



NEWS RELEASE

SELLAS Announces Positive Overall Survival and Overall Response Rate Data from the Phase 2 Trial of SLS009 in r/r AML

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- Median Overall Survival (mOS) Not Yet Reached, Now Exceeds 7.7 Months at Latest Follow-Up in the 30 mg BIW Cohort in Patients Relapsed or Refractory to Venetoclax-Based Regimens -
- Overall Response Rate (ORR) of 56% Achieved to Date in Patient with Acute Myeloid Leukemia with Myelodysplasia Related Changes (AML MRC) Prospectively Enrolled in Two Expansion Cohorts; Exceeding Prespecified Target Response Rate of 33% -

NEW YORK, Dec. 09, 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 additional data from the expansion cohorts in the Phase 2 trial of SLS009, a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML).

"We are highly encouraged by the emerging data, which continue to show the potential of SLS009 to transform outcomes of these heavily pretreated AML patients," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "In the Cohort 3, the optimal dosing regimen of 30 mg BIW, in patients relapsed or refractory to venetoclax-based regimens, the median overall survival has not been reached but exceeds 7.7 months at latest follow-up, marking a significant milestone for patients in this setting, where the expected mOS is historically around 2.5 months. In addition, we are seeing more than 50% ORR to date in our expansion cohorts in patients with AML-myelodysplasia-related changes (AML-MRC) with ASXL1 mutation and mutations and cytogenetic changes other than ASXL1, similar to the previously reported ORR in Cohort 3. We set up an aggressive threshold of 33% response rate before the trial started, and to date we achieved 56% in 5/9 evaluable patients. The rapid enrollment in the expansion cohorts further highlight the critical need for new treatments for our target patient population. These results support the potential of SLS009 to become an important new therapeutic option for this

underserved patient population.”

Key Highlights from the updated topline data:

- As of December 4, 2024, data cutoff, 14 patients were enrolled in Cohort 3 and 14 in Cohort 4 and 5, of which 9 were evaluable at the time of analysis.
- At latest follow-up, the mOS has not been reached yet but has exceeded 7.7 months in Cohort 3. This is particularly significant as the expected mOS for patients in this setting is typically 2.5 months.
- In expansion cohorts 4 and 5, in patients with AML-myelodysplasia-related changes (AML-MRC) with ASXL1 mutation (cohort 4) and mutations and cytogenetic changes other than ASXL1 (cohort 5) the ORR was 56% in 9 evaluable for efficacy patients.
- SLS009 was well-tolerated with no new safety signals observed to date as the regimen remains safe in additional patients enrolled to date.

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 randomized into 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. In addition to response and survival analyses, 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 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 (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.

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