



NEWS RELEASE

SELLAS Life Sciences Triggers Interim Analysis in Phase 3 REGAL Trial of GPS in Acute Myeloid Leukemia

2024-12-10

- Study Reaches Pre-Specified Threshold of 60 Events (Deaths) Initiating the Interim Analysis -
- REGAL Independent Data Monitoring Committee to Perform Interim Analysis in January 2025 -
- Company to Host Webcast Call Today at 9:00 am ET

NEW YORK, Dec. 10, 2024 (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 pre-specified threshold of 60 events (deaths) has been reached in its ongoing Phase 3 REGAL clinical trial of galinpepimut-S (GPS) in acute myeloid leukemia (AML), triggering the interim analysis to be conducted by the Independent Data Monitoring Committee (IDMC).

The IDMC will conduct a thorough review of the current REGAL data, and the interim analysis will provide an assessment of efficacy, futility as well as safety of GPS.

“This is an exciting and very important milestone in our efforts to bring forward a new potential treatment option for AML patients,” said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer of SELLAS. “Our mission at SELLAS is to develop novel therapies that prolong patients’ lives, and the outcome of the interim analysis will hopefully bring us closer to the potential of adding GPS as a powerful ally in the battle against AML. Today, we are here thanks to the unwavering support of our shareholders, dedication of our clinical investigators and the resilience of our patients and their families. The IDMC will now carefully review and analyze all the data and have scheduled a meeting in January to review results to date. We are extremely grateful to everybody who have contributed to the REGAL study, and we look forward to sharing the IDMC’s feedback and recommendations as



soon as they become available.”

The Company will host a call today to review the process leading up to the IDMC meeting and the potential outcomes of the REGAL interim analysis.

To access the webinar, please use the following information:

Date:	Tuesday, December 10, 2024
Time:	9:00 a.m. Eastern Time
Webcast:	SELLAS GPS REGAL

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 (formerly GFH009) - 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.

About the GPS Phase 3 REGAL Study

REGAL is a Phase 3 open-label 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.

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 28, 2024 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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