NEWS RELEASE

SELLAS Meets All Primary Endpoints in Phase 2 Trial of SLS009 in r/r AML and Receives FDA Guidance to Advance into First-Line Therapy Study

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- The Trial Exceeded Target Overall Response Rate (ORR) of 20%, with 44% Response Rate Among Patients with Acute Myeloid Leukemia-Myelodysplasia-Related Changes (AML MR) Treated at Optimal Dose of 30 mg Twice a Week (BIW) and 50% in AML MR with Myelomonocytic/Myelomonoblastic (M4/M5) Subtype
- Median Overall Survival (mOS) of 8.9 Months in Patients with AML MR and 8.8 mOS in Relapsed or Refractory to Venetoclax-Based Regimens at 30 mg BIW Dose Level Surpasses the Historical Benchmark of 2.4 Months
- FDA Recommends Advancement towards a Trial Including Newly Diagnosed First-Line AML Patient Cohorts That May Support a New Drug Application; Trial Preparation Underway with Enrollment Expected to Begin by Q1 2026

NEW YORK, July 15, 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 is has met all primary endpoints in its Phase 2 trial of SLS009 (tambiciclib), a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML).

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 mg and 60 mg. In the 60 mg dose cohort, patients were treated with either a 60 mg dose once per week or a 30 mg dose two times per week. The trial was expanded to include ASXL1-mutated AML patients as well as patients with myelodysplasia-related cytogenetic abnormalities other than ASXL1 mutations. The target response rate for this Phase 2 trial, at the optimal dose level, was at least 20% and a target median survival of at least 3 months. The primary endpoint for the trial was overall response rate (ORR), and key secondary endpoints included overall survival (OS), safety, and tolerability.

The trial met all endpoints, demonstrating strong efficacy and favorable safety and tolerability with robust anti-tumor activity. Based on these data, the Company plans to advance SLS009 into a randomized trial that will expand into the newly diagnosed AML populations where earlier intervention may enhance therapeutic outcomes, as well as patients refractory to venetoclax and azacitidine, with the study to support a potential New Drug Application (NDA) with the FDA.

“We are excited to report that our Phase 2 trial met all key endpoints, with clinical responses and survival outcomes that exceed targeted expectations and historical benchmarks,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “AML remains an area of urgent unmet medical need, particularly for patients with relapsed or refractory disease, where standard treatments are often ineffective and poorly tolerated. What sets SLS009 apart is its consistent efficacy across a broad range of molecular subtypes. The remarkable response rates of 44% among AML MR patients, 50% among ASXL1-mutated AML MR, and 50% among M4/M5 patients at the optimal 30 mg BIW dose far exceed the targeted 20% benchmark. We saw a clear survival benefit with median OS reaching 8.8 months in patients refractory to venetoclax-based regimens in the cohort of patients with median 1 prior line of therapy, surpassing the historical median of 2.4 months and 4.1 months in cohorts with median 2 lines of prior therapy, versus 1.8 months reported in similar patient population. The treatment was also well-tolerated, with no dose-limiting toxicities across any treatment arm, validating both the biological selectivity and safety profile of our approach. We believe these data strongly support the potential of SLS009 to meaningfully extend life in patients with otherwise limited options, and we look forward to sharing these findings in more detail in the future. With the expected Phase 3 REGAL study final analysis by year-end, our galinpepimut-S (GPS) immunotherapy and SLS009 are complementary therapies that together enable us to hopefully address AML patients across the treatment spectrum — from early intervention to maintenance.”

Key Phase 2 Results:

Patients Characteristics:

- 54 evaluable r/r AML patients who previously failed venetoclax-based therapies were enrolled and treated with SLS009, and venetoclax/azacitidine; patients were enrolled across all five cohorts. Among the 54 treated patients, 47 had AML MR (87%) and 23 had ASXL1 mutations (43%).
    - 47 out of 54 had AML MR (acute myeloid leukemia with myelodysplasia-related changes).
        - Among AML MR patients,17 had myelomonocytic/myelomonoblastic subtype of AML (M4 and M5), representing 31% of all patients.
- All patients had adverse risk cytogenetics except one patient who had intermediate risk cytogenetics.
- The median age of all patients was 69.

