



NEWS RELEASE

SELLAS Life Sciences Announces Enrollment of First Patient in Newly Diagnosed First-Line AML Trial of SLS009

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- Study to Enroll 80 Patients Unlikely to Benefit from Venetoclax/Azacitidine (Aza/Ven) Therapy in the US and Europe -
- SELLAS' Predictive Biomarker and AI Assisted Precision Medicine Models to be Utilized -
- Topline Data Expected in Q4 2026 -

NEW YORK, March 12, 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 the first patient has been enrolled in its randomized Phase 2 trial evaluating SLS009 (tambiciclib), a highly selective CDK9 inhibitor in newly diagnosed, first-line acute myeloid leukemia (AML) patients.

The newly initiated **NCT04588922** is designed to enroll approximately 80 patients and includes two AML cohorts with high unmet need and greatest potential benefit:

1. Predictive biomarker cohort: Newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling
2. Early resistance cohort: Patients who initiate treatment with aza/ven but demonstrate a confirmed lack of any response after two treatment cycles

"Enrolling the first patient in this first-line AML Phase 2 study represents an important milestone in the advancement of our SLS009 program and reflects our precision medicine strategy to address challenging subgroups of AML patients through our extensive transcriptomics, genomics, and proteomics models we have established," said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer of SELLAS. "The strength of



our Phase 2 data in r/r AML, particularly in high-risk molecular subtypes, together with the FDA's guidance, provided a strong foundation for moving into earlier lines of therapy. By targeting molecularly defined subgroups and those demonstrating early non-response, we aim to address a critical need in frontline AML and position SLS009 for potential registrational development.”

This milestone follows the Company's previously reported positive Phase 2 results in relapsed/refractory (r/r) AML and the FDA's guidance recommending advancement into a study that includes newly diagnosed AML patients eligible for venetoclax and azacitidine (aza/ven) therapy.

In the completed Phase 2 trial in r/r AML, SLS009 in combination with aza/ven met all endpoints, exceeding the pre-specified ORR threshold of 20%, demonstrating strong efficacy and favorable safety and tolerability with robust anti-tumor activity:

- 33% overall response rate (ORR) in all evaluable patients across all cohorts and dose levels, and 40% ORR for the recommended 30mg BIW dose level.
- ORR of 44% in AML patients with myelodysplasia-related changes (AML-MR) at the 30mg BIW dose
- ORR of 50% in ASXL1-mutated AML-MR at 30 mg BIW dose levels and 50% ORR in M4/M5 subtypes
- Median overall survival (mOS) of 8.8 months in patients treated with 30mg BIW, with a median of 1 prior line of therapy, and mOS of 8.9 months in AML MR patients vs 2.4 months with best available therapy.

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.

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