



CLINICAL TRIALS OPEN IN MANILA TO TEST THE WORLD'S FIRST TARGETED INJECTABLE GENE DELIVERY SYSTEM FOR TREATING METASTATIC CANCER

LOS ANGELES, Calif. and Manila, Philippines, June 3, 2003 – Epeius Biotechnologies Corporation (www.epeiusbiotech.com) today announced that clinical trials have started in Manila, testing the world's first targeted injectable gene delivery system for treating metastatic cancer, using Epeius' TDS technologies.

Doctors infuse tumor-targeted “smart” nanoparticles engineered to transport genetic medicine selectively to sabotage cancer cells and their blood supply without causing serious side effects. This year, clinical trials for deadly pancreatic cancer opened in Makati Medical Center to evaluate the safety and efficacy of bioengineered nanoparticles guided by Epeius Biotechnologies Targeted Delivery System (TDS) to seek out and deliver a designer “killer” gene to cancerous tumors.

The clinical study, led by Drs. Gerardo H. Cornelio and Conrado Lorenzo III of the Philippines combines state-of-the-art genetic medicine with a radically new delivery system that re-defines the cutting edge of cancer therapy. The first patients receiving intravenous infusions of the TDS-encapsulated genetic “bullets” responded favorably without serious side effects. This represents a momentous landmark in Philippine history: for Philippine physicians and U.S. scientists to team up as pioneers and world leaders in the advancement of genetic medicine.

Valentine's Day, 2003 marked the beginning of the gene therapy clinical trial for metastatic cancer in Manila. Three patients with advanced pancreatic cancer received infusions of the world's first targeted injectable gene therapy vector in history. The saga began with a plea for compassionate usage from a man whose wife was suffering from terminal pancreatic cancer. He had heard about a gene therapy clinical trial opening in Los Angeles, California, and hoped that his wife might be able to participate. Responding to the urgency of this request, Dr. Gordon, Medical Director, and Dr. Frederick L. Hall, President and CEO of Epeius Biotechnologies Corporation, arranged to export the Regin-G targeted vector and to open a compassionate use clinical trial in Makati Medical Center, a prestigious tertiary care hospital in Manila.

With regulatory guidance and authorization from the Philippine Bureau of Food and Drugs, a Dose-Escalation Regimen was given to each of the first two patients (to ensure Safety), followed by an Intensification Regimen (to evaluate Efficacy). In contrast to standard single-dose protocols, this innovative Dose-Escalation Regimen cautiously evaluated safety while enabling effective dosing over time. In the first patient, the combined regimens induced a significant reduction in the size of metastatic tumor nodules and shrinkage of the primary tumor without adverse side effects, thus improving and extending the patient's life beyond the predicted survival time. In the second patient, the reduction of the central tumor mass, and its retraction from major vessels, was so profound as to enable the consideration of a “curative” surgical excision of the cancerous pancreatic head, which was previously deemed inoperable.

Based on the remarkable single agent efficacy of Regin-G observed in the first two patients, a third patient was allowed to receive the initial Dose-Escalation regimen front line – prior to the standard chemotherapy – to assail and sensitize the tumors to subsequent chemotherapy. Follow-up CT scans showed a significant decrease in the size of the primary pancreatic tumor, complete eradication of more than a dozen metastatic liver nodules, and a decrease in the size of the remaining liver nodules. While the investigators remain appropriately cautious, the results are extremely promising.

The astonishing human story of compassion, perseverance, and rigorous medical research that led to the groundbreaking clinical trial in Manila is chronicled in an upcoming documentary entitled *The Holy Grail*, produced by an award-winning film director. The film depicts the mission and research collaboration established between Dr. Erlinda M. Gordon, a physician/scientist, and Dr. Frederick L. Hall, a biochemist/biophysicist, who together, against all odds, undertook enormous scientific and medical challenges to produce what Dr. Hall unassumingly refers to as “the accomplishment of a generation of physician/scientists, for the benefit of cancer patients that conventional medicine has failed”.

The “cancer killing” designer gene within the targeted vector, designated Regin-G, is a genetically altered (mutant) form of the human Cyclin-G1 gene, a growth-associated cell cycle control element that was first isolated by Dr. Hall and his co-workers in 1994. Cyclin-G1 is a prospective oncogene that favors the development of many types of cancer, including pancreatic, colon, breast and prostate cancer, as well as bone and soft tissue tumors. To sabotage their cell cycle and destroy the cancer cells, Dr. Hall engineered a mutant form of Cyclin-G1 that, when translated into protein, blocks the essential function of this growth control element. Further studies revealed that tumor-associated angiogenesis, i.e., the new blood supply that feeds the growing tumors, is also vulnerable to Cyclin-G1 knockout.

A built-in safety feature of Regin-G is that it only affects rapidly dividing cells, that is, cancer cells and their attendant blood supply, thus selectively killing only the tumor cells while sparing the normal cells and tissues of the body. Therefore, it is not expected to cause untoward systemic toxicity such as hair loss, nausea and vomiting, bone marrow suppression, liver, kidney or any organ damage. This aspect of Regin-G enhances the quality of life of cancer patients, in addition to its obvious desirable effects of arresting, reducing, and/or eliminating the cancer.

ABOUT EPEIUS: The mission of Epeius Biotechnologies is to develop and commercialize the first truly effective targeted delivery system (TDS) that can be injected directly into a vein to deliver genes and/or molecular therapeutics preferentially to cancerous tumors that have spread throughout the body (metastatic cancer), without eliciting systemic side effects or organ damage. These features make the targeted vectors more effective and less toxic than conventional medicines. The lead product, Regin-G, is the first tumor-targeted injectable gene therapy vector that has been approved by both the U.S. FDA and the Philippine BFAD for use in Phase I/II cancer clinical trials.

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