



NEWS RELEASE

SELLAS Life Sciences Announces First Patients Enrolled in 60 mg Dose Cohort in Phase 2a Clinical Trial of SLS009 in Acute Myeloid Leukemia

12/14/2023

- Enrollment Completed in 45 mg Safety Cohort; Safety Monitoring Committee Advocated Proceeding to Recommended Phase 2 Dose Level of 60 mg -

- Patients in 60 mg Dose Cohort Will be Dosed with 60 mg Once per Week or 30 mg Twice per Week -

- Early Data in 45 mg and 60 mg Cohort Expected Around Year-End 2023 -

NEW YORK, Dec. 14, 2023 (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 patients have been enrolled in the 60 mg dose cohort in its ongoing Phase 2a clinical trial of its novel and highly selective CDK9 inhibitor, SLS009, in combination with venetoclax and azacitidine (aza/ven) in patients with relapsed/refractory (r/r) acute myeloid leukemia (AML) who did not respond or stopped responding to venetoclax-based therapies.

A total of nine patients have been enrolled at the 45 mg safety dose level. Eight patients remain alive (one patient succumbed to sepsis having previously contracted COVID 19) and six continue treatment. The first enrolled patient achieved a complete response and is currently in the seventh month of treatment and the second enrolled patient is in the sixth month of treatment. Significant anti-leukemic effects ($\geq 50\%$ decrease in bone marrow blasts) were observed during treatment in five out of six assessable patients with no significant safety issues to date. No dose limiting toxicities (DLT) were observed in any of the patients. Topline data for the 45 mg cohort are expected around year-end 2023. Patients with AML that fail venetoclax-based therapies have limited treatment options and a poor

prognosis with a median overall survival (mOS) of approximately 2.5 months.

“We are thrilled with the Safety Monitoring Committee advocating that we proceed to the recommended Phase 2 dose level of 60 mg after finding no safety concerns with the 45 mg cohort, which represents important progress in the clinical advancement of SLS009. Based on the encouraging efficacy data and safety profile that continues to emerge in the Phase 2a trial, we remain excited about the potential for SLS009 as a promising treatment option for the many AML patients with poor prognosis and limited alternatives currently available once they become resistant to venetoclax,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer at SELLAS. “To align with the FDA’s Project Optimus initiative, our dosing strategy in this next arm of the Phase 2a trial will include evaluation of two dosing regimens, 60 mg once per week and 30 mg twice per week. We look forward to sharing early data from this cohort as well as further clinical data of the 45 mg cohort around the end of this year or early next year.”

The Phase 2a clinical trial of SLS009 is an open label, single arm, multi-center study that is designed to evaluate safety, tolerability, and efficacy at two dose levels, 45 mg and 60 mg, in combination with aza/ven. In the 60 mg dose cohort, patients will be randomized to one of two groups, 60 mg flat (fixed) dose once per week and 30 mg fixed dose two times per week. Each group will enroll 5 – 10 patients. In addition to safety and tolerability of SLS009 in combination with aza/ven, the primary endpoints are composite complete response rate (CRc) and duration of response (DOR). Additional endpoints include event free survival (EFS), OS, and pharmacokinetic (PK) and pharmacodynamic (PD) assessments. Venetoclax combinations with hypomethylating agents are a commonly used regimen in this target population but despite high efficacy (up to ~67% complete response rate), approximately one-third to one-half of patients do not respond to venetoclax based regimens, and among those who respond almost all eventually relapse.

SLS009 was recently granted orphan drug designation by the U.S. Food and Drug Administration in AML supported by the data from the Phase 1 study of SLS009 as a monotherapy that met all key study objectives. In the Phase 1 study one patient with AML achieved a complete response, making SLS009 the first CDK9 inhibitor to achieve a complete response in r/r AML as a monotherapy, and remained alive for 11 months as of the last follow up.

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 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), a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. 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 SLS009 clinical development program, including data therefrom, and future activities for the program. 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 16, 2023 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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