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## Groundbreaking Collaborative Clinical Trial Launched

### The Lung-MAP trial uses a multi-drug, targeted screening approach to match patients with promising new cancer treatments based on their unique tumor profiles

BETHESDA, Md., June 16, 2014 /PRNewswire/ -- A unique public-private collaboration among the National Cancer Institute (NCI), part of the National Institutes of Health, SWOG Cancer Research, Friends of Cancer Research (*Friends*), the Foundation for the National Institutes of Health (FNIH), five pharmaceutical companies (Amgen, Genentech, Pfizer, AstraZeneca, and AstraZeneca's global biologics R&D arm, MedImmune), and Foundation Medicine today announced the initiation of the Lung Cancer Master Protocol (**Lung-MAP**) trial.

Lung-MAP is a multi-drug, multi-arm, biomarker-driven clinical trial for patients with advanced squamous cell lung cancer. Squamous cell carcinoma represents about a quarter of all lung cancer diagnoses, but there are currently few treatment options beyond surgery for the disease. The trial will use genomic profiling to match patients to one of several different investigational treatments that are designed to target the genomic alterations found to be driving the growth of their cancer. This innovative approach to clinical testing should both improve access to promising drugs for patients and ease the significant recruitment and infrastructure burdens on researchers involved in traditional clinical trials.

"This diverse, collaborative approach, with support from leading lung cancer advocacy organizations, helps to ensure that the needs of patients, clinicians, developers, and regulators are all considered in the design and operation of the trial," said Dr. Ellen Sigal, Chair & Founder of Friends of Cancer Research.

The trial will initially test five experimental drugs—four targeted therapies and an anti-PD-L1 immunotherapy. It is anticipated that between 500 and 1000 patients will be screened per year for over 200 cancer-related genes for genomic alterations. The results of this test will be used to assign each patient to the trial arm that is best matched to their tumor's genomic profile.

"Lung-MAP represents the first of several planned large, genomically-driven treatment trials that will be conducted by NCI's newly formed National Clinical Trials Network (NCTN)," said Jeff Abrams, M.D., Associate Director of NCI's Cancer Therapy Evaluation Program. "The restructuring and consolidation of NCI's large trial treatment program, resulting in the formation of the NCTN, is quite timely, as it now can offer an ideal platform for bringing the benefits of more precise molecular diagnostics to cancer patients in communities large and small."

"Squamous cell lung cancer, like many other neoplasms, is increasingly recognized as consisting of a host of relatively rare genomic subsets, each of which may require treatment with a different targeted drug," said Dr. Charles Blanke, Chair of SWOG Cancer Research. "The Lung-MAP S1400 trial models a way to efficiently study a large number of these rare squamous cell subsets under one master protocol."

Lung-MAP aims to establish a model of clinical testing that more efficiently meets the needs of both patients and drug developers. Whereas a typical clinical trial for a targeted therapy tests each potential patient for a single biomarker and enrolls only a portion—sometimes a very small portion—of patients tested, Lung-MAP will simultaneously test patients for many biomarkers including selected base substitutions and small in/dels, gene fusions, and amplifications in order to assess compatibility with several different experimental treatments. All patients tested will then be enrolled into one of Lung-MAP's five trial arms.

"Traditional clinical trials have long imposed significant recruitment and infrastructure burdens on researchers and patients, with frustratingly slow results," said Maria Freire, Ph.D., President and Executive Director of the FNIH. "This master protocol will allow multiple enrollees to be tested once and assigned to a treatment most likely to work for them, rather than separate tests for separate trials with most patients ineligible. This strategy will validate biomarkers and facilitate drug development in one infrastructure, to more rapidly provide safer and more effective treatments to patients."

Lung-MAP will make it easier for patients and researchers to find one another. It will also be more flexible than traditional clinical trial models. Where typical clinical trials require the development of new protocols for each new drug tested, Lung-MAP uses a single "master protocol," which can be amended as needed as drugs enter and exit the trial, preserving infrastructure and patient outreach efforts.

The trial will be conducted at over 200 medical centers by NCI's NCTN, led by SWOG, and partly funded by NCI through its

Cancer Therapy Evaluation Program. Significant additional funding will be provided by the participating companies as part of a partnership managed by FNIH that also involves the Food and Drug Administration (FDA), *Friends*, and other patient advocacy organizations. The trial infrastructure is capable of testing as many as 5-7 additional drugs over the next 5 years, and will cost up to \$160 million.

