SELLAS Life Sciences Receives FDA Orphan Drug Designation for Galinpepimut-S (GPS) for Treatment of Multiple Myeloma (MM)

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NEW YORK, May 09, 2018 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group Inc. (Nasdaq:SLS) (“SELLAS”), a clinical-stage biopharmaceutical company focused on novel cancer immunotherapies for a broad range of cancer indications, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to its novel drug candidate, galinpepimut-S (GPS), for the treatment of multiple myeloma (MM). 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.

“We are delighted to receive this orphan drug designation as it underscores the great need for innovative, effective treatments for this rare cancer, and recognizes the potential benefits that GPS may provide for patients with MM,” said Angelos Stergiou, MD, ScD h.c., President & Chief Executive Officer of SELLAS. “Receiving orphan drug designation for the treatment of MM is a significant regulatory milestone in the development of GPS. We have reported median progression-free survival (PFS) of 23.6 months in the high-risk MM disease setting, compared to historically inferior outcomes in such a patient cohort of around 12 months, and GPS stimulated time-dependent and robust CD4+ T cell or CD8+ T cell immune responses as well as multifunctional cross-epitope T cell reactivity.”

GPS has also received orphan drug designation for the treatment of acute myeloid leukemia (AML) and malignant plural mesothelioma (MPM). SELLAS has Phase 3 clinical trials planned for GPS in both AML and MPM and is developing GPS as a potential treatment for a broad range of other cancer indications, including multiple myeloma.

The FDA’s Office of Orphan Drug Products grants orphan status to support development of medicines for safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people
in the United States. Orphan drug designation may provide certain benefits, including a seven-year period of market exclusivity if the drug is approved, tax credits for qualified clinical trials and an exemption from FDA application fees.

About SELLAS Life Sciences Group

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 Phase 3 clinical trials planned for GPS in two indications, acute myeloid leukemia (AML) and malignant plural mesothelioma (MPM) and is also developing GPS as a potential treatment for multiple myeloma and ovarian cancer. SELLAS has received Orphan Drug designations from the U.S. Food & Drug Administration (FDA), as well as the European Medicines Agency, for GPS in AML, MPM and MM; GPS also received Fast Track designation for AML and MPM from the FDA. SELLAS’ second product candidate, NeuVax™ (nelipepimut-S), is a first-in-class, HER2-directed cancer immunotherapy being investigated for the prevention of the recurrence of breast cancer after standard of care treatment in the adjuvant setting.

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

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