

SELLAS Life Sciences Reports Full Year 2023 Financial Results and Provides Corporate Update

3/28/2024

- Announced Phase 2a study of SLS009 in r/r AML Showing 50% Response Rate in the Selected Optimal Dose of 30 mg BIW Exceeding the Targeted 20% and 100% Response Rate in Patients with Identified Biomarkers -
- Completed Enrollment in Phase 3 REGAL Study of Galinpepimut-S in Patients with Acute Myeloid Leukemia; Steering Committee Guided Interim Analysis May Be Imminent; IDMC Scheduled in Late April-
- Phase 1b/2 Study of SLS009 in Relapsed/Refractory Peripheral T-cell Lymphoma Patients Ongoing with Top-line Data Expected in First Half 2024
- First Patient Dosed in Phase 1b/2 Study of SLS009 in Combination with Brukinsa® (Zanubrutinib, BTK Inhibitor) in Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

NEW YORK, March 28, 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 full year ended December 31, 2023, and provided a corporate update.

"We are off to a strong start this year highlighted by progress in our late-stage pipeline, strong data from Phase 2a study of SLS009 in r/r AML, completing enrollment in Phase 3 REGAL study, positive feedback from the REGAL Steering Committee, and the recent FDA Fast Track Designation granted for SLS009 in r/r AML," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "The data from the Phase 2a study of SLS009 in r/r AML patients resistant to venetoclax combination therapies achieved 50% response in the selected optimal dose regimen of 30 mg BIW and 100% response rate in patients with identified biomarkers to date. We were pleased to recently announce enrollment completion in the Phase 3 REGAL trial and we eagerly anticipate the

Independent Data Monitoring Committee (IDMC) meeting in late April. We also reported Phase 1 data of SLS009 in AML at ESH demonstrating the first-ever complete response achieved in a relapsed/refractory AML patient through CDK9 inhibition monotherapy. We enter 2024 well-positioned to execute on our goals with the priority of reporting data from the Phase 3 REGAL trial of GPS in AML, additional data from our Phase 2a study of SLS009 in r/r AML, and topline data from the Phase 1b/2 study of SLS009 in PTCL by the end of the second quarter.”

Recent Highlights:

Completed enrollment in Phase 3 REGAL study: Reached planned enrollment of patients in the United States, Europe, and Asia, in accordance with the predetermined statistical analysis plan.

Phase 3 REGAL study in AML: The Steering Committee has reviewed the study as of the March 1, 2024 cutoff date, signaling potentially imminent interim analysis of the ongoing global Phase 3 registrational clinical trial (the REGAL study) of GPS in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients). The next IDMC meeting is expected in late April 2024.

Reported data from the Phase 2a Study of SLS009 in Relapsed/Refractory AML Patients: A total of 21 patients were enrolled in the study as of March 15, 2024, 10 in the 45 mg safety cohort and 11 in the 60 mg cohort (2 x 30 mg twice a week or 60 mg once a week). The response rate of 10% was achieved in the 45 mg (safety cohort), 20% in the 60 mg QW cohort, and 50% response rate in the 60 mg, 2 x 30 mg BIW, the optimal dose level cohort. Additionally, in the patients with identified biomarkers, a 100% response rate was observed to date at the optimal dose level and a 57% response rate across all the levels tested in patients with those biomarkers. The SLS009 aza-ven treatment was well-tolerated and evoked anti-leukemic effects in 67% of patients across all levels dosed. The median survival rate has not been reached in any of the dose levels. The first patient who achieved a complete response continues on the study and remains leukemia-free 9 months post-enrollment.

Received \$20.0 million of gross proceeds from a registered direct offering priced at-the-market under Nasdaq rules: On March 19, 2024, announced the closing of a \$20.0 million registered direct offering with two institutional investors before deducting placement agent’s fees and related offering expenses. The net proceeds from the offering strengthen the Company’s financial position and will be used for research and development activities, working capital, and general corporate purposes.

Presented Phase 1 Data in AML at the 2024 European School of Haematology (ESH): All key study objectives regarding pharmacokinetic, pharmacodynamic, safety, and clinical activity were met. Data showed that for the first time, a relapsed/refractory patient achieved complete remission (CR) with a CDK9 inhibitor monotherapy. The CR was achieved after three months of treatment and lasted 8 months with one-year survival at the latest assessment.

Publication in Oncotarget: The preclinical data published revealed the underlying mechanisms of action behind the anti-proliferative effects of SLS009, a highly selective CDK9 small molecule inhibitor, in various hematologic malignancies. The publication, entitled, "The pharmacodynamic and mechanistic foundation for the antineoplastic effects of GFH009, a potent and highly selective CDK9 inhibitor for the treatment of hematologic malignancies", is **available online**.

