



NEWS RELEASE

SELLAS Announces Enrollment of First Patient in Phase 1 Trial of Galinpepimut-S (GPS) in Combination with Nivolumab (Opdivo®) in Patients with Malignant Pleural Mesothelioma (MPM)

2/11/2020

NEW YORK, Feb. 11, 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 the enrollment of the first patient in an investigator-sponsored clinical trial of its Wilms tumor-1 (WT1)-targeting peptide immunotherapeutic agent, GPS, in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab (Opdivo®), in patients with MPM.

The Phase 1 open-label clinical study is being 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. 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.

"We are pleased to be collaborating with Memorial Sloan Kettering on this Phase 1 trial and excited to have expanded the clinical evaluation of GPS in combination with nivolumab to patients with advanced MPM," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "There are few effective therapies for mesothelioma, a disease which is characterized by high expression of the WT1 antigen, and we believe that the combination of GPS and nivolumab could be promising for patients with MPM, due to the combination's potential synergistic immune-based mechanisms for anti-tumor activity. We look forward to gaining further insights on the safety and clinical outcomes of this combination in MPM."

The trial is investigating the potential of GPS in combination with nivolumab to demonstrate anti-tumor immune responses and meaningful clinical activity in the presence of macroscopic 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.

“There is significant preclinical and translational science evidence that PD-1 inhibitors may enhance the anti-cancer activity of cancer vaccines, with immuno-biologic and pharmacodynamic synergy from the combination of two such agents,” said Dr. Zauderer. “By mitigating the negative effects of tumor microenvironment factors on immune response, PD-1 inhibitors, such as nivolumab, potentially allow for a patient’s immune cells to destroy cancerous growths that may be sensitized by GPS against WT1. I believe that WT1 serves as an ideal target for directly immunizing therapies in MPM, and I look forward to evaluating the combination of GPS and nivolumab in the clinic.”

In a previous randomized, controlled, blinded Phase 2 clinical trial in MPM patients, GPS monotherapy, given as maintenance after first line tumor-debulking multimodality treatment, demonstrated meaningful clinical activity with median survival of 22.8 months vs. 18.3 months in the control group (N=41) and with associated sustained immune responses (both CD4+ and CD8+) against the WT1 antigen with the most common adverse events mild (grade 1 and 2) and self-limited injection site reactions.

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 MSKCC 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 (NPS), 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.

MSK has institutional financial interests related to SELLAS in the form of intellectual property rights in galinpepimut-S (GPS) and associated interests by virtue of the licensing agreement between MSK and SELLAS.

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 Company’s plans for further development of and regulatory plans for GPS. 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 immunology product development and clinical success thereof, 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 22, 2019 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.

For more information on SELLAS, please visit www.sellaslifesciences.com.

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Source: SELLAS Life Sciences Group