



NEWS RELEASE

SELLAS Life Sciences Announces Independent Data Monitoring Committee Periodic Review and Positive Recommendation to Continue Pivotal Phase 3 REGAL Trial of GPS in AML Without Modification

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- Final Analysis Anticipated by Year-End Upon Occurrence of 80 Events -

NEW YORK, Aug. 07, 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 announced that the Independent Data Monitoring Committee (IDMC) has completed a pre-specified analysis of the Phase 3 REGAL trial of galinpepimut-S (GPS) in acute myeloid leukemia (AML), and has issued a positive recommendation to continue the trial without modification.

The IDMC concluded that the risk-benefit profile of GPS supports continued evaluation under the current study protocol. No safety concerns were identified, and available efficacy data were consistent with expectations for continued trial conduct.

The study completed enrollment in April 2024, with a total of 126 patients randomized. Study sites in the U.S. and Europe accounted for approximately 75% of patients enrolled, with the U.S.-based sites representing the highest enrolling country.

The Phase 3 REGAL trial is a survival-driven study, and the next and final analysis will be triggered once 80 events (deaths) have occurred, further determining the potential of GPS in addressing the needs of AML patients. As of the time of this IDMC review, that threshold has not yet been reached.

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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