



NEWS RELEASE

SELLAS Announces First Patient Dosed in Phase 2a Clinical Trial of GFH009 in Acute Myeloid Leukemia

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NEW YORK, June 22, 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 patient has been dosed in a Phase 2a study of its novel and highly selective CDK9 inhibitor, GFH009, 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. Topline data is expected during the fourth quarter of this year.

The Phase 2a clinical trial is an open label, single arm, multi-center study that is designed to evaluate safety, tolerability, and efficacy at two dose levels of GFH009 (once weekly 45 mg or 60 mg) in combination with aza/ven. The study will enroll up to 20 *r/r* AML patients, 10 patients per dose level, all of whom will receive standard doses of aza/ven after they became unresponsive to venetoclax combinations including aza/ven, with the addition of GFH009. Treatment will continue for as long as there are no dose limiting toxicities and no progression of disease. Bone marrow will be assessed after the first two infusions of GFH009: at day 14 and day 28. Thereafter, bone marrow assessments will be made every 28 days.

In addition to safety and tolerability of GFH009 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), overall survival (OS), and pharmacokinetic (PK) and pharmacodynamic (PD) assessments.

"We are excited to advance GFH009 to the next phase of clinical development, which we believe holds great promise for patients who continue to suffer with advanced and difficult to treat AML," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "As far as we know, GFH009 is the only CDK9 inhibitor in

development that, as a single agent, has shown such unique and very encouraging clinical data which is the reason our hematology experts see high promise in this Phase 2a study. Treatment of the first patient in this study represents successful completion of one of several near-term potential value enhancing milestones.”

The Phase 2a study builds on strong data from the group of patients with AML in the Phase 1 study which demonstrated a favorable safety profile with strong early efficacy signals and evidence of anti-tumor activity increasing with higher doses. Durable complete remission (CR) with no minimal residual disease (MRD) was observed in one patient who had failed prior aza/ven therapy and is now lasting for more than six months which, to the Company’s knowledge, is the first CR ever reported for a CDK9 inhibitor in AML. No dose-limiting toxicities were observed at any level, and MCL1 and MYC biomarkers decreased in 97% of patients. Full Phase 1 AML data is expected to be presented at a major medical conference in the fourth quarter of 2023.

Based on preclinical results showing synergy between GFH009 and venetoclax, along with the topline Phase 1 data in patients with AML, SELLAS believes that GFH009 has potential to both improve venetoclax effectiveness and convert resistance to venetoclax into a response which, given its high selectivity and high therapeutic index as well as favorable safety profile, could differentiate it from other CDK9 inhibitors currently in development. Strong synergy with venetoclax could also allow it to improve patient response to the current standard of care.

GFH009 leads to suppression of MCL1 expression. As almost all AML patients have heterogeneous cancer cells, some cells will depend mostly on BCL2 and will be killed by venetoclax, some will depend on MCL1 and will potentially be killed by GFH009, and some will depend on both BCL2 and MCL1 and the two-fold assault by both anti-apoptotic agents at the same time. In this Phase 2a study, the addition of azacitidine also allows for a NOXA release enhancement, thus increasing pro-apoptotic effect, a triple hit which may potentially increase the response rates in relapse/refractory AML patients.

The Company recently held an expert panel discussion with hematology-oncology specialists who discussed the potential for GFH009 to address unmet medical needs for patients with relapsed and/or refractory AML.

Follow the link below for a replay of the panel discussion:

<https://lifescievents.com/event/sellas/>

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 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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