NEWS RELEASE

SELLAS Life Sciences Presents Positive Key Immunobiological and Clinical Data from Phase 1/2 Trial of Galinpepimut-S (GPS) in Combination with Keytruda® in WT1+ Platinum-Resistant Advanced Ovarian Cancer at the International Gynecologic Cancer Society 2023 Annual Global Meeting

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- Median overall survival for GPS and Keytruda ® combination was 18.4 Months compared to 13.8 Months in a Keytruda ® single agent study (KEYNOTE-028) and 11-14 Months with standard of care chemotherapy
- Combination of GPS and Keytruda ® yielded WT1-specific T-cell immune response and correlated positively in subset of patients with IFNγ and MIP1β biomarkers: 41% longer progression free survival and statistically significant difference: p=0.025

NEW YORK, Nov. 06, 2023 (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 final clinical and immunobiological data from the Phase 1/2 clinical trial of galinpepimut-S (GPS) in combination with pembrolizumab (Keytruda®) in Wilms’ tumor-1 (WT1)-positive platinum-resistant ovarian cancer (NCT03761914).

Results are being presented in an e-poster session by Roisin E. O’Cearbhaill, M.D., Research Director, Gynecologic Medical Oncology Service; Clinical Director, Solid Tumor, Cellular Therapy Service; and Associate Attending Physician at Memorial Sloan Kettering Cancer Center, New York, NY, at the 2023 International Gynecologic Cancer Society Annual Global Meeting taking place November 5-7, 2023, in Seoul, South Korea.

GPS is an HLA-unrestricted heteroclitic immunotherapy against WT1, an antigen highly expressed in more than 85% of patients with ovarian cancer. This Phase 1/2 trial was an open-label, multicenter, multi-arm basket study examining the effects of the combination of GPS and pembrolizumab in patients with measurable advanced selected cancers. In the ovarian cancer arm of the study, the effect of the combination was investigated in patients with measurable WT1+ platinum-resistant ovarian cancer relapsed after or refractory to 1st/2nd -or later- line of therapy. Today's presentation reported clinical efficacy and safety results as well as demographic and disease parameter data in a total of 16 evaluable patients. Historical illustrative comparisons were made between the outcomes in this study and those reported in comparable patients enrolled in the KEYNOTE-028 study, which investigated the effects of pembrolizumab monotherapy.

Study highlights include:

Patient Characteristics

- 17 patients enrolled; 16 safety and efficacy evaluable patients who received at least three doses of GPS and had follow-up cross-sectional imaging (CT/MRI) to determine tumor status.
- Median age was 65 years (50-76).
- Median number of prior lines of systemic therapy was two, while 23.5% of enrolled patients (4/17) had received 3-5 prior lines of therapy.

Efficacy

- Median Overall Survival (OS) was 18.4 months, compared to historical values in comparable patients of 11-14 months with standard of care chemotherapy and 13.8 months with pembrolizumab monotherapy as shown in the KEYNOTE-028 study.
- Median Progression-Free Survival (PFS) was 2.9 months, compared to eight weeks with pembrolizumab monotherapy as shown in the KEYNOTE-028 study.
- Actuarial OS rates at 6, 12, and 18 months were 88%, 68%, and 57%, respectively.
- 43.8% (7/16) of patients achieved stable disease (SD); median duration of SD in these patients was 14.4 months.
- Disease control rate (DCR), which is the sum of overall response rate (ORR) and rate of SD, was 50.1% (8/16 patients) at a median follow-up of 14.4 months; DCR for pembrolizumab alone in KEYNOTE-028 was 37.2%.
- ORR was 6.3%.
- An exploratory analysis of patients harboring tumors with detectable PD-L1 expression, i.e., those with a Combined Positive Score (CPS) >1, suggested the potential correlation between PD-L1 expression as quantified by the CPS in primary tumor samples and median PFS or median OS using two distinct cut-offs (CPS<1 vs CPS≥1 and CPS<10 vs CPS≥10). Reported data showed that:

All patients with CPS<1 progressed vs 36.4% of those with CPS≥1
Patients with CPS<1 had a median PFS of 1.9 months vs 3.8 months in those with CPS≥1
Patients with CPS<1 had a median OS of 3.2 months vs 18.4 months in those with CPS≥1
Safety

- Treatment-related adverse events (TRAEs) were mostly grade 1-2 and occurred in about 80% of patients receiving the GPS + pembrolizumab combination.
- Five patients reported 11 serious adverse events (SAEs). One SAE, grade 3 pneumonitis, was considered directly related to pembrolizumab.
- The remaining 10 SAEs were reported by four patients and all unrelated or unlikely to be related to study drug.
- No dose-limiting toxicities (DLT) or grade 5 events were reported.

Immune Response Profiles

- WT1-specific T-cell (CD8 and CD4) immune response (IR) data showed a positive trend over time post-baseline with highest consistency and potential biomarkers for consistency being IFNγ and MIP1β.
- GPS in combination with pembrolizumab was strongly immunogenic, as evidenced by the positive T-cell responses seen post-vaccination.
    - 42.8% of patients (6/14) achieved CD8 T-cell immune response.
    - 85.7% of patients (12/14) achieved CD4 T-cell immune response.
- A correlation between WT1 specific T-cell immune responses (CD8 or CD4) and PFS was observed in a subset of analyzed patients with 41% longer PFS in patients with recorded immune response vs without (p=0.025).

“We are excited to share positive, final results from the Phase 1/2 study of GPS in combination with pembrolizumab at this year’s IGCS meeting in a highly challenging patient population of women with measurable tumor in advanced platinum resistant ovarian cancer receiving second and later lines of salvage therapy,” said Dragan Cicic, MD, Senior Vice President, Clinical Development of SELLAS. “The combination shows clinical benefit in advanced ovarian cancer patients, achieving long-term disease stability and, notably, a median overall survival that exceeded 18 months, a benchmark for novel therapies, while a good safety profile was observed. The findings of 50% disease control rate and numerically superior overall survival over standard-of-care systemic therapy were consistent with the mechanism of action of GPS as a non-HLA-restricted vaccine which could be rendered more active against macroscopic metastases when aided by checkpoint blockade-induced amelioration of an immunologically adverse tumor microenvironment. Moreover, the correlation between the immune response and prolonged PFS underscores the transformative potential of GPS immunotherapy. The results strengthen our belief in GPS’s role alongside checkpoint inhibitors for WT1+ ovarian cancer and other WT1-expressing tumors, which warrant more in-depth investigation in future clinical studies in patients with measurable metastatic WT1+ malignancies, in the

context of further advancing GPS' clinical development," concluded Dr. Cicic.

The multicenter study was sponsored by SELLAS and 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). Based on data in this e-poster presentation, SELLAS is planning the submission of a full-length manuscript to a peer-reviewed journal during the first half of 2024.

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. Most 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 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 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**.

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 GPS clinical development program, further clinical development of GPS for ovarian cancer and the potential for GPS as a drug development candidate for ovarian 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 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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