NEWS RELEASE

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

8/6/2024

NEW YORK, Aug. 06, 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 European Medicines Agency (EMA) has granted Orphan Drug Designation (ODD) for SLS009, a novel, and highly selective CDK9 inhibitor, for the treatment of relapsed/refractory (r/r) peripheral T-cell lymphomas (PTCL).

"We are pleased to announce the EMA's granting of ODD for SLS009, highlighting another important milestone following recent FDA's Orphan Drug and Fast Track Designations for SLS009 in PTCL," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "PTCL is an aggressive form of lymphoma with limited treatment options, underscoring the urgent need for new and effective therapies. We are delighted that the potential of SLS009 has been recognized by both regulatory agencies and across multiple indications including acute myeloid leukemia (AML), pediatric AML, and pediatric acute lymphoblastic leukemia (ALL). This additional orphan drug designation also highlights our strong internal regulatory expertise, and we look forward to advancing the SLS009 development and our overall clinical programs to deliver its potential benefits to cancer patients."

In the completed dose-escalation portion of the Phase 1 trial in relapsed/refractory hematological malignancies, SLS009 demonstrated favorable safety/tolerability and promising clinical efficacy. Complete or partial responses were observed in AML and lymphoma patients, with a 36.4% response rate achieved specifically in the PTCL patient group, including one patient who remained in continuous treatment for over 56 weeks. The current standard of care for r/r PTCL, belinostat, 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.

Orphan Designation is granted to therapies aimed at the treatment, prevention, or diagnosis of life-threatening or chronically debilitating diseases that affect no more than five in 10,000 persons in the European Union (EU) and for which no satisfactory therapy is available. The treatment must also provide significant benefit to those affected by the condition1.

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' other 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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References:

1. European Medicines Agency (2023). "Orphan Designation." https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview

Source: SELLAS Life Sciences Group, Inc.