NEWS RELEASE

SELLAS Provides Corporate Updates and Highlights Key Upcoming Milestones

1/3/2024

- Company to Host Corporate Update Webinar Today, January 3, 2024, at 8:30 am ET-

-Interim Analysis of Phase 3 REGAL Study of Galinpepimut-S in Patients with Acute Myeloid Leukemia Expected in First Quarter 2024 -

- Phase 2a Study of SLS009 in Relapsed/Refractory AML Patients Ongoing with Topline Data Expected in First Quarter of 2024

- Phase 1b/2 Study in Relapsed/Refractory Peripheral T-cell Lymphoma Patients Ongoing with Top-line Data Expected in First Half 2024 –

NEW YORK, Jan. 03, 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 provided a business update and will host a corporate webinar at 8:30 am ET.

"2023 was a very productive year for SELLAS," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We advanced our clinical-stage programs for both galinpepimut-S (GPS) and SLS009, reported positive initial topline Phase 2a data of SLS009 which showed the first complete response achieved in an acute myeloid leukemia (AML) patient resistant to venetoclax combination therapies and significant antileukemic effect and apparent survival benefit, initiated a Phase 1b/2 trial of SLS009 in relapsed/refractory (r/r) peripheral T-cell lymphomas (PTCL) and held a successful FDA Type C meeting which solidified our GPS CMC program and commercial manufacturing and regulatory plans. We are pleased that the potential for SLS009 has been recognized

by the FDA as evidenced by the granting of Fast Track Designation for PTCL and Orphan Drug Designations for AML and PTCL."

Dr. Stergiou continued: “We hope to build on this excellent progress and look forward to multiple clinical milestones that have the potential to create significant value for our shareholders. These include reporting interim data from the Phase 3 REGAL trial of GPS in AML as well as topline data from our Phase 2a SLS009 r/r AML trial this quarter and topline data from the Phase 1b/2 study of SLS009 in PTCL by the end of the second quarter. We believe that 2024 will be a pivotal year for SELLAS as we continue to advance our clinical-stage GPS and SLS009 programs that address a broad spectrum of hematologic malignancies and solid tumor indications. We welcome you to join us on our 8:30am call this morning where we will discuss further relevant corporate matters.”

2024 Milestones:

Galinpepimut-S (GPS): Wilms Tumor-1 (WT1) targeting immunotherapeutic

- Phase 3 REGAL study in AML: The interim analysis of the ongoing global Phase 3 registrational clinical trial (the REGAL study) of GPS in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients) is expected in the first quarter of 2024. Because this analysis is event-driven, it may occur at a different time than currently expected.

SLS009: highly selective CDK9 inhibitor

- Phase 2a clinical trial in AML: The Company expects to report data from the fully enrolled 45 mg (safety dose level) cohort and initial data from the 60 mg (recommended Phase 2 dose level) cohort in the first quarter of 2024 and expects the 60 mg cohort to be analyzed in the second quarter of 2024.
- Phase 1b/2 clinical trial in r/r PTCL: Enrollment started in December 2023. Thirty-one sites are active for recruiting and approximately 10 more sites will be initiated. Interim analysis is planned after 20-25 patients are enrolled and have undergone initial follow-up which is projected to occur by June 2024. The interim efficacy data will be discussed with regulatory agencies to decide on continuation of the trial as a pivotal registrational study that would enroll approximately 70-75 additional patients. This study is fully funded by the Company’s partner for SLS009, GenFleet Therapeutics (Shanghai), Inc., and is being conducted in China.

2023 Highlights:

Galinpepimut-S (GPS): Wilms Tumor-1 (WT1) targeting immunotherapeutic

- In the fourth quarter of 2023, the Company reached, and exceeded, its target enrollment of 105 patients in the ongoing Phase 3 REGAL trial of GPS, excluding the approximately 20 patients intended for enrollment in

mainland China. Due to the uncertainty of timely participation of 3D Medicines in the REGAL study in mainland China, the Company is continuing to enroll patients in the United States, Europe and Asia to reach 126 patients, per the statistical analysis plan, for full enrollment in the first quarter of 2024. The number of patients needed for the pre-specified interim and final analyses are already enrolled.

