NEWS RELEASE

SELLAS Announces Positive Initial Topline Phase 2a Data of SLS009 in Acute Myeloid Leukemia

10/16/2023

– SLS009 Is First CDK9 Inhibitor in Combination with AZA/VEN to Achieve Complete Response in AML Patient Resistant to Venetoclax Combination Therapies –

– First Patient Enrolled Achieved CR and in Fifth Month of Treatment; Four Patients Continue on Treatment and All Patients Alive –

– Anti-leukemic Effects Observed in All Patients –

– No Significant Safety Issues Observed –

NEW YORK, Oct. 16, 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 announced positive initial topline data at the 45 mg (safety) dose level from its ongoing Phase 2a clinical trial of its novel and highly selective CDK9 inhibitor, SLS009, in combination with venetoclax and azacitidine (aza/ven) in patients with relapsed/refractory (r/r) acute myeloid leukemia (AML) who did not respond or stopped responding to venetoclax-based therapies. Topline data for the recommended Phase 2 dose (60 mg) is expected later this quarter.

A total of five patients with r/r AML who failed venetoclax-based therapies have been enrolled to date at the 45 mg dose level. The first patient enrolled in the study achieved a complete response, remains alive and is currently in the fifth month of treatment after relapsing on venetoclax, and the second patient is alive and in the fourth month of treatment. All patients enrolled were alive at the time of their last follow-up and four continue treatment. Anti-leukemic effects have been observed in all patients without any significant safety issues to date. Patients with AML

that fail venetoclax-based therapies have limited treatment options and a poor prognosis with a median overall survival (mOS) of approximately 2.5 months.

“This outcome may represent a long-awaited breakthrough in treating patients refractory to venetoclax combination therapies after multiple lines of treatment,” said Dr. Omer Jamy, a principal investigator in the study and Assistant Professor of Medicine at the O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB) and Associate Director of the Bone Marrow Transplant Program at UAB. “Almost all older AML patients in the United States are treated with venetoclax combinations at some point during their course of treatment and, unfortunately, the majority of them become resistant to venetoclax with limited options thereafter. Survival of those patients with currently available treatment options is approximately 2.5 to 3 months. Based on what we have seen to date in this Phase 2a study of SLS009, we have managed to reverse this resistance to therapy and, equally important, extend survival in addition to a very good safety profile and quality of life. I hope to see continuation of this pattern in other patients enrolled later.”

“This initial outcome that includes a complete response, anti-leukemic activity in all patients, good safety profile across the patients and indications of extended survival for our enrolled patients still continuing treatment, we believe opens multiple registrational opportunities for SLS009. We will be exploring these options in the coming weeks as we treat patients with the recommended Phase 2 dose, 60 mg, in this study,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “While these results are early, they are extremely encouraging and consistent with the Phase 1 study results, and further strengthen our initial proposition that the addition of CDK9 inhibition in combination with BCL-2 inhibition and hypomethylating agents could provide patients with a triple hit to increase response rates and survival outcomes without sacrificing safety and tolerability due to the specificity of SLS009. We look forward to providing additional updates this quarter from this study.”

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 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), overall survival (OS), and pharmacokinetic (PK) and pharmacodynamic (PD) assessments.

SLS009 was recently granted orphan drug designation by the U.S. Food and Drug Administration in AML supported by the data from the Phase 1 study of SLS009 as a monotherapy that met all key study objectives. In the Phase 1 study one patient with AML achieved a complete response, making SLS009 the first CDK9 inhibitor to achieve a complete response in r/r AML as a monotherapy and remained alive for 11 months as of the last follow up. Among the 31 Phase 1 AML patients, 29 out of 31 (94%) patients were alive as of their May 2023 follow-up.

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 (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 clinical data of SLS009 and plans for further development of SLS009. 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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