Lung-MAP Precision Medicine Trial Expands To Include More Patients

Washington, DC – The Lung Cancer Master Protocol (Lung-MAP), the first precision medicine trial in lung cancer supported by the National Cancer Institute (NCI), part of the National Institutes of Health, is undergoing a major expansion to include patients with all non-small cell lung cancers – which make up about 85 percent of all lung cancer diagnoses in the U.S.

The trial previously tested treatments for people with advanced stage squamous cell lung cancer. Opening the trial to all types of advanced stage non-small cell lung cancers means that thousands of new patients will be eligible to enroll in this landmark trial and benefit by taking new investigational drugs to fight their cancer.

"We have more than 200,000 new cases of non-small cell lung cancer in the United States each year, and we desperately need new treatments," said Lung-MAP principal investigator Dr. Vali Papadimitrakopoulou, chief of thoracic medical oncology and professor of medicine at the University of Texas MD Anderson Cancer Center. "When most people are diagnosed with non-small cell lung cancer, their cancer has already grown and spread to other organs. If standard therapies don't work for these patients – and often they don't – they need alternatives. Lung-MAP provides those alternatives."

This month, Lung-MAP will undergo other key changes. These include:

- A new screening protocol to include the addition of liquid biopsies, as well as a streamlined informed consent form that combines screening and prescreening – a step that will make it easier to enroll patients.
- Two new drug sub-studies, one testing a PARP inhibitor and another testing a PD-L1 and VEGF inhibitor in combination scheduled to open in early 2019. Two more sub-studies are scheduled to open in late summer 2019.
- A new mandate that requires hospitals, clinics, and other sites that open the trial to use the NCI's Central Institutional Review Board to oversee trial changes, another move to speed the process of opening the trial at sites and registering patients.

Lung-MAP is the first large-scale precision medicine trial in lung cancer backed by the NCI and the first major NCI cancer trial to test multiple treatments, simultaneously, under one "umbrella" design. Lung-MAP is also a groundbreaking public-private partnership, one that includes the National Cancer Institute and its National Clinical Trials Network (NCTN) including SWOG Cancer Research Network, Friends of Cancer Research, the Foundation for the National Institutes of Health (FNIH), Foundation Medicine, pharmaceutical companies which provided their drugs for the study, and several lung cancer advocacy organizations.

Since the trial is offered at more than 650 U.S. medical centers and community hospitals under the NCTN and the NCI Community Oncology Research Program (NCORP), Lung-MAP makes it easier for

patients to participate and receive investigational treatments to fight their cancer. Lung-MAP is more flexible, and faster, than traditional clinical trial models. Where typical trials require the development of individual studies for each new drug tested, Lung-MAP uses a single "master protocol," which is amended as drugs enter and exit the trial, preserving infrastructure and patient outreach efforts. This makes Lung-MAP more efficient and cost-effective, allowing researchers to quickly answer the critical question: Does this new drug work?

Since it launched in June 2014, Lung-MAP has registered more than 1,700 patients across the country. Trial leaders have worked with 10 pharmaceutical partners, in coordination with the FNIH, to launch nine studies, six of which are completed. The new trial is also addressing questions about the efficacy of immunotherapies and immunotherapy combinations and the validity of new biomarkers. The trial has also produced critical insights into the conduct of large-scale precision medicine trials, including tissue sampling and banking, genetic screening, and patient communication.

"The Lung-MAP trial has already proven its value by successfully completing trials with new targeted agents in selected, molecularly defined subsets of squamous cell lung cancer. This amendment to the trial will allow patients with all types of non-small cell lung cancer to potentially benefit," said Dr. Meg Mooney, acting associate director of the National Cancer Institute's Cancer Therapy Evaluation Program. "Checkpoint inhibitors have produced a major advance in this refractory cancer, and Lung-MAP now intends to build on the success of these immunotherapy agents by adding new agents to further increase the effectiveness of this approach."

"The changes to Lung-MAP are excellent for both patients and science," said Ellen Sigal, chair and founder of Friends of Cancer Research. "These additions to the trial mean patients will have a much easier time enrolling, so they may start fighting their cancer more quickly with investigational therapies better suited for them. Additionally, through these new procedures being introduced, researchers will be able to conduct more streamlined research and get answers to the important questions faster."

"Our industry and advocacy partners have been integral to Lung-MAP's success," said Dr. Maria C. Freire, president and executive director of the FNIH. "They bring extensive knowledge, experience, and financial resources to the trial. This exciting expansion allows us to engage new industry partners to bring promising new treatments to a broader group of lung cancer patients."

SWOG manages Lung-MAP. The study team, led by Dr. Papadimitrakopoulou at MD Anderson, also includes Dr. Roy Herbst from Yale Cancer Center, Dr. David Gandara from U.C. Davis Comprehensive Cancer Center, Mary Redman, PhD, from Fred Hutchinson Cancer Research Center, Dr. Fred Hirsch from the University of Colorado and Philip Mack, PhD, from UC Davis Comprehensive Cancer Center. Lung-MAP is partly funded by NCI through its Cancer Therapy Evaluation Program. Participating companies are providing significant additional funding to the partnership coordinated by the FNIH. Friends of Cancer Research is also a major partner in the Lung-MAP trial.

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About Friends of Cancer Research

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org.

About the Foundation for the National Institutes of Health

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 biomedical research 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 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information, please visit fnih.org.

About SWOG

SWOG was founded in 1956, and is a member of the National Cancer Institute's National Clinical Trials Network and the NCI Community Oncology Research Program, making it part of the oldest and largest publicly funded cancer research network in the United States. SWOG has over 12,000 members in 47 states and six countries who design and conduct cancer prevention and treatment trials. SWOG trials have led to the approval of 14 cancer drugs, changed more than 100 standards of cancer care, and saved more than 3 million years of human life. Learn more at swog.org.