



NEWS RELEASE

SELLAS Life Sciences to Present at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition 2024

2024-11-05

- Presentation at ASH will Feature Results from the Phase 2a Trial of SLS009 in Relapsed/Refractory Acute Myeloid Leukemia After Venetoclax Failure –
 - 50% Response Rate at the Selected Dose Level of 30 mg Twice a Week (BIW) –
- 45 mg (Safety Dose) Once a Week of SLS009 Showed a Median Overall Survival (OS) of 5.5 Months vs. <2.5 Months with Standard of Care; 60 mg Once a Week and 30 mg BIW Median OS Not Reached -

NEW YORK, Nov. 05, 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 data from its Phase 2a trial of SLS009, a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML) will be presented at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition, which is being held on December 7 –10, 2024, in San Diego, California.

“We are excited to have SLS009 featured at the 2024 ASH meeting and are pleased with the very promising safety and efficacy results from the Phase 2a trial in r/r AML,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Treatment with SLS009 in combination with azacitidine and venetoclax was well tolerated and led to a 50% response rate in the selected optimal dose. Clinical activity was even higher in patients with AML-myelodysplasia-related changes (AML-MRC) and in particular those with ASXL1 mutations, suggesting that this subset of patients may exhibit preferential sensitivity to SLS009. These findings contribute to the growing evidence supporting the potential of SLS009 to address unmet needs in difficult-to-treat populations, and future development efforts will focus on further exploring its impact in patients with AML-MRC.”

Poster presentation details:

Title: Phase 2a Study of SLS009, a Highly Selective CDK9 Inhibitor, In Combination with Azacitidine and Venetoclax for Relapsed/Refractory Acute Myeloid Leukemia After Prior Venetoclax Treatment

Session Date and Time: Sunday, December 8, 2024, 6:00 PM - 8:00 PM PST

Session Title: Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Poster II

Location: San Diego Convention Center, Halls G-H

Lead Author: Joshua F. Zeidner, MD, University of North Carolina, Lineberger Comprehensive Cancer Center, Chapel Hill, NC

Abstract Number: 2877

The study enrolled 30 patients across three dosing levels (DLs) of SLS009:45 mg IV QW, DL2: 60 mg IV QW, and DL3: 30 mg IV BIW. SLS009 was well-tolerated across the DLs tested with no dose-limiting toxicities (DLTs) observed. Among 29 evaluable pts, 16 (55%) had $\geq 50\%$ reduction in bone marrow (BM) blasts compared to baseline (DL1: 60%; DL2: 33%; DL3: 80%). Nine (31%) patients achieved an overall response (i.e., CR+CRi+MLFS), including 5 (17%) who achieved CR/CRi. The response rates per dose level were 10% in DL1, 33% in DL2, and 50% in DL3. All 9 responders had AML- Myelodysplasia Related (AML-MR) (9/23 of AMLMR pts responded) and 8/15 pts (53%) with somatic MR mutations responded. Among those with ASXL1 mutations, 5/9 (56%) achieved an overall response. 2/9 (22%) with TP53 mutations achieved a response including one patient with concomitant TP53 and ASXL1 mutation who had an ongoing response at data cut-off. Fifteen patients were still alive at the time of the data cutoff and the median OS for the trial has not been reached.

For more information on the study, visit clinicaltrials.gov identifier **NCT04588922**.

The accepted abstract is published and available on the ASH website [here](#).

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) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with

unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. 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 28, 2024 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.