NEWS RELEASE

SELLAS Announces Positive Phase 2 Preliminary Data of SLS009 in r/r AML Achieving a 100% Response Rate in Patients with ASXL1 Mutation At the Optimal Dose Level

5/1/2024

- The Company Filed IP Protection Related to the ASXL1 Mutation, a Highly Prevalent Gene Mutation in Myeloid Malignancies and Solid Tumors With Significant Market Potential –

- 100% Overall Response Rate in Patients with ASXL1 Mutation in the SLS009 30mg BIW Cohort to Date, All Patients Alive: Further Support for Potential Accelerated Approval Pathway in Defined Patient Population –

- SLS009 Exhibits Strong Anti-Leukemic Activity in 62% of Patients with a Favorable Safety Profile Across All Dose Levels and 67% in the 30 mg BIW Cohort –

- Study Enrollment Ongoing at 30mg BIW Dose of SLS009 with Expansion Cohort of ASXL1 Mutation Patients; Updates Expected in Q3 2024 –

NEW YORK, May 01, 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 announces the preliminary data from Phase 2a trial of SLS009, a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML) and successful filing of a provisional patent application around the ASXL1 mutation and SLS009, including all CDK9 inhibitor drugs. ASXL1 mutations are associated with poor prognosis in all myeloid diseases, owing to the reduced response to the current treatment options.

SELLAS has observed a high rate of responses in patients with myelodysplasia-related molecular mutations, as defined by the World Health Organization (WHO). Among all myelodysplasia-related mutations, those in the ASXL1 gene accounted for most responders across all dose cohorts. SELLAS has now expanded the ongoing Phase 2 r/r AML study to include two additional cohorts, one with ASXL1 mutated AML patients and one with patients with myelodysplasia-related molecular abnormalities other than ASXL1.

“These early clinical results are very promising and could open up a new avenue in the treatment of AML and potentially beyond,” said Joshua Zeidner, MD, Associate Professor of Medicine, Chief of Leukemia Research, Associate Chief of Research in the Division of Hematology, Director of Clinical Cancer Research Commercial Integration at the University of North Carolina Lineberger Comprehensive Cancer Center and the study’s principal investigator. “ASXL1 is a relatively common mutation in AML which leads to poor outcomes with conventional therapies. There are no known targeted therapies that are effective for these AML patients. I am extremely hopeful that SLS009 will make an impact in the management of patients with ASXL1-mutated AML and potentially other myeloid malignancies with similar disease biology.”

Study highlights:

- As of April 19, 2024 data cutoff, a 57% overall response rate has been achieved thus far, in the selected optimal dose regimen of 30 mg BIW, far surpassing the targeted 20% rate.
- 4/4 (100%) r/r AML patients with ASXL1 truncating mutations at the selected dose level achieved an overall response (CR/CRi/MLFS) and are alive.
- 5/8 (63%) of r/r AML patients, across all dose levels, with ASXL1 truncating mutations treated with SLS009 achieved an overall response.
- A review of the mutational status of the patient in the Phase 1 trial with SLS009 monotherapy, who achieved a CR lasting 8+ months, revealed that the patient also harbored an ASXL1 mutation.
- The ASXL1 mutation is found in both hematological malignancies as well as solid tumors.
- All patients in the study are diagnosed with AML refractory to or relapsed after venetoclax-containing regimens. Enrollment and treatment will be focused on the participants in the expansion cohort receiving 30 mg BIW dose and diagnosed with the ASXL1 mutation.

“The remarkable responses achieved in patients with the ASXL1 mutation underscores the transformative potential of SLS009 in addressing the unmet medical needs of AML but also targeting colorectal cancer, and other tumor types with this alteration,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “This is evidenced by strong enthusiasm from the participating investigators reflected in robust enrollment from the clinical sites. These compelling results from the Phase 2a study further reinforce our belief that SLS009 represents a

potential breakthrough for relapsed and/or refractory AML patients, and could pave the way for a potential accelerated approval in this defined patient population."

SELLAS intends to initiate discussions with the U.S. Food and Drug Administration (FDA) about the potential for an accelerated approval pathway with SLS009 in the ASXL1 molecularly defined r/r AML population as well as in patients harboring this mutation in other indications.

The Phase 2a clinical trial of SLS009 is an open-label, single-arm, multi-center study designed to evaluate the safety, tolerability, and efficacy of SLS009 in combination with aza/ven at two dose levels, 45 and 60 mg. In the 60 mg dose cohort patients were randomized into either a 60 mg dose once per week or a 30 mg dose two times per week. The target response rate at the optimal dose level is 20% with a target median survival over 3 months. In addition, the study aims to identify biomarkers for the target patient population and enrichment for further trials. For more information on the study, visit **clinicaltrial.gov** identifier **NCT04588922**.

About ASXL1

ASXL1 mutations are associated with poor prognosis in all myeloid diseases, owing to the reduced response to the current treatment options. In AML, ASXL1 mutations were an unfavorable prognostic factor as regards survival, with a significantly lower complete response rate. In MDS, ASXL1 mutations are independently associated with worse overall survival, as well as AML transformation. The tables below demonstrate ASXL mutation frequency across hematologic malignancies and solid cancers.

ASXL1 mutations in Hematologic Malignancies with ASXL1m Frequency ≥5%

Condition	ASXL1m Frequency	US Condition Incidence
AML (Acute Myeloid Leukemia)	20%	20,800
MDS (Myelodysplastic Syndrome)	20%	10,000
MPN (Myeloproliferative Neoplasms)	10%	20,000
CMML (Chronic Myelomonocytic Leukemia)	43%	1,100
	Total	51,900

ASXL1 in Solid Cancers with ASXL1m Frequency ≥5%

Condition	ASXL1m Frequency	US Condition Incidence
CRC MSI-high (Colorectal Cancer with High Microsatellite Instability)	55%	22,500
Cervical Ca. (invasive)	5%	13,800

Liver Ca.	10%	42,400
	Total	78,700

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), 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, 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 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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