

SELLAS Life Sciences Reports Positive Follow-Up Immune Response and Survival Data in Completed Phase 1 Study of Galinpepimut-S Combined with Opdivo® in Advanced Malignant Pleural Mesothelioma

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- Primary Endpoint of Safety and Efficacy Met with Clinical Activity and Increased Survival Observed -

- 70.3 Weeks Median Overall Survival for Patients Treated with Combination Therapy; Median Overall Survival in Relapsed/Refractory Patients Treated with Standard of Care is Approximately 28 Weeks -

- Median Overall Survival of Patients without GPS Immune Response was 9.0 Months vs. 27.8 Months for Patients with GPS-Specific Immune Response: a Three-fold or 208.3% Increase in Survival Time -

NEW YORK, Dec. 27, 2023 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on developing novel therapies for a broad range of cancer indications, today announced follow-up clinical/immune-response data from a Phase 1 investigator-sponsored clinical trial of its lead clinical candidate, galinpepimut-S (GPS), combined with the checkpoint inhibitor nivolumab (Opdivo®) in patients with refractory/relapsed malignant pleural mesothelioma (MPM).

As previously reported, ten patients were enrolled in the clinical study and nine of the ten patients enrolled received at least three doses of GPS, with the third GPS dose given in combination with nivolumab. Nine out of ten patients (90%) had sufficient samples collected to be analyzed for GPS-specific immune response. All enrolled patients had either received and progressed with or were refractory to frontline pemetrexed-based chemotherapy. Additional analyses for the correlation of immune response and survival benefit were performed. Immune

response was defined as a measurable increase in activated Wilms Tumor 1 (WT1) specific T cells, both CD8 T+ cells (killer T cells) and CD4+ T cells (regulatory T cells).

Of the 10 evaluable patients, eight were male and two were female, with a median age of 69 years. Sixty percent entered the study as Stage III or IV patients. Initial tumor stages were I (one patient), II (three patients), III (two patients) and IV (four patients). All patients had MPM epithelioid and/or sarcomatoid variant, a tumor that universally expresses WT1, one of the most widely expressed cancer antigens, ranked by the National Cancer Institute as the top priority among cancer antigens for immunotherapy.

The key clinical efficacy and immune response study outcomes are as follows:

- 70.3 weeks (17.6 months) median overall survival (OS) was achieved in patients who received the combination therapy (9/10 patients) and 54.1 weeks (13.5 months) for all 10 patients (nine patients with combination therapy and one GPS-only patient).
- Median OS for patients who entered the study as Stage IV patients was 62.3 weeks (15.6 months). OS was calculated as the time from cessation of the most recent previous therapy until confirmed death or most recent data update for patients who are still alive (40% of patients).
- The median OS among patients who did not have an immune response to GPS was 9.0 months; the median OS for patients who had an immune response to GPS was 27.8 months, more than three times longer median OS (208.3% increase). Among the nine evaluable patients, four patients had a CD4+ immune response (44.4%) and three patients had a CD8+ immune response (33.3%) to GPS. Three patients had both CD4+ and CD8+ immune responses (33.3%).
- Among patients who had a full immune response (both CD4+ and CD8+) to GPS, two patients achieved an objective response (66.7%), while among the patients who did not have an immune response to GPS one patient achieved an objective response (14.3%).
- 11.9 weeks median progression-free survival (PFS) was observed for all patients.
- The disease control rate (DCR) was 30% with three patients achieving stable disease per RECIST criteria with a tumor volume decrease of up to 17%. DCR is the sum of the overall response rate and rate of stable disease.

Angelos Stergiou, M.D., Sc.D. h.c., President and CEO, SELLAS commented: "We are excited that in a bulky, measurable disease setting, such as in this relapsed/refractory advanced mesothelioma study, we have observed yet again strong GPS-specific immune responses which appear to be correlated with significant survival benefit in patients when combined with checkpoint inhibitors, a more than 200% survival benefit. As we had hypothesized in the past, this increase in survival appears to be consistent with long-term immunity-mediated antitumor effect with our immunotherapy combination as we had seen in other studies with GPS, and, importantly, the positive survival outcomes seen in this study are accompanied with a safety profile which is similar to that of the checkpoint inhibitor alone. We believe that these observed survival benefits in the active disease setting further confirm the

strong biological effect of GPS in even the most challenging settings where GPS seems to contribute to stopping the progression of extremely aggressive cancers and demonstrates its utility as a potentially effective combination therapy.”

About Malignant Pleural Mesothelioma (MPM)

With approximately 3,300 cases in the United States each year, accompanied by a rising incidence in developing countries, MPM is notoriously difficult to treat and can lead to poor clinical outcomes with respect to both OS and PFS, especially for those patients with the sarcomatoid variant who show a median OS of approximately 4.0 to 5.0 months. In relapsed and refractory patients who progressed after the first line standard of care pemetrexed, a similar patient population to that in the GPS nivolumab combination trial, the common treatment regimen is vinorelbine and OS in those patients is reported to be between 4.5 and 6.2 months. In patients treated with other chemotherapy regimens, such as carboplatin and irinotecan, the median OS is reported to be approximately 7.0 months.

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), 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.

Opdivo® is a registered trademark of Bristol Myers Squibb and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

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 data therefrom. 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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