



NEWS RELEASE

# SELLAS Life Sciences Delivers Oral Presentation of SLS009 Phase 1 Data for Acute Myeloid Leukemia Patients at 2024 European School of Haematology (ESH) Conference

3/1/2024

- All key study objectives regarding pharmacokinetic, pharmacodynamic, safety, and clinical activity were met -
- Complete remission (CR) achieved after three months of treatment with duration of eight months and one year survival at the latest assessment -
- First time achievement of CR with CDK9 inhibition monotherapy in relapsed/refractory (r/r) acute myeloid leukemia (AML) patient -
- Phase 2a data in r/r AML patients expected in March and Q2 2024 -

NEW YORK, March 01, 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 delivery of an oral presentation of data for the cohort of patients with acute myeloid leukemia (AML) from the Phase 1 dose-escalation study of SLS009 (formerly GFH009) by Dr. Tapan Kadia, Professor at MD Anderson Cancer Center and the study's primary investigator, at the 2024 European School of Haematology Acute Leukaemias (ESH) Conference: How to Diagnose and Treat Acute Leukaemias, taking place March 1-3, 2024, in Stockholm, Sweden.

Positive topline data for the heavily pretreated AML patients showed evidence of anti-tumor activity increasing with higher dose levels and no significant safety issues. Treatment with SLS009 resulted in a complete remission (CR)

with no minimal residual disease (MRD) after three cycles as a monotherapy in an AML patient who had failed prior venetoclax plus azacytidine (aza/ven) therapy. The CR lasted eight months with the patient achieving one year survival at the latest assessment. This is the first time that a relapsed/refractory (r/r) AML patient achieved a CR with CDK9 inhibition monotherapy. Notably, the median survival for patients relapsed after aza/ven therapy is approximately 2.5 months.

All key study objectives regarding pharmacokinetic (PK), pharmacodynamic (PD), safety, and clinical activity were met. Presented findings included:

- No dose-limiting toxicities or significant off-target adverse events (AEs) at any dose level. Maximum tolerated dose was not reached due to a favorable safety profile.
- Dose-proportional anti-leukemic activity across all dose levels and administration regimens studied, including bone marrow blast reduction of greater than 50% in patients with high burdens of leukemic bone marrow blasts indicating a broad therapeutic index and meaningful cell killing activity.
  - Durable CR was observed in one patient who had previously failed aza/ven therapy, after three months of treatment, lasting eight months and one-year survival at the most recent assessment.
- Strong inhibitory activity against key biomarkers with a dose-proportional response and universal decrease of MYC and MCL-1 in evaluable patients.
- Proportional and well-controlled pharmacokinetics at all dose levels and at different dosing regimens.
- The recommended phase two dose (RP2D) for AML was established at 60 mg.
- Favorable safety profile observed with a notable absence of higher-grade extramedullary toxicities which have been frequently observed with other CDK9 inhibitors in development.

“SLS009 is a highly selective CDK9 inhibitor with high specificity, only low grade off-target toxicity, confirmed efficacy on relevant biomarkers and clinical outcomes in hematologic malignancies,” said Dragan Cicic, MD, Chief Development Officer at Sellas. “Its potential strong synergy with the standard regimen of venetoclax and hypomethylating agents could open up new avenues in the treatment of acute myeloid leukemia. We are looking forward to additional findings from the ongoing Phase 2a trial with the topline data from the initial 45 mg safety-dose level expected by the end of March and the 60 mg RP2D level in the second quarter of this year.”

The ongoing Phase 2a trial is designed to assess the safety and efficacy of SLS009 in combination with aza/ven in AML patients who stopped responding to standard aza/ven therapy and other venetoclax- based regimens. Patients are dosed at two SLS009 dose levels of 45 mg once a week and 60 mg either as a once-weekly dose or divided into two 30 mg doses weekly.

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, galinpepimut-S (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 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, 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 SLS009 clinical development program, including data therefrom, and the timing for release of additional data. 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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