



NEWS RELEASE

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

8/13/2024

- Announced Independent Data Monitoring Committee's (IDMC) Recommendation to Continue the Phase 3 REGAL Study in Patients with Acute Myeloid Leukemia (AML) Without Modifications: Interim Analysis Anticipated by Q4 2024 -

- Reported Positive Preliminary Data from the Phase 2a Trial of SLS009 in r/r AML Demonstrating to Date Overall Response Rate (ORR) of 33%, 50%, and 100% in 60 mg QW, 30 mg BIW and 30mg BIW with ASXL1 Mutation Cohorts Respectively -

- SLS009 Granted EMA Orphan Drug Designations and U.S. FDA Rare Pediatric Disease Designations -

- \$21 million of Gross Proceeds from Capital Raise Priced at a Premium to Market in August 2024 -

NEW YORK, Aug. 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 second quarter ended June 30, 2024, and provided a corporate update.

"We are pleased with our second-quarter performance marked by significant advancements in our development efforts and clinical programs," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "The initial Phase 2a dataset from the SLS009 trial in AML showed early signs of treatment efficacy across all cohorts exceeding the targeted ORR of at least 20% and median overall survival (mOS) of more than 3 months. We observed remarkable responses in patients with ASXL1 mutations and expanded the trial to include two cohorts of patients with ASXL1 and myelodysplasia-related changes other than ASXL1. As SLS009 continues to show promise

as a treatment for hematologic malignancies, its potential has been recently recognized by the European Medicines Agency (EMA) with the orphan drug designations for AML and peripheral T-cell lymphomas (PTCL) and FDA with two rare pediatric disease designations for pediatric AML and acute lymphoblastic leukemia (ALL). Furthermore, our recent \$21 million capital raise strengthens our financial position and provides sufficient resources to reach several meaningful data readouts.”

Dr. Stergiou continued: “As for our Phase 3 REGAL study of galinpepimut-S (GPS) in AML, we were pleased to report that based on recent efficacy and safety assessment, the IDMC has recommended trial continuation without modifications. The committee projects that the 60 events will occur by the fourth quarter which will trigger the interim analysis. We remain confident in the positive trajectory of both GPS and SLS009 and we look forward to the interim results from the Phase 3 REGAL study, as well as additional data from the Phase 2 trial of SLS009 in AML.”

### Pipeline Highlights

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

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

SLS009: highly selective and specific CDK9 inhibitor

Completed Enrollment in Phase 2a Trial of SLS009 in r/r AML: 30 patients relapsed after or refractory to venetoclax-based regimens were enrolled ahead of schedule in 5 centers across the US. Except for one, all patients in this 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. The expected overall survival in those patients is approximately 2.5 months.

Announced Positive Initial Phase 2 Data of SLS009 in r/r AML: The preliminary data showed the overall response rate (ORR) of 33% and 50% in 60 mg QW and 30 mg BIW cohorts, respectively. The ORR in patients with ASXL1 mutation in the 30 mg BIW reached a remarkable 100% to date. In the safety dose of 45 mg QW, the median overall survival (mOS) was 5.4 months vs 2.5 months with standard of care. The mOS in 60 mg QW and 30 mg BIW has not been reached yet. SLS009 was well-tolerated across all doses.

Additional Phase 2 Cohorts in Venetoclax Combinations in r/r AML Opened for Enrollment: Development of SLS009 continued with the opening of two new cohorts - AML with myelodysplasia-related changes (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.

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 throughout 2H 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 Second Quarter 2024:

R&D Expenses: Research and development expenses for the quarter ended June 30, 2024 were \$5.2 million, compared to \$5.9 million for the same period in 2023. Research and development expenses in the first half of 2024 were \$10.3 million, compared to \$13.1 million for the same period in 2023. The decrease was primarily due to decreases in consultants, personnel-related expenses due to changes in headcount, and clinical trial expenses.

G&A Expenses: General and administrative expenses for the second quarter of 2024 were \$2.4 million, compared to \$3.1 million for the same period in 2023. General and administrative expenses in the first half of 2024 were \$7.0 million, compared to \$7.2 million for the same period in 2023. The decrease was primarily attributed to personnel-related expenses due to changes in headcount and outside services and public company costs.

Net Loss: The net loss was \$7.5 million for the second quarter of 2024, or a basic and diluted loss per share of \$0.13, as compared to a net loss of \$8.8 million for the second quarter of 2023, or a basic and diluted loss per share of \$0.31. The net loss was \$17.0 million for the first half of 2024, or a basic and diluted loss per share of \$0.33, as compared to a net loss of \$19.9 million for the first half of 2023, or a basic and diluted loss per share of \$0.77.

Cash Position: As of June 30, 2024, cash and cash equivalents totaled approximately \$9.1 million. Subsequent to June 30, 2024, the Company consummated a registered direct offering priced at a premium to market, providing gross proceeds to the Company of \$21 million, before deducting placement agent fees and related offering expenses.

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](http://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.

#### Investor Contact

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 5,186	\$ 5,923	\$ 10,297	\$ 13,097
General and administrative	2,435	3,127	6,969	7,234
Total operating expenses	<u>7,621</u>	<u>9,050</u>	<u>17,266</u>	<u>20,331</u>
Loss from operations	<u>(7,621)</u>	<u>(9,050)</u>	<u>(17,266)</u>	<u>(20,331)</u>
Non-operating income:				
Change in fair value of warrant liability	—	2	—	4
Interest income	151	208	230	390
Total non-operating income	<u>151</u>	<u>210</u>	<u>230</u>	<u>394</u>
Net loss	<u>\$ (7,470)</u>	<u>\$ (8,840)</u>	<u>\$ (17,036)</u>	<u>\$ (19,937)</u>
Per share information:				
Net loss per common share, basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.31)</u>	<u>\$ (0.33)</u>	<u>\$ (0.77)</u>
Weighted-average common shares outstanding, basic and diluted	57,630,506	28,347,920	51,221,752	25,961,001

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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,147	\$ 2,530
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	3,055	542
Total current assets	<u>12,302</u>	<u>3,172</u>
Operating lease right-of-use assets	633	858
Goodwill	1,914	1,914
Deposits and other assets	270	275
Total assets	<u>\$ 15,119</u>	<u>\$ 6,219</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 6,331	\$ 5,639
Accrued expenses and other current liabilities	5,183	7,650
Operating lease liabilities	531	446
Total current liabilities	<u>12,045</u>	<u>13,735</u>
Operating lease liabilities, non-current	161	460
Total liabilities	<u>12,206</u>	<u>14,195</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; Series A convertible preferred stock, 17,500 shares designated; no shares issued and outstanding at June 30, 2024 and December		

31, 2023

Common stock, \$0.0001 par value; 350,000,000 shares authorized, 57,754,928 and 32,132,890 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively

Additional paid-in capital

Accumulated deficit

Total stockholders' equity (deficit)

Total liabilities and stockholders' equity (deficit)

	—	—
	5	3
	237,188	209,265
	(234,280)	(217,244)
	<u>2,913</u>	<u>(7,976)</u>
	\$ 15,119	\$ 6,219

Source: SELLAS Life Sciences Group, Inc.