Galena Biopharma Presents GALE-301 Phase 1 Data at the American Society of Clinical Oncology (ASCO) 50th Annual Meeting

- Phase 1 study demonstrates GALE-301 (Folate Binding Protein) cancer immunotherapy is well tolerated and induces an immune response in ovarian and endometrial cancer patients.
- Ongoing Phase 2a trials to establish preliminary efficacy, as well as evaluate a longer-term booster regimen, to complete enrollment this year.

PORTLAND, Ore., June 2, 2014 (GLOBE NEWSWIRE) -- Galena Biopharma (Nasdaq:GALE), a biopharmaceutical company developing and commercializing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care, today announced that data from the Company's Phase 1 study with GALE-301, or Folate Binding Protein (FBP), was presented at the American Society of Clinical Oncology (ASCO) 50th Annual Meeting. The poster entitled, "Comparison of recurrent and nonrecurrent ovarian and uterine cancer patients undergoing adjuvant folate receptor vaccine therapy," was presented during the Gynecologic Cancer General Poster Session.

Folate Receptor Alpha (FRα) (also known as FBP) is an immunogenic protein that is over-expressed in breast, lung, endometrial and ovarian cancers. FRα expression in malignant cells is 20-80 fold higher compared to normal cells. Galena conducted a Phase 1 dose escalation clinical trial with E39, an HLA-A2 positive, FRα peptide combined with the immune adjuvant, granulocyte macrophage-colony stimulating factor (GM-CSF). The vaccine is administered in the adjuvant setting to prevent recurrences in high-risk endometrial and ovarian cancer patients rendered clinically disease-free after standard-of-care therapy. The current analysis compared in vivo immunologic responses (IR) and disease features between vaccinated non-recurrent (vNR) and vaccinated recurrent (vR) patients.

Overall, 30 patients were enrolled in the Phase 1 trial. Of 14 control patients, 7 (50%) have recurred. Of 16 vaccinated patients, 4 (25%) have recurred after completing the primary vaccine series (PVS), 2 (12.5%) recurred prior to completing the PVS, and one patient withdrew. Of note, no recurrences have been seen in the optimal dose cohort of 1000 mcg E39. The vR patients displayed lower mean delayed type hypersensitivity (DTH) reactions as well as lower local reactions at every measured time point.

"These promising initial results demonstrate the vaccine is dose responsive with the immune system and we are encouraged about the potential for this compound to prevent recurrence in women suffering from high risk gynecological cancers where current treatment options are limited," said Mark J. Ahn, Ph.D., President and Chief Executive Officer. "The data from this study served as the basis for advancing GALE-301 into its ongoing Phase 2 trial that includes a booster regimen. We expect enrollment in this trial to complete shortly, ahead of schedule."

In the Phase 1 study, HLA-A2 positive patients were enrolled into the vaccine group and received intradermal inoculations of E39 + 250 mcg GM-CSF once a month for six months (the PVS) following assignment into a dose cohort: 100mcg, 500mcg, or 1000mcg of E39. In vivo IR was assessed by both local reaction (LR) after each inoculation and DTH reaction measured pre-vaccination and post-PVS (DTH2).

Comparison between vNR and vR patients demonstrates recurrences are likely related to trends in both disease features (age but not stage) as well as diminished response to the vaccine as seen by LR and DTH. As decreased vaccine response may be related to more aggressive disease, the most viable way to address this observation is to vaccinate in earlier stage disease. The ongoing Phase 2a trial is attempting to establish a preliminary efficacy signal, as well as evaluate a longer-term booster regimen.

"Folate binding protein is highly over-expressed in ovarian and endometrial cancers and is a key target for vaccine-induced immunity to prevent recurrence for women suffering from these diseases. This preliminary trial has shown that the FBP vaccine is well-tolerated and immunogenic, warranting the additional ongoing phase 2a trials to demonstrate the efficacy of the vaccine," concluded Dr. Erika J. Schneble, San Antonio Military Medical Center, San Antonio, TX who presented the results.

About GALE-301 (Folate Binding Protein (FBP) vaccine)

GALE-301 (Folate Binding Protein (FBP)) cancer immunotherapy targets FBP, a well-validated therapeutic target, which is
highly over-expressed in breast, ovarian and endometrial cancers. FBP is the source of immunogenic peptides that can stimulate cytotoxic T lymphocytes (CTLs) to recognize and destroy presenting FBP-expressing cancer cells. The FBP vaccine consists of the FBP peptide(s) combined with the immune adjuvant, granulocyte macrophage-colony stimulating factor (GM-CSF). Galena’s FBP vaccine is currently in Phase 2a trials in two gynecological cancers: ovarian and endometrial adenocarcinomas.

About Ovarian/Endometrial Cancers

Ovarian cancer occurs in more than 22,000 patients per year in the U.S. and is the most lethal gynecologic cancer. Despite the incidence of ovarian cancer being only approximately 20% of that of breast cancer, the number of patients that die from ovarian cancer is nearly 50% of that of breast cancer. Due to the lack of specific symptoms, the majority of ovarian cancer patients are diagnosed at later stages of the 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 most patients respond to this treatment regimen and become clinically free-of-disease, the majority of these patients will relapse, and once the disease recurs, the treatment options and successes drop dramatically.

Endometrial cancer is the most common gynecologic cancer and occurs in more than 46,000 women with more than 8,000 deaths in the U.S. annually. There are two basic types of endometrial cancer: endometrioid and papillary serous. The latter has a much more aggressive clinical course and the majority of these patients will die of this form of the disease.

About Galena Biopharma

Galena Biopharma, Inc. (Nasdaq:GALE) is a Portland, Oregon-based biopharmaceutical company developing and commercializing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care. 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 Abstral® and development of Galena’s product candidates, including patient enrollment in our clinical trials, as well as statements about our expectations, plans and prospects. 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, 2013 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 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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