



NEWS RELEASE

SELLAS Announces Positive Data from Phase 2a Trial of SLS009 in Combination with Zanubrutinib in DLBCL

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- Combination Achieved a 67% of Overall Response Rate, More than Double that of Zanubrutinib Alone; 83% Disease Control Rate in Difficult-to-Treat Non-GCB DLBCL (ABC DLBCL) Patients -

- Median Overall Survival Not Reached Yet – 67% of Patients Still Alive -

NEW YORK, Feb. 20, 2025 (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 data from Phase 2a trial of SLS009 (tambiciclib), a highly selective CDK9 inhibitor, in relapsed/refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL).

The trial, conducted and funded by GenFleet Therapeutics (Shanghai), Inc. ("Genfleet"), was an open-label single-arm multicenter Phase 2a study in China evaluating SLS009 in combination with BTK inhibitor, Brukinsa® (zanubrutinib) in r/r DLBCL. The results showed an overall response rate of 67%, more than double the expected overall response rate (ORR) of zanubrutinib alone. Among responders, one achieved complete response (CR), while three had partial response (PR) with target lesion shrinkages of 89%, 78%, and 56%, respectively. As of the last follow-up, after the median of 4.6 (range: 1.4 - 7.4) months follow-up, median overall survival (OS) was not reached, and six out of 9 patients were alive.

"These results represent a promising step forward in improving outcomes for DLBCL patients and underscores the potential of SLS009 in combination with zanubrutinib to deliver meaningful clinical benefits," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Achieving an ORR that significantly exceeds expectations, along with a complete response and multiple partial responses is a testament to the power of collaboration and innovation in tackling this challenging disease. We believe that the combination of SLS009 and zanubrutinib demonstrates a synergy that could pave the way for more effective treatment options. Moving

forward, GenFleet will determine the next steps regarding the trial's continuation around lymphoma as SELLAS' focus remains in AML and spliceosome – chromatin mutations, including ASXL1 mutations.”

Summary of Phase 2a data of SLS009 in DLBCL

Patients Characteristics

- 9 r/r DLBCL patients were enrolled: 3 with germinal center B-cell like (GCB) and 6 with activated B-cell like (ABC) subtype of DLBCL
 - ABC DLBCL, also known as non-GCB DLBCL, carries a worse prognosis vs. GCB DLBCL
- The median age was 55 years old and the median of previous lines of therapy was 2 (range 2-4)

Efficacy and Safety

- Among 6 non-GCB DLBCL (ABC DLBCL) patients, 4 had an objective response and one patient achieved stable disease (SD) for the disease control rate (DCR) of 5/6 (83%)
- Overall response rate (ORR) was 4/6 (67%), more than double the expected ORR with zanubrutinib alone
- One patient achieved complete response (CR), and three patients had partial response (PR) with target lesion shrinkages of 89%, 78%, and 56%, respectively
- As of the last follow-up, after the median of 4.6 (range: 1.4 - 7.4) months follow-up, median overall survival (OS) was not reached
- Six patients were alive as of the last follow-up, including 5 non-GCB DLBCL and 1 GCB DLBCL. Adverse events (AEs) grade ≥ 3 AEs were reported in 55.6% of patients, comparable to safety outcomes expected with Zanubrutinib alone
- Genetic data of 6 out of 9 enrolled patients showed that none of the patients carried MYD88 or CD79B mutations predictive of better response to BTK inhibitors. The patient who achieved complete response (CR) by CT had MYC amplification, which is expected, but interestingly also harbored TP53 mutations, indicating that CDK9 inhibition with SLS009 could circumvent TP53 mutated cancers drug resistance.

“These additional data from yet another indication help us further expand the scope of SLS009,” said Dragan Cicic, MD, Chief Development Officer of SELLAS. “In parallel with our very advanced clinical development in acute myeloid leukemia, we are continuously working on additional clinical and preclinical programs in other indications and uncovering genetic biomarkers that make all the difference in today's drug development.”

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 the 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) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. 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 GPS clinical development program, including the REGAL study and the timing of future milestones related thereto. 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 28, 2024 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

Media Contact

Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

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