



NEWS RELEASE

SELLAS Life Sciences Provides Galinpepimut-S and Nelipepimut-S Program Update

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Dr. Richard Maziarz and Dr. Roisin O'Cearbhaill Named Co-Principal Investigators for Galinpepimut-S (GPS) – Pembrolizumab Phase 1/2 Basket Trial

Immune Response Data from the Phase 2b Nelipepimut-S (NPS) plus Trastuzumab Combination Study Demonstrates Antigen-Specific T-cell Clonal Expansion Over Time with Correlations to Clinical Activity in TNBC

NEW YORK, Feb. 12, 2019 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today provides an update on its galinpepimut-S (GPS) and nelipepimut-S (NPS) clinical development programs.

The Company announces that Richard Maziarz, M.D., Medical Director of the Adult Blood and Marrow Stem Cell Transplant & Cellular Therapy Program at the Knight Cancer Institute and Professor of Medicine at Oregon Health and Science University (OHSU) in Portland, OR, and Roisin O'Cearbhaill, M.D., Assistant Attending Physician in Gynecologic Medical Oncology Service at the Memorial Sloan Kettering Cancer Center (MSKCC), will serve as co-principal investigators of the Company's Phase 1/2 open-label, non-comparative, multicenter, multi-arm study of GPS in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with selected WT1-positive advanced cancers, including both hematologic malignancies and solid tumors. This study, which is being conducted under a Clinical Trial Collaboration and Supply Agreement (CTSA) with Merck (known as MSD outside the United States and Canada), will assess the efficacy and safety of the combination, with exploratory long-term follow-up for overall survival and safety. The study will enroll approximately 90 patients at up to 20 centers in the United States. The initial tumor types to be treated will be acute myelogenous leukemia (AML) (patients unable to

attain deeper morphological response than partial on hypomethylating agents and who are not eligible for allogeneic hematopoietic stem cell transplant) and ovarian cancer (second or third line), to be followed by triple negative breast cancer (second line), small cell lung cancer (second line), and colorectal cancer (third or fourth line).

“We are thrilled to announce that Drs. Maziarz and O’Cearbhaill will serve as co-principal investigators of this important study,” said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Both Rich and Roisin will be indispensable in overseeing the scientific rigor of the investigation, helping to interpret both clinical and correlative immuno-response data, and guiding us to optimally advance the development of GPS as a uniquely positioned active immunizer of the peptide vaccine type for the treatment of recalcitrant malignancies in the presence of measurable disease.”

Additionally, the Company announces preliminary immune response data in a subgroup of patients with triple-negative breast cancer (TNBC) from the prospective, randomized, single-blinded, controlled Phase 2b independent investigator-sponsored clinical study of the combination of trastuzumab (Herceptin®) +/- nelipepimut-S (NPS, NeuVax™) targeting HER2 low-expressing breast cancer patient cohorts. These data originate from an analysis of the patterns of induction of antigen (NPS)-specific T-cell responses over time in patients treated in this study. CD8+ cytotoxic T-lymphocytes (CTLs) from peripheral blood samples from study patients with TNBC were measured using specifically designed NPS-specific dextramers in a flow cytometry-based assay in duplicate. In 64 evaluable TNBC patients (39 in the NPS plus trastuzumab arm; 25 in the trastuzumab alone arm) across a median of four time-points (including baseline), NPS + trastuzumab administration generated up to 3-fold higher frequencies of NPS-specific CTLs compared to trastuzumab alone. Moreover, CTL frequencies were much higher among non-recurrent patients compared with those who recurred (on either arm). The complete set of data from these correlative analyses will be presented in an upcoming major scientific meeting.

“These new data provide important insights on the immunobiological mechanism underlying the statistically significant and clinically meaningful decrease in detectable tumor relapses and associated increase in 24-month disease-free survival (DFS) rate with the combination of NPS plus trastuzumab versus trastuzumab alone observed within the TNBC cohort of the Phase 2b study we have previously reported. We are looking forward to completing the underlying correlative analyses in order to further dissect the intriguing association between induction of antigen-specific T-cell immunity and clinical effect post-vaccination, which strongly suggests a contribution of NPS in the emergence of antitumor activity in TNBC patients in the adjuvant treatment setting. We are continuing our discussions with the FDA on the most optimal development path forward for NPS in TNBC and will provide the immune response data to the Agency as well,” commented Dr. Stergiou.

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About SELLAS Life Sciences Group, Inc.

SELLAS is a clinical-stage biopharmaceutical company focused on novel cancer immunotherapeutics for a broad range of cancer indications. SELLAS' lead product candidate, galinpepimut-S (GPS), is licensed from Memorial Sloan Kettering Cancer Center and targets the Wilms Tumor 1 (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 has a Phase 3 clinical trial planned (pending funding availability) for GPS in acute myeloid leukemia (AML) and is also studying GPS in combination with pembrolizumab in multiple indications. SELLAS has received Orphan Drug designations for GPS from the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) for AML, malignant pleural mesothelioma (MPM), and multiple myeloma (MM); GPS has also received Fast Track designation for AML, MPM and MM from the FDA. SELLAS' second product candidate, nelipepimut-S (NeuVax™, NPS), is a HER2-directed cancer immunotherapy being investigated for the prevention of the recurrence of breast cancer after standard of care treatment in the adjuvant setting. NPS has received Fast Track status designation by FDA 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 (TNBC) patients, following standard of care.

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

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