NEWS RELEASE

SELLAS Receives European Medicines Agency Orphan Drug Designation for SLS009 for the Treatment of Acute Myeloid Leukemia

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NEW YORK, July 08, 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 Commission, based on a positive opinion issued by the European Medicines Agency (EMA), has granted Orphan Drug Designation (ODD) for SLS009, a novel, and highly selective CDK9 inhibitor, for the treatment of acute myeloid leukemia (AML).

"We are thrilled to receive ODD from the EMA for the treatment of AML. This designation along with the recently announced strong preliminary Phase 2 data and previous FDA ODD designation reinforces our continued progress and commitment to developing SLS009 as a potential treatment for AML," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "We look forward to working closely with the EMA and the FDA to advance SLS009 clinical development and ultimately deliver it to the patients who need it most. To that end, we remain on track to share further data around SLS009 in the third quarter of this year."

Orphan drug designation in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the European Medical Association (EMA) Committee for Orphan Medicinal Products. The EMA's orphan designation is available to companies developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the EU. Medicines that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase, and access to centralized marketing authorization. The treatment must also provide significant benefit to those affected by the condition.

“We are excited to receive this designation from the EMA to complement the earlier FDA’s ODD. The ongoing clinical trial data continues to support significant benefit in patients with AML relapsed after or refractory to venetoclax regimens and the EMA recognizes the significant benefit of SLS009 for patients impacted by AML. Together with EMA’s Protocol Assistance will define a path to an eventual regulatory approval in the European Union and working with the FDA towards a potential approval in the US,” said Andrew Elnatan, Vice President of Regulatory Affairs at SELLAS.

The Phase 2a clinical trial of SLS009 is an open-label, single-arm, multi-center study designed to evaluate the safety, tolerability, and efficacy of SLS009 in combination with aza/ven at two dose levels, 45 and 60 mg. In the 60 mg dose cohort patients were randomized into either a 60 mg dose once per week or a 30 mg dose two times per week. The target response rate at the optimal dose level is 20% with a target median survival over 3 months. ASXL1 mutation has been identified as the most promising target mutation based on biology of the mutation and the SLS009 mechanism of action that has been confirmed by the clinical results to date. The trial continues enrollment in two cohorts, both enrolling patients with myelodysplasia-related mutations, one with ASXL1 mutations and the other with myelodysplasia-related mutations other than ASXL1. For more information on the study, visit **clinicaltrial.gov** identifier **NCT04588922**.

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 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 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.