NEWS RELEASE

SELLAS Life Sciences Provides Business Update and Reports First Quarter 2023 Financial Results

5/11/2023

Phase 1 Study of Novel, Highly Selective CDK9 Inhibitor GFH009 Successfully Completed for Patients with Acute Myeloid Leukemia; 94% of Patients Enrolled to Date Alive and Durable Remission in Patient with Acute Myeloid Leukemia > 6 months

Phase 3 REGAL Study of Galinpepimut-S in Patients with Acute Myeloid Leukemia on Track for Interim Analysis by Late 2023/Early 2024

NEW YORK, May 11, 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 March 31, 2023.

"We are pleased with the continued advancement of both our galinpepimut-S (GPS) and GFH009 clinical programs during the first quarter of 2023, which positions us for near-term execution of several key value-driving milestones," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Positive topline data for the patient group with acute myeloid leukemia (AML) from the GFH009 Phase 1 dose-escalation trial in relapsed/refractory myeloid malignancies suggests strong evidence of anti-tumor activity and survival benefit in this group with no significant safety issues. This supports advancement to a Phase 2a trial in patients with AML in combination with azacitidine and venetoclax, which we are initiating this quarter, with topline data expected in Q4 2023. Last month, the Independent Data Monitoring Committee (IDMC) also recommended that our GPS Phase 3 REGAL study continue without any modifications and is expected to meet again in Q3 to provide further guidance."

Dr. Stergiou continued "The key objectives for us this quarter and next, among others, will include:

- the initiation of the GFH009 Phase 2a study in AML patients in combination with azacitadine and venetoclax;
- completion of, and report of, data from the lymphoma patient group from the GFH009 Phase 1 study;
- report of topline data from the GPS investigator-sponsored trial (IST) in malignant pleural mesothelioma (MPM);
- abstract acceptance of our GPS ovarian cancer data from a major medical gynecological conference;
- 3D Medicines participation in the REGAL study; and
- meeting of, and feedback from, the IDMC for the REGAL study."

"It was a great pleasure meeting our SELLAS colleagues last month at our Shanghai headquarters where we had a chance to discuss and further strengthen our strategic partnership," said John Gong, M.D., Ph.D., Chairman and Chief Executive Officer of 3D Medicines. "The blinded pooled analysis of GPS in AML conducted at the end of last year is indeed very exciting and may have the potential to improve AML patients' quality of life and extend survival. We eagerly anticipate joining the REGAL trial very soon and to enroll about 20 patients in China to satisfy Chinese regulatory requirements towards a potential market approval. In addition, we will work together to explore solid tumor indications for GPS by combination with our subcutaneous anti-PD-L1, envafolimab, and other products."

Pipeline Update:

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

Phase 3 REGAL study in AML: Enrollment continued in the global Phase 3 REGAL registrational clinical trial in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients), with interim analysis continuing to be expected to occur in late 2023 or early 2024. The participation of 3D Medicines in the REGAL study through the enrollment of patients from the Greater China territory will trigger milestone payments totaling $13.0 million to SELLAS, which the Company expects to receive by the end of the third quarter of 2023. The IDMC performed a routine, prespecified risk-benefit assessment of unblinded data from the REGAL study in April 2023 and recommended that the trial continue without modifications. The IDMC endorsed all clinical trial initiatives undertaken in REGAL to advance GPS, including the addition of clinical sites in China. The next routine IDMC meeting is scheduled for the third quarter of 2023.

3D Medicines Phase 1 clinical trial in China: 3D Medicines continued enrollment in China for their open-label, single-arm, multi-center Phase 1 clinical trial in patients with AML, multiple myeloma, non-Hodgkin's lymphoma, or higher-risk myelodysplastic syndrome.

Phase 1/2 Study in combination with pembrolizumab (Keytruda®) in ovarian cancer: Top-line data released in November 2022 showed clinical benefit of GPS in combination with pembrolizumab anti-PD-1 therapy in WT1 positive relapsed or refractory platinum resistant advanced metastatic ovarian cancer patients. The study was conducted under a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Rahway, N.J., USA (known as MSD outside the United States and Canada), and SELLAS plans to present final data at a medical conference during the fourth quarter of 2023.

Phase 1 Study in combination with nivolumab (Opdivo®) for MPM: Patient enrollment was completed at the end of 2022 for an investigator sponsored open-label Phase 1 trial for GPS combination therapy with checkpoint inhibitor nivolumab (Opdivo®) for treatment of MPM in patients who were either refractory to or relapsed after at least one line of the standard of care therapy. SELLAS expects to report topline data during the first half of 2023.

