NEWS RELEASE

SELLAS Life Sciences Receives Favorable FDA Type C Meeting Feedback on Chemistry, Manufacturing, and Controls (CMC) Biologics License Application (BLA) Filing Strategy for Galinpepimut-S (GPS)

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– FDA feedback indicates Company's CMC plans are in alignment with FDA's requirements and expectations towards a BLA –

– CMC regulatory alignment is critical step in approval pathway for GPS –

NEW YORK, Nov. 13, 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 it recently concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's Chemistry, Manufacturing, and Controls (CMC) sections in a potential biologics license application ("BLA") for SELLAS' lead product candidate, galinpepimut-S (GPS). SELLAS submitted a CMC Briefing Package to the FDA which provided an up-to-date overview of the extensive work completed for the GPS CMC program and commercial manufacturing and regulatory plans. The FDA reviewed this package of data and accompanying questions to the agency and responded with favorable guidance.

To date, the Company has successfully completed numerous clinical development and CMC objectives in advancing GPS monotherapy into its Phase 3 REGAL study in patients with acute myeloid leukemia ("AML") in the maintenance setting after achievement of second complete remission. CMC activities in support of the clinical development leading to this Type C meeting include:

- Manufacturing lyophilized clinical GMP batches;

- Qualifying processes;
- Validating analytical methods; and
- Monitoring the stability program.

The FDA also agreed on the Company's proposed stability data generation plan for the commercial presentation of GPS. GPS is expected to be stored at 2-8 C (36 – 46 F) making it more accessible for end-users.

Andrew Elnatan, Vice President of Regulatory Affairs, CMC & Quality at SELLAS, stated, "We are pleased with the positive outcome of the Type C meeting and FDA's guidance on the advancement of the CMC plans as part of the GPS program development. The responses to questions regarding our proposed potency assay and manufacturing processes validation are aligned with our expectations and will help guide our plans towards a potential future successful BLA assuming positive data from the REGAL study."

"We look forward to completing our enrollment in the Phase 3 REGAL trial, outside of China, this month and working closely with the FDA as we continue to advance our GPS development program. GPS, through its unique mechanism of action and novel technology, has the potential to become the first immunotherapy, cancer vaccine to reach the market for AML. There are currently no FDA-approved drugs to address the high unmet medical need that exists in treating patients in the maintenance setting in second complete remission," said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer at SELLAS. "Our off-the-shelf therapy, GPS, was precisely and deliberately designed to target Wilms Tumor 1 and the multivalent approach of GPS targets 25 carefully selected WT1 epitopes, allowing it to be maximally immunogenic by eliciting both CD4 and CD8 immune responses. GPS has the potential to offer clinical benefit to this population of leukemia patients and the positive CMC regulatory feedback is a critical step in its 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 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), 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 GPS clinical development program, including CMC data therefrom, regulatory strategy and future activities, including the potential filing of a BLA with the FDA. 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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