

# Advanced Phase I and Phase II Studies of Targeted Gene Delivery Confirm That Rexin-G Impacts Survival in Chemotherapy-resistant Bone and Soft Tissue Sarcoma (ASCO 2010)

SAN MARINO, Calif., June 1 (SEND2PRESS NEWSWIRE) – Epeius Biotechnologies Corporation ([www.epeiusbiotech.com](http://www.epeiusbiotech.com)) today announces the results of the clinical trial entitled “Advanced Phase I/II Evaluation of Tumor-Targeted Gene Delivery: Intravenous Rexin-G as Stand Alone Therapy for Chemotherapy-resistant Bone and Soft Tissue Sarcoma” at the ASCO Annual Meeting on June 8, 2010. The presentation will be discussed by Dr. Kristen N. Ganjoo, Stanford University Medical Center, Palo Alto CA.

**STUDY SUMMARY:** The goals of the study were to evaluate the over-all safety and efficacy of intravenous infusions of Rexin-G, a tumor-targeted retrovector bearing a cytotoxic anti-cyclin G1 construct, in chemotherapy-resistant bone and soft tissue sarcoma. A Phase II “run-in” component was integrated by adaptive design by continuing treatment if the patient had Grade 1 or less toxicity.

Thirty-six patients received escalating doses of Rexin-G intravenously three times a week for four weeks. Analysis of safety showed no dose-limiting toxicity and no cumulative toxicity in patients treated with Rexin-G monotherapy for up to 2 years.

Analysis of efficacy revealed a dose-dependent relationship between progression-free survival/overall survival and Rexin-G dosage ( $p = 0.02$  and  $0.002$  respectively) which was significant at the 5% statistical level by the log-rank test. Median survival was 11.5 months and one-year survival was 40% in the high-dose groups.

These findings indicate that intravenous Rexin-G is safe and well-tolerated with no cumulative toxicity, and that Rexin-G controls tumor growth, and prolongs progression-free survival and over-all survival times in a dose-dependent manner in patients with chemotherapy resistant bone and soft tissue sarcoma.

## **About Epeius Biotechnologies:**

Epeius Biotechnologies Corporation ([www.epeiusbiotech.com](http://www.epeiusbiotech.com)) is a privately held biopharmaceutical company dedicated to the advancement of genetic medicine with the development and commercialization of its lead products, Rexin-G and Reximmune-C, and its high-performance gene delivery systems.

To learn more about these agents and/or ongoing clinical trials, please contact Dr. Erlinda M. Gordon at [egordon@epeiusbiotech.com](mailto:egordon@epeiusbiotech.com).

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