

NEWS RELEASE

# SELLAS Announces Promising Initial Clinical Data for Galinpepimut-S (GPS) in Combination with Checkpoint Inhibitors in Two Solid Tumor Indications

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- Early Data from Study of GPS in Combination with Keytruda® in Patients with Advanced WT1(+) Ovarian Cancer Shows Disease Control Rate of 87.5% at a Median Follow-up of 9.4 Weeks and 100% Progression Free Survival at 6 Weeks -
- Early Data from Mesothelioma Study of GPS in Combination with Opdivo® Shows Clinically Intriguing Activity with Median Progression Free Survival of at Least 10 Weeks -
- Updated Data Expected in First Half of 2021 -

NEW YORK, Dec. 21, 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 initial data from two clinical studies of galinpepimut-S (GPS), the Company's Wilms Tumor-1 (WT1)-targeting peptide immunotherapeutic, in combination with checkpoint inhibitor therapies in patients with two different types of advanced solid cancers who had exhausted their standard therapy options.

In the first study, a phase 1/2 'basket' trial of GPS in combination with the checkpoint inhibitor pembrolizumab (Keytruda), which is conducted under a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), the first set of evaluable patients (n = 8) diagnosed with 2nd or 3rd line WT1(+) relapsed or refractory metastatic ovarian cancer demonstrated a disease control rate (the sum of overall response rate and rate of stable disease) of 87.5% with a median follow-up of 9.4

weeks. In this difficult to treat patient population, at the first assessment time-point of 6 weeks post-therapy initiation, 100% of the patients were free of disease progression. Using a validated immunohistochemistry (IHC) assay during the screening period, the rate of WT1 positivity in this ovarian cancer patient population was approximately 70%. Six of the eight evaluable patients are continuing to receive GPS plus pembrolizumab. Enrollment is continuing with a target of a total of 20 patients. More mature clinical and immunobiological data are expected to be announced by the end of the second quarter of 2021.

In the second study, a Phase 1 investigator-sponsored clinical trial (IST) of GPS in combination with the checkpoint inhibitor nivolumab (Opdivo) in patients with macroscopic measurable deposits of malignant pleural mesothelioma (MPM) who were either refractory to or relapsed after frontline tri-modality standard therapy, the first set of evaluable patients (n = 3) had a median progression free survival of at least 10 weeks since therapy initiation. In primary refractory MPM patients, any prolongation of progression-free interval greater than 8 weeks would be considered clinically meaningful, considering the current lack of effective therapies. All patients had the epithelioid variant of MPM, a tumor which is universally expressing WT1. Moreover, in this study, GPS was found to be appropriately immunogenic, leading to the emergence of antigen (WT1)-specific CD4+ T-memory cell responses at 3 months post-therapy initiation. Additional MPM patients are currently being enrolled; completion of study enrollment (target total n = 10) and more mature clinical and immunobiological data are expected by the end of the second quarter of 2021.

In both studies, the safety profile of the combination of GPS with the checkpoint inhibitor was similar to that seen with checkpoint inhibitors alone, with the addition of only low grade, transitory local reactions at the site of injection of GPS, consistent with previously performed clinical studies of GPS.

“These early data confirm the tolerability profile seen in earlier studies of GPS, which is one of the primary endpoints in these solid cancer trials, in a variety of cancer indications, even in the most refractory patients who underwent numerous prior therapies,” commented Jeffrey S. Weber, MD, PhD, Deputy Director of the Perlmutter Cancer Center at New York University (NYU)-Langone Health, co-Director of its Melanoma Research Program Center and Chair of SELLAS’ Scientific Advisory Board. “These safety findings are accompanied by promising early indications of an efficacy signal for patients with advanced metastatic disease, whose management is extremely challenging even with checkpoint inhibitor monotherapy.”

“We are encouraged by the data shown in these two studies of GPS in combination with checkpoint inhibitors and look forward to additional data from these studies,” stated Dragan Cicic, MD, Senior Vice President, Clinical Development of SELLAS. “We now have early evidence that supports further expanding the field of potential GPS indications into solid cancers with high rates of WT1 positivity. GPS has previously been shown to invoke multi-epitope, broad cross-reactivity along the full-length of the WT1 protein, suggestive of epitope spreading, and

immunologically mediated cancer cell destruction, which are hallmarks of an effective cancer vaccine. The scientific rationale in combining GPS with checkpoint inhibitors is the immunobiologic and pharmacodynamic synergy between the two agents, whereby the negative influence of the tumor microenvironment is mitigated by checkpoint inhibitors and thus allowing the patients' own immune cells specifically sensitized against WT1, by GPS, to invade and destroy cancerous cells."

#### About the Phase 1/2 Basket Study of GPS in Combination with Pembrolizumab (Keytruda®) in Patients with Selected WT1-Positive Advanced Cancers, Including Ovarian Cancer

This is a Phase 1/2 open-label, multicenter, multi-arm study conducted under a Clinical Trial Collaboration and Supply Agreement (CTSA) with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada) to assess the efficacy and safety of the combination of GPS and pembrolizumab (Keytruda®) (**ClinicalTrials.gov** identifier: NCT03761914). The primary endpoints of the study include safety and overall response rate, while secondary endpoints include progression-free survival, overall survival and immune response correlates. The study will enroll approximately 90 patients at up to 20 centers in the United States. The trial is currently evaluating patients with ovarian cancer (second or third line).

#### About the Phase 1 Trial of GPS in Combination with Nivolumab (Opdivo®) in Patients with Malignant Pleural Mesothelioma (MPM)

This is a Phase 1 open-label clinical study conducted by Memorial Sloan Kettering Cancer Center (MSK) and is enrolling patients with MPM who harbor relapsed or refractory disease after having received frontline, standard-of-care multimodality therapy (target total n = 10; **ClinicalTrials.gov** identifier: NCT04040231). The principal investigator for the study is Marjorie G. Zauderer, MD, Co-Director, Mesothelioma Program and Associate Attending Physician in the Thoracic Oncology Service, Department of Medicine at MSK. The trial is investigating the potential of GPS in combination with nivolumab (Opdivo®) to demonstrate anti-tumor immune responses and meaningful clinical activity in the presence of macroscopic advanced disease in MPM patients and gauging the degree of clinical benefit by assessment of the overall response rate with the combination in comparison with that reported with nivolumab alone in historical comparable patient populations.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., 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. 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.

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 MSK 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.

For more information on SELLAS, please visit [www.sellaslifesciences.com](http://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 clinical development of GPS for various cancer indications, including ovarian cancer and 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 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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