

SELLAS Life Sciences Successfully Completes Phase I Trial Dose Escalation of Novel, Highly Selective CDK9 Inhibitor GFH009 in Acute Myeloid Leukemia

4/20/2023

- GFH009 showed strong anti-tumor effect and clinical and biological efficacy; PK profile supports anticipated once weekly dosing -
- GFH009 demonstrated a favorable tolerability profile with no dose limiting toxicities -
- SELLAS plans to commence Phase 2a trial with GFH009 in combination with venetoclax and azacitidine in patients with AML during 2Q 2023 with topline data expected in Q4 2023 -

NEW YORK, April 20, 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 completion of the safety evaluation stage of the highest dose cohort of patients with acute myeloid leukemia (AML) who relapsed after or were refractory to available antileukemic therapies in its Phase 1 dose escalation clinical trial of GFH009. No further dose escalations are planned in the AML group, while dose escalation continues in the lymphoma group with the addition of a 75 mg once-a-week dose cohort, which is planned to be the highest dose level for that group.

"We are very encouraged by the strong efficacy signals and safety profile of our highly selective CDK9 inhibitor, GFH009, observed in this positive Phase 1 trial. We believe GFH009 could have the potential to address a major unmet medical need of patients with AML who relapse following treatment," said Angelos Stergiou, M.D., Sc.D. h.c., President and CEO of SELLAS. "We are highly motivated to expedite advancement of GFH009 with our upcoming Phase 2a trial, in order to potentially bring this novel treatment to AML patients who need it as quickly as possible."

"I am very much looking forward to participation in the Phase 2a clinical trial of GFH009," said M. Yair Levy, MD, the Director of Hematologic Malignancies research at Texas Oncology Baylor Charles A. Simmons Cancer Center in Dallas, TX. "Although venetoclax is a backbone of many AML treatments, some patients do not respond to treatment and many relapse after initial response. CDK9 inhibition in general, and GFH009 in particular with the AML data seen thus far, has a strong biological basis of synergy with the BCL2 inhibitor venetoclax and we hope that it may overcome leukemic cell resistance in the upcoming trial, given that it appears that MCL-1 upregulation plays a key role in developing venetoclax resistance and we have seen in the Phase 1 trial that GFH009 decreases MCL-1 levels."

The Company is finalizing the comprehensive data analysis to determine the recommended Phase 2 dose (RP2D) in AML, which will be announced following review by the U.S. Food and Drug Administration (FDA). SELLAS plans to commence a Phase 2a clinical trial during the second quarter of 2023 with GFH009 in combination with venetoclax and azacitidine (aza/ven) in patients with AML who relapsed after or are refractory to treatment with venetoclax based therapies. The trial will be a single arm open label dose ranging study with one dose level at the RP2D and one dose below RP2D. Primary endpoints will be complete response composite (CRc) rate and safety, and secondary endpoints will include duration of response (DOR), event free survival (EFS), overall survival (OS) and proportion of patients proceeding to transplant. The trial will include several sites in the United States, will initially enroll approximately 20 patients and, based on initial results, may be expanded into a registrational trial. Topline data from this study are expected in the fourth quarter of 2023.

Phase 1 results from the AML group :

In the Phase 1 trial, the AML group included dose levels of 9 mg, 15 mg, 22.5 mg, 30 mg, 40 mg, 45 mg and 60 mg. Dose levels of 9 mg to 40 mg were administered two times per week and dose levels of 30 mg, 45 mg and 60 mg were administered once a week.

Anti-tumor activity has been observed in both the AML and lymphoma groups in the Phase 1 trial at multiple dose levels, including a complete response, partial responses, stable disease, and decreases in tumor burden. GFH009 continued to be safe and well tolerated at all dose levels, with no dose limiting toxicities and no significant off target toxicities observed. Due to the encouraging safety profile, the maximum tolerated dose level has not been reached.

In the AML group, no further dose escalation is planned as all Phase 1 trial objectives in AML have been successfully met and results are summarized below:

- Clinical efficacy was demonstrated with a complete response achieved at an intermediate dose level
- Biological efficacy was observed with 50% or more decrease in leukemic cell blasts in bone marrow at

- multiple dose levels and 75% bone marrow blasts decrease at the highest studied dose level
- Pharmacokinetics above IC90 in peripheral blood was maintained for 24 hours at target dose level
- IC90 plus concentrations in peripheral blood were achieved after first infusion with once-a-week administration at the highest studied dose level
- Pharmacodynamics representing consistent and dose related decrease in MCL1 and MYC biomarkers expression

Phase 2a trial in combination with aza/ven in patients with AML :

Disease relapse in patients with AML after initial response to aza/ven is a major unmet medical need with median overall survival of only 2.5 months. While the aza/ven regimen is a backbone of AML treatment, approximately one-third of patients do not respond to treatment and almost all patients who initially respond eventually relapse.

Based on the available Phase 1 data, the Phase 2a trial design will be submitted to the FDA by the end of the month. GFH009 will be studied in the Phase 2a trial in combination with aza/ven in patients relapsed after or refractory to venetoclax based therapies and will be based on the parameters discussed with the FDA. The study regimen is designed based on clinical data that showed efficacy in patients relapsing after aza/ven induced complete responses, preclinical in vivo data that demonstrated high levels of synergy of GFH009 and venetoclax in mouse models of AML, and in vitro biological synergies between BCL2 and MCL1 inhibition and AML cells dependence on MCL1 and BCL2. In addition, a significant proportion of patients with AML exhibit MYC dependence.

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, galinpepimut-S (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 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 clinical data of GFH009, the pre-clinical

development of GFH009, plans for further clinical development of GFH009 and the potential for GFH009 as a drug development candidate. 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 associated 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.

Investor Contact

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

SELLAS@lifesciadvisors.com

Source: SELLAS Life Sciences Group, Inc.