



NEWS RELEASE

SELLAS Receives IMPD Approval from the French Regulatory Authority for its Pivotal Phase 3 REGAL Study of Galinpepimut-S in Patients with Acute Myeloid Leukemia

9/9/2020

NEW YORK, Sept. 09, 2020 (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 cancer immunotherapies for a broad range of cancer indications, today announced that it has received approval of its Investigational Medicinal Product Dossier (IMPD) from the French regulatory authority, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), to advance in France its pivotal Phase 3 REGAL study of galinpepimut-S (GPS) in patients with Acute Myeloid Leukemia (AML) who have achieved complete remission after second-line anti-leukemic therapy (CR2).

"This clearance marks an important milestone for SELLAS, as the IMPD allows us to expand AML patient enrollment for our pivotal Phase 3 REGAL study of GPS in France," commented Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Obtaining IMPD clearance is a stringent process, and includes submission of information related to the quality, manufacture and controls of GPS as well as data from non-clinical and clinical studies. We look forward to advancing our REGAL study in France and, upon the receipt of requisite approvals, other countries in Europe, particularly given the previously obtained orphan drug designation for GPS in AML by the European Medicines Agency. "

In February 2020, SELLAS announced positive follow-up data from its Phase 2 study of GPS in CR2 AML patients. The final data showed a median overall survival (OS) of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS compared to 5.4 months in patients treated with best standard care (p-value < 0.02). GPS therapy

continued to be well tolerated throughout the study.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel cancer immunotherapeutics 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 or in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipepimut-S, is a HER2-directed cancer immunotherapy with potential for the treatment of patients with early stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes triple negative breast cancer patients, following standard of care.

About the REGAL Study

The REGAL study is a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators' choice best available treatment in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. The primary endpoint is overall survival from the time of study entry. Secondary endpoints include leukemia-free survival, antigen-specific T-cell immune response dynamics, measurable residual disease by multigene array, and assessments of AML clonal evolution and inflammasome molecular signatures in the tumor microenvironment in bone marrow biopsy samples. The Company anticipates interim analysis for safety and futility in the fourth quarter of 2021.

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 Company's plans for further development of and regulatory plans for GPS including the timing of clinical results and additional regulatory filings, and the potential for GPS as a drug development candidate. 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 associated with the COVID-19 pandemic and its impact on the Company's clinical plans and business strategy, risks and uncertainties associated with immune-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 13, 2020 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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Source: SELLAS Life Sciences Group