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Phase I/II Study Of Targeted Gene Delivery *In Vivo*—Intravenous Infusions Of Rexin-G—Demonstrates Dose-Dependent Anti-Tumor Activity Without Toxicity In Patients With Progressive Chemo-Resistant Bone And Soft Tissue Sarcoma (Asco 2008)

May 29, 2008, San Marino, California—Epeius Biotechnologies (www.epeiusbiotech.com) announced today the results of an on-going Phase I/II study of Rexin-G for metastatic bone and soft tissue sarcoma (J Clin Oncol 26: 14509, 2008). Rexin-G is the first and so far only targeted gene therapy vector that has been tested in the clinic (Nature Reviews/Genetics 2007). In this open label study, cohorts of 6 to 7 patients with all types of sarcoma, including osteosarcoma, Ewing's sarcoma, leiomyosarcoma, malignant fibrous histiocytoma, chondrosarcoma, fibrosarcoma, liposarcoma, angiosarcoma, spindle cell sarcoma, and malignant mixed Mullerian tumor of ovary, were treated with 1×10^{11} cfu Rexin-G, administered i.v. over 5 minutes, 2 times a week for 4 weeks (Cumulative Dose = 8×10^{11} cfu) followed by a 2-week rest period. Patients with Grade 1 or less toxicity were given progressive intra-patient dose-escalations consisting of additional treatment cycles of 1 to 2×10^{11} cfu three times a week for 4 weeks (Cumulative Dose per cycle: 1.2-2.4 $\times 10^{12}$ cfu). These higher dosing regimens were associated with prolonged disease stabilization and a median overall survival of greater than 6 months, which was three times longer than that observed in the low-dose group. Further, histologic examination of resected tumors showed 50-90% necrosis. No dose-limiting toxicity was observed, even at the higher doses of Rexin-G, thus confirming that repeated infusions of Rexin-G are safe and well-tolerated. Taken together with previous clinical studies conducted in the Philippines and Japan, these studies confirm the exemplary safety and dose-dependent efficacy of Rexin-G in a broad spectrum of chemotherapy-resistant cancers.

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.