**Protocol Title:** Phase II / III Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (S1400 Lung-MAP)

**Target Population:** Stage IV or Recurrent Squamous Cell Lung Carcinoma

**Summary:** This Screening and Multi Sub-study Randomized Phase II / III Trial will establish a method for genomic screening of similar large cancer populations followed by assigning and accruing simultaneously to a multi-sub-study hybrid "Master Protocol" (S1400). The type of cancer trait (biomarker) will determine to which sub-study a participant will be assigned to compare new targeted cancer therapy, designed to block the growth and spread of cancer, or combinations to standard of care therapy with the ultimate goal of being able to approve new targeted therapies in this setting. In addition, the protocol includes a "non-match" sub-study which will include all screened patients not eligible for any of the biomarker-driven sub-studies. This sub-study will compare a non-match therapy to standard of care also with the goal of approval.

**Key Inclusion Criteria:**

- **SCREENING/PRE-SCREENING REGISTRATION:**
  - Patients must have pathologically proven Squamous Cell Carcinoma of the Lung.
  - Patients must either be eligible to be screened at progression on prior treatment or to be pre-screened prior to progression on current treatment; patients will either consent to the screening consent or the pre-screening consent, not both; these criteria are:
    - Screening at Progression on Prior Treatment: To be eligible for screening at progression, patients must have received at least 1 line of systemic therapy for any stage of disease.
      - ≥ 1 of these lines of therapy must have been Platinum-based chemotherapy regimen.
      - Patients must have progressed following the most recent line of therapy.
      - For patients whose prior systemic therapy was for Stage I-II disease only (i.e. patient has not received any treatment for Stage IV Disease), disease progression on platinum-based chemotherapy must have occurred within 1 Year from the last date that patient received that therapy.
    - Pre-screening Prior to Progression on Current Treatment: To be eligible for pre-screening, current treatment must be for Stage IV Disease and patient must have received at least 1 dose of the current regimen.
      - Patients must have previously received or currently be receiving a platinum-based chemotherapy regimen.
      - Patients on first-line platinum-based treatment are eligible upon receiving Cycle 1, Day 1 infusion.
  - Note: Patients will not receive their sub-study assignment until they progress and the S1400 Notice of Progression is submitted.
  - No known EGFR Mutation or Anaplastic Lymphoma Kinase (ALK) Fusion.

- **SUB-STUDY REGISTRATION:**
  - Patients must have progressed following the most recent line of therapy.
  - Patients must not have received any prior systemic therapy within 21 Days prior to Sub-Study Registration.
  - Localized Palliative Radiation Therapy is allowed for symptom management, provided treatment is completed ≥ 28 Days prior to sub-study registration.
    - All other types of Radiation must be completed ≥ 28 Days prior to sub-study registration.
  - Patients must have measurable disease documented by CT Scan or MRI.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT02154490](https://clinicaltrials.gov/ct2/show/NCT02154490)