



C O P E R N I C U S T H E R A P E U T I C S , I N C .

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For Immediate Release

Copernicus Presents Progress in the Development of its Non-Viral Gene Transfer Aerosol Product for Treating Patients with Cystic Fibrosis

Minneapolis, MN, June 8, 2004 – Copernicus Therapeutics, Inc. presented data at the 7th Annual Meeting of the American Society of Gene Therapy showing that compacted DNA nanoparticles can be successfully formulated as aerosol mists suitable for treating the lungs of cystic fibrosis (CF) patients, that compacted DNA can be repetitively dosed in animals without any fall off in effectiveness, and that there is no significant size limitation to the DNA drug payload its nanoparticle technology can deliver.

“Copernicus has developed compacted DNA nanoparticles that are highly active gene delivery systems to the airway cells of animals and humans, and which are stable after formulation as aerosol mists,” said Mark J. Cooper, M.D., Senior VP of Science and Medical Affairs at Copernicus. “Our recently completed clinical trial in CF subjects indicated that our DNA drug was safe and very encouraging gene transfer and expression results were observed in the majority of subjects. Replacement of a normal copy of the CF gene in the lung cells of CF patients is predicted to stabilize and potentially improve some of the devastating lung complications of this disease. We now have shown that DNA nanoparticles retain full structural integrity and biological activity when formulated as aerosol mists suitable for efficient lung dosing. In addition, data were presented showing that compacted DNA nanoparticles can be multiply dosed to the lungs of mice without any decrease in gene expression. These important studies will accelerate the timeline for initiation of our planned study in CF patients using an aerosol mist of DNA nanoparticles for pulmonary delivery of a normal replacement copy of the CF gene.”

Also presented at the ASGT meeting were results indicating that the Copernicus formulation of compacted DNA can effectively deliver and express payload DNAs of large sizes to the lungs of mice. These data indicate no significant DNA size limitation for this gene transfer technology, and these findings will further extend the product indications for this breakthrough technology.

“We are quite pleased with our clinical trial results and drug development programs,” said Robert C. Moen, M.D., Ph.D., President and CEO of Copernicus. “Our non-viral gene delivery system appears to be safe and effective, and both animal and human studies show no evidence for immune recognition of our complexes or the induction of a significant inflammatory response. These important results suggest that our DNA drugs could be repetitively administered as needed to CF patients throughout their lives, and thus may provide a unique therapy to correct the underlying cause of this devastating lung disease. Additional clinical trials will, of course, need

to be conducted before final FDA approval of a marketed product. As a physician, it is very exciting to see the continued rapid and steady progress towards the goal of treating the root cause of CF. We expect that developing a therapy for CF is just the first of many important therapeutic products that we will develop”

Cystic Fibrosis is the most common genetic disease in the Caucasian population of North America and Europe, affecting an estimated 70,000 people. The defective gene results in a thick, tenacious mucus that blocks lung passages and provides an environment for recurrent lung infections, leading to permanent lung damage and respiratory failure. The median lifespan of persons with CF is now thirty-three years. Current therapies are designed to treat the symptoms of the underlying disease but not the root cause, which is the goal of the Copernicus program.

Copernicus Therapeutics, Inc., a privately held biotechnology company, is advancing novel targeting and delivery systems with broad applications in human therapeutics, DNA vaccines, and functional genomics. Copernicus’ technologies include a targeting platform enabling the efficient uptake of drugs by specific cells and tissues, and a multi-component delivery platform that can be applied to nucleic acids to develop therapies for a variety of human diseases. The Company’s targeting, delivery, and expression platforms are complementary and can be combined to enhance the efficacy and safety of existing drugs, to create novel therapeutics, and to speed up the drug discovery process. Additional information about Copernicus is available at <http://www.copernicustherapeutics.com>

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