NEWS RELEASE

SELLAS Announces Positive Topline Data from the Phase 2a Study of SLS009 in r/r AML and Provides Steering Committee Update on Phase 3 REGAL Study

3/26/2024

- Phase 3 REGAL Study of GPS in AML: Enrollment Completed; Steering Committee Guided Interim Analysis Imminent; IDMC Now Scheduled in Late April -

- Phase 2a study of SLS009 in r/r AML: 50% Response Rate in the Selected Optimal Dose of 30 mg BIW Exceeding the Targeted 20%; 100% Response Rate in Patients with Identified Biomarkers to Date -

- Median OS Has Not Been Reached in the Phase 2a Study of SLS009; First CR Patient Continues on Study and Remains Leukemia-Free 9 Months Since Enrollment –

- SLS009 Exhibits Strong Anti-Leukemic Activity in ~70% of Patients with a Favorable Safety Profile at All Dose Levels -

- Company to Host Corporate Update Webinar Today, March 26, 2024, at 8:15 am ET-

NEW YORK, March 26, 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 announces topline data from the Phase 2a study of SLS009 and provides an update on Phase 3 REGAL Study of GPS in AML. The Company will host a webinar to discuss the data and the REGAL update today at 8:15 am ET.

"Completion of enrollment in the Phase 3 REGAL trial represents an important milestone in our goal to deliver GPS to AML patients," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We are

extremely grateful to the patients, their families, and investigators who have helped us achieve this significant milestone. Additionally, we are pleased to share that the Steering Committee has reviewed the study as of the March 1, 2024, cutoff date. As of this evaluation, 123 patients were enrolled with 66 of them 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. Therefore, almost all patients who are off treatment may have most likely either relapsed or passed away. The most frequent cause of death in this patient population is relapse. As the study sponsors, we lack specific information on the outcomes of these 66 patients, hindering our ability to confirm whether the required number of events for interim analysis – 60 – has been reached. The determination of such outcomes, the primary endpoint of the trial, lies within the purview of the IDMC, which is now scheduled to meet by the end of April."

The REGAL Steering Committee met on March 22, 2024, to discuss the study and believes the high number of patients who completed participation in the study signals that the interim analysis requiring 60 events may be imminent. The Committee also expressed its satisfaction with SELLAS' overall clinical study conduct and complimented SELLAS for addressing such a debilitating and high unmet medical need as no drugs are approved in the AML CR2 maintenance setting.

Dr. Stergiou continued: "We are extremely excited to share positive topline data from the Phase 2a trial of SLS009 in AML patients resistant to venetoclax combination therapies. In the selected optimal dose regimen of 30 mg BIW a 50% response rate was achieved, far surpassing the targeted 20% rate. Notably, we identified promising biomarkers and observed a 100% response rate at the optimal dose level and a 57% response rate across all the levels tested in patients with those biomarkers. The SLS009 aza-ven treatment was well-tolerated and evoked anti-leukemic effects in 67% of patients across all levels dosed. The first patient who achieved a complete response continues on the study and remains leukemia-free 9 months post-enrollment. These compelling results from the Phase 2a reinforce our belief that SLS009 represents a potential breakthrough for relapsed and/or refractory AML patients, addressing one of the most urgent unmet medical needs."

Summary of Topline Data from Phase 2a data of SLS009 in AML

Patients Characteristics

- As of March 15, 2024 data cutoff, 21 patients were treated
- All patients were diagnosed with AML refractory to or relapsed after venetoclax containing regimens

- 20 out of 21 (95%) enrolled patients had adverse/high-risk cytogenetics and 1 patient (5%) had intermediate cytogenetics
- Median age was 70 and 19/21 (90.5%) of patients were older than 60

Safety

- SLS009 in combination with aza/ven has been well-tolerated at all tested dose levels
- No dose-limiting toxicities (DLT) at any of the studied dose levels and no treatment-related high-grade (≥G3) toxicities were observed
- Hematologic toxicities profile was consistent with aza/ven standalone treatment

Efficacy

A total of 21 patients were enrolled in the study as of March 15, 2024: 10 in the 45 mg safety cohort, 11 in the 60 mg cohort (2 x 30 mg twice a week or 60 mg once a week)

- 10% response rate in the 45 mg QW safety cohort (dose level below the recommended Phase 2 dose, RP2D)
- 20% response rate in the 60 mg QW cohort
- 50% response rate in the 60 mg, 2 x 30 mg BIW cohort
- Observed strong anti-leukemic activity, defined as 50% or more bone marrow blast reduction in 67% of patients across all dose levels
- Median survival rate has not been reached in any of the dose levels
- The first patient enrolled in the study who achieved a complete response (CR) continues on the study and remains leukemia-free 9 months after enrollment

Biomarkers

- During the trial the Company identified potential biomarkers currently undergoing testing as predictive markers in the most recent portion of the study
- Patients with the identified biomarkers exhibited significantly higher response rates:
    - 100% response rate at the optimal dose level (30 mg BIW)
    - 57% response rate across all dose levels

- Furthermore, the Company has clarified the proposed biological basis and mechanism of action for SLS009 activity in patients with these biomarkers
- The relevant biomarkers are present in multiple hematologic and solid cancer indications, with a substantial proportion of patients exhibiting them in additional indications, ranging up to ~50% of patients in some indications

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 aza/ven 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 over 3 months. In addition, the study aims to identify biomarkers for the target patient population and enrichment for further trials.

Corporate update call details are as follows:

Date:	Tuesday, March 26, 2024
Time:	8:15 a.m. Eastern Time
Dial-in (U.S.):	1-877-423-9813
International Dial-in:	1-201-689-8573
Webcast:	**SELLAS Update Call**

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 (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 SLS009 clinical development program, including data therefrom, and regulatory strategy. 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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