Expression Genetics, Inc. Announces Successful Completion of Phase I Trial of Gene-Based IL-12 for Treatment of Ovarian Cancer

HUNTSVILLE, Ala., April 16 /PRNewswire/ -- Expression Genetics, Inc., announced today the completion of a Phase I clinical study evaluating the Company's lead drug candidate, EGEN-001. The study, conducted at The University of Alabama at Birmingham and Baylor College of Medicine, evaluated the safety, tolerance, preliminary efficacy, and biological activity of the EGEN-001 in 13 patients with advanced recurrent epithelial ovarian cancer. The product, utilizing the Company's proprietary TheraPlas(R) delivery technology, is composed of interleukin-12 (IL-12) gene expression plasmid formulated with a biocompatible delivery polymer and is designed to increase local concentration of IL-12 protein. IL-12 is a potent anti-cancer cytokine which works by enhancing the body's immune system against cancer and inhibiting tumor blood supply. EGEN-001 for treatment of ovarian cancer has been granted Orphan Drug Status by the FDA.

The Phase I clinical trial was an open-label dose escalation study involving four dose levels of EGEN-001 administered intraperitoneally by four weekly infusions in chemotherapy-resistant advanced stage recurrent ovarian cancer patients. The treatment was well tolerated with no apparent dose- related trends in clinical laboratory, ECG, or vital sign parameters. General observations included abdominal cramping, mild to moderate peritonitis, nausea, and mild elevation of body temperature. These data demonstrate that this IL-12 gene therapeutic is safe for intraperitoneal administration in ovarian cancer patients.

Several clinical and biological parameters were evaluated as secondary endpoints of this study. Tumor burden of patients was monitored during treatment and results show 31% of patients showed stable disease. To date, the overall median survival is over 12.2 months with 7 out of 13 patients still surviving. There appeared to be some trend with respect to clinical benefit in the patients treated with higher dosages. IL-12 plasmid was detectable in peritoneal fluid of all evaluable patients and in blood samples of only a few patients at considerably lower level, suggesting that the plasmid delivery following EGEN-001 administration was localized at the delivery site, a major advantage of EGEN-001 therapy over recombinant protein therapy. The IP administered EGEN-001 was biologically active since it increased the peritoneal levels of interferon-gamma, the predominant cytokine activated by IL-12, in all patients.

"We are quite pleased with the safety profile of EGEN-001 observed in this initial clinical trial and are encouraged by some of the preliminary efficacy and activity results we have seen resulting from the administration of EGEN- 001 monotherapy in advanced ovarian cancer patients," said Dr. Danny H. Lewis, CEO of Expression Genetics. "We have completed the necessary regulatory process and expect to immediately begin enrollment of patients in our next study which will combine EGEN-001 administration with conventional chemotherapy in platinum-sensitive recurrent ovarian cancer patients."

The lead investigator, Ronald Alvarez, M. D., Director of Gynecologic Oncology, The University of Alabama at Birmingham, stated, "We are encouraged by the initial clinical results of this trial and look forward

to moving ahead with expanded clinical testing of EGEN-001 in order to evaluate the safety of this experimental drug in combination with paclitaxel and platinum based chemotherapy treatment regimens."

About Ovarian Cancer

Ovarian cancer accounts for approximately 4 percent of all women's cancers and is the fourth leading cause of cancer-related death among women in the U.S. The American Cancer Society statistics for ovarian cancer estimate that there will be 22,430 new cases and 15,280 deaths in 2007. The death rate for this disease has not changed much in the last 50 years. Ovarian cancer has the highest mortality of all cancers of the female reproductive system. This cancer is often diagnosed at an advanced stage after the cancer has spread beyond the ovary. Over $2 billion is spent in the U.S. each year on treatment of ovarian cancer.

About Expression Genetics, Inc.

Expression Genetics, Inc. (EGEN), with laboratories and headquarters in Huntsville, Alabama is a privately held biopharmaceutical company focused on developing therapeutics for the treatment of human diseases including cancer and cardiovascular disease. The Company specializes in the delivery of therapeutic nucleic acids (DNA and RNAi) and proteins aimed at specific disease targets. The Company has a significant intellectual property position in biocompatible polymers, their combination with DNA, and their therapeutic applications. EGEN has research pipeline products aimed at treatment of various cancers and cardiovascular disease. These projects involving siRNA, shRNA, tumor antigens, and angiogenic genes are in early stages. EGEN has collaborations with outside investigators, biotech organizations, and universities on various projects in these areas.

Safe Harbor for Forward-Looking Statements

Certain statements contained in this press release may be deemed to be forward looking statements under federal securities laws and Expression Genetics intends that such forward-looking statements be subject to the safe harbor created thereby. Expression Genetics does not undertake an obligation to publicly update or revise any forward looking statements, whether as a result of new information, future events or otherwise. Actual events or results may differ from our expectations as a result of a number of factors, including but not limited to uncertainties in clinical trials and product development programs, ability and success level of the Company in securing adequate capital for operations, market place acceptance of any resulting product and other factors common to biotechnology research and development. There can be no guarantee that any product in our pipeline will be successfully developed.

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