

SELLAS Life Sciences Reports Encouraging Updated Clinical Data Indicating Increased Survival from Ongoing Phase 1 Mesothelioma Study of Galinpepimut-S Combined with Opdivo

6/8/2022

Median Overall Survival of 45.7 Weeks for Patients Treated With Combination Therapy for at Least One Month; Median Overall Survival in Relapsed/Refractory Patients Treated with Standard of Care is Approximately 28 Weeks
NEW YORK, June 08, 2022 (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 encouraging updated clinical 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 malignant pleural mesothelioma (MPM) who were either refractory to or relapsed after at least one line of the standard of care therapy.

Data from eight patients enrolled in the study have been analyzed, with final data in the clinical trial expected by the end of 2022. Of the eight patients, seven received at least three doses of GPS, the last of which was given in combination with nivolumab. All enrolled patients have received and progressed with, or were refractory to, frontline pemetrexed-based chemotherapy.

The study details are as follows:

- Of the eight evaluable patients, six were male and two were female, with the median age of 66. 75 percent of the patients entered the study as Stage III or IV patients, with 50 percent of patients entering as Stage IV. Initial tumor stages were II (two patients), III and IIIB (two patients) and IV (four patients).
- All patients had the MPM epithelioid and/or sarcomatoid variant, a tumor which is universally expressing

Wilms Tumor 1 (WT1), one of the most widely expressed cancer antigens, ranked by the National Cancer Institute as the top priority among cancer antigens for immunotherapy.

- Median overall survival (OS) calculated as the time from the cessation of the most recent previous therapy until confirmed death or most recent data update for patients who are still alive (50 percent of patients) was 40.9 weeks (9.4 months) for all eight patients and 45.7 weeks (10.5 months) in patients who received the combination therapy (seven out of eight patients). The median progression-free survival (PFS) was 11.1 weeks for all eight patients and 11.9 weeks in patients who received the combination therapy.
- The safety profile of the GPS-nivolumab combination was similar to that seen with nivolumab alone, with the addition of only low-grade, temporary local reactions at the GPS injection site, consistent with previously performed clinical studies with GPS. No Grade 3/4 toxicities were observed for GPS and there were no dose-limiting toxicities.

“This updated data is very encouraging, as it not only confirms our data reported in June 2021, but now reflects an increased survival benefit even though almost all additionally enrolled patients had Grade III and IV malignant mesothelioma,” said Angelos Stergiou, M.D., Sc.D. h.c., President and CEO, SELLAS. “This increase in survival appears to be consistent with long term immunity-mediated antitumor effect with this immunotherapy combination and it reinforces the data we unveiled earlier this year from the Phase 1/2 clinical trial of GPS in combination with another checkpoint inhibitor, pembrolizumab, in relapsed and refractory ovarian cancer patients, in which GPS showed a superior disease control rate compared to that seen with checkpoint inhibitors alone.”

“Of additional importance is the fact that both trials addressed patients with bulky active disease, the setting in which other cancer vaccines have historically had very little effect. We believe that the results of both studies demonstrate the potential effectiveness of GPS as a combination therapy,” concluded Dr. Stergiou.

About 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, median OS is reported to be approximately 7.0 months.

About SELLAS Life Sciences Group, Inc.

SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) 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 potential as a monotherapy or in combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing 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 clinical development of GPS for MPM, 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, 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 31, 2022 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, Inc.