



NEWS RELEASE

SELLAS Life Sciences Provides Clinical Update on Phase 2b NeuVax™ (nelipepimut-S) Study in Combination with Trastuzumab in HER2 1+/2+ Breast Cancer Patients

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Phase 2b trial met key clinical objectives and is being discontinued early by the sponsor

Clinical and regulatory meetings held at the American Society of Clinical Oncology (ASCO) conference

Dr. Jeffrey S. Weber, preeminent immuno-oncology expert, appointed Chairman of Scientific Advisory Board (SAB)

NEW YORK, June 01, 2018 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group Inc., (Nasdaq:SLS) (SELLAS) today announced that the sponsor-principal investigator, after taking into account that key clinical development objectives were met as well as other regulatory considerations, and in agreement with SELLAS, determined to terminate early the Phase 2b independent investigator-sponsored clinical trial (IST) of trastuzumab (Herceptin®) +/- nelipepimut-S (NeuVax™) in HER2 1+/2+ breast cancer patients. In this Phase 2b study, Herceptin® was provided under a Clinical Trial Supply Agreement by Genentech, Inc. The decision to early terminate this Phase 2b study was based in part on the previously announced recommendation of the independent Data Safety Monitoring Board (DSMB) to further advance the development of the NeuVax + Herceptin combination for the triple negative breast cancer (TNBC) patient population. Data from the Phase 2b has been submitted for presentation at a major medical conference that will take place during the second half of 2018.

"We wish to thank our patients and their families for their participation in this trial. Based on data demonstrating that this combination therapy has the potential to become an important therapeutic option for TNBC patients facing a life-threatening disease and for whom current options in the adjuvant setting are extremely limited, we

have determined, in consensus with SELLAS, to close out the current study,” stated COL (ret) George E. Peoples, MD, FACS, Founder and Director of Cancer Insight, LLC and study Principal Investigator. “We look forward to supporting SELLAS’ interactions and discussions with regulatory bodies.”

SELLAS conducted this week two advisory meetings with global experts in regulatory affairs and breast cancer clinical development in order to determine the optimal path for further development of the NeuVax + Herceptin combination in TNBC in a pivotal setting and engagement with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

As previously announced, a pre-specified interim analysis of safety and efficacy conducted by the DSMB, demonstrated a clinically meaningful and statistically significant difference between the TNBC cohort of patients and the control arm with a hazard ratio of 0.26, p-value = 0.023, in favor of the NeuVax + Herceptin combination compared to Herceptin alone. The analysis also showed an adverse event profile with no notable differences between treatment arms and no additional cardiotoxicity in the NeuVax + Herceptin arm. Based on these positive results, the DSMB recommended to expeditiously seek regulatory guidance from the FDA for further development of the combination of NeuVax + Herceptin in TNBC, a population with a large unmet medical need.

“We agree with Dr. Peoples’ decision to close this Phase 2b study earlier than planned and it is a priority to advance the development program for NeuVax + Herceptin in TNBC. Indeed, we have initiated the necessary steps for prompt engagement with the regulatory authorities for their guidance on the expeditious development of this combination therapy, as exemplified by the clinical and regulatory advisory board meetings we just conducted during this year’s ASCO meeting,” said Nicholas J. Sarlis, MD, PhD, FACP, Executive Vice President and Chief Medical Officer of SELLAS.

Providing their impressions from the discussion of the Phase 2b study data during the Clinical Advisory Board meeting at the ASCO conference, Debu Tripathy, MD, Professor and Chairman, Department of Breast Medical Oncology, The University of Texas - MD Anderson Cancer Center, mentioned that “in early stage TNBC the benefit of chemotherapy in the adjuvant setting is incomplete and leaves room for improvement. Further, to date, targeted therapies have not proven effective for TNBC. Targeting HER2 as an immune therapy target with the Herceptin plus NeuVax combination in HER2 1+/2+ TNBC makes sense biologically, especially considering the baseline presence of activated cellular immunity components in most patients with this tumor type,” while Prof. Dr. med. Volkmar Müller, MD, PhD, Professor and Deputy Director, Department of Gynecology, University Clinic of Hamburg-Eppendorf, Germany commented, “The data from the Phase 2b study of Herceptin + NeuVax are promising in the TNBC cohort. SELLAS’ decision to pursue clinical and regulatory strategies with this combination in TNBC based on the current findings is justified, due to the high unmet need, low number of competing trials in the maintenance/adjuvant setting and feasibility of a pivotal Phase 3 study design whereby a relapse-based endpoint

