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**Cato Research Presents at OMICS Group Conference,
4th International Conference on Pharmaceutical Regulatory Affairs**

Durham, NC, September 9, 2014 — Cato Research regulatory expert William Lee, Ph.D., R.A.C., Vice President of Regulatory Affairs at Cato Research, will present in Raleigh, North Carolina at the OMICS Group Conference, 4th International Conference on Pharmaceutical Regulatory Affairs.

Dr. Lee's presentation is titled: " Regulatory Roadmap For Initiating a Cell Therapy Drug into Clinical Trials in the US"

Abstract of Presentation:

> Exciting progress has been made in the development of cell therapy, and experimental research has brought forward novel treatment opportunities for immune cell therapies, stem cell therapies, and gene-modified cell therapies. Clinical development of a cell therapy drug is challenging, requiring understanding of controlled manufacturing, relevant nonclinical pharmacology and safety studies, and clinical risk factors. For initiating clinical trials in the United States, regulatory requirements for investigational cell therapy drugs are more stringent than those with other investigational drugs. This talk will highlight these requirements, including submissions to regulatory authorities and the required non-clinical studies.

Dr. William Lee received his B.A. from The Johns Hopkins University and his Ph.D. from Cornell University Graduate School of Medical Sciences. Dr. Lee has 20 years of research and industry experience. His focus is on gene therapy with retroviral vectors, adeno-associated viral vectors, and DNA vectors. He spent 9 years at the gene therapy start-up firm Viagene, Inc., followed by 2 years at Chiron. In 1999, he joined Cato

Research, in Durham, North Carolina, where he is currently Vice President, Regulatory Affairs. His projects have included the design of Phase 1 and Phase 2 protocols for a gene therapy drug and interactions with the FDA and NIH/OBA. Currently, he manages projects involving regulatory strategy and submissions of investigational new drug applications and marketing applications for biologics and drugs.

For more information about this event, please visit:
http://www.cato.com/events.shtml

About Cato Research

Founded in 1988 by Dr. Allen Cato and Lynda Sutton and headquartered near Research Triangle Park, North Carolina, Cato Research is a full-service, global contract research and development organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, and medical device industries. Services range from design and management of preclinical and clinical studies to submission of regulatory documents required for marketing approval. With a staff of approximately 300 and offices located in the United States, Europe, Canada, Israel, and South Africa, the Cato Research team consistently demonstrates an unsurpassed level of responsiveness, flexibility, attention to detail, and passion for bringing their clients' products to market with speed and cost-effectiveness.

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