NEWS RELEASE

SELLAS Life Sciences Announces First Pediatric AML Patient Dosed in the Ongoing Phase 2 Trial of SLS009 r/r AML

2025-05-15

- First ASXL1 Pediatric Acute Myeloid Leukemia (AML) Patient Dosed at MD Anderson Cancer Center: Program Supported by Rare Pediatric Disease Designation (RPDD)

NEW YORK, May 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 the first pediatric AML patient has been dosed in the ongoing Phase 2 trial of SLS009 (tambiciclib), a highly selective CDK9 inhibitor, in relapsed/refractory acute myeloid leukemia (r/r AML).

"Building upon our **promising Cohort 3 data**, we are pleased to dose our first pediatric AML patient as part of the ongoing Phase 2 trial," said Dragan Cicic, MD, Chief Development Officer of SELLAS. "This milestone reflects our commitment to addressing critical unmet needs in hematologic disorders as we develop treatments for the most difficult to treat patients, particularly pediatric patients, with very few available options, including multi-hit TP53 mutation, failure of azacitidine and venetoclax, failure of transplant, and almost all available high-intensity chemotherapies. With the Rare Pediatric Disease Designation already in place, we are hopeful that our work will bring meaningful progress and potential regulatory advantages as we continue to advance this important program."

SELLAS was granted the FDA RPDD for the treatment of pediatric AML in July 2024. If, in the future, a New Drug Application (NDA) for SLS009 for the treatment of pediatric AML is approved by the FDA, SELLAS will be eligible to receive a Priority Review Voucher (PRV) that could be redeemed to receive a priority review for any subsequent marketing application. PRVs may be used by the sponsor or sold to another sponsor for their use and have recently sold for approximately $100 million.

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** 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.

Investor Contact

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

SELLAS@lifesciadvisors.com

Source: SELLAS Life Sciences Group, Inc.