- Median number of prior lines of therapy was 2.

Efficacy:

- The results exceeded the pre-specified ORR threshold of 20%, demonstrating robust clinical activity and supporting advancement into late-stage development.
- The ORR in all evaluable patients was 33% across all cohorts and dose levels and 40% for the 30mg BIW dose level.
- At the 30 mg BIW dose, among AML MR patients, the ORR was 44%.
- The highest efficacy was observed among patients with ASXL1 mutations, with an ORR of 50% (9/18) at 30 mg BIW dose levels and M4/M5 patients with 50% (6/12) ORR.
- The mOS surpassed the historical benchmark of best available therapy of 2.4 months1 for patients who received one prior line of therapy and 1.8 months for those who received more than one prior line of therapy.
- The mOS for patients treated with 30mg BIW, with a median of 1 prior line of therapy, was 8.8 months, while the mOS in AML MR patients reached 8.9 months vs. 2.4 months with best available therapy.
- The mOS for cohorts with a median of 2 prior lines of therapies was 4.1 months vs.1.8 months with best available therapy.

Safety:

- The addition of SLS009 to the venetoclax/azacitidine regimen was well tolerated and did not result in increased toxicities compared to ven/aza alone. No dose-limiting toxicities were observed across all dose levels.

Front Line Trial Planning Underway Following FDA Guidance

- Following a productive end of Phase 2 meeting, the FDA recommended that SELLAS proceeds into a trial to include newly diagnosed, first-line AML patients eligible for venetoclax/azacitidine (aza/ven) therapy, where the agency believes clinical benefit might be greatest.
- The randomized 80-patient trial is currently in preparation and is expected to begin enrollment by Q1 2026. The trial will include two groups:
    - Predictive biomarker cohort: Newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling
    - Early resistance cohort: Patients who initiate treatment with aza/ven but demonstrate confirmed lack of

any response after two treatment cycles

- This precision approach allows SELLAS to target subpopulations with high unmet need and greatest potential for benefit.

"These SLS009 results represent an important advancement for patients with r/r AML, where treatment options remain limited and outcomes are often poor," said Dr. Yair Levy, Director of Hematologic Malignancies Research at Texas Oncology Baylor University Medical Center. "The response rates and survival outcomes are particularly compelling, especially given the consistency of responses across high-risk molecular subtypes and the favorable safety profile. What's especially encouraging is the opportunity to now explore this therapy in the first-line setting, where outcomes are often dictated by how patients respond to initial treatment. The FDA's recognition of this unmet need and its support for a trial in newly diagnosed patients reflects SLS009's potential to address a critical gap in AML care."

"Following constructive FDA guidance, we are preparing the trial focused on newly diagnosed AML patients as well as those early refractory to venetoclax and azacitidine," said Dragan Cicic, MD, Chief Development Officer of SELLAS. "The study will include two groups – one comprising patients predicted not to benefit from standard aza/ven, based on cytogenetic risk factors, and a second comprising patients who begin aza/ven treatment but demonstrate confirmed resistance after two cycles. We believe earlier intervention with SLS009 may offer greater clinical benefit before patients' bone marrow reserve is depleted by disease or prior therapies, and before the disease evolves into more resistant and aggressive forms. Data from other recent clinical trials suggests meaningful differences in response rates between newly diagnosed and relapsed/refractory patients, reinforcing the importance of this strategic approach. In addition, our ongoing collaboration with one of the nation's most prestigious cancer centers continues to generate insights in genomics, proteomics, and transcriptomics, which will refine patient selection and our precision medicine strategy and help us unlock the full potential of SLS009 as we prepare to enter pivotal development."

1. Zainaldin et al, Leukemia and Lymphoma, 2022

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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