Protocol Title: LungMAP: A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)

Target Population: Non-Small Cell Lung Cancer

Summary: The primary objective of this screening study is to test patient specimens to determine eligibility for participation in the biomarker-driven and non-matched sub-studies included within Lung-MAP umbrella protocol.

Eligibility Criteria:

- **Step 0:**
  - Patients who need the fresh biopsy must also submit whole blood for ctDNA testing.
  - To participate in LungMAP, patients must be registered to Step 1 after evaluation of patient eligibility, including tumor tissue adequacy.

- **Step 1:**
  - Pathologically proven Stage IV Non-Small Cell Lung Cancer (all histologic types) confirmed by tumor biopsy and/or fine-needle aspiration.
  - Eligible to be screened at progression on prior treatment or pre-screened prior to progression on current treatment.
  - Must have adequate tumor tissue available, defined as ≥ 20% tumor cells and ≥ 0.2 mm³ tumor volume.
  - Must agree to have this tissue submitted to Foundation Medicine for common broad platform CLIA biomarker profiling, PD-L1, and c-MET IHC.
    - Previous next-generation DNA sequencing (NGS) will be repeated if done outside this study for sub-study assignment.
  - Must agree to have any tissue that remains after testing retained for the use of sub-study Translational Medicine (TM) studies at the time of consent the patient is enrolled in.
  - Patients with known EGFR sensitizing mutations, EGFR T790M mutation, ALK gene fusion, ROS 1 gene rearrangement, or BRAF V600E mutation are NOT eligible unless they have progressed following all standard of care targeted therapy.
    - EGFR/ALK/ROS/BRAF testing is not required prior to Step 1 registration, as it is included in the Foundation One testing for screening/pre-screening.
  - Must have Zubrod performance status 0-1 documented within 28 days prior to Step 1 registration.
  - Must be ≥ 18 years of age.
  - Must also be offered participation in banking for future use of specimens.
  - Must be willing to provide prior smoking history as required on the LungMAP Ondata Study Form.

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