

SELLAS Announces Positive Topline Data in Lymphoma Cohort from SLS009 Phase 1 Dose-Escalation Trial, Supporting Advancement to Phase 2 Clinical Study; Primary and Secondary Endpoints Met

9/21/2023

- 52 Relapsed and Refractory Lymphoma Patients Enrolled: 96% Alive at Last Assessment Indicating Favorable Survival Benefit -
- Responses Observed Across Dose Levels with a 14.7% Clinical Response Rate Overall, 35.3% Overall Disease Control Rate, and 36.4% Clinical Response Rate in PTCL Patients -
- Decrease in MCL1 and/or MYC Biomarkers Observed in 100% of Patients in a Dose-Dependent Manner in Once Per Week Administration Regimen -
- Recommended Phase 2 Dose for Lymphoma Patients Established at 100 mg Once Per Week-
- No Off-Target Safety Issues at any Dose Level -

NEW YORK, Sept. 21, 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 positive topline data for the patient group with relapsed/refractory (r/r) lymphomas from the Phase 1 dose-escalation trial of its CDK9 inhibitor, SLS009 (GFH009).

All primary and secondary study objectives, including safety, clinical activity, pharmacokinetics (PK), and pharmacodynamics (PD), were successfully achieved. The recommended Phase 2 Dose (RP2D) for lymphoma

patients has been established at the highest dose level evaluated of 100 mg, administered as a once-weekly infusion. The maximum tolerated dose (MTD) was not reached. A dose-limiting toxicity occurred in one out of five patients treated at the 100 mg dose level. No dose-limiting toxicities were observed at any other dose level, and there were no unexpected toxicities across the study.

“We are excited to share strong topline data from the Phase 1 trial of SLS009 in lymphoma patients, building upon the promising results in the cohort of patients with acute myeloid leukemia (AML) which we reported earlier this year,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The data demonstrate meaningful anti-tumor activity and clinical responses as a monotherapy. Based on its favorable therapeutic profile, SLS009 continues to emerge as a potential treatment for patients with hematologic malignancies who have exhausted available treatment options. Our partner, GenFleet Therapeutics, plans to advance GFH009 (SLS009) into Phase 2 clinical studies in China for patients with peripheral T-cell lymphoma (PTCL) later this year.”

A total of 52 r/r lymphoma patients were enrolled. Of these, 24 received two bi-weekly doses (BIW), while 28 were administered weekly doses (QW). Among the 52 r/r lymphoma patients, 15 were diagnosed with PTCL, with 6 of them receiving the BIW regimen and 9 the QW regimen.

The dose-escalation trial investigated a range of doses from 2.5 mg to 100 mg, employing two dosing regimens: once-weekly infusions (QW) and twice-weekly infusions (BIW).

Key findings from the study include :

Efficacy:

- Among 34 evaluable r/r lymphoma patients, five (14.7%) achieved a clinical response with a reduction in tumor burden of up to 62%.
- An additional seven patients (20.6%) achieved stable disease (SD) resulting in an overall disease control rate of 35.3%.
- In the subgroup of PTCL patients, four out of 11 (36.4%) evaluable patients achieved a clinical response.

Safety:

- There were no drug-related fatalities at any dose level, and the drug was well tolerated.
- In patients treated with the BIW regimen, no significant safety events appeared to be dose-dependent.
- In patients receiving the QW regimen, \geq G3 treatment-related adverse events (TRAEs) occurred, primarily hematologic events, at higher dose levels.
- Non-hematologic toxicities were rare across all dose levels with five out of 52 patients (9.6%) experiencing higher grade toxicities, including hypokalemia (3/52 patients, 5.8%), upper respiratory tract infection (1/52

patients, 1.9%) and increase in bilirubin (1/52 patients, 1.9%).

- Maximum Tolerated Dose (MTD) was not reached with only 1/5 patients at the highest dose level studied (100 mg) experiencing a dose-limiting toxicity (DLT).
- No dose-limiting toxicities were observed at any other dose level, and there were no unexpected toxicities across the study.

Pharmacokinetic (PK) Data: Exposure parameters (C_{max} and AUC) increased in an approximately proportional manner with the dose range of 30 mg~60 mg QW. The exposure of 100 mg was the highest, and the mean plasma concentration remained above IC₉₀ for the longest time period (nearly 50 hours).

Pharmacodynamic (PD) Data: Desired levels of suppression in peripheral blood were achieved, leading to a decrease in MCL1 or MYC biomarkers in all (100%) studied patients. Biomarker suppression was dose-dependent in patients receiving QW dosing. The biomarkers studied included MYC and MCL1 with SLS009 administration resulted in biomarkers suppression across dose levels in both administration regimens (BIW and QW) and a dose-dependent decrease in QW groups. 100mg QW DL resulted in the longest sustained inhibition of both MCL1 and MYC.

The totality of the r/r lymphoma data will be presented at a major medical conference.

For more information on the Phase 1 study of SLS009 in r/r AML and r/r lymphomas, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference 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' 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 clinical data of SLS009 and plans for further development of SLS009. 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.