NEWS RELEASE

SELLAS Life Sciences Reports Full Year 2024 Financial Results and Provides Corporate Update

2025-03-20

– Announced Positive Outcome of Interim Analysis for its Pivotal Phase 3 REGAL Trial of Galinpepimut-S (GPS) in Acute Myeloid Leukemia (AML) with Next and Final Analysis Planned Upon Reaching 80 Events, Anticipated in 2025 –

– Reported Positive Overall Survival and Overall Response Rate Data from the Ongoing Phase 2 Trial of SLS009 (Tambiciclib) in r/r AML – Full Data and FDA Regulatory Path Feedback Expected in 1H 2025 –

– Raised $25 Million in Gross Proceeds in a Registered Direct Offering in January 2025 –

NEW YORK, March 20, 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 reported financial results for the full year ended December 31, 2024, and provided a corporate update.

“We are pleased with the progress of our pipeline as we continue to advance our two key assets through clinical development,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The most anticipated milestones in 2025 will be the final analysis of our Phase 3 pivotal REGAL trial of GPS in acute myeloid leukemia (AML) and the full topline Phase 2 data of SLS009 in AML, both of which represent significant opportunities and offer hope to AML patients in need. If successful, the REGAL trial provides a pathway for regulatory approval in AML, and GPS could become a transformative treatment for patients in their second complete remission. Furthermore, the promising data from the ongoing Phase 2 trial of SLS009 has shown a 56% overall response rate (ORR) in AML patients with myelodysplasia-related changes (AML MRC) prospectively enrolled in two expansion cohorts, exceeding the prespecified target ORR of 33%. In the optimal dosing regimen of 30 mg BIW, the median overall survival (mOS) has not been reached but exceeds 7.7 months at the latest follow-up, where the expected mOS is historically approximately 2.5 months.”

Dr. Stergiou continued, “We are especially encouraged by the multiple regulatory designations granted to our programs in 2024, including three FDA Rare Pediatric Disease Designations, one FDA Fast Track Designation, and two EMA Orphan Drug Designations, which reflect the significant potential impact of our therapies and provide valuable regulatory benefits that may accelerate development and potential approval. With strong regulatory recognition and two potentially pivotal inflection points ahead, we remain committed to driving innovation and delivering value to patients and shareholders.”

Recent Highlights:

Announced Positive Outcome of Interim Analysis for Phase 3 REGAL Trial of GPS in AML: The interim futility, efficacy, and safety analysis was designed to assess whether the therapy is safe, demonstrates potential efficacy, and merits continuation. The IDMC’s review supports the continuation of the study according to its original protocol. Based on this positive evaluation, GPS has shown preliminary signals of effectiveness, allowing the trial to advance toward completion. Fewer than 50% of enrolled patients were confirmed deceased after the median follow-up of 13.5 months, indicating a median survival of over 13.5 months in the trial vs. historical median survival of 6 months for conventional therapy, as reported in a similar Phase 2 study. The next and final analysis will be conducted once 80 events (deaths) are reached, further determining the potential of GPS in addressing the needs of AML patients. SELLAS anticipates that 80 events will be reached this year.

Promising Data from Phase 2a Trial of SLS009 in Combination with Zanubrutinib in DLBCL: The trial, conducted and funded by GenFleet Therapeutics (Shanghai), Inc. (“Genfleet”), was an open-label single-arm multicenter Phase 2a study in China evaluating SLS009 in combination with BTK inhibitor, Brukinsa® (zanubrutinib) in r/r DLBCL. The results showed an overall response rate (ORR) of 67%, more than double the expected ORR of zanubrutinib alone. Among responders, one achieved complete response (CR), while three had partial response (PR) with target lesion shrinkages of 89%, 78%, and 56%, respectively. As of the last follow-up, after the median of 4.6 (range: 1.4 - 7.4) months follow-up, median overall survival (OS) was not reached, and 6 out of 9 patients were alive. GenFleet will determine the next steps in development around lymphoma as SELLAS’ focus remains on AML and spliceosome–chromatin mutations, including ASXL1 mutations.