Fast Track Designation: The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to SLS009, for the treatment of r/r AML. The Fast Track Designation is intended to facilitate the development and review of drugs to treat serious conditions and fill an unmet medical need.

2024 Milestones:

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

- Phase 3 REGAL study in AML: Anticipated interim analysis of the ongoing global Phase 3 registrational clinical trial (the REGAL study) of GPS in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients) in 1H 2024. Final analysis expected to occur by the end of 2024.

SLS009: highly selective CDK9 inhibitor

- Phase 2a clinical trial in r/r AML: Additional data expected in 1H 2024. Initially planned enrollment of approximately 20 patients has been completed and additional patients continue to enroll. Confirmation of safety and further exploration of efficacy in additional patients will be combined with additional biomarkers related data to enable us to plan for further development.
- Phase 1b/2 clinical trial in r/r PTCL: Enrollment started in December 2023. Thirty-one sites are active for recruiting and approximately 10 more sites will be initiated. Interim analysis is planned after 20-25 patients are enrolled and have undergone initial follow-up which is projected to occur in 1H 2024. The interim efficacy data will be discussed with regulatory agencies to decide on the continuation of the trial as a pivotal registrational study that would enroll approximately 70-75 additional patients. This study is fully funded by the Company's partner for SLS009, GenFleet Therapeutics (Shanghai), Inc. ("GenFleet"), and is being conducted in China.
- Phase 1b/2 clinical trial in combination with BTK inhibitor, Brukinsa® (zanubrutinib), in r/r DLBCL: Genfleet entered into a clinical trial collaboration and supply agreement with BeiGene Switzerland GmbH and the first patient dosed in March 2024. The trial is an open-label single-arm multicenter Phase 1b/2 trial to be conducted in two parts. In the Phase 1b portion, 6-18 patients will be enrolled and in the Phase 2 portion,

approximately 45 patients will be enrolled. This study is being conducted in China and is funded by GenFleet.

- PIVOT program with the National Cancer Institute (NCI) in multiple pediatric cancer indications continues. Initial safety and efficacy data are expected to be reported throughout 2H 2024.

2023 Highlights:

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

- Positive immunobiological and clinical data from the completed Phase 1/2 clinical trial of GPS in combination with Keytruda® (pembrolizumab) in WT1+ platinum-resistant advanced ovarian cancer was presented at the International Gynecologic Cancer Society 2023 annual global meeting in November 2023.
- The Company reported positive follow-up immune response and survival data in the fourth quarter of 2023 for the completed Phase 1 clinical trial of GPS combined with Opdivo® (nivolumab) in advanced malignant pleural mesothelioma.
- In the fourth quarter of 2023, the Company announced that it had concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's Chemistry, Manufacturing, and Controls (CMC) sections in a potential biologics license application (BLA) for GPS. SELLAS had submitted a CMC Briefing Package to the FDA which provided an up-to-date overview of the extensive work completed for the GPS CMC program and commercial manufacturing and regulatory plans. The FDA reviewed this package of data and accompanying questions to the agency and responded with favorable guidance.

SLS009: highly selective CDK9 inhibitor

- The Phase 1 clinical trial for patients with AML and lymphomas was completed in 2023. For patients with AML, SLS009 demonstrated a favorable tolerability profile with no dose limiting toxicities. Anti-tumor activity and clinical responses across dose levels were observed, indicating a broad therapeutic index. Meaningful cell killing activity, defined as $\geq 50\%$ reduction in blasts in the bone marrow, was observed at several dose levels. A durable complete remission (CR) with no minimal residual disease (MRD) was observed in one patient with AML who had failed prior venetoclax plus azacytidine (aza/ven) therapy. The patient achieved CR three months after the treatment that lasted 8 months and continues to be alive 12 months following commencement of treatment per last follow-up. The recommended Phase 2 dose for patients with AML was established at 60 mg. For the patients with lymphomas, no off-target safety issues were observed at any dose level and responses were observed across dose levels with a 14.7% clinical response rate overall, 35.3% overall disease control rate, and 36.4% clinical response rate for patients with PTCL. The recommended Phase 2 dose for patients with lymphomas was established at 100 mg administered as a once weekly infusion.

