

## **NEWS RELEASE**

## SELLAS Announces Positive Phase 1 Data with CDK9 Inhibitor GFH009 Monotherapy in Patients with Relapsed/Refractory Hematologic Malignancies

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GFH009 is First CDK9 Inhibitor Monotherapy to Achieve Compete Response in Acute Myeloid Leukemia

Anticancer Effects Observed Across Multiple Dose Levels in Both Acute Myeloid Leukemia and Lymphoma Patients

No Dose Limiting Toxicities Observed at Any Dose Level to Date

Biomarkers of CDK9 Activity Decreased in 97.6% of Patients

NEW YORK, Dec. 13, 2022 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) ("SELLAS" or the "Company"), today announced positive results from its ongoing dose escalating Phase 1 first-in-human study of its highly selective CDK9 inhibitor, GFH009, in patients with relapsed and/or refractory (r/r) hematologic malignancies. Results include preliminary safety and efficacy data presented this week at the American Society of Hematology (ASH) Annual Meeting, along with updated data since the ASH abstract cutoff date of August 2, 2022.

One patient treated with GFH009, in the 30 mg once per week cohort, achieved a confirmed complete response (CR), which is the first CR reported in acute myeloid leukemia (AML) with any CDK9 inhibitor monotherapy. No minimal residual disease (MRD) was detected in this CR patient and full neutrophil, platelet and red blood cell recovery was reported. Anti-cancer effects were also observed at multiple dose levels in both the r/r AML and r/r lymphoma treatment groups. Neutrophil counts improved in most patients from both groups while on treatment, and drug-related severe neutropenias were observed in less than 10% of enrolled patients. Dose limiting toxicities have not been identified at any of the levels studied to date and the maximum tolerated dose has not yet been

reached.

"We are excited to see a CR with GFH009 in a r/r AML patient who had failed all previous lines of therapy, including azacytidine-venetoclax combination, and we were also encouraged that a second patient in the same dosing cohort continued on GFH009 treatment for three months with good health status. These encouraging initial data, with efficacy seen across multiple dose levels, support the potential of GFH009 as a treatment option in AML and lymphoma patients where almost all approved therapies have failed," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "The compelling safety profile even at high dose levels, and significant tumor burden reduction even at low levels, indicates a therapeutic window and combination potential of GFH009 in hardest to treat disease states, including solid cancers."

A total of 57 patients have been enrolled to date, including 31 with r/r lymphoma and 26 with r/r AML. All enrolled patients to date were heavily pretreated with up to six lines of previous therapy. The dose escalating trial was originally planned at fixed per patient doses ranging from 2.5 mg to 30 mg, administered as 30-minute infusions twice a week. The initial design was based on expected toxicities observed in previously published trials with other CDK9 inhibitors, which were primarily severe neutropenias. However, the lack of observed severe toxicities, even at the highest dose level of 30 mg, provided the opportunity to both further escalate the dose levels, and to explore a more patient friendly once a week dosing regimen without sacrificing efficacy. New dosing regimens added to the ongoing trial include 40 mg administered twice per week and 30 mg, 45 mg and 60 mg administered once a week, all of which have been fully enrolled except for the 60 mg cohort. All initially planned dose escalation cohorts with 2.5 mg, 9 mg, 15 mg, 22.5 mg and 30 mg of GFH009 administered twice per week are also fully enrolled. The 45 mg once a week cohort, although fully enrolled, has not yet been analyzed.

Apparent efficacy was noted without significant toxicities at multiple dose levels ranging from 9 mg to 30 mg, suggesting a broad therapeutic window, which is a key trait for high combination potential. Stable disease (SD) was maintained in certain patients for more than 8 months and one patient still on treatment has maintained SD for more than a year, which suggests a favorable safety profile with potential for prolonged treatment.

Selective Preliminary GFH009 Monotherapy Efficacy Data in r/r AML Group:

- One patient has a confirmed CR and is MRD negative after failing azacytidine-venetoclax regimen
- One patient continued on treatment for 3 months
- Two patients had blast count decreases of ≥50% in bone marrow (both r/r on azacytidine- venetoclax treatment)

Selective Preliminary GFH009 Monotherapy Efficacy Data in r/r Lymphoma Group:

- 2 patients had partial response (PR)
- 4 patients achieved SD with one of them maintaining SD for over a year while still continuing GFH009 monotherapy

The pharmacokinetics (PK) profile of GFH009 shows dose proportional concentrations with a biphasic profile of rapid initial tissue distribution followed by slower elimination from tissues. There were no apparent time-dependent changes in volume of distribution or clearance.

Initial pharmacodynamics (PD) studies have shown clear reductions in two known biomarkers of CDK9 activity, MCL-1 and MYC. Biomarker response was observed in 97.6% of analyzed patients (41 of 42 patients) with a decrease for either MCL-1 or MYC expression and 95.2% (40 of 42 patients) had a decrease in both biomarkers.

## 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 the COVID-19 pandemic and its impact on the Company's clinical plans and business strategy, 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 31, 2022 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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