NEWS RELEASE

SELLAS Provides Business Update and Reports Third Quarter 2023 Financial Results

11/9/2023

-Phase 3 REGAL Trial of Galinpepimut-S (GPS) on Track to Complete Enrollment ex-China in November 2023 -

- Positive Initial Topline Phase 2a Data of SLS009 Reported with First Complete Response Achieved in Acute Myeloid Leukemia (AML) Patient Resistant to Venetoclax Combination Therapies -

- SLS009 Granted Orphan Drug Designation by U.S. Food & Drug Administration (FDA) for Treatment of AML -

- SLS009 Granted Fast Track Designation by FDA for Treatment of Relapsed/Refractory Peripheral T-cell Lymphomas (PTCL) -

- First Patient Dosed in Phase 1b/2 Trial of SLS009 in Relapsed/Refractory PTCL -

NEW YORK, Nov. 09, 2023 (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 reported its financial results for the quarter ended September 30, 2023.

“In the last several weeks, SELLAS has achieved several exciting milestones. We reported initial positive topline Phase 2a data at the 45 mg (safety) dose level demonstrating that SLS009 in combination with venetoclax and azacitidine (aza/ven) exhibited anti-leukemic effects with a favorable safety profile in AML patients resistant to venetoclax combination therapies. Importantly, as of the last follow-up, six of the seven patients enrolled to date were alive. The first patient enrolled in the study achieved a complete response and is in the sixth month of treatment and the second enrolled patient is in the fifth month of treatment, underscoring the potential benefit of

adding CDK9 inhibition to the aza/ven regimen. We will share further topline data, including data of patients treated with the recommended Phase 2 dose level of 60 mg, by the end of the year. We also shared compelling topline results from the lymphoma group of patients in our Phase 1 trial of SLS009, showing anti-tumor activity and clinical responses with a tumor burden reduction of up to 68.9%," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "SLS009 continues to emerge as a promising treatment for hematologic malignancies and we are pleased by the FDA's recognition of its potential by the grant of Fast Track Designation for PTCL and Orphan Drug Designation for AML. These designations position us to expedite SLS009 clinical development with the goal of delivering this groundbreaking treatment to patients in need."

Dr. Stergiou further stated "We are also on track to complete enrollment (other than 20-25 patients from China) of the Phase 3 registrational REGAL study of GPS in patients with AML this month and, while the interim and final analyses are event (death) driven and therefore not within our control, we expect interim data from the study by the end of this year or early next year based upon our assumptions in our statistical analysis plan. We also look forward to the upcoming meeting of the Independent Data Monitoring Committee for the REGAL study towards the end of the month. Last, but not least, we are planning to hold a corporate update call with our shareholders in December to provide an update on the REGAL study and the SLS009 clinical programs as well as our projected outlook for 2024."

Pipeline Update:

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

Phase 3 REGAL study in AML:

In August 2023, the Independent Data Monitoring Committee (IDMC) recommended that REGAL continue as planned, following a routine, prespecified risk-benefit assessment of unblinded data from the study. The next routine IDMC meeting is scheduled for the end of November 2023. The Company expects to complete enrollment in the REGAL study, other than the 20-25 patients to be enrolled in China, in November 2023 and anticipates that 3D Medicines Inc., its commercialization partner for GPS in Greater China, will begin enrolling patients in China in the fourth quarter of 2023, subject to any further delays as a result of supply chain or other operational reasons, which will trigger two development milestone payments totaling $13.0 million.

The interim analysis of the REGAL study is expected in late 2023 or early 2024; however, because these analyses are event-driven, they may occur at a different time than currently expected.