- In the second quarter of 2023, the Company announced the dosing of the first patient (45 mg) in an open-label, single-arm, multi-center Phase 2a study that is designed to evaluate safety, tolerability, and efficacy at two dose levels of SLS009 (once weekly 45 mg or 60 mg) in combination with aza/ven in patients with AML. Enrollment in the 45 mg cohort was completed in the fourth quarter of 2023. Also in the fourth quarter of 2023, the Company announced the dosing of the first patients in the 60 mg dose cohort. The patients in the 60 mg dose cohort will be dosed with 60 mg once per week or 30 mg twice per week.
- Early topline data from the Phase 2a study in patients with AML dosed at the 45 mg level (n=9) include one patient with a CR and significant anti-leukemic effects ($\geq 50\%$ decrease in bone marrow blasts) were observed in five out of six assessable patients with no significant safety issues to date.
- In the fourth quarter of 2023, the Company announced the dosing of the first patient in a Phase Ib/II open-label, single-arm trial in r/r PTCL which will enroll up to 95 patients to evaluate safety and efficacy and, based on results, may serve as a registrational study. This study is fully funded by the Company's partner for SLS009, GenFleet Therapeutics (Shanghai), Inc., and is being conducted in China.
- The Company received the following regulatory designations from the FDA for SLS009 in 2023:
 - Orphan Drug Designation (ODD) for the treatment of AML
 - ODD for the treatment of PTCL
 - Fast Track Designation for the treatment of r/r PTCL

Financial Results for the Full Year 2023:

R&D Expenses: Research and development expenses for the year ended December 31, 2023, were \$24.0 million, compared to \$20.3 million for the year ended December 31, 2022. The increase was primarily due to an increase in clinical trial expenses related to the ongoing Phase 3 REGAL clinical trial and our clinical trials of SLS009, increase in clinical and regulatory consulting expenses due to the advancement of our clinical programs

Acquired In-Process Research and Development: There was no acquired in-process research and development for the year ended December 31, 2023, compared to \$10.0 million during the year ended December 31, 2022 from the in-licensing of SLS009.

G&A Expenses: General and administrative expenses for the year ended December 31, 2023, were \$13.9 million, as compared to \$12.6 million for the year ended December 31, 2022. The increase was primarily due to personnel-related expenses and an increase in intellectual property related expenses.

Net Loss: The net loss was \$37.3 million for the year ended December 31, 2023, or a basic and diluted loss per share of \$1.34, as compared to a net loss of \$41.3 million for the year ended December 31, 2022, or a basic and

diluted loss per share of \$2.13.

Cash Position: As of December 31, 2023, cash and cash equivalents totaled approximately \$2.5 million. On January 8, 2024, the Company received gross proceeds of \$9.0 million from a public offering. On March 19, 2024, the Company received gross proceeds of \$20.0 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 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.

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 and the timing for achievement of milestones. 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)

	Year Ended December 31,	
	2023	2022
Licensing revenue	\$ —	\$ 1,000
Operating expenses:		
Cost of licensing revenue	—	100
Research and development	24,007	20,268
General and administrative	13,862	12,582
Acquired in-process research and development	—	10,000
Total operating expenses	<u>37,869</u>	<u>42,950</u>
Loss from operations	(37,869)	(41,950)
Non-operating income:		
Change in fair value of warrant liability	4	36
Change in fair value of contingent consideration	—	296
Interest income	525	317
Total non-operating income	<u>529</u>	<u>649</u>
Net loss	<u>\$ (37,340)</u>	<u>\$ (41,301)</u>
Per share information:		
Net loss per common share, basic and diluted	<u>\$ (1.34)</u>	<u>\$ (2.13)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,777,111</u>	<u>19,395,709</u>

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

	December 31,	
	2023	2022

ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,530	\$ 17,125
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	542	531
Total current assets	<u>3,172</u>	<u>17,756</u>
Operating lease right-of-use assets	858	874
Goodwill	1,914	1,914
Deposits and other assets	275	399
Total assets	<u>\$ 6,219</u>	<u>\$ 20,943</u>
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 5,639	\$ 3,357
Accrued expenses and other current liabilities	7,650	6,286
Operating lease liabilities	446	372
Acquired in-process research and development payable	—	5,500
Total current liabilities	<u>13,735</u>	<u>15,515</u>
Operating lease liabilities, non-current	460	573
Warrant liability	—	4
Total liabilities	<u>14,195</u>	<u>16,092</u>
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; 0 shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 32,132,890 and 21,005,405 shares issued and outstanding at December 31, 2023 and 2022, respectively	3	2
Additional paid-in capital	209,265	184,753
Accumulated deficit	<u>(217,244)</u>	<u>(179,904)</u>
Total stockholders' (deficit) equity	<u>(7,976)</u>	<u>4,851</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 6,219</u>	<u>\$ 20,943</u>

Source: SELLAS Life Sciences Group, Inc.