Renowned Cancer Researcher Dan Von Hoff, M.D. Advocates for 'The Lost Opportunity in Phase I Oncology Trials'

Renowned oncology researcher Dr. Daniel Von Hoff, a member of President Bush's National Cancer Advisory Board, provides an in-depth look at the "lost opportunity" in phase I oncology clinical trials. While most biotechnology companies use the phase I trial to evaluate a drug's toxicity and tolerability, Dr. Von Hoff advocates that it can also provide valuable efficacy data and a compelling rationale for further study and investment, which ultimately lead to improved patient care. The complete interview is available for download from Medelis, an oncology contract research organization providing worldwide oncology clinical trial design, management and execution.

Phoenix, Arizona (PRWEB) December 22, 2008 -- Cancer drug developers traditionally use the phase I trial solely to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of a drug. Today, Medelis, Inc., an oncology contract research organization, has published a free downloadable abstract, "The Lost Opportunity in Phase I Oncology Trials," an interview with renowned oncology investigator Daniel D. Von Hoff, M.D., who advocates for a phase I approach that looks beyond toxicity and gleans meaningful efficacy data, creating a more compelling rationale for further investment and improved patient care.

"A Chief Medical Officer looking at the phase I typically sees it as a toxicity trial, not a therapeutic trial, because of course it is not randomized," Dr. Von Hoff explains. "But we - doctors at the bedside and the patients themselves - do not see it that way. We are looking for improvement and survival."

Dr. Von Hoff supports an additional analysis that uses a cancer patient as his or her own control. Rather than solely relying on the traditional data captured in normal phase I clinical trial protocols, he recommends measuring the tumor's "time to progression" on the current drug versus the tumor's "time to progression" on the patient's previous treatment. This data -- time to progression on each drug -- should be systematically tracked in the protocol so it becomes part of each patient's data bank.

"I have never seen a Chief Medical Officer plot time on a new drug versus the time on a just-prior therapy to build a story for raising money," Dr. Von Hoff continues. "This idea of using the patient as his or her own control is a lost concept in drug development. Dr. Bob Temple at the FDA, an icon in clinical trial design, calls it a lost art. He's referring to the ability to document changes in the natural history of a patient's tumor, and how this information can give you a sense of whether the drug will work."

"If you treat 30 patients and 30% stay on a new therapy for a longer time than the just-prior drug they had progressed on, then that would justify a deeper investment," he explains. "Patients' tumors grow at an inexorable, ever-quickening rate. If you find an agent that can taper that growth, then it is probably doing something and should be pursued."

In the abstract, Dr. Von Hoff answers many questions about this "lost art" in the phase I oncology clinical trial:
* The distinction between "time on therapy" and "time to progression";
* Why CMOs should place greater value on this data;
* Why the practice isn't more common;
* How to leverage the clinical investigator's observations and clinical judgment in the analysis of a treatment;
* Why the subjective nature of this approach benefits patients and drug developers alike;
* Why time to progression should be included in the trial protocol so it becomes part of each patient's data bank;
* How to appropriately incorporate efficacy into the story you tell to sponsors and investors when raising money;
* When to invest more deeply in a new therapy based on this data.

A member of President Bush's National Cancer Advisory Board, Dr. Von Hoff's major interest is in the development of new anticancer agents both in the clinic and in the laboratory. His laboratory interests and contributions have been in the area of in vitro drug sensitivity testing to individualize treatment for the patient. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies with a focus on pancreatic cancer.

Dr. Von Hoff currently serves as Senior Investigator and Head of Translational Research at the Translational Genomics Research Institute's (TGen) Translational Drug Development Division and Head, Pancreatic Cancer Research Program in Phoenix, Arizona. He also serves as Chief Scientific Officer for U.S. Oncology and the Scottsdale Clinical Research Institute and is a founding shareholder and chair of the medical advisory board of Medelis.

The abstract is the fourth in Medelis' complimentary "Peer Perspectives in Oncology" Q&A series, which brings together respected researchers to discuss issues that face Chief Medical Officers today: rising costs, optimum patient accrual, targeted therapeutics, patient safety, FDA regulations, efficacy, budgets, and timelines.

The abstract is available for download at Medelis.com.

About Medelis, Inc.

Medelis is an oncology contract research organization providing a total solution for biotechnology and pharmaceutical companies seeking rapid drug development and approval. Medelis' medical founders, clinical trial management physicians and advisory board members, including Dan Von Hoff, James Gourzis and Michael Gordon, are internationally-recognized oncology thought and opinion leaders who understand the future of personalized medicine and threshold of credibility trials. Offerings include strategic plans for regulatory approval from phase I through NDA and complete oncology clinical trial design, management and execution.

Medelis is privately-held and located in Phoenix, Arizona with other U.S. locations in Nashville, Boston and Reno. Medelis Europe, which also delivers complete oncology drug development services from preclinical through marketing approval, is headquartered in Port Vendres, France.

###
Contact Information
Bob Bosserman
Medelis, Inc.
http://www.medelis.com
1-602-840-1101

Online Web 2.0 Version
You can read the online version of this press release here.