NEWS RELEASE

# SELLAS Announces Completion of Enrollment and Initial Positive Data in Phase 2a Trial of SLS009 in r/r AML

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- 30 Patients Relapsed or Refractory to Venetoclax-Based Regimens Enrolled Ahead of Schedule -

- Overall Response Rate (ORR) of 33% and 50% Achieved to Date in 60 mg QW and 30 mg BIW Cohorts, Respectively -

- 45 mg (Safety Dose) Once a Week of SLS009 Showed a Median Overall Survival (OS) of 5.4 Months vs. 2.5 Months with Standard of Care; 60 mg Once a Week and 30 mg Twice a Week Median OS Have Not Been Reached Yet -

- 100% Overall Response Rate in Patients with ASXL1 Mutation in the 30 mg BIW Cohort to Date -

- Trial Continues with Two Expansion Cohorts of Patients with ASXL1 Mutations and Myelodysplasia-Related Molecular Mutations Other Than ASXL1; Additional Update Expected in Q3 2024 -

NEW YORK, June 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 the completion of enrollment as well as positive initial data from the ongoing Phase 2a trial of SLS009, a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML).

“We are pleased to announce the completion of enrollment in the initial portion of our Phase 2a trial representing a significant milestone in the development of SLS009 in AML,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “There has been a high level of enthusiasm from the clinical sites, trial

investigators, and patients, reflecting the significant unmet need in the AML patient population previously treated with venetoclax-based regimens. We are extremely grateful to everyone who has helped us achieve this important milestone ahead of schedule."

Dr. Stergiou continued: "In addition, we are excited to share very promising initial data from this Phase 2a trial. Efficacy was demonstrated across all cohorts far exceeding the targeted ORR of 20% and median overall survival (mOS) of 3 months. The results also showed that SLS009 was well-tolerated across all doses. These data give us increased confidence in SLS009 as a potential new treatment for AML. We remain committed to advancing the treatment landscape for this underserved patient population and we look forward to continuing the trial, mainly the expansion cohorts, and reporting additional study updates and data in Q3 of this year."

Thirty heavily pretreated patients were recruited in 5 centers across the US, reflecting the high unmet need of this refractory/relapsed patient population. Except for one, all patients in this Phase 2a trial had unfavorable/poor cytogenetic and/or molecular genetics risk (97%) and were treated with continued venetoclax – azacytidine combination therapy after having failed it or similar venetoclax combinations, often more than once. The expected overall survival in those patients is approximately 2.5 months.

Key Highlights from the Initial Data:

Safety:

- SLS009 was generally well-tolerated with no safety issues observed across all doses.
- There were no dose-limiting and no high-grade treatment-related non-hematologic toxicities. Hematologic toxicities profile was not different from that of venetoclax-based regimens alone.
- 27 patients had at least one efficacy assessment as of May 25, 2024, and were considered evaluable for efficacy.

Efficacy:

- The overall response rate was 29.6% in all evaluable patients, and across all SLS009 doses, with the highest response rate of 50% observed at the dosing regimen of 30 mg BIW.
- In the first dose level (safety level, one dose level below recommended Phase 2 dose) of 45 mg once a week (QW), the median overall survival among evaluable patients followed for survival was 5.4 months, compared to the expected survival of 2.5 months in patients refractory to and relapsed on standard venetoclax in combination with hypomethylating agents.

- In the second dose level, 60 mg, administered once a week, 3 out of 9 evaluable patients (33%) achieved an overall response defined as leukemia-free status that includes complete response (CR), complete response with incomplete hematologic recovery (CRi), and morphologic leukemia-free state (MLFS). Median survival has not been reached.
- In the third dose level of 30 mg twice a week, 4 out of 8 patients (50%) evaluable to date achieved overall response defined as leukemia-free status that includes complete response (CR), complete response with incomplete hematologic recovery (CRi), and morphologic leukemia-free state (MLFS). Median survival has not been reached.
- Observed efficacy outcomes exceeded the target ORR of 20% and mOS of 3 months.
- The highest response rates were observed among patients harboring ASXL1 mutations as previously reported. Notably, responses were highly correlated with mutational status, with 6 out of 8 responding patients having myelodysplasia-related somatic mutations and 5 having specifically ASXL1 mutations.
- A 100% overall response rate (CR/CRi/MLFS) was achieved in patients with ASXL1 mutations in the 30 mg BIW cohort to date.
- Based on the preliminary findings from this Phase 2a trial, the trial has been expanded to include two additional cohorts consisting of dosing at 30 mg BIW. One cohort will enroll AML patients with ASXL1 mutations and the other AML patients with myelodysplasia-related molecular mutations other than ASXL1. Study enrollment continues and additional updates and data are expected in Q3.

The Phase 2a clinical trial of SLS009 is an open-label, single-arm, multi-center study designed to evaluate the safety, tolerability, and efficacy of SLS009 in combination with venetoclax and azacitidine at two dose levels, 45 and 60 mg. In the 60 mg dose cohort patients were randomized into either a 60 mg dose once per week or a 30 mg dose two times per week. The target response rate at the optimal dose level is 20% with a target median survival of at least 3 months. In addition, the study aims to identify biomarkers for the target patient population and enrichment for further trials. For more information on the study, visit **clinicaltrial.gov** identifier **NCT04588922**.

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' other 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 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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