Raised $25.0 Million of Gross Proceeds from a Registered Direct Offering Priced At-the-Market under Nasdaq Rules: On January 28, 2025, SELLAS announced the closing of a $25 million registered direct offering with a single healthcare-focused institutional investor before deducting placement agent’s fees and related offering expenses. The net proceeds from the offering strengthens the Company’s financial position and will be used for working capital purposes and general corporate procedures, including the purchase of any pending or future acquisitions.

2024 Key Achievements:

SLS009 (tambiciclib): highly selective CDK9 inhibitor

- The World Health Organization (WHO) 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, where the expected mOS is historically ~ 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 patients evaluable for efficacy, 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.
- 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.
- 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 tumors.

Regulatory:

Received multiple regulatory designations: for GPS, FDA Rare Pediatric Disease Designation (RPDD) for pediatric AML; and 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).

Financial Results for the Full Year 2024:

R&D Expenses: Research and development expenses for the year ended December 31, 2024, were $19.1 million,

compared to $24.0 million for the year ended December 31, 2023. The decrease was primarily due to decreases in clinical trial expenses, manufacturing costs and clinical drug supply purchases, and clinical and regulatory consulting costs primarily driven by the completion of enrollment in the REGAL study in the first quarter of 2024 and a decrease in employee-related expenses due to a decrease in headcount.

G&A Expenses: General and administrative expenses for the year ended December 31, 2024, were $12.4 million, as compared to $13.9 million for the year ended December 31, 2023. The decrease was primarily due to a decrease in employee-related expenses due to a decrease in headcount, outside services and public company costs, and insurance premiums, partially offset by a one-time severance charge in 2024 and an increase in legal fees.

Net Loss: The net loss was $30.9 million for the year ended December 31, 2024, or a basic and diluted loss per share of $0.50, as compared to a net loss of $37.3 million for the year ended December 31, 2023, or a basic and diluted loss per share of $1.34.

Cash Position: As of December 31, 2024, cash and cash equivalents totaled approximately $13.9 million. Subsequent to December 31, 2024, on January 28, 2025, the Company received gross proceeds of $25.0 million from a registered direct offering priced at-the-market under Nasdaq rules.

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 (tambiciclib) - 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 20, 2025 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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SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 19,096	$ 24,007
General and administrative	12,417	13,862
Total operating expenses	31,513	37,869
Loss from operations	(31,513)	(37,869)
Non-operating income:		
Change in fair value of warrant liability	—	4
Interest income	632	525
Total non-operating income	632	529
Net loss	$ (30,881)	$ (37,340)
Per share information:		
Net loss per common share, basic and diluted	$ (0.50)	$ (1.34)

Weighted-average common shares outstanding, basic and diluted	61,202,412	27,777,111

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,886	$ 2,530
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	2,341	542
Total current assets	16,327	3,172
Operating lease right-of-use assets	925	858
Goodwill	1,914	1,914
Deposits and other assets	266	275
Total assets	$ 19,432	$ 6,219
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,500	$ 5,639
Accrued expenses and other current liabilities	5,466	7,650
Operating lease liabilities	544	446
Total current liabilities	9,510	13,735
Operating lease liabilities, non-current	457	460
Total liabilities	9,967	14,195
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, 0.0001 par value; 350,000,000 shares authorized, 73,977,459 and 32,132,890 shares issued and outstanding at December 31, 2024 and 2023, respectively	7	3
Additional paid-in capital	257,583	209,265
Accumulated deficit	(248,125)	(217,244)
Total stockholders' equity (deficit)	9,465	(7,976)
Total liabilities and stockholders' equity (deficit)	$ 19,432	$ 6,219

Source: SELLAS Life Sciences Group, Inc.