



NEWS RELEASE

SELLAS Announces Positive Overall Survival in Cohort 3 from the Ongoing Phase 2 Trial of SLS009 in r/r AML

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- 8.9 Months Median Overall Survival (mOS) in Patients with AML-Myelodysplasia-Related Changes (AML-MRC) and 8.8 mOS in All Relapsed or Refractory to Venetoclax-Based Regimens Patients; Surpassing Historical Benchmark of 2.5 Months -

- Overall Response Rate (ORR) of 67% Achieved in Patients with AML-MRC (Target Patient Population of SLS009 in r/r AML) – Exceeding Targeted 20% ORR -

- Trial Continues with Full Data and FDA Regulatory Path Feedback Expected in 1H 2025 –

NEW YORK, April 08, 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 Cohort 3 data from the ongoing Phase 2 trial of SLS009 (tambiciclib), a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML).

"The remarkable results from Cohort 3 of the ongoing Phase 2 trial reinforce the potential of SLS009 to transform outcomes for these heavily pretreated AML patients," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Not only have we observed unprecedented survival benefits, but the high response rate underscores the therapy's efficacy profile. The data reveal that relapsed or refractory to venetoclax-based regimens patients receiving 30 mg BIW achieved a mOS of 8.8 months, far surpassing the historical benchmark of 2.5 months. Additionally, the therapy demonstrated a 67% ORR in patients with AML-MRC and 46% in all evaluable patients, significantly exceeding the targeted 20% ORR. With responses seen across different genetic mutations, this approach could be transformational for many underserved patients. We are continuing to explore SLS009's potential in expansion cohorts to further validate its potential to address critical unmet medical needs."

Patients Characteristics:

- 14 relapsed and refractory AML patients who previously failed venetoclax-based therapies were enrolled and treated with SLS009 and venetoclax/azacitidine in Cohort 3.
 - 10 out of 14 patients (71%) had AML MRC (acute myeloid leukemia with myelodysplasia-related cytogenetics).
 - 4 of those patients had myelomonocytic phenotype (M4 per FAB classification). The myelomonocytic phenotype has been shown to exhibit inferior responses to venetoclax-based therapies. It is thought to depend more on the MCL1 anti-apoptotic protein than on the BCL2 anti-apoptotic protein.
 - In terms of specific mutations, 6 patients had ASXL1, 5 had RUNX1 and 3 had TP53.
- The median age was 71 (range 35-89 years).
- The median number of prior failed therapy was 1 (range 1-6).
- 13/14 patients were evaluable for efficacy.
- All patients had adverse risk cytogenetics per ELN 2022.

Key Results from Cohort 3:

- The median overall survival (mOS) for all patients in Cohort 3 was 8.8 months, while the mOS in AML MRC patients reached 8.9 months.
- The overall response rate (ORR) in all evaluable patients was 46% in all Cohort 3 patients and 67% in AML-MRC patients, far exceeding the targeted ORR of 20%.
 - In the subgroup of patients with myelomonocytic AML, 75% of patients responded (3 out of 4).
- Among patients with mutation ASXL1, 4/6 (67%) responded; among those with RUNX1 3/5 (60%) responded, and among those with TP53 1/3 (33%) responded. In addition, there were 3 patients with adverse karyotypes and 1 responded.
- SLS009 was well-tolerated with no new safety signals observed to date as the regimen remains safe in additional patients enrolled to date.
- Phase 2 trial continues in expansion cohorts 4 and 5, in patients with AML-myelodysplasia-related changes (AML-MRC) with ASXL1 mutation (cohort 4) and mutations and cytogenic changes other than ASXL1 (cohort 5).

The Phase 2 clinical trial of SLS009 is an open-label, single-arm, multi-center study designed to evaluate the safety, tolerability, and efficacy of SLS009 in combination with venetoclax and azacitidine at two dose levels, 45 and 60 mg.

In the 60 mg dose cohort patients were treated at either a 60 mg dose once per week or a 30 mg dose two times per week. The trial was expanded to include two additional cohorts, one with ASXL1 mutated AML patients and one with patients with myelodysplasia-related molecular abnormalities other than ASXL1. The target response rate at the optimal dose level is 20% with a target median survival of at least 3 months. In addition, the study aims to identify biomarkers for the target patient population and enrichment for further trials. For more information on the study, visit [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04588922) identifier **NCT04588922**.

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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