Phase 1 Study in combination with nivolumab (Opdivo®) in ovarian cancer: Final analysis was published in the peer-reviewed journal Cancers on previously reported data from the Phase 1 clinical trial showing clinical benefit of GPS combination with anti-PD-1 antibody nivolumab (Opdivo®) in patients with relapsed WT1-expressing ovarian cancers (NCT02737787).

GFH009: highly selective CDK9 inhibitor

Phase 1 clinical trial in hematological malignancies: In the Phase 1 trial of GFH009, dose escalation was successfully completed in the group of patients with AML, while dose escalation continues in the lymphoma group at the highest dose level for that group (75 mg). Positive topline data for the group of patients with AML showed evidence of anti-tumor activity increasing with higher doses and no significant safety issues even at the highest dose levels. The recommended Phase 2 dose (RP2D) has been established for AML. SELLAS plans to commence a Phase 2a trial with GFH009 in combination with venetoclax and azacitidine (aza/ven) in patients with AML during the second quarter of 2023 with topline data expected in the fourth quarter of 2023.

Corporate Updates:

Underwritten Public Offering: On February 28, 2023, the Company closed an underwritten public offering providing gross proceeds of $20.0 million, before deducting underwriting discounts and commissions and offering expenses.

Appointment of Vice President, Head of Regulatory Affairs: Andrew Elnatan joined the leadership team in January 2023 as Vice President, Regulatory Affairs, CMC and Quality. He brings nearly three decades of global regulatory experience with successful breakthrough therapy designation and global drug approvals.

Financial Results for the First Quarter 2023:

Licensing Revenue: There was no licensing revenue for the first quarter of 2023, as compared to $1.0 million for the same period in 2022.

Cost of Revenue: There was no cost of revenue for the first quarter of 2023, as compared to $0.1 million for the same period in 2022.

R&D Expenses: Research and development expenses for the first quarter of 2023 were $7.2 million, compared to $4.6 million for the same period in 2022. The increase was primarily due to the ongoing Phase 3 REGAL clinical trial of GPS in AML patients and the Phase 1 clinical trial of GFH009 in hematological malignancies.

G&A Expenses: General and administrative expenses for the first quarter of 2023 were $4.1 million, as compared to $3.0 million for the same period in 2022. The increase was primarily due to personnel-related expenses due to increased headcount.

Acquired In-Process Research and Development: There was no acquired in-process research and development for the first quarter of 2023, compared to $10.0 million for the same period in 2022 from the in-licensing of GFH009.

Net Loss: Net loss was $11.1 million for the first quarter of 2023, or a basic and diluted loss per share of $0.47, compared to a net loss of $16.7 million for the same period in 2022, or a basic and diluted loss per share of $1.05.

Cash Position: As of March 31, 2023, cash and cash equivalents totaled approximately $23.9 million.

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA and is not a trademark of SELLAS. Opdivo® is a registered trademark of Bristol-Myers Squibb Company, New York, NY, USA and is not a trademark of SELLAS. The manufacturers of these brands are not affiliated with and do not endorse SELLAS or its products.

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 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 and GFH009 clinical development programs, clinical data for both GPS and GFH009, plans for further clinical development of GFH009 and the potential for GPS and GFH009 as drug development candidates. 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 March 31,	
	2023	2022
Licensing revenue	$ —	$ 1,000
Operating expenses:		
Cost of licensing revenue	—	100
Research and development	7,174	4,611
General and administrative	4,107	3,024
Acquired in-process research and development	—	10,000
Total operating expenses	11,281	17,735
Operating loss	(11,281)	(16,735)
Non-operating income (expense), net:		

Change in fair value of warrant liability	2	(11)
Interest income	182	2
Total non-operating income (expense), net	184	(9)
Net loss	$ (11,097)	$ (16,744)
Per share information:		
Net loss per common share, basic and diluted	$ (0.47)	$ (1.05)
Weighted-average common shares outstanding, basic and diluted	23,547,562	15,897,479

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,902	$ 17,125
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	2,020	531
Total current assets	26,022	17,756
Operating lease right-of-use assets	784	874
Goodwill	1,914	1,914
Deposits and other assets	384	399
Total assets	29,104	20,943
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,099	$ 3,357
Accrued expenses and other current liabilities	6,485	6,286
Operating lease liabilities	427	372
Acquired in-process research and development payable	5,500	5,500
Total current liabilities	15,511	15,515
Operating lease liabilities, non-current	422	573
Warrant liability	2	4
Total liabilities	15,935	16,092
Commitments and contingencies		
Stockholders' 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 March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized, 28,347,920 and 21,005,405 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	204,167	184,753
Accumulated deficit	(191,001)	(179,904)
Total stockholders' equity	13,169	4,851
Total liabilities and stockholders' equity	$ 29,104	$ 20,943

Source: SELLAS Life Sciences Group, Inc.