukemia (AML). The pivotal trial evaluated GPS as maintenance monotherapy in patients who achieved a second or later complete remission (CR2 or later) or complete remission with insufficient platelet recovery (CRp2 or later) following second- or later-line salvage therapy and who were ineligible for, or unable to undergo, allogeneic stem cell transplantation.

The REGAL trial met its primary endpoint of overall survival (OS), with GPS demonstrating a statistically significant

and clinically meaningful improvement in OS compared with investigator's choice of best available treatment (BAT). In the trial, GPS showed a 41% reduction in the risk of death (hazard ratio of 0.59) and a two-sided p=0.035 with a median OS of 24.0 months among GPS-treated patients versus 14.7 months with BAT.

GPS was generally well tolerated, with a safety profile consistent with prior clinical experience and no new safety signals identified. Treatment-related adverse events were predominantly mild to moderate (grade 1/2), most commonly consisting of local injection site reactions. Both treatment arms were well balanced for prognostic stratification factors. Patients who proceeded to hematopoietic stem cell transplantation were limited in number and equally distributed between the study arm and control arm.

"We are deeply grateful to the patients and their families, investigators, clinical teams, and everyone who contributed to REGAL over the course of this study. Their commitment has helped make this important milestone possible," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

Dr. Stergiou continued, "REGAL has delivered on its primary objective, demonstrating a statistically significant and clinically meaningful improvement in overall survival for patients with AML who have very limited options after achieving a second remission. The magnitude of the survival benefit observed with our investigational GPS immunotherapeutic cancer vaccine represents a defining milestone for SELLAS and provides Phase 3 validation of our WT1-targeted immunotherapeutic technology. We also believe GPS has the potential to become an important paradigm-shifting option for this high-risk population that desperately needs effective therapies. Given the significant unmet need in this patient population, we look forward to engaging with the FDA to discuss the results and the regulatory path forward, with the goal of making this therapy available to patients as rapidly as possible."

The topline primary endpoint data analysis was conducted following the pre-specified occurrence of 80 events (deaths) in accordance with the trial's pre-specified statistical analysis plan (SAP). Based on these results, SELLAS plans to meet with the U.S. Food and Drug Administration (FDA) to discuss an accelerated filing strategy and advance preparations for a Biologics License Application (BLA) submission for GPS in the first half of 2027. In accordance with standard registrational trial reporting practices, comprehensive statistical evaluation of all secondary endpoints and additional pre-specified analyses per the SAP and study protocol is underway and will be presented in detail at an upcoming major medical conference and submitted for publication in a peer-reviewed journal.

"Patients with AML in second remission who cannot undergo allogeneic stem cell transplantation face poor survival outcomes and have a significant need for new treatment approaches. The landmark data from the Phase 3 REGAL trial demonstrate a statistically significant and clinically meaningful overall survival advantage for the GPS immunotherapeutic cancer vaccine in this underserved population. By training the immune system to target residual leukemia cells, GPS addresses a critical unmet need and has the potential to redefine the treatment

paradigm in AML maintenance therapy. We look forward to sharing the detailed results from REGAL with the medical community at a future scientific meeting," commented the members of the REGAL Study Steering Committee.

The REGAL Study Steering Committee comprises Hagop M. Kantarjian, MD, Professor, Department of Leukemia and Samsung Distinguished Leukemia Chair in Cancer Medicine at The University of Texas MD Anderson Cancer Center, Chair of the REGAL Study Steering Committee and global Principal Investigator of the REGAL trial; Javier Pinilla-Ibarz, MD, PhD, Director of Immunotherapy and Head of the Lymphoma Section, Department of Malignant Hematology at Moffitt Cancer Center; and M. Yair Levy, MD, Director of Hematologic Malignancies Research at Texas Oncology-Baylor Charles A. Sammons Cancer Center.

Webcast Details

SELLAS will host a webcast today, November 17, 2026, at 7:45 a.m. Eastern Time, to discuss the topline results from the Phase 3 REGAL trial and provide an overview of the Company's planned next steps.

To access the live webcast, please click the link **here**. The webcast will also be available through the Events & Presentations section of the Company's investor relations website **here**. A replay of the webcast will be available on the Company's website following the conclusion of the event and will remain available for one year.

About Galinpepimut-S (GPS)

Galinpepimut-S (GPS) is an investigational WT1-targeting off-the-shelf immunotherapeutic cancer vaccine, licensed from Memorial Sloan Kettering Cancer Center and discovered by the laboratory of David A. Scheinberg, and designed to stimulate both CD4+ and CD8+ T-cell immune responses against WT1-expressing cancer cells. WT1 is expressed in a broad range of hematologic malignancies and solid tumors, including AML. GPS consists of four WT1-derived peptides designed to generate a broad immune response across multiple HLA types. GPS is being evaluated as a maintenance therapy intended to prolong remission and survival by directing the immune system against residual WT1-expressing cancer cells.

About the REGAL Trial

The Phase 3 REGAL trial **(NCT04229979)** is a global, randomized, open-label, registrational clinical trial evaluating GPS as maintenance therapy in patients with AML who achieved a second complete remission or later (CR2 or later) or complete remission with insufficient platelet recovery (CRp2 or later) following second- or later-line salvage therapy and who were ineligible for, or unable to, undergo allogeneic stem cell transplantation.

A total of 126 patients were randomized 1:1 to receive GPS monotherapy or investigator's choice of best available treatment (observation, hypomethylating agent, and/or venetoclax, and/or low-dose cytarabine). The primary endpoint of the trial is overall survival from the time of study entry. Secondary endpoints include safety and tolerability, leukemia-free survival, landmark overall survival and relapse-free survival in patients with prior allogeneic transplant, antigen-specific T-cell immune response dynamics, measurable residual disease, and other molecular and clinical assessments.

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, discovered by the laboratory of David A. Scheinberg, 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 in 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 and SLS009 clinical development programs, including the REGAL study and the timing of future milestones related thereto, the topline results and results of further analyses of the REGAL trial, the Company's regulatory strategy and timelines, including submission timing and potential approval and commercialization of GPS, and the presentation and publication of the results of the REGAL 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, the risk that the final REGAL trial results or other analyses may differ from the topline results or may not support regulatory submission or approval, the risk that the FDA may not agree with the Company's analyses or interpretation of REGAL trial data or expedited review, or BLA submission

based on the REGAL trial results, uncertainties regarding the timing and outcome of the Company's interactions with the FDA, the uncertainty of regulatory approval, risks and uncertainties with oncology product development and clinical success thereof, 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 19, 2026 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.

Memorial Sloan Kettering has institutional financial interests and each of Dr. Scheinberg and Dr. Javier Pinilla-Ibarz has financial interests related to SELLAS Life Sciences Group, Inc.

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