

NEWS RELEASE

SELLAS Announces Confirmatory Top-Line Data Showing Survival and Clinical Benefits Based on the Final Analysis of the Phase 1/2 Clinical Trial of Galinpepimut-S in Combination with Keytruda® (pembrolizumab) in Patients with WT1+ Platinum-Resistant Advanced Ovarian Cancer

11/10/2022

- Median Overall Survival for GPS Combination (GPS in Combination with Keytruda) was 18.4 Months Compared to 13.8 months in a Checkpoint Inhibitor Single Agent Study in a Similar Patient Population Treated with Checkpoint Inhibitor Alone -
- Median Progression Free Survival for GPS Combination (GPS in Combination with Keytruda) was 12 Weeks

 Compared to Eight Weeks in a Checkpoint Inhibitor Single Agent Study in a Similar Patient Population Treated with

 Checkpoint Inhibitor Alone -
 - Clinical Benefit (Increased Disease Control Rate, Progression Free Survival and Overall Survival) Observed in Patients Harboring Tumors with Detectable PD-L1 Biomarker –
 - Full Clinical Trial Data to be Presented at a Major Medical Conference in 1H 2023 -

NEW YORK, Nov. 10, 2022 (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 confirmatory top-line clinical data from the final analysis of results from its Phase 1/2 clinical trial of galinpepimut-S (GPS), the Company's Wilms Tumor-1 (WT1)-targeting

peptide immunotherapeutic, in combination with Merck's anti-PD-1 therapy, pembrolizumab (KEYTRUDA®), in patients diagnosed with WT1(+) relapsed or refractory platinum-resistant advanced metastatic ovarian cancer.

Data from 17 patients enrolled in the study, conducted under a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Rahway, N.J., USA (known as MSD outside the United States and Canada), have undergone final analysis for safety and efficacy. All enrolled patients were resistant to standard of care platinum-based therapy and 76.5 percent (13/17) of the patients were refractory to or had failed their first- or second-line therapies, with 23.5 percent (4/17) having failed three or more lines of therapy, including one patient (5.9 percent) who failed five previous lines of therapy. Of the 17 patients, 16 received at least three doses of GPS and had follow-up cross-sectional imaging (CT/MRI) to determine tumor status.

Summary of Top-Line Overall Survival and Progression-Free Survival Data:

- Median Overall Survival (OS) was 18.4 months compared to 13.8 months in a checkpoint inhibitor single agent study in a similar patient population treated with checkpoint inhibitor alone
- Median Progression-Free Survival (PFS) was 12 weeks compared to eight weeks in a checkpoint inhibitor single agent study in a similar patient population treated with checkpoint inhibitor alone
- The overall response rate (ORR) of the trial is 6.3 percent with a disease control rate (DCR), which is the sum of overall response rate and rate of stable disease, of 50.1 percent at a median follow-up of 14.4 months. In a checkpoint inhibitor single agent study in a similar platinum-resistant ovarian cancer patient population treated with a checkpoint inhibitor alone, the observed DCR was 37.2 percent, consistent with a DCR rate increase of approximately 45 percent in the GPS combination with Keytruda over that seen for checkpoint inhibitors alone.

Importantly, survival and disease control benefits were observed in patients harboring tumors with any level of detectable PD-L1 expression, i.e., those with Combined Positive Score (CPS) of one or higher. The DCR is 63.6 percent in patients with a CPS of one or higher in this study.

In the Phase 1/2 study, patients with a CPS score of less than one showed a median OS of 3.2 months vs. patients with a CPS greater than or equal to one who had a median OS of 18.4 months and, as it relates to time to progression, patients with a CPS score of less than one had a median PFS of 1.9 months and patients with a CPS score of greater than or equal than one showed a median PFS of 3.8 months.

In 16 evaluable patients in whom serial peripheral blood samples were available, a correlation was observed between PFS and OS and WT1-specific immune response after GPS vaccination across more than one channel with intracellular cytokine flow-cytometry assays in peripheral blood lymphocytes assaying reactivity against the four pooled WT1 antigens comprising GPS. The data were consistent with those seen in previous studies of GPS.

The safety profile of GPS in combination with pembrolizumab was similar to pembrolizumab alone, with the only addition of low-grade, rapidly resolving local reactions at the GPS injection site, consistent with observations from other GPS clinical studies.

"GPS has been primarily studied as maintenance therapy to provide an overall survival benefit after patients reach a state of minimal residual disease or complete remission. In contrast, in this very difficult to treat patient population with relapsed or refractory measurable advanced platinum-resistant ovarian cancer, who underwent intensive chemotherapy with no apparent enduring clinical benefit, the data suggests that the combination of GPS plus pembrolizumab may be effective in stabilizing active disease. We are excited that both the disease control rate and overall survival results support our belief that GPS has the potential to become an important therapeutic addition to a backbone of checkpoint blockade for WT1(+) ovarian cancer patients, as well as other WT1-expressing tumor types," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "SELLAS plans to submit the full dataset at a major medical conference by mid-next year. I would like to extend my sincere gratitude to all patients who have participated in this clinical trial, as well as the collective study teams at SELLAS and Merck," concluded Dr. Stergiou.

"What I find particularly important for patients with advanced platinum-resistant ovarian cancer is that GPS appears to enhance efficacy of checkpoint inhibitors in patients with tumors with detectable PD-L1 expression, whilst demonstrating a low adverse event burden. Until now, in immunotherapy-recalcitrant tumor types, like ovarian cancer, the impression by many experts has been that patients with CPS scores equal to or higher than 10 may be the most probable candidates to derive clinically meaningful benefit from checkpoint inhibitor therapy, either alone or in combination," stated Bruno Bastos, MD, Medical Oncologist and Study Investigator at the Miami Cancer Institute, Physician Lead of the Multiple Tumors/Phase 1 Clinic, and Assistant Professor at the Herbert Wertheim College of Medicine. "Based on these results, it appears that any ovarian cancer patient whose tumor expresses any level of PD-L1, as long as this biomarker is detected, may benefit from the addition of GPS to a checkpoint inhibitor regimen. If these data are confirmed in larger studies in PD-L1+, WT1+ advanced ovarian cancer, it could enable us to bring the benefits of immunotherapy drugs to a broader patient population in a very difficult setting. This is indeed exciting for the ovarian cancer field, as well as patients suffering from other types of WT1+ malignancies," concluded Dr. Bastos.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic malignancies and the fifth most frequent cause of cancer death in women in the United States. Over 22,000 cases are diagnosed annually, and there are an estimated 15,500 deaths per year. The majority of patients have widespread disease at presentation. The 5-year survival for advanced-stage disease remains less than 30 percent. Combining GPS with the checkpoint inhibitor

pembrolizumab, which beneficially and profoundly alters the tumor microenvironment (TME) is hypothesized to increase the proportion of patients who develop an immune response against their cancer and potentially improve their clinical outcome over checkpoint inhibitors monotherapy, without the burden of additional toxicities in macroscopically measurable malignancies.

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.

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA 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 further clinical development of GPS for ovarian cancer, and the potential for GPS as a drug development candidate for ovarian cancer patients. 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.

Investor Contact

Allison Soss

KCSA Strategic Communications

Email: SELLAS@kcsa.com

Phone: 212.896.1267

Media Contacts

Raquel Cona / Michaela Fawcett

KCSA Strategic Communications

Email: SELLAS@kcsa.com

Phone: 212.896.1204

Source: SELLAS Life Sciences Group, Inc.

5