



Contact:

Erlinda M. Gordon, M.D.
Epeius Biotechnologies Corporation
Tel: 626-441-6695
egordon@epeiusbiotech.com

ASCO 2008: TUMOR-TARGETED REXIN-G DEMONSTRATES DOSE-DEPENDENT ANTI-TUMOR ACTIVITY WITHOUT TOXICITY IN METASTATIC PANCREATIC CANCER

May 19, 2008, San Marino, California—Epeius Biotechnologies announced today the results of an on-going Phase I/II study of Regin-G for metastatic pancreatic cancer (Chawla et al., ASCO meeting, 2008). Continuing on with the planned dose-escalations of Regin-G which began in 2005 using lower doses of Regin-G in a Phase I safety study (Molecular Therapy, 2008), the current Phase I/II study employed higher dose-escalations of Regin-G given i.v. two to three times a week for 4 weeks, beginning with 8×10^{11} cfu to 6×10^{12} cfu with a goal to safely reach the point where the clinical anti-tumor activity of Regin-G would be clearly and unequivocally demonstrated.

The results of this latest Phase I/II study of targeted gene delivery in vivo are very encouraging— intravenous infusions of Regin-G demonstrated significant biological activity without toxicity in patients with progressive chemo-resistant pancreatic cancer. Once the overall safety record of repeated infusions of Regin-G was clearly demonstrated, the FDA approved across the board intra-patient dose-escalations (an adaptive design) to gain better tumor control. These higher doses of Regin-G were associated with stabilization of disease, using both RECIST and International PET criteria, significant reductions in CA 19.9 levels, and an increase in median overall survival (greater than 6 months) which was twice that observed in the low-dose safety study. No dose-limiting toxicity was observed, even at these higher doses of Regin-G, thus confirming that repeated infusions of Regin-G are safe and well-tolerated.

The importance of these progressive dose-escalation studies—which clearly establish safety before escalating to more potent tumoricidal levels—is of primary concern in the development of a new genetic medicine like Regin-G. Moreover, the establishment of a functional dose-response relationship is also of fundamental significance, not only in terms of basic pharmacology, but in establishing the physiological mechanisms-of-action that are of major importance in determining the predictability of a new anti-cancer agent, in establishing the optimal dose regimens for a given type of cancer, and ultimately in gaining regulatory approval for Regin-G in the United States. Taken together with the results of previous studies, the current on-going Phase I/II study confirms the exemplary safety and therapeutic potential of Regin-G, the first and so far only targeted gene delivery system shown to be safe and effective in the clinic. For more information about Regin-G, on-going clinical trials in the USA and abroad, and/or Epeius pathotropic (disease-seeking) gene delivery systems, please contact Dr. Erlinda M. Gordon at egordon@epeiusbiotech.com.