NEWS RELEASE

SELLAS Life Sciences Announces Positive Recommendation of Independent Data Monitoring Committee Following Completion of Enrollment in REGAL Phase 3 Study

4/29/2024

– Based on the Efficacy and Safety Data Assessed, the Independent Data Monitoring Committee (IDMC) Recommends Continuation of Phase 3 REGAL Trial Patients Treatment and Follow-Up Without Any Modifications –

– IDMC Will Convene Again Ahead of Scheduled IDMC Charter Meeting –

– Next Efficacy and Safety Assessment of All REGAL Patients (n=127) in June 2024 –

NEW YORK, April 29, 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 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 conducted a prespecified risk-benefit assessment of unblinded data from the study and has recommended that the trial continue without modifications, and scheduled its next meeting in June 2024, earlier than prescribed in the IDMC charter schedule to review the most up-to-date information regarding the number of events (deaths) required for triggering prespecified interim analysis.

“We thank the IDMC members for the work and their guidance to continue the Phase 3 REGAL trial patients’ treatment without any modifications,” said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer of SELLAS. “This recommendation was made based on the assessment of efficacy and safety of the accumulated data. We are pleased with the recently concluded enrollment for the study in the US, Europe, and Asia, per the

predetermined statistical analysis plan, and we look forward to the interim analysis potentially later this quarter. If approved, GPS would be a promising new treatment in this severely underserved indication."

"As reported in March 2024, the REGAL Study Steering Committee reviewed the blinded study data with 66 patients discontinuing the treatment. In the trial, patients are recorded as having stopped the study treatment in cases of death for any reason, relapse, intolerable toxicity, or treatment completion. Regarding the GPS arm, we are pleased to report that we have not observed any intolerable toxicities in any patient population across all our clinical studies thus far, although toxicities are commonly observed with therapies used in the control arm. The IDMC also confirmed no safety issues in their recent review. Therefore, patients off treatment likely either relapsed or passed away, but as the study sponsor, we lack information on the actual number of events (60 events are required for interim analysis). This lies within the purview of the IDMC, which will now meet again in June and will review both efficacy and safety data from all enrolled REGAL patients (n=127) with a data cut-off date of around the end of May. At this point I would like to thank again all our global investigators who enrolled high numbers of patients with the top three enrolling countries, the US, Greece, and India, leading the way as a testament to the broad appeal of GPS."

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.

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**.

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.

Investor Contact

Bruce Mackle
Managing Director
LifeSci Advisors, LLC
SELLAS@lifesciadvisors.com

Source: SELLAS Life Sciences Group, Inc.