Galena Biopharma to Present GALE-302 Preliminary Immunological Data Optimizing GALE-301, and the Phase 2 NeuVax™ Data Impact on Cancer Survivorship at Two Upcoming Medical Conferences

SAN RAMON, Calif., Oct. 22, 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 that data from the Company’s NeuVax™ (nelipepimut S) and GALE-301 and GALE-302 clinical programs will be presented at two upcoming medical conferences. Details of the presentations are as follows:

Conference: Society for Immunotherapy of Cancer (SITC) 30th Anniversary Annual Meeting
Poster #: 166
Abstract #: November 4, 2015.
Title: Preliminary report of a clinical trial supporting the sequential use of an attenuated E39 peptide (E39’) to optimize the immunologic response to the FBP (E39+GM-CSF) vaccine
Date: Friday, November 6, 2015
Time: 6:15 p.m. to 7:30 p.m. Eastern time
Location: Prince George's Exhibition Hall at the Gaylord National Hotel & Convention Center in National Harbor, Maryland

GALE-301 (E39) and GALE-302 (E39’ – variant of E39; previously named J65) are folate binding protein-derived (FB) peptides capable of stimulating cytotoxic T lymphocytes (CTLs) targeting FBP expressing tumors. The data to be presented at SITC is from a single-center, randomized, single-blinded, three-arm Phase 1b study of GALE-301 and GALE-302 in patients with breast or ovarian cancer diagnosis who have been treated by standard of care and are without evidence of disease. The primary endpoint of the trial is immunologic and designed to determine which of the three primary vaccination sequence strategies maximizes long-term specific immunity defined as E39-specific CTLs six months following completion of the primary vaccination series.

Conference: 33rd Annual Chemotherapy Foundation Symposium: Innovative Cancer Therapy for Tomorrow®
Poster #: 309
Title: NeuVax™ (nelipepimut S) for the prevention of recurrence in HER2-expressing node positive breast cancer patients
Date: Wednesday, November 4, 2015
Time: 6:00 p.m. to 7:00 p.m. Eastern time
Location: Crown Plaza Hotel, New York, NY

In 2014, it is estimated there are 14.5 million cancer survivors in the United States. By 2024, it is projected there will be 19 million cancer survivors (DeSantis CE et al., 2014). In breast cancer patients, 50-60% who are HER2 IHC 1+/2+ or FISH < 2.0 achieve a response with current standard of care (SOC), but have no treatment options to maintain disease-free status. NeuVax is being studied to prevent breast cancer recurrence in these women in the adjuvant setting and maintain patients’ “survivor” status as a single agent in node positive as well as in combination with Herceptin® in node positive and triple negative disease (IHC 1+/2+) as well as high risk node positive and triple negative (IHC3+).

About GALE-301 and GALE-302

GALE-301 and GALE-302 are cancer immunotherapies that consist of a peptide derived from Folate Binding Protein (FBP) combined with the immune adjuvant, granulocyte macrophage-colony stimulating factor (GM-CSF) for the prevention of cancer recurrence in the adjuvant setting. GALE-301 is the E39 peptide, while GALE-302 is an attenuated version of this peptide, known as E39 prime (E39’). FBP is a well-validated therapeutic target that is highly over-expressed in ovarian, endometrial and breast cancers, and is the source of immunogenic peptides that can stimulate cytotoxic T lymphocytes (CTLs) to recognize and
About NeuVax™ (nelipepimutS)

NeuVax™ (nelipepimutS) 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. 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). PRESENT is targeting node positive HER2 IHC 1+/2+ patients (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 high risk, node positive or negative HER2 IHC 3+ patients (clinicaltrials.gov identifier: NCT02297698). Phase 2 clinical trials with NeuVax are also planned in patients with ductal carcinoma in situ (DCIS), and in patients with gastric cancer.

About HER2 1+/2+ Breast Cancer

According to the National Cancer Institute, over 230,000 women in the U.S. are diagnosed with breast cancer annually. Of these women, only about 25% are HER2 positive (IHC 3+). NeuVax targets approximately 50%-60% of these women who are HER2 low to intermediate (IHC 1+/2+ or FISH < 2.0) and achieve remission with current standard of care, but have no available HER2-targeted adjuvant treatment options to maintain their disease-free status.

About Ovarian/Endometrial Cancers

New cases of ovarian cancer occur at an annual rate of 12.1 per 100,000 women in the U.S., with an estimated 21,290 cases for 2015. Although ovarian cancer represents about 1.3% of all cancers, it represents about 2.4% of all cancer deaths, or an estimated 14,180 deaths in 2015. Approximately 1.3% of women will be diagnosed with ovarian cancer at some point during their lifetime (2010 - 2012 data). The prevalence of ovarian cancer in the U.S. is about 192,000 women, and the five-year survivorship for women with ovarian cancer is 45.6%.

Due to the lack of specific symptoms, the majority of ovarian cancer patients are diagnosed at later stages of the disease, with an estimated 75% of women presenting with advanced-stage (III or IV) disease. These patients have their tumors routinely surgically debulked to minimal residual disease, and then are treated with platinum- and/or taxane-based chemotherapy. While many patients respond to this treatment regimen and become clinically free-of-disease, the majority of these patients will relapse. Depending upon their level of residual disease, the risk for recurrence after completion of primary therapy ranges from 60% to 85%. Unfortunately for these women, once the disease recurs, treatment options are limited and the disease remains incurable.

New cases of endometrial cancer occur at an annual rate of 25.1 per 100,000 women in the U.S., with an estimated 54,870 cases for 2015. Although endometrial cancer represents about 3.3% of all cancers, it represents about 1.7% of all cancer deaths, or an estimated 10,170 deaths in 2015. Approximately 2.8% of women will be diagnosed with endometrial cancer at some point during their lifetime (2010 - 2012 data). The prevalence of endometrial cancer in the U.S. is about 620,000 women, and the five-year survivorship for women with endometrial cancer is 81.7%.

Source: National Cancer Institute Surveillance, Epidemiology, and End Results Program

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, GALE-301 and GALE-302, 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.

Abstral and NeuVax are trademarks of Galena Biopharma, Inc. All other trademarks are the property of their respective owners.

CONTACT: Remy Bernarda

SVP, Investor Relations & Corporate Communications

(503) 405-8258

rbernarda@galenabiopharma.com