NEWS RELEASE

SELLAS Life Sciences Presents Positive Phase 2 Data of SLS009 in Combination with AZA/VEN in Relapsed/Refractory AML-MR at ASH 2025

2025-12-07

- SLS009 in combination with AZA/VEN achieved a 46% overall response rate across all cohorts, a 58% overall response rate in patients with one prior line of therapy, and encouraging survival outcomes in heavily-pretreated AML-MR following prior VEN-based treatment

- Median overall survival (mOS) of 8.9 months in the least pretreated patient cohort; across all cohorts, mOS was not yet reached in patients with one prior line of therapy vs historical benchmark of approximately 2.5 months

- SLS009 30 mg IV twice weekly added to AZA/VEN was safe and feasible, with no dose-limiting toxicities (DLTs) observed

- Study expansion to evaluate SLS009 plus AZA/VEN in newly diagnosed AML with high-risk features is planned for Q1 2026

NEW YORK, Dec. 07, 2025 (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 clinical data from its ongoing Phase 2 study of SLS009, a highly selective CDK9 inhibitor, in combination with azacitidine (AZA) and venetoclax (VEN) for the treatment of patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with myelodysplastic syndrome-related changes (AML-MR) after prior VEN-based treatment were presented today at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition, being held December 6 – 9, 2025, in Orlando, Florida.

In this Phase 2 expansion study, R/R AML-MR patients (N = 35 evaluable) were studied in three separate cohorts (cohorts 3-5) who were previously treated with VEN-based regimens and either relapsed and/or were refractory to VEN and were then treated with SLS009 plus AZA/VEN. The median age of participating patients was 69 years, and 98% of patients had ELN adverse-risk AML, with the most frequent mutations being ASXL1, RUNX1, TP53, and SRSF2.

SLS009 in combination with AZA/VEN demonstrated clinically meaningful activity in patients with R/R AML-MR, and among the 35 evaluable patients, the overall response rate (CR+CRi+MLFS) was 46%, including 29% achieving CR/CRi. Patients harboring ASXL1 or TP53 mutations achieved response rates of 48% (19% CR/CRi) and 57% (29% CR/CRi), respectively. The median overall survival (mOS) was exceedingly higher than the expected 2.6 months in this R/R AML patient population, and in the least pretreated cohort, mOS reached 8.9 months. Across all cohorts, patients with one prior line of therapy experienced the greatest benefit, with a 58% response rate and mOS not yet reached. No dose-limiting toxicities (DLTs) or treatment-related deaths were observed, and the combination was well tolerated.

“These results further reinforce the therapeutic potential of SLS009 to overcome resistance to venetoclax-based regimens by suppressing the expression of MCL-1, a key mechanism of resistance to BCL-2 inhibition in AML,” said Dr. Dragan Cicic, Senior Vice President and Chief Development Officer of SELLAS. “The combination of SLS009 with azacitidine and venetoclax demonstrates encouraging activity in a heavily pretreated population with adverse-risk AML-MR, including those harboring ASXL1 and TP53 mutations. We are particularly encouraged by the strong responses in patients with limited prior therapy and look forward to expanding this combination regimen into newly diagnosed AML with high-risk features.”

Presentation Details:

Title: Phase 2 Study of SLS009 in Combination with Azacitidine and Venetoclax for Relapsed/Refractory AML with MDS-Related Changes (AML-MR) After Prior Venetoclax Treatment

Session Date and Presentation Time: Sunday, December 7, 2025, 6:00 – 8:00 PM EST

Session Title: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Poster II

Location: Orange County Convention Center (OCCC) – West Halls B3-B4

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

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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 (tambiciclib) - 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 20, 2025 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

John Fraunces

Managing Director

LifeSci Advisors, LLC

jfraunces@lifesciadvisors.com

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