NEWS RELEASE

SELLAS Life Sciences Reports Second Quarter 2025 Financial Results and Provides Corporate Update

2025-08-12

- Positive IDMC Recommendation to Continue Pivotal Phase 3 REGAL Trial of Galinpepimut-S (GPS) in AML Without Modification; Final Analysis Anticipated by Year-end 2025 –

- Reported Positive Phase 2 Results of SLS009 in Relapsed/Refractory (r/r) Acute Myeloid Leukemia (AML) with Trial Meeting All Primary Endpoints; Full Data Presentation Expected Later This Year -

- Alignment with FDA to Advance SLS009 in a First-Line AML Trial with Enrollment Anticipated by Q1 2026 -

- $25.3 million in Cash and Cash Equivalents as of June 30, 2025; Additional $4.0 million Proceeds Received in July 2025 for Warrant Exercises -

NEW YORK, Aug. 12, 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 second quarter ended June 30, 2025, and provided a corporate update.

“We continue to make significant progress in advancing our AML-focused pipeline, as demonstrated by the positive Phase 2 results evaluating our novel CDK9 inhibitor, SLS009, for the treatment of r/r AML,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The Phase 2 trial met all primary endpoints, achieving a 44% response rate among patients with Acute Myeloid Leukemia-Myelodysplasia-Related Changes (AML-MRC), which at the optimal dose level, nearly tripled the median overall survival compared to a historical benchmark. Based on the strength of these data, we conducted an end-of-Phase 2 meeting and the FDA recommended advancing SLS009 into the front-line setting for AML. We are now preparing an 80-patient trial that is focused on newly diagnosed and early refractory to venetoclax and azacitidine AML patients, with enrollment anticipated to begin by Q1 2026.”

Dr. Stergiou continued, “During the quarter, we also presented promising preclinical data at ASCO supporting

SLS009 as a potential targeted therapy for ASXL1 mutated colorectal cancer and strengthened our scientific leadership with the addition of three world-class oncology experts to our Scientific Advisory Board. With the final pivotal Phase 3 REGAL data of GPS in AML expected by year-end, positive Phase 2 data of SLS009 in r/r AML, and our upcoming ESMO presentation showcasing SLS009's impact in T-PLL, we enter the second half of 2025 with tremendous momentum and a clear focus on advancing our late-stage clinical programs and growing shareholder value."

Recent Corporate Highlights:

Phase 3 REGAL Trial of GPS: On August 7, 2025, SELLAS announced that the IDMC completed a pre-specified analysis of the Phase 3 REGAL trial of GPS in AML and issued a positive recommendation to continue the trial without modification. The IDMC concluded that the risk-benefit profile of GPS supports continued evaluation under the current study protocol. No safety concerns were identified, and available efficacy data were consistent with expectations for continued trial conduct. The final analysis will be conducted once 80 events (deaths) are reached and is anticipated by year-end.

Announced Positive Results from Phase 2 Trial of SLS009 in r/r AML: The trial met all primary endpoints, demonstrating a 44% response rate among patients with Acute Myeloid Leukemia-Myelodysplasia-Related Changes (AML-MRC) at an optimal dose of 30 mg twice weekly and 50% in AML-MRC with myelomonocytic/myelomonoblastic (M4/M5) subtype, significantly exceeding the targeted 20% ORR. In addition, the treatment achieved a median overall survival (mOS) of 8.9 months in AML-MRC patients, while all relapsed or refractory to venetoclax-based regimens patients receiving 30 mg BIW achieved a mOS of 8.8 months, far surpassing the historical benchmark of 2.4 months.

SLS009 End-of-Phase 2 Meeting: The FDA recommended that SELLAS proceed into a trial to include newly diagnosed, first-line AML patients eligible for venetoclax/azacitidine (aza/ven) therapy, where the Agency believes clinical benefit might be greatest. The randomized 80-patient trial is currently in preparation and is expected to begin enrollment by Q1 2026. The FDA indicated a preference for response rate as the primary endpoint. The trial will include two groups: 1) predictive biomarker cohort of newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling, and 2) early resistance cohort of patients who initiate treatment with aza/ven but demonstrate confirmed lack of any response after two treatment cycles. Whether additional patients will be needed – either for broader study expansion or only within one of the study arms – will depend on the outcomes observed in the initial cohorts (n=40 per arm). This study may support a New Drug Application (NDA), including accelerated approval.

