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EPEIUS BIOTECHNOLOGIES' REXIN-G RECEIVES FDA FAST TRACK DESIGNATION FOR THE TREATMENT OF PANCREATIC CANCER

San Marino, Calif. – June 17, 2009 – Epeius Biotechnologies (www.epeiusbiotech.com) announced today that its lead product, Regin-G, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for use as a second-line treatment for advanced or metastatic pancreatic cancer. The FDA Fast Track program, like Priority Review and Accelerated Approval, was implemented to facilitate the development and expedite the review of potentially important new drugs. The Fast Track Product designation, in particular, is granted following a critical evaluation of the “seriousness” or life-threatening nature of the unmet medical need, namely pancreatic cancer, and the potential of Regin-G and its progressive clinical development to address this unmet need.

“This is an excellent affirmation of all that we have worked for,” says Dr. Erlinda Maria Gordon, Medical Director of Epeius Biotechnologies, “and an important validation of our medical mission.” Indeed, Regin-G is the first in an entirely new class of targeted anti-cancer agents, with a sophistication that goes well beyond a simplistic antibody. Regin-G is the flagship of tumor-targeted genetic medicine: “smart,” “stealth,” “selective” and “potent” nano-medicine that not only seeks out and accumulates in cancerous lesions that have spread throughout the body, but delivers a tumor-killing designer gene where it is needed most, selectively destroying tumor cells and their attendant blood supply, while sparing normal cells and healthy tissues. As presented at the 2009 ASCO G.I. Symposium, “*Regin-G Shrinks Metastatic Tumors and Triples Survival Time in Chemotherapy-Resistant Pancreatic Cancer*,” documenting survival benefits, without toxicity, as monotherapy, when all else fails.

The FDA’s timely decision to grant Regin-G Fast Track Product Designation is not only validating in terms of the potential of this Investigational New Drug to meet an unmet medical need, but it reflects on the design and integrity of the clinical development program of Epeius Biotechnologies. “It took years of sustained effort, but our decision to firmly establish the overall safety of repeated infusions of Regin-G in early-stage clinical trials, before we moved on to progressively higher doses, has served us well,” said Dr. Gordon. “For it was in determining the actual needs of our patients, in concordance with ongoing FDA guidance, that eventually achieved the control of tumor growth and metastasis,” she added.

Remarkably, the adaptive designs of the strategic dose-escalation studies not only served to confirm the overall safety of Regin-G and the lack of either systemic or dose-limiting toxicity, but it served to establish the critical thresholds of bioactivity and the dose-response relationships in several intractable cancers, which confirms and reveals the physiological mechanisms-of-action. These quantitative aspects of applied pharmacology are of paramount importance in establishing the clinical utility of a major new class of biological agents. Moreover, the progressive and adaptive trial designs helped to create and refine the clinical protocols for future medical praxis.

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 high-performance gene delivery systems that are embodied in Rexin-G and Reximmune-C, a tumor-targeted cancer vaccine. To learn more about ongoing clinical trials, please contact Dr. Erlinda M. Gordon at egordon@epeiusbiotech.com.

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