SELLAS Life Sciences’ Phase 2 Results for Galinpepimut-S in High-Risk Multiple Myeloma Presented at European Society for Blood and Marrow Transplantation Meeting

3/19/2018

- Galinpepimut-S (GPS) induced immune activation against Wilms tumor-1 (WT1) antigen as well as multifunctional cross-epitope T-cell reactivity in patients with aggressive multiple myeloma

- Correlation noted between clinical and immune responses with promising progression free survival benefit

NEW YORK, March 19, 2018 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (NASDAQ:SLS) (“SELLAS” or “the Company”) today announced the presentation of open label Phase 2 clinical and immunological data for its lead cancer immunotherapeutic candidate, galinpepimut-S (GPS), in the treatment of high-risk multiple myeloma at the 44th Annual European Society for Blood and Marrow Transplantation (EBMT) Meeting. Safety results from the study were also presented. The EBMT presentation is being delivered by Guenther Koehne, M.D., Ph.D., Chief of Bone Marrow Transplantation and Hematologic Oncology at Miami Cancer Institute, Baptist Health South Florida.

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. The open-label Phase 2 study consisted of 19 patients with multiple myeloma who had high-risk cytogenetics at diagnosis and remained at least minimal residual disease (MRD)-positive after a successful autologous stem cell transplant (“ASCT”).

“These results are encouraging particularly given the patients’ poor prognosis due to their high-risk cytogenetic profile at disease presentation and their still harboring minimal residual disease prior to GPS treatment”, said
Angelos M. Stergiou, M.D., Sc.D. h.c., President and CEO of Sellas. “The improved PFS at 23.6 months in this setting instills further confidence in our advancing GPS development as an important immuno-therapeutic treatment option for aggressive multiple myeloma.”

GPS was administered to patients in the study who achieved a stable disease or better status following ASCT, but still exhibited at least measurable minimal residual disease. GPS, a novel WT1-targeting direct immunizer, was evaluated as consolidation therapy to potentially stimulate a highly-specific immune response against WT1 to prevent or delay myeloma progression.

In the study, key data findings were:

- Clinical activity was linked to antigen-specific immune responses.

- 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.

- The GPS data suggest a distinctive link between clinical and immune responses, which has not been previously described for a peptide vaccine in multiple myeloma. The results offer mechanistic underpinnings for immune activation against WT1 in patients with aggressive multiple myeloma and are supportive of further testing of the putative anti-myeloma activity of GPS in more extensive clinical studies.

Dr. Koehne’s complete EBMT presentation covering the GPS results can be accessed at: www.sellaslifesciences.com/publications/galinpepimut-s-gps/default.aspx.

“High-risk multiple myeloma is a disease subset with high potential of short-term disease progression following autologous stem cell transplants, providing opportunities to improve on this limited clinical outcome. We are seeing an encouraging signal from GPS in our Phase 2 study with progression-free survival (PFS) exceeding historical outcomes with standard therapies,” stated Guenther Koehne, M.D., Ph.D. Dr. Koehne added that “Currently, post-transplant maintenance therapies for these difficult-to-treat patients are seemingly limited, with PFS rarely exceeding 12-14 months”. Dr. Koehne was the Principal Investigator for this study while at MSKCC.

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 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. 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 and ovarian cancer. SELLAS plans to study GPS in up to four additional indications. 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 and MPM; GPS also received Fast Track designation for AML and MPM from the FDA.

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 multiple myeloma as well as for a broad range of cancer indications. 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, uncertainties related to timing and ability to obtain needed shareholder consent in a timely manner, the uncertainty of regulatory approval, the uncertainty of partnering its clinical assets, and other risks and uncertainties affecting SELLAS and its development programs. 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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