Presented Preclinical Efficacy of SLS009 in ASXL1 Mutated Colorectal Cancer at ASCO 2025: The presentation demonstrated SLS009's ability to selectively target ASXL1-driven tumors at concentrations well below the known

safety threshold. The ASXL1 mutation status could serve as a potential biomarker for response to SLS009 inhibition, which may allow the Company to further refine patient selection and improve outcomes.

Expanded Scientific Advisory Board: New members, Philip C. Amrein, MD, Alex Kentsis, MD, PhD, and Linghua Wang, MD, PhD, bring decades of expertise in cancer research, clinical oncology, and translational medicine, further strengthening the Company's strategic guidance as it advances its pipeline.

Announced Inclusion in the Russell 3000® and Russell 2000® Indexes: The Russell 3000® Index tracks the performance of the largest 3,000 publicly traded U.S. companies and serves as a broad benchmark for the U.S. equity market. The Russell 2000® Index, a subset of the Russell 3000®, measures the performance of the small-cap stocks and represents approximately 10% of the total market capitalization of the U.S. equity market.

Preclinical Efficacy of SLS009 in T-Cell Prolymphocytic Leukemia (T-PLL) to be Showcased at ESMO 2025: The poster, entitled, CDK9 Inhibition Enhances Venetoclax Activity and Prolongs Survival in a T-PLL Patient-Derived Xenograft Model, will be presented during the ESMO congress to be held in Berlin, 17-21 October 2025.

Financial Results for the Second Quarter 2025:

R&D Expenses: Research and development expenses for the quarter ended June 30, 2025 were $3.9 million compared to $5.2 million for the same period in 2024. Research and development expenses in the first half of 2025 were $7.1 million compared to $10.3 million for the same period in 2024. The decrease was primarily due to decreases in clinical trial expenses, manufacturing costs and clinical drug supply purchases, and clinical and regulatory consulting costs, which were primarily driven by the completion of enrollment in the REGAL study in the first quarter of 2024.

G&A Expenses: General and administrative expenses for the second quarter of 2025 were $3.0 million compared to $2.4 million for the same period in 2024. The $0.6 million increase was primarily attributable to increases in professional fees, personnel related expenses, including non-cash stock-based compensation, and outside services and public company costs. General and administrative expenses were $5.9 million for the first half of 2025 compared to $7.0 million for the same period in 2024. The $1.1 million decrease was primarily attributable to a decrease in personnel related expenses driven by the initial recognition of a one-time severance charge in the prior period.

Net Loss: The net loss was $6.6 million for the second quarter of 2025, or a basic and diluted loss per share of $0.07, compared to a net loss of $7.5 million for the second quarter of 2024, or a basic and diluted loss per share of $0.13. The net loss was $12.4 million for the first half of 2025, or a basic and diluted net loss per share of $0.13, compared to a net loss of $17.0 million for the first half of 2024, or a basic and diluted net loss per share of $0.33.

Cash Position: As of June 30, 2025, cash and cash equivalents totaled approximately $25.3 million. Subsequent to June 30, 2025, the Company received $4.0 million in proceeds in July 2025 from the exercise of warrants.

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)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 3,871	$ 5,186	$ 7,076	$ 10,297
General and administrative	3,002	2,435	5,860	6,969
Total operating expenses	6,873	7,621	12,936	17,266
Loss from operations	(6,873)	(7,621)	(12,936)	(17,266)
Non-operating income:				
Interest income	272	151	522	230
Total non-operating income	272	151	522	230
Net loss	$ (6,601)	$ (7,470)	$ (12,414)	$ (17,036)
Per share information:				
Net loss per common share, basic and diluted	$ (0.07)	$ (0.13)	$ (0.13)	$ (0.33)
Weighted-average common shares outstanding, basic and diluted	98,558,567	57,630,506	93,189,273	51,221,752

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

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,297	$ 13,886
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	4,050	2,341
Total current assets	29,447	16,327
Operating lease right-of-use assets	683	925
Goodwill	1,914	1,914
Deposits and other assets	261	266
Total assets	$ 32,305	$ 19,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,336	$ 3,500
Accrued expenses and other current liabilities	2,083	5,466
Operating lease liabilities	580	544
Total current liabilities	5,999	9,510
Operating lease liabilities, non-current	157	457
Total liabilities	6,156	9,967

Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 350,000,000 shares authorized, 100,367,113 and 73,977,459 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	10	7
Additional paid-in capital	286,678	257,583
Accumulated deficit	(260,539)	(248,125)
Total stockholders' equity	26,149	9,465
Total liabilities and stockholders' equity	$ 32,305	$ 19,432

Source: SELLAS Life Sciences Group, Inc.