



NEWS RELEASE

SELLAS Life Sciences Announces Completion of Enrollment in Phase 2 Randomized Controlled Clinical Study of Nelipepimut-S Plus Trastuzumab in High-risk, High-expression HER2 Breast Cancer Patients

11/26/2018

Data Expected in Fourth Quarter of 2019

Second Clinical Study of Nelipepimut-S Plus Trastuzumab After Recently Announced Positive Phase 2b Study in Low-expression HER2 or Triple Negative Breast Cancer

Study supported by SELLAS and the Department of Defense's Congressionally Directed Medical Research Programs in this new indication for high-expression HER2 breast cancer patients

NEW YORK , Nov. 26, 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 the completion of enrollment for a Phase 2 independent investigator-sponsored clinical trial of the combination of trastuzumab (Herceptin®) +/- nelipepimut-S (NPS) targeting high-risk, high-expression HER2-positive (IHC3+) breast cancer patients. This trial enrolled 100 patients and top-line data are expected in the fourth quarter of 2019. SELLAS recently reported positive data from a separate Phase 2b study of trastuzumab +/- NPS in low-expression HER2 (IHC 1+/2+) or triple negative breast cancer patients whose tumors are also identified by low-to-no expression of hormone receptors.

This trastuzumab + NPS clinical study is a multi-center, prospective, randomized, single-blinded investigator-sponsored Phase 2 trial focusing on patients with a diagnosis of HER2-positive (immunohistochemistry [IHC] 3+ and/or HER2 FISH-amplified) breast cancer who are HLA-A02, A03, A24 or A26-positive and at high-risk for

recurrence after standard therapy for early-stage disease. Eligible patients were randomized to receive NPS plus trastuzumab or trastuzumab alone in the adjuvant setting to prevent or delay disease recurrence. The primary endpoint of the study is disease-free survival (DFS). Support for this trial is provided, in part, by the Congressionally Directed Medical Research Program (CDMRP), funded through the Department of Defense via a Breast Cancer Research Program Breakthrough Award to Elizabeth Mittendorf, MD, PhD. The National Breast Cancer Coalition led the effort to establish the CDMRP to enhance the funding for breast cancer research and remains integrally involved in the grant selection process.

“The completion of enrollment of this Phase 2 clinical trial of NPS marks an important milestone, as it brings us one step closer to providing this potentially life-saving therapy to high-risk HER2-positive breast cancer patients facing limited treatment options,” said Dr. Nicholas J. Sarlis, MD, PhD, Executive Vice President and Chief Medical Officer of SELLAS. “We are encouraged for a favorable outcome based on rigorous preclinical work showing potential synergy between NPS and trastuzumab, and are eager to gain further insights on the effect of this combination in HER2-positive early-stage breast cancer in patients with the highest risk of disease recurrence. This combination has a solid clinical and immunobiological rationale, as demonstrated by the recent data from the Phase 2b study of NPS plus trastuzumab in the maintenance setting in patients with early-stage triple negative breast cancer. We look forward to reporting data from this second combination study next year.”

“We are thrilled to complete enrollment in this very important Phase 2 clinical trial of NPS and trastuzumab as a treatment for high-risk HER2-positive breast cancer patients. We look forward to completing the study and to reporting the trial results,” said Elizabeth A. Mittendorf, MD PhD, Rob and Karen Hale Distinguished Chair in Surgical Oncology, Director of Research, Breast Surgical Oncology at Brigham and Women’s Hospital, and Director, Breast Immuno-Oncology Program Dana-Farber/Brigham and Women’s Cancer Center and the Principal Investigator of the study. “The addition of trastuzumab to standard therapy has dramatically improved the prognosis for patients with early stage, HER2-positive (IHC 3+/HER2 gene FISH-amplified) breast cancer to unprecedented survival outcomes. Yet, long-term follow-up data indicate that 15-24% of such patients still develop recurrent disease. Moreover, dual blockade of HER2 signaling in the adjuvant setting has led to only small incremental benefits in disease-free survival and the addition of NPS may prove to be clinically beneficial and enhance the armamentarium in breast cancer treatments. This unmet medical need is more prevalent in patients who are unable to achieve a pathologic complete response after standard neoadjuvant therapy or those found to have positive lymph nodes above certain number thresholds at the time of surgery, and then treated with standard adjuvant therapy.”

Herceptin® is a registered trademark of Genentech, Inc. and is not a trademark of SELLAS. The manufacturer of this brand is not affiliated with and does not endorse SELLAS or its products.

About the National Breast Cancer Coalition

Founded in 1991, the National Breast Cancer Coalition's (NBCC) mission is to end breast cancer through the power of action and advocacy. NBCC is a collaboration of activists, survivors, researchers, policy makers, grassroots groups, and national organizations that have come together as disruptive innovators for social change. NBCC links hundreds of organizations and tens of thousands of individuals from across the country giving breast cancer a meaningful voice in Washington, DC, and state capitals, in laboratories and health care institutions, and in local communities everywhere. NBCC's activism has generated more than \$3 billion new dollars for breast cancer research, and such research initiatives and advocacy are helping bring about novel models of research.

For more information, click on the following link:

<http://www.breastcancerdeadline2020.org/about-nbcc/about-nbcc.html>

About the Congressionally Directed Medical Research Programs

The Congressionally Directed Medical Research Programs (CDMRP) originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders—the American public, the military, and Congress.

The CDMRP fills research gaps by funding high impact, high-risk/high-gain projects that share the common goal of advancing paradigm shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The CDMRP strives to transform healthcare for Service Members and the American public through innovative and impactful research.

For more information, please visit: **<https://cdmrp.army.mil/aboutus>**

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 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) and the European Medicines Agency (EMA) for AML, MPM, and 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 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+, which includes triple negative breast cancer patients, following standard of care.

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

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, forward-looking statements can be identified by terminology such as "plan," "expect," "anticipate," "may," "might," "will," "should," "project," "believe," "estimate," "predict," "potential," "intend," or "continue" and other words or terms of similar meaning. These statements include, without limitation, statements related to the further development of nelipepimut-S (NeuVax™, NPS) for breast cancer and the timing of availability of clinical data. 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, the uncertainty of finding potential partners for product candidate development, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption "Risk Factors" in Exhibit 99.1 in its Current Report on Form 8-K filed on July 18, 2018 and in its other SEC filings. 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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