

EARLY STUDIES WITH MOLECULAR TEST SHOW THAT SPECIFIC GENE PATTERNS ARE LINKED TO RESPONSE TO TREATMENT WITH POTENT EGFR DRUG IN PATIENTS WITH ADVANCED LUNG CANCER

CHICAGO, IL - June 2, 2003 – As researchers discover more about the role that genes play in the development of cancer, they've learned that no two people's cancer is exactly alike. In that light, their biggest challenge is to find the most effective drug to treat an individual patient. New drugs that directly target the molecular switches turned on in cancer may ultimately offer patients the most personalized and effective medicine. But despite their promise, not all patients respond to these drugs, pointing to the need for a test to identify patients who will benefit from targeted therapies based on the genomics of their tumor.

Now, researchers at Cedars-Sinai Medical Center report that a molecular test was used to identify a panel of genes that correlated with tumor response to gefitinib or Iressa™, a drug developed by AstraZeneca and recently approved by the FDA, that shrinks tumors in 10-12 percent of patients with advanced lung cancer. Their early findings, presented at the 39th annual meeting of the American Society of Clinical Oncology in Chicago, may ultimately lead to a new way of selecting patients who will respond to particular therapies.

“Having a test that indicates whether a patient will or won't respond to a given therapy, will ultimately enable us to offer our patients the most appropriate treatment,” said Ronald Natale, M.D., Acting Medical Director of the Cedars-Sinai Comprehensive Cancer Center. “Patient selection will ultimately increase the chances that individual patients will respond to a specific therapy.”

The test, developed by Genomic Health, Inc., involves the use of fixed or stored tumor tissue samples embedded in paraffin wax (FPET). It was used to examine the expression of 185 genes associated with the epidermal growth factor receptor (EGFR) – a key growth signaling pathway in cancer and the target of gefitinib.

“This method of examining genes provides us with a basic road map of the genes involved in the EGFR pathway, so that we can see which genes are in the `on' position and which are in the `off' position,” said David Agus, Research Director of the Louis Warschaw Prostate Cancer Center at Cedars-Sinai Medical Center.

In this study, the researchers used FPET to evaluate tumor samples from 39 patients with non-small cell lung cancer prior to treatment with gefitinib. From these tumor samples, they were able to profile a total of 185 genes, which were identified based on involvement with the EGFR pathway as

confirmed in the scientific literature. The investigators found several patterns of gene expression or 'on-off' patterns, which correlated to either a response, or a lack of clinical benefit. (Cedars-Sinai IRB No. EX-1182)

“We saw several patterns or clusters of genes associated with each type of lung cancer, confirming the molecular differences between types of lung cancer,” said Dr. Natale.

Among the 39 patient tumors analyzed using FPET, the investigators found that seven patients responded to treatment with gefitinib, which directly correlated with a distinct pattern of genes. In addition, the investigators identified a unique pattern of genes that directly correlated with the 32 patients who failed to respond to treatment with gefitinib.

“Knowing the genetic profile of patients who will respond to gefitinib will enable us to identify more patients who will respond to the therapy,” said Dr. Agus.

Further multicenter clinical trials are necessary to confirm these early findings. Genomic tumor profiling is not yet commercially available for patients with cancer.

Cedars-Sinai Medical Center is one of the largest non-profit academic medical centers in the Western United States. For the fifth straight two-year period, Cedars-Sinai has been named Southern California's gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. Named one of the 100 “Most Wired” hospitals in health care in 2001, the Medical Center ranks among the top 10 non-university hospitals in the nation for its research activities.

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