NEWS RELEASE

SELLAS Life Sciences Receives FDA Fast Track Designation for SLS009 for Treatment of Relapsed/Refractory Acute Myeloid Leukemia and Provides Updated Data for Phase 2a Study of SLS009 in Relapsed/Refractory Acute Myeloid Leukemia Patients

1/9/2024

- Phase 2a Enrollment Completed in 45 mg Safety Cohort: Median Overall Survival (OS) Not Reached; 89% of Patients Alive with Significant Antileukemic Effect Observed in 87.5% of Evaluable Patients -

- First Enrolled Patient in Phase 2a Study Achieved Complete Remission and Continues on Study With Full Recovery and in Seventh Month of Survival; Second Enrolled Patient Continues on Study in Sixth Month of Survival; Median OS in Relapsed/Refractory (r/r) Acute Myeloid Leukemia (AML) Patients Treated with Standard of Care is Approximately 2.5 Months -

- Fast Track Designation Accelerates SLS009's Path for U.S. Regulatory Submission for Treatment of r/r AML -

NEW YORK, Jan. 09, 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 announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to SLS009 (formerly GFH009), its novel and highly selective CDK9 inhibitor, for the treatment of relapsed/refractory (r/r) acute myeloid leukemia (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.

“Receiving Fast Track Designation for SLS009 for r/r AML, following the recent Orphan Drug Designation for the same indication, underscores the potential for SLS009 and highlights the critical unmet need for patients with AML who face a poor prognosis due to the progressive nature of the disease,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The initial positive topline Phase 2a data at the 45 mg (safety) dose level demonstrate that SLS009 in combination with venetoclax and azacitidine (aza/ven) exhibits anti-leukemic effects with a favorable safety profile in AML patients resistant to venetoclax combination therapies. Importantly, as of the last follow-up, eight of the nine patients enrolled in the 45 mg cohort were alive. The first patient enrolled in the study achieved a complete response (CR) and continues on study in the seventh month with full peripheral blood recovery. The second enrolled patient is in the sixth month of treatment, further underscoring the potential benefit of adding CDK9 inhibition to the aza/ven regimen. We have now also enrolled several patients in the ongoing 60 mg dose cohort. Our team is committed to advancing the development of SLS009 with the goal of providing effective solutions to patients in need of viable treatment options.”

Dr. Stergiou continued, “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 and Orphan Drug Designations for AML. These designations position us to accelerate SLS009 clinical development with the goal of delivering this potentially groundbreaking treatment to AML patients in need.”

A total of nine patients have been enrolled at the 45 mg safety dose level. Eight patients (89%) remain alive (one patient succumbed to sepsis having previously contracted COVID 19) and six continue treatment. The first enrolled patient achieved a complete response and continues on the study in the seventh month with full blood recovery and the second enrolled patient is in the sixth month of treatment. The follow-up duration for the patients who are alive ranges from two to seven months and median OS has not been reached. Significant anti-leukemic effects (≥50% decrease in bone marrow blasts) were observed during treatment in seven out of eight (87.5%) assessable patients with no significant safety issues to date. No dose limiting toxicities were observed in any of the patients. In the Phase 1 study of SLS009 as monotherapy, a durable CR with no minimal residual disease (MRD) was observed in one patient with AML who had failed prior aza/ven therapy. The patient continues to be alive 16 months following commencement of treatment per last follow-up. Patients with AML that fail venetoclax-based therapies have limited treatment options and a poor prognosis with a median OS of approximately 2.5 months.

The Phase 2a clinical trial of SLS009 is an open label, single arm, multi-center study that is designed to evaluate safety, tolerability, and efficacy at two dose levels, 45 mg and 60 mg, in combination with aza/ven. In the 60 mg dose cohort, patients are being randomized to one of two groups, 60 mg flat (fixed) dose once per week and 30 mg fixed dose two times per week. Each group will enroll 5 – 10 patients. In addition to safety and tolerability of SLS009 in combination with aza/ven, the primary endpoints are composite complete response rate (CRc) and duration of response (DOR). Additional endpoints include event free survival (EFS), OS, and pharmacokinetic (PK) and

pharmacodynamic (PD) assessments. Venetoclax combinations with hypomethylating agents are a commonly used regimen in this target population but despite high efficacy (up to ~67% complete response rate), approximately one-third to one-half of patients do not respond to venetoclax based regimens, and among those who respond almost all eventually relapse.

The Company expects to report additional data from the fully enrolled 45 mg (safety dose level) cohort and initial data from the 60 mg (recommended Phase 2 dose level) cohort in the first quarter of 2024 and expects the 60 mg cohort to be analyzed in the second quarter of 2024.

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, galinpepimut-S (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 SLS009 clinical development program, including regulatory matters related thereto and the timing for receipt of additional data from the clinical program. 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.

Investor Contact

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

SELLAS@lifesciadvisors.com

Source: SELLAS Life Sciences Group, Inc.