Lung-MAP Precision Medicine Trial Makes Exciting Changes, With New Science and Treatment Options for Patients

Lung-MAP, the most collaborative and comprehensive lung cancer clinical trial active in the U.S., uses a targeted screening approach to match patients with promising new cancer treatments based on their genomic profile.

For Immediate Release

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WASHINGTON, DC – The team behind the Lung Cancer Master Protocol (Lung-MAP), a groundbreaking clinical trial for patients with advanced squamous cell lung cancer, is announcing exciting new changes and enrolling more patients as it adapts to the latest science and treatments. The nation-wide precision medicine trial now includes nivolumab, the immunotherapy treatment recently approved by the U.S. Food and Drug Administration.

Lung-MAP tests several new treatments for patients with advanced stage squamous cell lung cancer. In advanced stage squamous patients, cancer has usually spread from the lungs to other organs. The trial is for these patients, whose cancer has continued to grow – even after being treated with standard therapy.

Lung-MAP gives these patients access to innovative therapies. The trial design allows several drugs to be tested simultaneously. Currently, the trial has four trial options for patients. Here's how it works. All qualifying patients enrolled in Lung-MAP get free genomic profiling. Based on results of that DNA tumor tissue test, patients can be assigned to one of three biomarker-driven sub-studies, each evaluating a promising new drug. If there is no genomic match, patients can enroll in a fourth sub-study, which is testing the FDA-approved nivolumab, an immunotherapy made by Bristol Myers

Squibb, against a nivolumab combination therapy. Regardless of their genomic profile, all Lung-MAP patients receive a treatment – not a placebo.

"This type of late stage lung cancer represents a very high unmet need for patients worldwide," said Lung-MAP principal investigator Dr. Vali Papadimitrakopoulou, a medical oncologist at MD Anderson Cancer Center and a professor of medicine at the University of Texas. "We don't have a lot of effective treatments for squamous cell lung cancer if standard therapy doesn't work. Lung-MAP is evaluating promising treatments for patients who have failed prior treatment – regardless of their genomic profile. In fact, no other lung cancer trial now active in the U.S. is offering so many targeted therapies."

Lung-MAP is unique. It's one of the first large-scale precision medicine trials backed by the National Cancer Institute. And it is also a groundbreaking collaboration, one that includes the National Cancer Institute and its National Cancer Trials Network (NCTN), SWOG, an international cancer clinical trials network, Friends of Cancer Research, the Foundation for the National Institutes of Health, five pharmaceutical companies (Bristol Myers Squibb, Genentech, Pfizer, and AstraZeneca and its subsidiary, MedImmune), Foundation Medicine, and several lung cancer advocacy organizations.

Because it is offered at over 700 major U.S. medical centers and community hospitals under the NCTN, Lung-MAP makes it easier for patients and researchers to find one another. It is also more flexible, and faster, than traditional clinical trial models. Where typical trials require the development of new 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, and allows researchers to more quickly get an answer to this critical question: Does this new lung cancer drug work?

"The Lung-MAP trial models a way to efficiently study a large number of these rare squamous cell subsets under one master protocol," said Dr. Jeff Abrams, Associate Director of the National Cancer Institute's Cancer Therapy Evaluation Program. "These drugs target each patient's disease variation and provides researchers with effective data to compare the tumor response rates and the frequency and severity of side effects on each targeted-therapy sub-study versus the standard-of-care sub-study."

"This trial is breaking down the old paradigms of traditional clinical trials, allowing multiple enrollees to be tested and assigned to the treatment most likely to work for them," said Ellen Sigal, Chair and Founder, Friends of Cancer Research. "Lung-MAP takes advantage of new advances in biomarkers, targeted therapies, and advanced stage cancer treatments while tailoring these treatments to those who need them most – patients."

Squamous cell lung cancer accounts for about 20 percent of all lung cancers. Squamous cells are thin, flat cells that line the airways of the lungs. While squamous cell lung cancer starts in a single group of cells, it is not a single disease. There are many different changes to a person's cancer genes that can cause squamous cells to

grow out of control and become cancerous. Recently, researchers have developed new drugs that might "target" these genetic changes better and with fewer side effects.

SWOG manages the Lung-MAP trial. 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 through a partnership coordinated by FNIH. Friends of Cancer Research is also a major partner in the Lung-MAP trial.

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Website: www.Lung-MAP.org