Phase 1/2 Study in combination with pembrolizumab (Keytruda®) in ovarian cancer:

Final data were presented in November 2023 at the International Gynecologic Cancer Society Annual 2023 Annual Global Meeting. The topline data showed clinical benefit of GPS and anti-PD-1 pembrolizumab combination therapy in WT1-positive relapsed or refractory platinum-resistant advanced metastatic ovarian cancer patients with a 50% disease control rate and a median overall survival benefit of 18.4 months as compared to 13.8 months with pembrolizumab monotherapy in a similar patient population shown in the KEYNOTE-028 study and historical values in comparable patients of 11-14 months with standard of care chemotherapy.

SLS009: highly selective CDK9 inhibitor

Phase 1 clinical trial in relapsed/refractory (r/r) hematological malignancies completed:

In September, the Company reported positive topline data from the cohort of patients with lymphomas from the Phase 1 dose escalation clinical trial of SLS009 showing that the study met all the primary and secondary endpoints supporting its advancement to Phase 2. The maximum tolerated dose was not reached. A dose-limiting toxicity occurred in one out of five patients in the lymphoma cohort treated at the 100 mg dose level. No dose-limiting toxicities were observed at any other dose level, and there were no unexpected toxicities across the study. Among 34 evaluable r/r lymphoma patients, five (14.7%) achieved a clinical response with a reduction in tumor burden of up to 68.9%. An additional seven patients (20.6%) achieved stable disease (SD) resulting in an overall disease control rate of 35.3%. In the subgroup of PTCL patients, four out of 11 (36.4%) evaluable patients achieved a clinical response. Additionally, one patient achieved a complete response (CR) in late October 2023, and remains on the trial after 16 weeks of treatment. The recommended Phase 2 dose for patients with lymphoma was established at 100 mg.

Phase 2a clinical trial in AML:

In October 2023, SELLAS announced positive, initial results from the Phase 2a study of SLS009 combination treatment with aza/ven in r/r AML patients who did not respond or stopped responding to venetoclax-based therapies. The Phase 2a clinical trial is an open-label, single-arm, multi-center study that is designed to evaluate safety, tolerability, and efficacy at two dose levels of SLS009. Six of the seven patients enrolled are still alive as of the latest follow-up, five remain on treatment and the first enrolled patientachieved a complete response and is in the sixth month of treatment while the second enrolled patient is in the fifth month of treatment. Anti-leukemic effects have been observed in all patients without any significant safety issues to date. Patients with AML who fail venetoclax-based therapies have limited treatment options and a poor prognosis with a median overall survival of approximately 2.5 months.

Phase 1b/2 clinical trial in r/r peripheral T-cell lymphomas:

The Company announced in October 2023 that the first patient was dosed in the Phase 1b/2 trial evaluating SLS009 in r/r PTCL. The open-label, single-arm trial will enroll up to 95 patients to evaluate safety and efficacy and, based on the results, may serve as a registrational study. This initial PTCL study is fully funded by GenFleet Therapeutics (Shanghai), Inc., and is being conducted in China.

Regulatory matters:

In October 2023, the FDA granted Orphan Drug Designation (ODD) for SLS009 for the treatment of AML.

In October 2023, the FDA granted Fast Track Designation to SLS009 for the treatment of r/r PTCL. The Fast Track Designation is intended to facilitate the development and review of drugs.

Financial Results for the Third Quarter 2023:

Research and Development Expenses: Research and development expenses for the third quarter of 2023 were $5.8 million, compared to $4.3 million for the same period in 2022. The increase was primarily due to an increase in clinical trial expenses related to the ongoing Phase 3 REGAL clinical trial of GPS in AML patients and the Phase 2a and Phase 1 clinical trials of SLS009 in hematological malignancies, an increase in manufacturing costs related to clinical drug supply purchases, and an increase in clinical and regulatory consulting. Research and development expenses were $18.9 million for the first nine months of 2023, compared to $14.4 million for the same period in 2022. The increase was primarily due to an increase in clinical trial expenses, an increase in clinical and regulatory consulting, and an increase in personnel related expenses due to increased headcount.

