Galena Biopharma Collaborates With the National Cancer Institute on a Phase 2 Clinical Trial With NeuVax(TM) (nelipepimut-S) in Ductal Carcinoma in Situ Patients

Clinical Trial Expected to Initiate in Q4, 2015

PORTLAND, Ore., Sept. 30, 2015 (GLOBE NEWSWIRE) -- Galena Biopharma, Inc. (NASDAQ:GALE), a biopharmaceutical company developing and commercializing innovative, targeted oncology therapeutics that address major medical needs across the full spectrum of cancer care, today announced a collaboration with the National Cancer Institute (NCI) to initiate a new, Phase 2 clinical trial with NeuVax™ (nelipepimut-S) in patients diagnosed with Ductal Carcinoma in Situ (DCIS). The trial will be entitled, VADIS: Phase 2 trial of the Nelipepimut-S Peptide VAccine in Women with DCIS of the Breast. The University of Texas M.D. Anderson Cancer Center (MDACC) Phase I and II Chemoprevention Consortium is the lead for this multi-center trial with Elizabeth Mittendorf, MD, PhD serving as the study Principal Investigator. The Consortium is funded through the Division of Cancer Prevention at NCI, which will provide financial and administrative support for the trial. Galena will provide NeuVax, as well as additional financial and administrative support. The trial is expected to initiate in the fourth quarter of 2015.

"We are pleased to have been chosen by the NCI and M.D. Anderson, two world-renowned institutions, on this groundbreaking study to potentially advance NeuVax earlier in the treatment cycle towards primary prevention of breast cancer," said Mark W. Schwartz, PhD, President and Chief Executive Officer. "NeuVax generates a significant and potent HER2 directed T-cell response, and this Phase 2 clinical trial will evaluate the CD8+ T cell response generated by NeuVax and whether this induced activation of the immune system suppresses the growth of DCIS cells. We look forward to initiating this trial with our partners before year end."

The Phase 2 clinical trial will be a single-blind, double arm, randomized, controlled trial comparing NeuVax combined with the immunoadjuvant granulocyte-macrophage colony-stimulating factor (GM-CSF) versus GM-CSF alone. Adult women eligible for the trial will be pre- or post-menopausal with DCIS diagnosed via their core needle biopsy and will be positive for the human leukocyte antigen (HLA) allele A2, or HLA-A2 positive. The trial will enroll a total of 48 patients randomized in a 2:1 ratio, 32 in the active arm and 16 in the control arm. After completion of local therapy to include surgery and when indicated, radiation, the treatment regimen will consist of three doses prior to, and three doses after surgery, for a total of six injections of either vaccine or control, depending on the arm in which the patients are randomized. The primary endpoint for the trial is immunological, evaluating NeuVax peptide-specific cytotoxic T lymphocyte (CTL; CD8+ T cell) response in vaccinated patients compared to patients receiving GM-CSF alone. Secondary endpoints include safety, immune response via epitope spreading, presence of DCIS at resection, and difference in HER2 expression.

The NCI's Division of Cancer Prevention (DCP) conducts and supports research to determine a person's risk of cancer and to find ways to reduce the risk. This knowledge is critical to making progress against cancer because risk varies over the lifespan as genetic and epigenetic changes can transform healthy tissue into invasive cancer. With an overall goal to detect such changes and intervene early in the cancer process to prevent symptomatic disease and death, DCP funds and provides administrative support to clinical and laboratory researchers, community and multidisciplinary teams, and collaborative scientific networks.

About Ductal Carcinoma in Situ

Ductal Carcinoma in Situ (DUK-tul KAR-sih-NOH-muh in SY-too), or DCIS, is defined by the NCI as a noninvasive condition in which abnormal cells are found in the lining of a breast duct, and is the most common type of breast cancer. The abnormal cells have not spread outside the duct to other tissues in the breast. In some cases, DCIS may become invasive cancer and spread to other tissues, and at this time, there is no way to know which lesions could become invasive. Current treatment options for DCIS include breast-conserving surgery and radiation therapy with or without tamoxifen, breast-conserving surgery without radiation therapy, or total mastectomy with or without tamoxifen. According to the American Cancer Society, in 2014 there were an estimated 51,933 diagnoses of ductal carcinoma in situ.

About NeuVax™ (nelipepimut-S)

NeuVax™ (nelipepimut-S) is a first-in-class, HER2-directed cancer immunotherapy under evaluation to prevent breast cancer recurrence after standard of care treatment in the adjuvant setting. It is the immunodominant peptide derived from the
extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast carcinoma. NeuVax has been shown to bind to HLA-A2 and A3, as well as HLA-A24 and A26 molecules. The nelipepimut-S sequence stimulates specific CD8+ cytotoxic T lymphocytes (CTLs) following binding to specific HLA molecules on antigen presenting cells (APC). These activated specific CTLs recognize, neutralize and destroy, through cell lysis, HER2 expressing cancer cells, including occult cancer cells and micrometastatic foci. The nelipepimut-S immune response can also generate CTLs to other immunogenic peptides through inter- and intra-antigenic epitope spreading.

NeuVax is currently in an international, Phase 3 PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax Treatment) study under a Special Protocol Assessment (SPA) granted by the U.S. Food and Drug Administration (FDA). Additional information on the PRESENT trial can be found at www.neuvax.com (clinicaltrials.gov identifier: NCT01479244). Galena has two additional breast cancer studies ongoing with NeuVax in combination with trastuzumab (Herceptin®; Genentech/Roche): a Phase 2b trial in node positive and triple negative HER2 IHC 1+/2+ (clinicaltrials.gov identifier: NCT01570036); and, a Phase 2 trial in neoadjuvantly treated node positive and negative HER2 IHC 3+ patients not achieving a pathological complete response (pCR) or adjuvantly treated node positive HER2 IHC 3+ patients (clinicaltrials.gov identifier: NCT02297698).

About Galena Biopharma

Galena Biopharma, Inc. (NASDAQ:GALE) is a biopharmaceutical company developing and commercializing innovative, targeted oncology therapeutics that address major medical needs across the full spectrum of cancer care. Galena's development portfolio ranges from mid- to late-stage clinical assets, including a robust immunotherapy program led by NeuVax™ (nelipepimut-S) currently in an international, Phase 3 clinical trial. The Company's commercial drugs include Abstral® (fentanyl) Sublingual Tablets and Zuplenz® (ondansetron) Oral Soluble Film. Collectively, Galena's clinical and commercial strategy focuses on identifying and advancing therapeutic opportunities to improve cancer care, from direct treatment of the disease to the reduction of its debilitating side-effects. For more information, visit www.galenabiopharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the progress of the commercialization of our commercial products and development of Galena's product candidates, including NeuVax, patient enrollment in our clinical trials, as well as other statements related to the progress and timing of our development activities, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those identified under "Risk Factors" in Galena's Annual Report on Form 10-K for the year ended December 31, 2014 and most recent Quarterly Reports on Form 10-Q filed with the SEC. Actual results may differ materially from those contemplated by these forward-looking statements. Galena does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this press release.

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