



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 Non-Viral Gene Transfer System is Non-Toxic and Non-Immunogenic *Chronic Administration of DNA Drugs Is Feasible*

Cleveland, OH June 12, 2002 – Copernicus Therapeutics, Inc. presented data at the American Society of Gene Therapy meeting showing that their compacted DNA formulation is non-toxic and non-inflammatory in mice following an intrapulmonary dose.

Mark J. Cooper, M.D., Senior Vice President of Science and Medical Affairs said, “As part of our IND-directed studies, Copernicus has extensively evaluated our formulation of compacted DNA nanoparticles for safety and efficacy following an intrapulmonary dose. As also presented at the meeting, compacted DNA nanoparticles efficiently introduce DNA into airway epithelial cells. We now report that compacted DNA is non-toxic in out-sourced GLP toxicity studies. In collaborative studies with Drs. Pamela Davis and Assem Ziady of Case Western Reserve University and University Hospitals of Cleveland, only minor changes in cytokine levels were observed in bronchial alveolar lining fluid or serum following an intrapulmonary dose. Importantly, compacted DNA does not induce an immune response to the gene transfer reagent, permitting biologically robust gene expression in animals that have received multiple prior doses of the complexes. These results provide part of the background and rationale for using these complexes in an ongoing human clinical trial in subjects with cystic fibrosis. These new findings suggest that compacted DNA may be safe in the setting of chronic administration, providing a pharmaceutically-relevant gene transfer composition.”

“Copernicus has established platform gene transfer and expression technologies that are effective and safe,” said Robert C. Moen, M.D., Ph.D., President and CEO of Copernicus. “Compaction of single molecules of DNA produces a gene transfer system that is stable in serum, permits targeting and uptake by specific cell types, traffics effectively in the cell, and crosses the intact nuclear membrane. The modular design of our technology gives us the flexibility to co-develop gene therapies for a variety of clinical indications, including cystic fibrosis and hemophilia.”

Copernicus Therapeutics, Inc. is advancing novel targeting and delivery systems with broad applications in human therapeutics and vaccines. Copernicus' technologies include a multi-component delivery platform that can be applied to nucleic acids to develop therapies for a variety of human diseases and a targeting platform enabling the efficient uptake of drugs by specific cells and tissues. The Company's targeting and delivery platforms are complementary and can be combined to enhance the efficacy and safety of existing drugs or to create novel therapeutics.

Founded in 1843, the Case Western Reserve University School of Medicine is the largest medical research institution in Ohio and the 14th largest among the nation's medical schools for research funding from the National Institutes of Health. Seven Nobel Laureates have been affiliated with the school. The School of Medicine is recognized throughout the international medical community for outstanding achievements in research, teaching and service. Annually, the School of Medicine trains more than 600 M.D. and M.D./Ph.D. students.

University Hospitals Health System (UHHS) is the region's premier healthcare delivery system, serving patients at more than 150 locations throughout northern Ohio. The System's 947-bed, tertiary medical center, University Hospitals of Cleveland (UHC), is the primary affiliate of Case Western Reserve University. Together, they form the

largest center for biomedical research in the State of Ohio. The System provides the major clinical base for translational researchers at The Research Institute of University Hospitals of Cleveland, as well as a broad and well-characterized patient population for clinical trials involving the most advanced treatments. Included in UHC are Rainbow Babies & Children's Hospital, among the nation's best children's hospitals; Ireland Cancer Center, northern Ohio's only National Cancer Institute-designated Comprehensive Cancer Center (the nation's highest designation); and MacDonald Women's Hospital, Ohio's only hospital for women.

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