

# FDA Approves the Opening of a Phase II Registration Protocol Using REXIN-G(R) for Osteosarcoma in California U.S.A.

SAN MARINO, Calif. – Nov. 5 (SEND2PRESS NEWSWIRE) – Epeius Biotechnologies Corporation announced today that the company has taken a major step toward the commercialization of its lead product with the opening of a Phase II Registration Protocol using Regin-G for osteosarcoma in the United States. Following the accelerated approval of Regin-G for the treatment of all solid tumors by the Bureau of Food and Drugs in the Philippines, Epeius opened a number of Phase I/II clinical trials in the United States for pancreatic cancer, breast cancer and all types of sarcoma in the summer of 2007.



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Based on the exceptional safety profile of Regin-G in the first 18 patients who participated in these U.S.-based clinical trials, and the profound demonstration of single agent efficacy in metastatic osteosarcoma, the FDA approved a Phase II Registration Protocol using intravenous Regin-G for recurrent or metastatic osteosarcoma that is refractory to known therapies. The study will recruit 20-30 patients in 12-18 months. Children who are at least 10 years of age or older are eligible to participate in the study. The adaptive trial design of this advanced Phase II registration protocol incorporates (i) a dosing schedule based on the patient's estimated tumor burden and not on standard dosing per kilogram body weight or body surface area, and (2) a tumor response evaluation process that is unique to the manner in which osteosarcoma responds favorably to therapy, i.e., with necrosis and increasing calcification in metastatic tumors and decreased glucose utilization using PET-CT imaging studies.

Regin-G is a tumor-targeted gene medicine that seeks out and destroys both primary tumor and metastatic cancers that have spread throughout the body. Delivered by simple intravenous infusion, Regin-G has demonstrated unprecedented single-agent efficacy against a broad spectrum of solid tumors where chemotherapy, radiotherapy and other targeted therapies have failed. With more than three years of clinical experience with Regin-G in an increasing number of otherwise intractable cancers in the Philippines, Japan and the U.S., we have gained valuable insights into the general safety, optimal dosing parameters, and best treatment regimens that provide the greatest benefits for the cancer patient without compromising safety.

The on-going clinical trials of Regin-G are centered in San Marino CA, where Epeius Biotechnologies Corporation has its headquarters, and in Santa Monica CA at the Sarcoma Oncology Center. Dr. Sant P. Chawla, M.D., who trained at the University of Texas M.D. Anderson Cancer Center, is a renowned expert on malignant sarcomas, and serves as Principal Investigator (PI) for these

clinical trials.

### **About Epeius Biotechnologies**

Epeius Biotechnologies Corporation is a privately held biopharmaceutical company dedicated to the advancement of genetic medicine with the development and commercialization of its proprietary targeted delivery systems. Credited with innovations ranging from oncogene discovery, to designer therapeutic genes, to pathotropic (disease-seeking) targeting, to high-performance vector engineering, to advanced biopharmaceutical manufacturing and bioprocess development, Epeius Biotechnologies is well positioned to “launch” its enabling platform technologies for the benefit of cancer patients worldwide. Rapid advances in clinical drug development provide Epeius with a unique opportunity for early revenues from the exportation and sale of its lead product to the Philippines and reciprocating Southeast Asian countries- thus demonstrating the high growth potential of a small biotechnology company while maintaining the lowered risk profile of a biopharmaceutical company with a high-value, late-stage product.

To learn more about Rexin-G and Epeius’ pipeline of proprietary compounds currently available for partnership or clinical trials, please visit us at [www.epeiusbiotech.com](http://www.epeiusbiotech.com).

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