



NEWS RELEASE

# SELLAS Announces Positive Topline Data from GFH009 Phase 1 Dose-Escalation Trial in Acute Myeloid Leukemia Cohort Supporting Advancement to Phase 2 Clinical Study

5/4/2023

- 72 Acute Myeloid Leukemia and Lymphoma High-Risk Advanced Patients Enrolled: 94% Alive at Last Assessment Indicating Favorable Survival Benefit -

- Long-Term Complete Remission and Significant Bone Marrow Blast Reductions in Acute Myeloid Leukemia: Durable Complete Remission with No Minimal Residual Disease Continues > 6 Months vs. Historic Median Survival of 2.5 Months in AML Patient; 77% Bone Marrow Blast Elimination in Highest Dose -

- Decrease in MCL1 and MYC Biomarkers Observed in 97% of Patients -

- No Dose Limiting Toxicity or Significant Safety Issues at any Dose Level -

NEW YORK, May 04, 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 positive topline data for the cohort of patients with acute myeloid leukemia (AML) from its Phase 1 dose-escalation trial in relapsed/refractory (r/r) myeloid malignancies for GFH009, its CDK9 inhibitor. Dose escalation continues in the lymphoma cohort with the last dose level of 75 mg weekly. Clinical activity observed in the lymphoma group will be announced after completion of the last dose level and is expected by the end of the second quarter or early third quarter of 2023.

In the cohort of patients with AML, GFH009 treatment showed evidence of anti-tumor activity increasing with higher

doses and no significant safety issues, including at the highest dose levels. The recommended Phase 2 dose (RP2D) for AML has been established and submitted to the U.S. Food and Drug Administration (FDA). SELLAS plans to commence a Phase 2a trial with GFH009 in combination with venetoclax and azacitidine (aza/ven) in patients with AML during the second quarter of 2023 with topline data expected by the end of the year.

“We are thrilled to share promising signs of safety and clinical activity for GFH009 that support advancement into the Phase 2 clinical study in patients with AML, in parallel to completing the Phase 1 lymphoma cohort dose escalation,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “These data include results from patients with difficult to treat advanced heavily pretreated blood cancers, which highlight the significant unmet need of patients that have failed current standards of care. The strength of the AML cohort data supports expediting our clinical strategy to initiate a Phase 2a trial in patients with AML during the second quarter of 2023.”

The Phase 1 interim analysis included 72 patients in the AML (n = 31) and lymphoma (n = 41) cohorts who were high-risk, advanced, heavily pretreated and resistant to multiple prior therapies. In these difficult to treat cohorts of patients with advanced blood cancer, 94% of patients are alive to date (29/31 in AML cohort and 39/41 in lymphoma cohort) with one patient alive more than 18 months following the beginning of treatment. Two dosing regimens were tested in incremental GFH009 dose levels from 2.5 mg to 75 mg, either a twice a week (BIW) regimen or once a week (QW) regimen. No further dose escalations are planned in the AML cohort,

All key study objectives regarding pharmacokinetic (PK), pharmacodynamic (PD), safety and clinical activity data were met:

- Efficacy: Anti-tumor activity and clinical responses across groups and dose levels were observed, indicating a broad therapeutic index. Meaningful cell killing activity was defined as  $\geq 50\%$  reduction in blasts in the bone marrow.
  - AML cohort: cell killing activity observed at the following dose levels:
    - 9 mg BIW: 50.0% bone marrow blast (BMB) reduction;
    - 15 mg BIW: 53.8% BMB reduction;
    - 30 mg QW: 57.1% BMB reduction;
    - 45 mg QW: 61.3% BMB reduction;
    - 60 mg QW: 77.3% BMB reduction.
  - Durable complete remission (CR) with no minimal residual disease (MRD) in one patient with AML who had failed prior venetoclax plus azacytidine (aza/ven) therapy. The patient continues to be in CR 7 months following commencement of treatment. Historic, best available therapy median survival for

patients relapsed after aza/ven is estimated at 2.5 months.

- Safety: No dose limiting toxicities, no higher grade non-hematologic toxicities of any kind, some hematologic toxicities difficult to determine in patients with hematologic cancers but short in duration and reversible.
- Pharmacokinetic (PK) Data: Achieved desired 24 hours > IC90 peripheral blood concentrations after the first infusion, with IC90 concentrations resulting in up to 97% cancer cell killed.
- Pharmacodynamic (PD) Data: Achieved desired levels of MCL1 and MYC suppression in peripheral blood with decrease in MCL1 or MYC observed in 97% (66/68) of analyzed patients. A trend of proportionally increased maximum inhibition of MCL1 and MYC observed among higher doses (22.5 mg to 60 mg) in both AML and lymphoma patients, which is more prominent in QW cohorts compared to BIW cohorts. QW regimen was able to induce longer sustained inhibition (at least 6 hours) of MCL1 and MYC than BIW treatment, allowing longer period for CDK9 inhibition to induce cancer cell apoptosis.

"I am encouraged by the results from the Phase 1 GFH009 trial thus far," said Joshua Zeidner, MD, Associate Professor of Medicine, Chief of Leukemia Research, Associate Chief of Research in Division of Hematology, and Director of Clinical Cancer Research Commercial Integration at University of North Carolina Lineberger Comprehensive Cancer Center. "Novel agents are sorely needed in relapsed/refractory AML. I am looking forward to the next step of combining GFH009 with azacitidine and venetoclax where the mechanism of action of GFH009 is promising and has potential to add to our treatment armamentarium in AML."

The totality of the AML data will be presented at a major medical conference in Q4 2023 and the lymphoma topline data is expected by late second quarter/early third quarter 2023.

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 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](http://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 GFH009 clinical development program, including clinical data of GFH009 and plans for further development of GFH009. 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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