General and Administrative Expenses: General and administrative expenses for the third quarter of 2023 were $3.5 million, as compared to $2.9 million for the same period in 2022. The increase was primarily due to an increase in outside services and public company costs and an increase in legal and intellectual property fees. General and administrative expenses were $10.8 million for the first nine months of 2023, compared to $9.0 million for the same period in 2022. The increase was primarily due to personnel-related expenses due to increased headcount, an increase in legal and intellectual property fees, and an increase in outside services and public company costs.

Acquired In-Process Research and Development: There was no acquired in-process research and development in the third quarter of 2023 or the third quarter of 2022. There was no acquired in-process research and development in the first nine months of 2023, compared to $10.0 million for the same period in 2022, resulting from the in-licensing of SLS009.

Net Loss: Net loss was $9.3 million for the third quarter of 2023, or a basic and diluted loss per share of $0.33, compared to a net loss of $7.0 million for the same period in 2022, or a basic and diluted loss per share of $0.34.

Net loss was $29.2 million for the first nine months of 2023, or a basic and diluted loss per share of $1.09, compared to a net loss of $32.2 million for the same period in 2022, or a basic and diluted net loss per share of $1.70.

Cash Position: As of September 30, 2023, cash and cash equivalents totaled approximately $4.0 million. Following the end of the quarter, on November 2, 2023, the Company received gross proceeds of approximately $4.0 million from a registered direct offering at-the-market of shares of common stock, pre-funded warrants to acquire shares of common stock, and warrants to acquire shares of common stock with a single, healthcare-focused investor. Additionally, the Company is anticipating $13.0 million in milestone payments from 3D Medicines, Inc. upon patients enrolling in China in the REGAL study which the Company expects to be triggered in the fourth quarter of 2023, subject to any further delays as a result of supply chain or other operational reasons.

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 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), a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. For more information on SELLAS, please visit **www.sellaslifesciences.com**.

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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 and SLS009 clinical development programs, including data therefrom, regulatory strategy and the timing of future milestones, including the receipt of payments as a result thereof. 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 16, 2023 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,	
	2023	2022	2023	2022
Licensing revenue	$ —	$ —	$ —	$ 1,000
Operating expenses:				
Cost of licensing revenue	—	—	—	100
Research and development	5,813	4,282	18,910	14,422
General and administrative	3,548	2,864	10,782	8,982
Acquired in-process research and development	—	—	—	10,000
Total operating expenses	9,361	7,146	29,692	33,504
Operating loss	(9,361)	(7,146)	(29,692)	(32,504)
Non-operating income:				
Change in fair value of warrant liability	—	2	4	39
Change in fair value of contingent consideration	—	11	—	126
Interest income	94	111	484	159
Total non-operating income	94	124	488	324
Net loss	$ (9,267)	$ (7,022)	$ (29,204)	$ (32,180)
Per share information:				
Net loss per common share, basic and diluted	$ (0.33)	$ (0.34)	$ (1.09)	$ (1.70)
Weighted-average common shares outstanding, basic and diluted	28,355,427	20,562,351	26,767,914	18,932,571

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,969	$ 17,125
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	1,134	531
Total current assets	5,203	17,756
Operating lease right-of-use assets	592	874
Goodwill	1,914	1,914
Deposits and other assets	377	399
Total assets	$ 8,086	$ 20,943
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 4,340	$ 3,357
Accrued expenses and other current liabilities	6,929	6,286
Operating lease liabilities	466	372
Acquired in-process research and development payable	—	5,500
Total current liabilities	11,735	15,515
Operating lease liabilities, non-current	178	573
Warrant liability	—	4
Total liabilities	11,913	16,092
Commitments and contingencies		
Stockholders' (deficit) equity:		
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 September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized, 28,393,958 and 21,005,405 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	205,278	184,753
Accumulated deficit	(209,108)	(179,904)
Total stockholders' (deficit) equity	(3,827)	4,851
Total liabilities and stockholders' (deficit) equity	$ 8,086	$ 20,943

Source: SELLAS Life Sciences Group, Inc.