In addition to the individuals quoted above, key members of the Lung-MAP trial leadership also include: David Gandara, Chair, Lung Committee, SWOG and director The Thoracic Oncology Program at UC Davis Cancer Center; Roy Herbst, Ensign Professor of Medicine and Chief of Medical Oncology at Yale Cancer Center; Vali Papadimitrakopoulou, Professor, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson; and David Wholley, Executive Director, The Biomarkers Consortium, FNIH.

Said Vincent Miller, M.D., Chief Medical Officer of Foundation Medicine, "Squamous cell carcinoma of the lung is a deadly cancer killer and like many common solid tumors, analysis of no one or even several genes provides a sufficiently comprehensive characterization of the actionable alterations present in a population of patients to ensure a high screen hit rate when evaluating patients for a targeted therapy approach. Rather, multiple genes often altered by one or more classes of DNA changes and often co-occurring are unpredictably altered in any given patient. The comprehensive, broad based nature of FoundationOne testing allowed us to be uniquely suited to provide reliable results across an unprecedented broad swath of predictive biomarkers in a clinically relevant turnaround time to attract multiple interested pharma partners with distinct therapeutic targets".

**Website:** [www.Lung-MAP.org](http://www.Lung-MAP.org)

**ClinicalTrials.gov Entry Page:** <https://clinicaltrials.gov/ct2/show/NCT02154490?term=1400&recr=Open&rank=4>

## About the Lung-MAP Partners

### SWOG Cancer Research

SWOG Cancer Research is a consortium that designs and conducts multidisciplinary clinical trials to improve the practice of medicine in preventing, detecting, and treating cancer, and to enhance the quality of life for cancer survivors. The approximately 5,000 physician-researchers in the group's network practice at more than 650 institutions nationwide, including 28 of the National Cancer Institute (NCI)-designated cancer centers, as well as cancer centers in almost a dozen other countries. Formerly the Southwest Oncology Group, SWOG is part of the NCI's National Clinical Trials Network and is supported primarily through NCI research grant funding. The group is headquartered at the Knight Cancer Institute at the Oregon Health & Science University in Portland, Oregon, (503-494-5586), has an operations office in San Antonio, Texas, and has a statistical center in Seattle, Washington. Learn more at [swog.org](http://swog.org) (@SWOG).

### The National Cancer Institute

The National Cancer Institute (NCI) leads the National Cancer Program and the NIH effort to dramatically reduce the prevalence of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI website at <http://www.cancer.gov> or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).

### The Foundation for the NIH

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world's premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate key issues of scientific study and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1996, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit [www.fnih.org](http://www.fnih.org).

### Foundation Medicine

[Foundation Medicine](http://www.FoundationMedicine.com)<sup>®</sup> (NASDAQ: FMI) is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer.

The company's clinical assays, [FoundationOne](http://www.FoundationOne.com)<sup>®</sup> for solid tumors and [FoundationOne](http://www.FoundationOne.com)<sup>®</sup> Heme for hematologic malignancies, sarcomas and pediatric cancers, each provide a fully informative genomic profile to identify the molecular alterations in a patient's tumor and match them with relevant targeted therapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit [www.FoundationMedicine.com](http://www.FoundationMedicine.com) or follow Foundation Medicine on [Twitter](https://twitter.com/FoundationATCG) (@FoundationATCG).

### Friends of Cancer Research

Friends of Cancer Research develops groundbreaking partnerships and creates a more open dialogue among both public and private sectors and tears down the barriers that stand in the way of conquering cancer. By collaborating with premier academic research centers, professional societies, and other advocacy organizations, Friends is able to accelerate innovation. For more information, please visit: <http://www.focr.org> or follow us on twitter [@CancerResrch](https://twitter.com/CancerResrch)

### **Amgen**

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential. For more information, visit [www.amgen.com](http://www.amgen.com) and follow us on [www.twitter.com/amgen](https://www.twitter.com/amgen).

### **AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

### **MedImmune**

MedImmune is the worldwide biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information, please visit [www.medimmune.com](http://www.medimmune.com).

### **Genentech**

Founded more than 35 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com>.

### **Pfizer Oncology**

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline of biologics and small molecules, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information, please visit [www.Pfizer.com](http://www.Pfizer.com).

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