ZIOPHARM CEO Jonathan J. Lewis Calls For Faster Cancer Drug Development

Drug Candidates Linger Too Long In Irrelevant Animal Studies; Decision To Ditch A Molecule Needs To Come Much Quicker

NEW YORK, NY MAY 5 - New cancer treatments could be developed faster and cheaper if outdated study strategies were replaced with more relevant science-based methods designed to facilitate faster decisions.

In today's invited lecture (May 6th-Melbourne, Australia time) to the 2004 Annual Scientific Congress of the Royal Australasian College of Surgeons (May 2-7), Jonathan J. Lewis, MD, PhD, a leading cancer researcher who pioneered new cancer treatments at Yale University School of Medicine and Memorial Sloan-Kettering Cancer Center, said clinical trial design has become the single most deficient aspect of new drug development.

"The methods by which we clinically develop drug candidates are dismally out of step with the tremendous progress in basic science and our ability to discover promising new compounds," Dr. Lewis said.

"The issues are cost and time. The current approach results in clinical strategies that prolong the time it takes to get a possible 'yes' answer," he continued. "Instead, we need to shorten the time it takes to produce a 'no.' The ability to quickly rule out unpromising compounds or ill-conceived indications could cut 50 percent or more off the typical time and money devoted to cancer drug development."

Dr. Lewis, who has authored myriad cancer papers, said the low productivity of cancer research dollars is partially evidenced by statistics compiled by the US Dept of Health & Human Services which show deaths from cancer dropped 5.3 percent between 1995 and 2002, while heart disease mortality decreased 14.4 percent during the same period.

Dr. Lewis told the audience that way too much time is spent testing cancer candidates in animal models that are neither relevant nor predictive of a molecule's behavior against cancer in humans. He said early human trials should be designed to quickly lead to one of three conclusions: (1) stop development; (2) modify the molecule; or (3) move the molecule directly into larger verification trials.

He called for "high throughput" clinical trials that (1) get to "no" quickly; (2) utilize Bayesian statistics; (3) employ a homogeneous population; (4) specify surrogate endpoints; and (5) end with dispassionate evaluation.

"Clinicians need to become smarter at narrowing indications and using genotyping to zero in on treatable populations," Dr. Lewis said. "If there's one thing everyone knows by now, it's that no one drug works against all cancers in all people," he added. "We have to rigorously build that simple notion into trial design - it's the most productive change we can make to remedy the trickling rate of progress and high costs of creating more effective weapons against cancer." Dr. Lewis cited the push by the National Institutes of Health to employ translational research as a very important step in improving the speed and economics of cancer drug development.

Dr. Lewis was a member of the executive committee of Antigenics, Inc., New York, and served as the company's chief medical officer until last year when he became a founder and chief executive officer of ZIOPHARM, Inc.

About ZIOPHARM, Inc.

ZIOPHARM, Inc. is a privately held company founded in January 2004 to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer therapies. All products are focused on addressing unmet medical needs, with the potential for expedited approval and broad usage. For more information, please visit www.ziopharm.com