NEWS RELEASE

SELLAS Announces U.S. FDA Rare Pediatric Disease Designation (RPDD) Granted to Galinpepimut-S (GPS) for the Treatment of Pediatric Acute Myeloid Leukemia

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- GPS Currently Investigated in Phase 3 REGAL Trial in Adult AML Patients – Interim Analysis Anticipated in Q4 2024 -

- RPDD Provides Eligibility for GPS to Receive a Priority Review Voucher (PRV) Upon Marketing Approval that can be Transferred/Sold to Other Parties –

- Recent Valuations for PRVs Remain Attractive (~$100 million/each) –

NEW YORK, Oct. 15, 2024 (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 U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RPDD) to Galinpepimut-S (GPS), an immunotherapeutic targeting Wilms Tumor-1 (WT1), for the treatment of pediatric acute myeloid leukemia (AML).

“GPS has already demonstrated promise in clinical settings for AML, and we believe its potential could extend to pediatric patients,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Receiving RPDD from the FDA is another acknowledgment of the critical need for new treatment options for AML and our results in adult patients. In our Phase 2 trial in adult patients which included patients as young as 25, clinical benefits were significantly higher in younger patients, which was expected based on the mechanism of action of GPS that is mediated via the immune system that is generally better preserved in younger patients, and even more so in children. With both of our development candidates, GPS and SLS009, now granted RPDD for AML, this recognition further reinforces our commitment to delivering potential new therapies to children affected by this challenging condition.”

AML prognosis with currently available treatments in the refractory and/or relapsed pediatric patient population remains poor. In a representative study, the 5-year overall survival (OS) rate in relapsed pediatric AML was 33% for all patients, and in patients whose remission lasted less than 12 months only 15.7%. In patients who did not achieve complete remission after one course of chemotherapy, 5-year overall survival was 0%. About 50% of children with pediatric AML relapse. Generally, the only therapy considered curative in relapsed and refractory patients is a bone marrow transplant and the primary goal of chemotherapy is to achieve remission so that pediatric patients can be transplanted.

In adult AML patients in first complete remission, GPS showed a median OS of 67.6 months across all ages with a favorable safety profile in an earlier Phase 2 study and induced T-lymphocytes response in both cytotoxic CD8+ cells and memory and helper CD4-+ cells with its innovative heteroclitic technology. In that study, outcomes were even better in younger patients in whom neither the median disease-free survival (DFS) nor OS was reached, i.e. among younger patients more than half of the patients were alive and leukemia-free for more than 5 years after treatment commenced.

Rare Pediatric Disease Designation is granted by the FDA for serious or life-threatening diseases that affect fewer than 200,000 people in the United States and in which the serious or life-threatening manifestations primarily affect individuals less than 18 years of age. If, in the future, a New Drug Application (NDA) for GPS for the treatment of pediatric AML is approved by the FDA, SELLAS will be eligible to receive a Priority Review Voucher (PRV) that could be redeemed to receive a priority review for any subsequent marketing application. PRVs may be used by the sponsor or sold to another sponsor for their use and have recently sold for approximately $100 million.

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.

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