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Alliance, NCI Networks Launch Integrated Lung Cancer Trials Called ALCHEMIST

Trials to screen for uncommon genetic features in patients with early-stage lung cancer and help determine better treatment options for patients

The **Alliance for Clinical Trials in Oncology**, in conjunction with the National Cancer Institute (NCI) and ECOG-ACRIN Cancer Research Group, today launched the **A**djuvant **L**ung **C**ancer Enric**h**m**e**nt **M**arker **I**dentification and **S**equencing **T**rials, or **ALCHEMIST** – three trials to identify patients with early-stage lung cancer who have tumors that contain uncommon genetic changes and evaluate whether drug treatments aimed at those changes can improve their survival. As lead network group, the **Alliance** will coordinate two of the three trials, including the ALCHEMIST screening trial and the adjuvant treatment trial for patients with epidermal growth factor receptor (EGFR) mutations. All of the NCI-supported National Clinical Trials Network (NCTN) groups are participating in the trials.

The three trials of ALCHEMIST are:

ALCHEMIST - Screening component (A151216)
Coordinated by the Alliance | Principal Investigators: Pasi A. Jänne, MD, PhD and Geoffrey Oxnard, MD, Dana-Farber Cancer Institute, Boston.
http://www.cancer.gov/clinicaltrials/NCT02194738

ALCHEMIST - EGFR Treatment component (A081105)
Coordinated by the Alliance | Principal Investigator: Ramaswamy Govindan, MD, Washington University, St. Louis.
http://www.cancer.gov/clinicaltrials/NCT02193282

ALCHEMIST - ALK Treatment component (E4512)
Coordinated by ECOG-ACRIN | Principal Investigator: David Gerber, MD, University of Texas Southwestern Medical Center at Dallas.
http://www.cancer.gov/clinicaltrials/NCT02201992

Participants enrolled in ALCHEMIST need to have been diagnosed with lung adenocarcinoma or other types of non-squamous, non-small cell lung cancer (or NSCLC), and must be planning to undergo surgery or have already undergone surgical removal of their tumors.

In the ALCHEMIST screening trial, tissue from the participant's surgical resection will be tested in a central laboratory for genetic changes in two specific genes – EGFR and anaplastic lymphoma kinase (ALK). Participants with tumors found to contain EGFR mutations or rearrangement in the ALK gene will then be referred to one of the two randomized, placebo-controlled treatment trials evaluating specific drugs targeted against these genetic alterations, erlotinib and crizotinib, respectively. These drugs have been approved by the U.S. Food and Drug Administration (FDA) in the treatment of advanced non-small cell lung cancer in patients whose tumors contain the targeted molecular alterations; however, it is not known if these drugs will be beneficial for patients with early-stage disease. Those participants that receive standard therapy after their surgery (consisting of chemotherapy with or without radiation therapy, as prescribed by their treating physicians) will complete the therapy prior to participating in the ALCHEMIST treatment trials. At the conclusion of the treatment trials, statisticians will analyze the survival benefit of patients who received the additional targeted drug therapy to patient who received standard therapy alone.

"We are excited to participate in this ambitious undertaking led by the Alliance, in collaboration with the NCI and NCTN," said Geoffrey Oxnard, MD, co-principal investigator of the screening component (A151216). "Through this large scale collaborative effort to genotype thousands of early-stage lung cancer patients, ALCHEMIST allows us to test better adjuvant treatments while simultaneously teaching us important lessons about the genetic complexity of lung cancer."

Approximately 10 percent of patients in the U.S. with non-squamous NSCLC will have tumors with alterations in the EGFR gene and five percent will have alterations in the ALK gene. ALCHEMIST will screen about 6,000 to 8,000 potential participants at hundreds of sites across

the U.S. over five to six years in order to identify those with EGFR and ALK alterations that would be eligible for the treatment trial, resulting in about 800 patients being enrolled in the two ALCHEMIST treatment trials. All screened participants, irrespective of the marker (EGFR, ALK) status of their tumors, will be followed for a period of five years in the screening trial.

"If molecularly targeted drugs for EGFR and ALK prolong patient survival in the adjuvant setting, ALCHEMIST participants will be among the first lung cancer patients to benefit from the addition of a molecularly targeted lung cancer treatment following potentially curative surgical resection," said Ramaswamy Govindan, MD, principal investigator of the EGFR treatment component (A081105). "This will also provide infrastructure to test other emerging targeted therapies in appropriately selected patients with completely resected lung cancer."

For NCTN members interested in more information and participating in **ALCHEMIST** trials, visit the NCI Cancer Trials Support Unit (CTSU) website at http://www.ctsu.org or on the *Alliance Featured Trials* page, https://www.allianceforclinicaltrialsinoncology.org/main/public/standard.xhtml?path=%2FPublic%2FAlliance-Feature. Also for additional information, visit http://www.cancer.gov/newscenter/newsfromnci/2014/ALCHEMISTlaunchQandA and http://www.cancer.gov/newscenter/newsfromnci/2014/ALCHEMISTlaunch/?cid=EBalchemistalliance_pr

ALCHEMIST involves significant collaborations with biotechnology and pharmaceutical partners as well. Central laboratory testing for EGFR gene mutations and for the ALK gene rearrangement will be performed by Response Genetics, Inc., Los Angeles. For the ALCHEMIST treatment trials, Pfizer, New York City, will be providing crizotinib under a Clinical Trials Agreement with the ECOG-ACRIN Cancer Research Group and Astellas Pharma US, Inc., Northbrook, Illinois, will be providing erlotinib under a Cooperative Research and Development Agreement with NCI for the clinical development of erlotinib.

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ABOUT ALLIANCE

The Alliance for Clinical Trials in Oncology comprise nearly 10,000 cancer specialists at hospitals, medical centers and community clinics across the United States and Canada. Through collaboration with the NCI National Clinical Trials Network (NCTN), the Alliance develops and conducts clinical trials with promising new cancer therapies, and utilizes the best science to develop optimal treatment and prevention strategies for cancer, as well as research methods to alleviate side effects of cancer and cancer treatments. To learn more about the Alliance, visit http://www.allianceforclinicaltrialsinoncology.org.