NEW YORK, July 20, 2018 (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 announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company’s lead asset, 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.

The Company reported nal clinical and immunological data from a Phase 2 clinical trial for GPS in the treatment of high-risk multiple myeloma at the 44th Annual European Society for Blood and Marrow Transplantation (EBMT) Meeting on March 19, 2018.

The FDA’s Fast Track program facilitates the development of drugs intended to treat serious conditions that have the potential to address unmet medical needs. A product candidate with Fast Track status is afforded greater access to the FDA for the purpose of expediting the product candidate’s development, review and potential approval. For a product candidate with Fast Track designation, the FDA may consider sections of its Biologics License Application (BLA) for review on a rolling basis before the complete application is submitted if relevant criteria are met.

“The designation of Fast Track for GPS represents important recognition by the FDA of the potential of this novel immunotherapeutic to address the significant unmet need in the treatment of patients with high-risk multiple myeloma in patients with poor-risk cytogenetics at diagnosis who still harbor minimal residual disease (MRD) after
autologous stem cell transplant,” said Angelos Stergiou, M.D., Sc.D. h.c., President and Chief Executive Officer of SELLAS. “We are fully committed to working closely with the FDA as we continue development of our potential first-in-class novel WT1-targeting cancer vaccine for select high-risk MM patients in the post-autotransplant maintenance setting after standard first-line treatment.”

About the Phase 2 GPS multiple myeloma study

The open-label Phase 2 study consisted of 19 patients with multiple myeloma who had high-risk cytogenetics at initial diagnosis and remained at least minimal residual disease (MRD)-positive after a successful autologous stem cell transplant (“ASCT”). GPS was administered to patients in the study who achieved a stable disease or better status (per International Myeloma Working Group criteria) following ASCT. GPS was evaluated as consolidation therapy to potentially stimulate a highly-specific immune response against WT1 in order to prevent or delay myeloma progression. Median progression-free survival (PFS) of 23.6 months was reported in the high-risk disease setting, compared to historically inferior outcomes while on an immunomodulatory drug (IMID) or proteasome inhibitor post-ASCT maintenance. Median overall survival has not been reached to date. GPS stimulated time-dependent and robust CD4+ T cell or CD8+ T cell immune responses (IRs) specific for all four WT1 peptides within GPS, two of which are heteroclitic (mutated, by design). In addition, GPS stimulated similar IRs against the two counterpart native peptides. The IRs were confirmed in up to 91% of patients across HLA allele types, with multivalent IRs emerging in up to 64% of patients. Multifunctional cross-epitope T cell reactivity was observed in 75% of patients to antigenic epitopes against which hosts were not specifically immunized, in a pattern akin to epitope spreading. A link of clinical activity to antigen-specific immune responses was suggested.

About Galinpepimut-S (GPS):
GPS is a heteroclitic multivalent, multi-peptide cancer immunotherapeutic agent composed of four peptides, addressing over 20 epitopes, and derived from the WT1 protein, which has been ranked by the National Cancer Institute as a top priority among cancer antigens for immunotherapy. Importantly, because the WT1 antigen is overexpressed in many malignancies, and is not found in most normal tissues, GPS has the potential to be a broad immunotherapy, effective across a multitude of diverse cancer types and patient populations.

About SELLAS:
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 (pending funding availability) for GPS in two indications, acute myeloid leukemia (AML) and malignant pleural mesothelioma (MPM) and is also developing GPS
as a potential treatment for multiple myeloma (MM) and ovarian cancer. SELLAS plans to study GPS in up to four additional indications. SELLAS has received Orphan Drug designations for GPS from the U.S. Food & Drug Administration (FDA) for AML, MPM, and MM, as well as from the European Medicines Agency, for AML and MPM; GPS also received Fast Track designation for AML and MPM from the FDA. SELLAS’ second product candidate, NeuVax™ (nelipepimut-S), 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. NeuVax™ 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+, following standard of care.

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

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the results of clinical studies and as to further development of GPS for ovarian cancer as well as for a broad range of cancer indications, including the timing of clinical trials. 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 immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, and other risks and uncertainties affecting SELLAS and its development programs. These risks and uncertainties are described more fully in SELLAS’ Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS’ forward-looking statements. 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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