



Press Releases

Jennerex Reports Positive Phase 1 Results for JX-594 Administered Intravenously

San Francisco, California, May 20, 2010 --Jennerex, Inc., a clinical-stage cancer biotherapeutics company, today reported positive results from its Phase 1 dose escalation study evaluating the intravenous (IV) administration of JX-594 to patients with metastatic cancer. The data presented today demonstrated clear dose-related delivery to solid tumors, cancer-targeted replication and gene expression, and anti-cancer effects of JX-594 delivered IV. Choi (necrotic) responses were more commonly observed in patients treated at higher doses. In addition, intravenous infusion of JX-594 was safe and well-tolerated. These data were presented today at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting in Washington DC.

"These data represent a significant milestone for the field of oncology and viral therapy as this is the first time that a viral or genetic product has demonstrated reproducible, biopsy-proven delivery to multiple solid tumor types following intravenous administration," said David H. Kirn, M.D., president and chief executive officer of Jennerex. "We look forward to extending our experience with IV JX-594 in our planned Phase 3 trial in patients with advanced liver cancer. This pivotal trial will utilize both IV and targeted intratumoral injections of JX-594 to maximize potential patient benefit. We expect to initiate this study in Q4 of 2010."

"JX-594 represents a promising potential treatment option for patients with multiple types of cancer. As the first intravenous biological immunotherapy to demonstrate safety and tumor-specific delivery, JX-594 may add significantly to the armamentarium for many solid tumors," stated Andrew R. Haas, M.D., Ph.D., Hospital of the University of Pennsylvania, and investigator on JX-594 Phase 1 trial.

This open-label, dose-escalation study was completed at four sites in the United States and Canada. A total of 23 patients with solid tumors refractory to standard therapy were enrolled. Patients received a single treatment at one of five dose levels, with follow-up at periodic intervals. Six out of eight patients in the higher-dose cohorts evaluable to date (cohorts 3, 4, 5) exhibited disease control as defined by stable disease by RECIST (Response Evaluation Criteria in Solid Tumors) criteria and/or Choi (necrotic) response. Two out of six patients in the low dose cohorts exhibited disease control (RECIST stable disease) but no responses. The primary endpoints of the trial included safety and determination of the maximum tolerated dose given through intravenous administration. No serious adverse events related to JX-594 therapy were reported and no dose-limiting toxicities were reported. A biomarker analysis further strengthened the finding of dose-dependent replication in tumors following IV administration.

About JX-594

JX-594, currently in Phase 2 clinical trials, is a cancer biotherapeutic product from a proprietary breakthrough class of targeted and armed oncolytic and immunotherapeutic poxviruses. Tumor destruction and safety was shown in patients with diverse cancer types in three Phase 1 trials; treated patients were end-stage and had no effective therapies available. JX-594 multiplies selectively within cancer cells, leading to their destruction. These newly created copies of JX-594 are then released and are able to infect and eradicate other tumor cells both locally and in distant sites in the body. This cycle of JX-594 replication, cancer cell destruction, release and spread is then repeated. Normal cells are not affected by JX-594 resulting in safety and tolerability.

The poxvirus strain backbone of JX-594 has been used safely in millions of people as part of a worldwide vaccination program. This strain naturally targets cancer cells due to common genetic defects in cancer cells. JX-594 was engineered to enhance this natural safety and cancer-selectivity by deleting its thymidine kinase (TK) gene, thus making it dependent on the cellular TK expressed at persistently high levels in cancer cells. To enhance product efficacy,

JX-594 is also engineered to express the GM-CSF protein. GM-CSF complements the cancer cell lysis work of the product candidate, leading to a cascade of events resulting in tumor necrosis, tumor vasculature shutdown and an anti-tumoral immune attack.

About Jennerex

Jennerex is a clinical-stage biopharmaceutical company focused on the development and commercialization of first-in-class, breakthrough targeted oncolytic products for cancer. The company's lead product JX-594, currently in an international Phase 2 trial for primary liver cancer and colorectal cancer, demonstrated promising Phase 1 efficacy and safety results in patients with a diverse array of common cancers. Jennerex's products target, attack and eradicate cancers through a novel and potent oncolytic mechanism that is dependent on highly-specific replication of the company's poxviruses in cancer cells. These products simultaneously stimulate the body's immune response to the cancer. Of note, this mechanism of action and the results in patients to date put the company's product class in a leadership position. Jennerex's therapeutic approach is markedly different from gene therapy and standard cancer vaccine approaches. Jennerex Biotherapeutics was established in San Francisco CA and in Ottawa Canada in 2006 with Dr. David Kim (CEO) in San Francisco and Dr. John Bell (CSO) from the Ottawa Health Research Institute/University of Ottawa. For more information about Jennerex and the company's robust pipeline and three clinical-stage products, please visit www.jennerex.com.

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