NCI/FDA lung cancer workshop leads to the innovatively designed clinical trials

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The recent launch of two clinical trials offer innovative study designs for patients with lung cancer. These clinical trials are the direct result of a National Cancer Institute (NCI) sponsored workshop chaired by Drs. Fred R. Hirsch, Shakun Malik and Claudio Dansky- Ullman, that brought together the NCI Thoracic Malignancies Steering Committee, the US Food and Drug Administration (FDA), academicians, clinicians as well as industry and government stakeholders to discuss issues and challenges related to clinical trial design and biomarkers for lung cancer targeted-therapies.

The purpose of the NCI/FDA workshop was to collaboratively design a high priority biomarker-driven clinical trial that could expeditiously evaluate the clinical utility of a targeted-therapy in a molecularly defined lung cancer population and aid in data collection needed for regulatory approval. The workshop, whose consensus report appears in the October issue of the *Journal of Thoracic Oncology*, the official journal of the International Association for the Study of Lung Cancer (IASLC), discussed the types of biomarkers (prognostic vs predictive), the various clinical trial designs that can be employed with predictive biomarkers as well as primary endpoints for clinical trials. Also discussed were the regulatory challenges related to drug development, biomarker and biomarker assay development, trial design, and the amount of data needed for approval of both drugs and in vitro diagnostics. The attendees agreed that "in order to accelerate development of biomarker-driven trials it is critical to enhance coordination between pharmaceutical industries, FDA, academic and community-based clinical investigators,

NCI, and patient organizations with the intention to enhance collaboration between these organizations, bring forward new drugs much more rapidly for approval and ultimately improving long-term outcomes for patients"

The Lung Cancer Master Protocol (Lung-MAP) clinical trial for patients with advanced lung squamous cell carcinoma was launched in June 2014. This trial is a public-private collaboration between NCI, the "Friends of Cancer" organization led by Dr. Ellen Sigal, the Southwest Oncology Group (SWOG) thoracic oncology committee led by Dr. David Gandara, Foundation Medicine, the Foundation for the National Institutes of Health, and five pharmaceutical companies (Amgen, Genentech, Pfizer, AstraZeneca, and AstraZeneca's global biologics R&D arm, MedImmune). Dr. Roy Herbst is chairing the overall steering committee and Dr. Vassiliki Papadimitrakopoulou is the overall principle investigator (PI). Patients are screened using a comprehensive genomic profiling platform that examines over 200 cancer-related genes for genomic alterations and then based on the results of this screening, patients are assigned to one of five sub-studies testing different investigational regimens best suited for their genomic profile. This innovative approach improves a patient's likelihood of receiving a drug that will work for them while allowing for new therapies in development to be added as the trial progresses.

ALCHEMIST (Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial) launched in August 2014 and is an integrated research effort with 3 component trials for early stage non-squamous lung cancer that has been surgically resected. In the screening component trial eligible patients will have their tumor tissue tested for EGFR mutations and ALK rearrangements initially and possibly hundreds of other genomic abnormalities at disease recurrence. Those positive for EGFR mutations or ALK rearrangements will be referred to one of the treatment trials and those negative will be followed for 5

years. All patients contribute information to the national public resource for research. The Alliance for Clinical Trials in Oncology is the lead coordinating center for both the screening component (PI Dr. Pasi Jänne) and EGFR inhibitor treatment (PI Dr. Ramaswamy Govindan). Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group is the coordinating center for the ALK inhibitor treatment component (PI Dr. David Gerber).

"The concept of a "Master protocol" in lung cancer is unique for rapid identification of active drugs and a rapid pathway to drug approval based on predetermined efficacy parameters. It is a unique public-private partnership, which rapidly should lead to offering the many desperate lung cancer patients a long awaited hope", says Dr. Hirsch chair for the workshop and Chief Executive Officer of the IASLC. He adds "the Master Protocol concept is now a role model for other tumor types, such as colorectal cancer, where similar trials are planned".

Provided by International Association for the Study of Lung Cancer

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