could be reached with confidence.” Neither Prof. Tripathy nor Prof. Dr. med. Müller participated in the NeuVax + Herceptin Phase 2b study.

SELLAS also announced that it has appointed Jeffrey S. Weber, MD, PhD, as Chairman of its SAB. In his new role, together with the other members of the Company’s SAB, Dr. Weber will strengthen the Company’s capacities to drive, position and prioritize pipeline development with key focus on two assets, galinpepimut-S and nelipepimut-S (NeuVax™).

“We are very proud to expand Jeff’s role on the Company’s SAB. Jeff is a leading expert in cancer immunotherapeutics, with broad advisory experience to biopharmaceutical companies in the immuno-oncology field and has a proven leadership track in academic centers. His insights and ability to coordinate and collaborate with our SAB members and our scientific and clinical leadership will help us to more efficiently develop our peptide immunotherapeutic vaccines candidates,” said Dr. Sarlis. “Having worked with Jeff as a member of our SAB over the past 2 years, we are delighted to strengthen our collaboration,” added Dr. Sarlis.

Dr. Weber currently serves as Co-Director of the Melanoma Program at the New York University (NYU)-Langone Perlmutter Cancer Center and Deputy Director of the Center. Prior to this position, he was Head of the Melanoma Center of Excellence at H. Lee Moffitt Cancer Center. Earlier in his career, Dr. Weber worked as a Senior Investigator in the Surgery Branch of the National Cancer Institute (NCI) at the National Institutes of Health (NIH) and before that served as Chief of Medical Oncology at the University of Southern California (USC)’s Keck School of Medicine. He is a member of the Editorial Boards at Journal of the National Cancer Institute, Clinical Cancer Research, Human Gene Therapy and Journal of Immunotherapy and has served on or chaired numerous NCI study sections. Dr. Weber has published more than 180 articles in the top peer-reviewed journals, including New England Journal of Medicine and Nature Medicine. Dr. Weber was the recipient of the Bob Chandler Courage Award from the USC, of a K24 Mid-Career Mentor Award from NIH, has been recognized as one of the “Best Doctors in America” for over a decade and was the OncoLive Giants of Cancer in Melanoma for 2016. He was also the first investigator to demonstrate that PD-1 inhibitors had encouraging activity in resected melanoma patients.

“I am delighted to become the Chairman of the Scientific Advisory Board of SELLAS and honored to work together with my colleagues at the SAB to meaningfully support the company’s quest to change the field by innovative approaches to vaccinate patients using immunogenic peptides for the treatment of cancer,” commented Dr. Weber.

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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 (pending funding availability) 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 plans to study GPS in up to four additional indications. SELLAS has received Orphan Drug designations from the U.S. Food and Drug Administration (FDA) in AML, MPM, and multiple myeloma, 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. NeuVax™ (nelipepimut-S), a HER2-directed cancer immunotherapy, is also 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 the 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. You can identify such forward-looking statements by the use of the words "expect," "will," "anticipate," "estimate," "plan" and other words of similar import. The forward-looking statements in this press release include, but are not limited to, statements related to the potential of nelipepimut-S (NeuVax™) as a therapeutic option for TNBC, the ability to further clinical development of NeuVax, Dr. Weber's impact in his new role on the SAB, the general development of the Company's product candidate pipeline and the effects of the Company's approach to cancer treatment. 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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