

NEWS RELEASE

SELLAS Life Sciences to Present Positive Phase 2 Data Demonstrating Encouraging Response and Survival Outcomes with SLS009 Combination in High-Risk AML at ASH 2026

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− Company to present Phase 2 clinical data evaluating SLS009 (tambiciclib) in combination with azacitidine and venetoclax in patients who have previously failed venetoclax-based therapy −

− Patients with relapsed/refractory monocytic AML achieved a 54% ORR with a median overall survival (mOS) of 5.8 months and patients with TP53-mutated AML achieved a 57% ORR and a mOS of 8.8 months, comparing favorably to historical outcomes in these adverse-risk settings of ~2.5 months −

− Study showed that SLS009 (tambiciclib) combination was well-tolerated with no meaningful added toxicity −

NEW YORK, Nov. 04, 2026 (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 completed Phase 2 study of SLS009 (tambiciclib) for the treatment of relapsed or refractory acute myeloid leukemia (r/r AML) will be presented at the 68th American Society of Hematology (ASH) Annual Meeting and Exposition, being held December 12–15, 2026 in New Orleans. This Phase 2 trial evaluated SLS009, a highly selective CDK9 inhibitor, in combination with azacitidine (AZA) and venetoclax (VEN) for the treatment of patients with r/r AML after prior VEN-based treatment.

“There is an urgent need in AML to address the growing number of patients who have either relapsed or become refractory to treatment with venetoclax,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS Life Sciences. “Our participation at this year’s ASH Annual Meeting reflects our continued focus on addressing this population by evaluating SLS009 in patients who have failed venetoclax therapy. We look forward to sharing these Phase 2 results with the hematology community and the continued advancement of our SLS009

program, which is currently being studied in newly diagnosed AML patients."

"Furthermore, we are excited and hopeful with our galinpepimut-S (GPS) clinical program, as we anticipate reporting the topline primary endpoint data in the Phase 3 REGAL study soon. Overall, we expect to have a strong presence at this year's ASH meeting as we continue our mission to develop medicines with the potential to advance the standard of care for patients with AML," added Dr. Stergiou.

Key outcomes of the SLS009 dose-ranging study in combination with azacitidine and venetoclax:

- Population: 62 heavily pretreated patients whose AML relapsed or did not respond after venetoclax-based therapy. Median age was 70, and median number of prior lines was 2, with up to 8. High-risk mutations were common: ASXL1 41%, RUNX1 33%, TP53 29%.

- Successfully Overcomes Venetoclax Resistance: SLS009 targets two primary drivers of venetoclax resistance: TP53 mutations and MCL-1 reliance. The combination demonstrates robust anti-leukemic activity in difficult-to-treat genetic and phenotypic populations following venetoclax failure.

- Efficacy, All Doses (n=59): ORR 34% (12 CR/CRi, 8 MLFS) — 38% in AML-MR, 44% in monocytic AML and 36% in TP53-mutated AML.

- Efficacy at the Selected Dose (30 mg twice weekly): Patients with monocytic AML achieved a 54% ORR with a median overall survival (mOS) of 5.8 months and patients with TP53-mutated AML achieved a 57% ORR and a mOS of 8.8 months, comparing favorably to historical outcomes in these adverse-risk settings of ~2.5 months.

- Safety: Adding SLS009 to Aza/Ven was well tolerated with limited additive toxicities or treatment-related deaths. Non-hematologic treatment-related adverse events were predominantly mild (Grade 1/2) nausea and diarrhea.

"AML patients who progress after venetoclax-based therapy have very limited treatment options. Venetoclax resistance is largely driven by MCL-1 dependence," said Joshua Zeidner, MD, Principal Investigator and Professor of Medicine at University of North Carolina, Lineberger Comprehensive Cancer Center. "Furthermore, AML patients with TP53 mutations have poor outcomes with venetoclax-based therapy. The response rates of 57% in relapsed TP53-mutated and 54% in relapsed monocytic AML are encouraging and suggest that SLS009 acts on the biology that drives resistance. Continued investigation of SLS009 in combination with azacitidine and venetoclax in the frontline setting is now a natural development course for this therapy."

Enrollment and dosing continue in the ongoing 80-patient Phase 2 trial in newly diagnosed AML patients, including those who become refractory early to AZA/VEN treatment identified through extensive transcriptomics, genomics, and proteomics models. Early topline data are expected in Q4 2026. Additional information about the trial can be found at **clinicaltrials.gov** (**NCT04588922**).

“These results show that adding SLS009 can restore responses in this setting, including in TP53-mutated disease, without adding meaningful toxicity, which matters most for patients who have struggled to remain on venetoclax-based treatments due to poor tolerability,” said Dragan Cicic, MD, Senior Vice President and Chief Development Officer of SELLAS Life Sciences. “We have now taken SLS009 into the frontline setting, guided by precision medicine. Our extensive biological and multi-omics analyses, including genomics and single-cell profiling, help us identify which patients could benefit most and when to add SLS009 to azacitidine and venetoclax. We expect first topline data from the Phase 2 frontline trial in Q4 2026, and we believe moving SLS009 into earlier lines of treatment will give it the best chance to change the course of this disease.”

SLS009 (tambiciclib) Abstract Presentation Details:

Title: Tambiciclib (SLS009), a highly selective CDK9 inhibitor, in combination with azacitidine and venetoclax in relapsed/refractory AML after prior venetoclax: Results from a Phase 2 study
Session Date and Presentation Time: Monday, December 14, 2026, 6:00 – 8:00 PM CST
Session: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies (Poster III)
Location: Ernest N. Morial Convention Center (MCCNO) – Hall F
Lead Author: Joshua F. Zeidner, MD, Professor of Medicine, Chief of Leukemia Research, The University of North Carolina School of Medicine
Abstract Number: 5155

The poster will be available on SELLAS’ website following the conference **www.sellaslifesciences.com**.

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 and SLS009 clinical development programs, 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 19, 2026 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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