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Targeted Gene Delivery *In Vivo*: Regin-G Monotherapy Reveals Significant Biological Activity Without Toxicity In Chemo-Resistant Metastatic Breast Cancer (Asco 2008)

May 22, 2008, San Marino, California—Epeius Biotechnologies announced today the promising results of an on-going United States-based Phase I/II study of Regin-G for metastatic breast cancer that is refractory to conventional chemotherapy (J Clin Oncol 26:14509, 2008). This clinical trial employed intra-patient dose-escalations of Regin-G given i.v. two to three times a week for 4 weeks, with doses ranging from 2×10^{11} cfu to 6×10^{11} cfu per week. The goal of the adaptive trial design is to confirm the over-all safety of Regin-G and to determine the optimal dosing regimen for Regin-G that would document the significant clinical benefits required to support a Phase II pivotal study.

The interim results of this 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 rapidly progressive chemo-resistant breast cancer. Once the general safety of repeated infusions of Regin-G was documented, the FDA approved across the board intra-patient dose-escalations in order to gain better tumor control. These escalating doses of Regin-G were associated with stabilization of disease, using both RECIST and International PET criteria, significant reductions in CA 15.3 levels, a median progression-free survival of 6 months (RECIST) and a median over-all survival of greater than 7 months with all patients surviving at the 8-month follow-up period. No dose-limiting toxicity was observed, even at the higher doses of Regin-G, thus confirming that repeated infusions of Regin-G are safe and well-tolerated.

According to Dr. Erlinda M. Gordon, Medical Director of Epeius “The importance of these dose-escalation studies—which clearly establish safety before escalating to more potent tumoricidal levels—is a primary concern in the development of a new genetic medicine like Regin-G.” 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 in chemotherapy-resistant metastatic breast cancer.

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.