NEWS RELEASE

SELLAS Announces Key Business Objectives for 2025

2025-01-08

- Independent Data Monitoring Committee to Perform Interim Analysis of Phase 3 REGAL Study in January 2025 -

- SLS009: Full Topline Phase 2 Data in Acute Myeloid Leukemia and FDA Regulatory Review Expected in 1H 2025 -

- Approval of “tambiciclib” as Recommended International Nonproprietary Name for SLS009 -

- Applied for Non-Dilutive Grant Funding to Expand SLS009 Development Into Frontline Setting in AML -

- Developing SLS009 Pediatric Programs in Hematological and Potentially Other Malignancies -

- Company to Host Corporate Update Webinar Today, January 8, 2025, at 9:00 am ET -

NEW YORK, Jan. 08, 2025 (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 webinar at 9:00 am ET.

“We believe that 2025 will be a pivotal year for SELLAS as we continue to advance our clinical stage portfolio of novel therapeutics for hematologic malignancies,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “We aim to build on the excellent progress achieved in 2024 and look forward to several, potentially transformative clinical milestones. Specifically, we anticipate full topline dataset from our Phase 2 trial of SLS009 in acute myeloid leukemia (AML) patients resistant to venetoclax combination therapies and FDA regulatory feedback around our SLS009 study, as well as the interim analysis from Phase 3 REGAL being conducted by the Independent Data Monitoring Committee (IDMC). Based on the results of this analysis, the IDMC will provide their recommendation in January to either stop the trial early for efficacy, stop for futility, or continue the study without modification. If the recommendation is to continue, the next and final analysis will take place upon reaching a total of 80 events, as predefined in the study protocol.”

Dr. Stergiou continued, “We are also pleased that the potential of both of our assets has been recognized by the regulatory agencies. During 2024, GPS was granted FDA Rare Pediatric Disease Designation for pediatric AML and SLS009 was granted RPDD for pediatric AML and pediatric acute lymphoblastic leukemia, FDA Fast Track Designation for AML, and EMA orphan drug designation for AML and peripheral T-cell lymphoma. These designations underscore the significant unmet medical needs which our therapies aim to address and reinforce the confidence of regulatory authorities in our innovative approach to treating a broad range of cancer indications.”

Expected Milestones in 2025:

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

- Phase 3 REGAL study in AML:

The interim analysis from the ongoing REGAL global Phase 3 registrational clinical trial of GPS in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients) is expected in January 2025. Based on the results of this analysis, the IDMC will provide recommendations to either stop the trial early for efficacy, stop for futility, or continue the study without modification. If the recommendation is to continue without modification, the next and final analysis will take place upon reaching a total of 80 events, as predefined in the study protocol.

SLS009: highly selective CDK9 inhibitor

- Phase 2 clinical trial in AML: Full topline data from expansion cohorts which include AML-MRC patients with ASXL1 mutation (cohort 4) and mutations and cytogenic changes other than ASXL1 (cohort 5) are expected in 1H 2025.
- FDA feedback on regulatory path for r/r AML study expected in 1H 2025.

2024 Key Achievements:
Galinpepimut-S (GPS): Wilms Tumor-1 (WT1) targeting immunotherapeutic

- Phase 3 REGAL study of GPS in AML reached pre-specified threshold of 60 events (deaths) initiating the interim analysis being conducted by the Independent Data Monitoring Committee (IDMC).

SLS009: highly selective CDK9 inhibitor

- The World Health Organization (WHO) has approved “tambiciclib” as the recommended International Nonproprietary Name (INN) for SLS009

- Reported positive data from the ongoing Phase 2 trial of SLS009 in r/r AML in Q4 2024. The median overall survival (mOS) has not been reached but exceeds 7.7 months at the latest follow-up, marking a significant milestone for patients in this setting, where the expected mOS is historically around 2.5 months. In expansion cohorts in patients with AML-myelodysplasia-related changes (AML-MRC) with ASXL1 mutation and mutations and cytogenic changes other than ASXL1, the ORR was 56% in 9 evaluable for efficacy patients, exceeding pre-specified target response rate of 33%.
- Presented data from Phase 2a trial of SLS009 in r/r AML at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition 2024. Treatment with SLS009 in combination with azacitidine and venetoclax was well tolerated and led to a 50% response rate in the selected optimal dose level of 30 mg twice a week. Clinical activity was even higher in patients with AML-MRC and in particular, those with ASXL1 mutations, suggesting that this subset of patients may exhibit preferential sensitivity to SLS009. In the safety dose of 45mg once a week, SLS009 showed a mOS of 5.5 months.
- Completed enrollment in Phase 2a Trial of SLS009 in r/r AML: 30 patients relapsed after or refractory to venetoclax-based regiments were enrolled ahead of schedule in 5 centers across the US. Except for one, all patients in the Phase 2a trial had adverse risk AML (97%) and were treated with continued venetoclax–azacytidine combination therapy after having failed it or similar venetoclax-based combinations, often more than once.
- Opened enrollment in additional Phase 2 cohorts in venetoclax combinations in r/r AML. Development of SLS009 continues with the opening of two new cohorts - AML MRC with ASXL1 mutations and AML with myelodysplasia related changes other than ASXL1 mutations. These new cohorts are also open for enrollment of certain pediatric patients.
- Announced positive preclinical data indicating ASXL1 mutations as predictors of response to SLS009 in solid cancers.
- **Published in Oncotarget**, revealing the underlying mechanisms of action behind the anti-proliferative effects of SLS009 in various hematologic malignancies.
- Continued National Cancer Institute (NCI) Pediatric Preclinical in Vivo Testing (PIVOT) Program in pediatric tumor.

Regulatory:

- Received multiple regulatory designations: for GPS: FDA Rare Pediatric Disease Designation (RPDD) for pediatric AML, for SLS009: RPDD for pediatric AML, pediatric acute lymphoblastic leukemia (ALL), FDA Fast Track Designation for AML, and EMA orphan drug designation (ODD) for AML and peripheral T-cell lymphoma (PTCL).

To access the webinar, please use the following information:

Date: Wednesday, January 8, 2025

Time: 9:00 a.m. Eastern Time

Webcast: **2025 Business Outlook**

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 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) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. 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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