- Positive immunobiological and clinical data from the completed Phase 1/2 clinical trial of GPS in combination with Keytruda® (pembrolizumab) in WT1+ platinum-resistant advanced ovarian cancer was presented at the International Gynecologic Cancer Society 2023 annual global meeting in November 2023.
- The Company reported positive follow-up immune response and survival data in the fourth quarter of 2023 for the completed Phase 1 clinical trial of GPS combined with Opdivo® (nivolumab) in advanced malignant pleural mesothelioma.
- In the fourth quarter of 2023, the Company announced that it had concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's Chemistry, Manufacturing, and Controls (CMC) sections in a potential biologics license application (BLA) for GPS. SELLAS had submitted a CMC Briefing Package to the FDA which provided an up-to-date overview of the extensive work completed for the GPS CMC program and commercial manufacturing and regulatory plans. The FDA reviewed this package of data and accompanying questions to the agency and responded with favorable guidance.

SLS009: highly selective CDK9 inhibitor

- The Phase 1 clinical trial for patients with AML and lymphomas was completed in 2023. For patients with AML, SLS009 demonstrated a favorable tolerability profile with no dose limiting toxicities. Anti-tumor activity and clinical responses across dose levels were observed, indicating a broad therapeutic index. Meaningful cell killing activity, defined as ≥50% reduction in blasts in the bone marrow, was observed at several dose levels. A durable complete remission (CR) with no minimal residual disease (MRD) was observed in one patient with AML who had failed prior venetoclax plus azacytidine (aza/ven) therapy. The patient continues to be alive 11 months following commencement of treatment per last follow-up. The recommended Phase 2 dose for patients with AML was established at 60 mg. For the patients with lymphomas, no off-target safety issues were observed at any dose level and responses were observed across dose levels with a 14.7% clinical response rate overall, 35.3% overall disease control rate, and 36.4% clinical response rate for patients with PTCL. The recommended Phase 2 dose for patients with lymphomas was established at 100 mg administered as a once weekly infusion.
- In the second quarter of 2023, the Company announced the dosing of the first patient (45 mg) in an open label, single arm, multi-center Phase 2a study that is designed to evaluate safety, tolerability, and efficacy at two dose levels of SLS009 (once weekly 45 mg or 60 mg) in combination with aza/ven in patients with AML. Enrollment in the 45 mg cohort was completed in the fourth quarter of 2023. Also in the fourth quarter of 2023, the Company announced the dosing of the first patients in the 60 mg dose cohort. The patients in the 60 mg dose cohort will be dosed with 60 mg once per week or 30 mg twice per week.

- Early topline data from the Phase 2a study in patients with AML dosed at the 45 mg level (n=9) include one patient with a CR and significant anti-leukemic effects (≥50% decrease in bone marrow blasts) were observed in five out of six assessable patients with no significant safety issues to date.
- In the fourth quarter of 2023, the Company announced the dosing of the first patient in a Phase Ib/II open-label, single arm trial in r/r PTCL which will enroll up to 95 patients to evaluate safety and efficacy and, based on results, may serve as a registrational study. This study is fully funded by the Company's partner for SLS009, GenFleet Therapeutics (Shanghai), Inc. and is being conducted in China.
- The Company received the following regulatory designations from the FDA for SLS009 in 2023:

    - Orphan Drug Designation (ODD) for the treatment of AML
    - ODD for the treatment of PTCL
    - Fast track designation for the treatment of r/r PTCL

Webinar:	
Date:	Wednesday, January 3, 2024
Time:	8:30 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, 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**.

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA and is not a trademark of SELLAS. Opdivo® is a registered trademark of Bristol-Myers Squibb Company, New York, NY, USA and is not a trademark of SELLAS. The manufacturers of these brands are not affiliated with and do

not endorse SELLAS or its products.

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 and SLS009 clinical development programs, including data therefrom, regulatory strategy and expected milestones. 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.