



NEWS RELEASE

# SELLAS Life Sciences Announces Positive Recommendation from REGAL Independent Data Monitoring Committee of Galinpepimut-S in Acute Myeloid Leukemia

12/4/2023

- Independent Data Monitoring Committee (IDMC) Recommended Continuation of Phase 3 REGAL Trial Without Any Modifications -

- IDMC Expressed Satisfaction with Speed of Enrollment and High Study Integrity -

- IDMC Will Review Most Current Survival Data at Next Scheduled IDMC Meeting in Q1 2024 -

NEW YORK, Dec. 04, 2023 (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 a positive review of the ongoing Phase 3 REGAL clinical trial of galinpepimut-S (GPS) in acute myeloid leukemia (AML) by the Independent Data Monitoring Committee (IDMC). The IDMC performed a routine, prespecified risk-benefit assessment of unblinded data from the study and has recommended that the trial continue without modifications. The IDMC also requested that the survival database be updated immediately prior to the next IDMC meeting, which will take place in Q1 2024, and be provided to the IDMC for its review at the meeting.

"We are very encouraged by the IDMC's recommendations to continue the Phase 3 trial without any modifications as well as positive commentary on the high level of study integrity and conduct and their request of an ad hoc database update that could potentially expedite their review and analyses of all current survival and safety data," said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer at SELLAS. "This review comes on the heels

of reaching our patient enrollment target, ex-China, and we very much look forward to the IDMC's next meeting in the first quarter of 2024. We believe that, based on its unique mechanism of action, GPS may offer a promising new treatment option to patients with AML."

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 for 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 (formerly GFH009), a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. 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 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 16, 2023 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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