ASCO 2008: Tumor-Targeted Rexin-G Demonstrates Dose-Dependent Anti-Tumor Activity without Toxicity in Metastatic Pancreatic Cancer

SAN MARINO, Calif., May 19 (SEND2PRESS NEWSWIRE) — Epeius Biotechnologies announced today the results of an on-going Phase I/II study of Rexin-G for metastatic pancreatic cancer (Chawla et al., ASCO meeting, 2008). Continuing on with the planned dose-escalations of Rexin-G which began in 2005 using lower doses of Rexin-G in a Phase I safety study (Molecular Therapy, 2008), the current Phase I/II study employed higher dose-escalations of Rexin-G given i.v. two to three times a week for 4 weeks, beginning with 8 x 10e11 cfu to 6 x 10e12 cfu with a goal to safely reach the point where the clinical anti-tumor activity of Rexin-G would be clearly and unequivocally demonstrated.

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The results of this latest Phase I/II study of targeted gene delivery in vivo are very encouraging-intravenous infusions of Rexin-G demonstrated significant biological activity without toxicity in patients with progressive chemo-resistant pancreatic cancer. Once the overall safety record of repeated

infusions of Rexin-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 Rexin-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 Rexin-G, thus confirming that repeated infusions of Rexin-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 Rexin-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 Rexin-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 Rexin-G, the first and so far only targeted gene delivery system shown to be safe and effective in the clinic.

For more information about Rexin-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.

On the Web: www.epeiusbiotech.com.

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