

# SELLAS Receives FDA Orphan Drug Designation for SLS009 for Treatment of Peripheral T-cell Lymphomas

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- SLS009 Demonstrated Promising Efficacy in Phase 1 Study with 36.4% Clinical Response (ORR) in r/r Peripheral T-cell Lymphomas (PTCL); ORR in r/r PTCL Patients with Standard of Care is 25.8% -
- One Patient with Complete Metabolic Response Continuing Treatment for over 62 weeks and another patient with Complete Response by CT Continuing Treatment for over 24 weeks -
- Phase 1b/2 Study in PTCL Ongoing with top line data expected in 1H 2024 -

NEW YORK, Dec. 21, 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 U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for SLS009, the Company's novel and highly selective CDK9 inhibitor, for the treatment of relapsed/refractory (r/r) Peripheral T-cell Lymphomas (PTCL).

"We are delighted to announce the FDA's granting of ODD for SLS009, marking another significant milestone following the recent Fast Track Designation by the FDA for PTCL," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "In the recently completed dose-escalation portion of the Phase 1 trial in r/r hematological malignancies, SLS009 achieved clinical responses in PTCL including two patients reaching complete response. We are excited to see a favorable safety profile, strong initial efficacy signals, and evidence of anti-tumor activity across the Phase 1 study as well as the ongoing Phase 2 studies. With both designations in hand, we look forward to advancing the development of SLS009 and continuing to work closely with regulators with the goal of

delivering this treatment to those who may benefit from it.”

As it relates to PTCL, SLS009 is currently being evaluated in a Phase 1b/2 trial in patients with r/r PTCL. The open-label, single-arm study will enroll up to 95 patients to evaluate safety and efficacy and, based on the results, may serve as a registrational study. This initial PTCL study is fully funded by GenFleet Therapeutics, Inc. and is being conducted in China.

In the recently completed dose-escalation portion of the Phase 1 trial in r/r hematological malignancies, SLS009 demonstrated a favorable safety profile and promising clinical efficacy. Complete or partial responses were observed in patients with acute myeloid leukemia as well as lymphoma, including four PTCL patients (36.4%) who achieved clinical responses with one patient with complete metabolic response who is continuing treatment for over 62 weeks, and another patient with complete response by CT scan who is continuing treatment for over 24 weeks. The current standard of care for r/r PTCL, belinostat, an HDAC inhibitor, showed in its pivotal Phase 2 study a 25.8% response rate in a similar patient population to that in the SLS009 Phase 1 clinical trial. The patients who achieved complete response in the SLS009 study were previously treated with regimens containing an HDAC inhibitor.

The FDA's Office of Orphan Products Development grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for qualified clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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 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](http://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 SLS009 clinical development program, including data therefrom, and regulatory strategy. 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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