NEWS RELEASE

SELLAS Life Sciences Reports Third Quarter 2024 Financial Results and Provides Corporate Update

2024-11-13

– Pre-specified Events to Trigger Interim Analysis of Phase 3 REGAL Study in Patients with Acute Myeloid Leukemia (AML) Remains on Track for Q4 2024 –

– Data from the Phase 2a Trial of SLS009 in Relapsed/Refractory AML After Venetoclax Failure to be Presented at the Upcoming American Society of Hematology (ASH) Annual Meeting in December –

– GPS Granted FDA Rare Pediatric Disease Designation (RPDD) for the Treatment of Pediatric AML –

NEW YORK, Nov. 13, 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 reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

“We continue to make considerable progress across our pipeline, and we are particularly excited to announce the updated SLS009 Phase 2a data at ASH in December and to provide topline data from cohorts four and five in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) this quarter,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “We are extremely grateful to the patients and their families, principal investigators and study teams, SELLAS employees, and all of those who have contributed to our Phase 3 REGAL study of galinpepimut-S (GPS). We are excited to be on the cusp of potentially adding a novel immunotherapy to physicians’ arsenals in their mission to prolong patients’ lives. We are looking forward to the significant milestones on the horizon, with interim analysis from our Phase 3 REGAL study of GPS in AML anticipated in the coming weeks.”

Pipeline Highlights

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

Phase 3 REGAL study in AML: In June, the IDMC conducted a prespecified risk-benefit assessment of unblinded data from the study and recommended that the trial continue without modifications. Based on a detailed analysis of all unblinded data, the IDMC projected that the interim analysis (60 events) will occur in the fourth quarter of 2024.

Granted FDA Rare Pediatric Disease Designation (RPDD): The FDA granted Rare Pediatric Disease Designation (RPDD) to GPS for the treatment of pediatric AML. GPS has already demonstrated promise in clinical settings for AML, which could extend to pediatric patients.

SLS009: highly selective and specific CDK9 inhibitor

ASH Poster Presentation Upcoming December 8, 2024: Phase 2a Study of SLS009, a Highly Selective CDK9 Inhibitor, In Combination with Azacitidine and Venetoclax for Relapsed/Refractory Acute Myeloid Leukemia After Prior Venetoclax Treatment.

The study enrolled 30 patients across three dosing levels (DLs) of SLS009:45 mg IV QW, DL2: 60 mg IV QW, and DL3: 30 mg IV BIW. SLS009 was well-tolerated across the DLs tested with no dose-limiting toxicities (DLTs) observed. Among 29 evaluable pts, 16 (55%) had ≥50% reduction in bone marrow (BM) blasts compared to baseline (DL1: 60%; DL2: 33%; DL3: 80%). Nine (31%) patients achieved an overall response (i.e., CR+CRi+MLFS), including 5 (17%) who achieved CR/CRi. The response rates per dose level were 10% in DL1, 33% in DL2, and 50% in DL3. All 9 responders had AML- Myelodysplasia Related (AML-MR) (9/23 of AMLMR pts responded) and 8/15 pts (53%) with somatic MR mutations responded. Among those with ASXL1 mutations, 5/9 (56%) achieved an overall response. 2/9 (22%) with TP53 mutations achieved a response including one patient with concomitant TP53 and ASXL1 mutation who had an ongoing response at data cut-off. Fifteen patients were still alive at the time of the data cutoff and the median OS for the trial has not been reached.

Additional Phase 2 Cohorts in Venetoclax Combinations in r/r AML Continue Enrollment: Development of SLS009 continued with the ongoing enrollment of two additional cohorts: AML with myelodysplasia-related changes (AML MRC) with ASXL1 mutations and AML with myelodysplasia-related changes other than ASXL1 mutations. These cohorts are also open for enrollment of certain pediatric patients. Additional topline data updates are expected in the fourth quarter of 2024.

National Institute of Health PIVOT program in Pediatric Tumors: The program in multiple pediatric cancer indications continues in collaboration with the National Cancer Institute (NCI). Initial safety and efficacy data are expected to be reported in the fourth quarter of 2024.

Recently Granted Regulatory Designations for SLS009: The FDA granted Rare Pediatric Disease Designation (RPDD) to SLS009 for the treatment of pediatric ALL in June 2024 and the FDA granted RPDD to SLS009 for the treatment of pediatric AML in July 2024. Also, the EMA granted Orphan Drug Designation for SLS009 in AML and in PTCL in June 2024 and July 2024, respectively. The FDA previously granted SLS009 Orphan Drug Designations in AML and PTCL and Fast Track designations for r/r AML and r/r PTCL.

Financial Results for the Third Quarter 2024:

R&D Expenses: Research and development expenses for the quarter ended September 30, 2024, were $4.4 million, compared to $5.8 million for the same period in 2023. The decrease was primarily due to decreases in global clinical supply purchases, consultants, personnel-related expenses due to changes in headcount, and clinical trial expenses.

G&A Expenses: General and administrative expenses for the third quarter of 2024 were $3.0 million, compared to $3.5 million for the same period in 2023. The decrease was primarily attributed to personnel-related expenses due to changes in headcount and insurance premiums.

Net Loss: The net loss was $7.1 million for the third quarter of 2024, or a basic and diluted loss per share of $0.10, as compared to a net loss of $9.3 million for the third quarter of 2023, or a basic and diluted loss per share of $0.33. The net loss was $24.1 million for the nine months ended September 30, 2024, or a basic and diluted loss per share of $0.42, as compared to a net loss of $29.2 million for the same period in 2023, or a basic and diluted loss per share of $1.09.

Cash Position: As of September 30, 2024, cash and cash equivalents totaled approximately $21 million.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				

Research and development	$ 4,362	$ 5,813	$ 14,659	$ 18,910
General and administrative	2,967	3,548	9,936	10,782
Total operating expenses	7,329	9,361	24,595	29,692
Loss from operations	(7,329)	(9,361)	(24,595)	(29,692)
Non-operating income:				
Change in fair value of warrant liability	—	—	—	4
Interest income	221	94	451	484
Total non-operating income	221	94	451	488
Net loss	$ (7,108)	$ (9,267)	$ (24,144)	$ (29,204)
Per share information:				
Net loss per common share, basic and diluted	$ (0.10)	$ (0.33)	$ (0.42)	$ (1.09)
Weighted-average common shares outstanding, basic and diluted	68,254,021	28,355,427	56,940,617	26,767,914

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,031	$ 2,530
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	2,904	542
Total current assets	24,035	3,172
Operating lease right-of-use assets	513	858
Goodwill	1,914	1,914
Deposits and other assets	43	275
Total assets	$ 26,505	$ 6,219
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,547	$ 5,639
Accrued expenses and other current liabilities	5,490	7,650
Operating lease liabilities	576	446
Total current liabilities	10,613	13,735
Operating lease liabilities, non-current	—	460
Total liabilities	10,613	14,195
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 350,000,000 shares authorized, 64,381,979 and 32,132,890 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	6	3
Additional paid-in capital	257,274	209,265
Accumulated deficit	(241,388)	(217,244)
Total stockholders' equity (deficit)	15,892	(7,976)
Total liabilities and stockholders' equity (deficit)	$ 26,505	$ 6,219

Source: SELLAS Life Sciences Group, Inc.