Protocol Title: Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers (Adjuvant Nivolumab in Resected Lung Cancers [ANVIL])

Target Population: Stage IB, IIA, IIB, or IIIA Non-Small Cell Lung Carcinoma

Summary: To evaluate whether adjuvant therapy with Nivolumab will result in improved Overall Survival (OS) and/or Disease-Free Survival (DFS) over standard observation in patients with Stage IB ≥ 4 cm, II, and IIIA Non-Small Cell Lung Cancer (NSCLC) following surgical resection and standard adjuvant therapy.

Key Inclusion Criteria:
- Patients must have undergone complete surgical resection of their Stage IB (≥ 4 cm), II, or IIIA NSCLC according to the AJCC 7th edition and have had negative surgical margins.
- Baseline Chest CT must be performed within 1 Month (30 Days) of randomization to ensure no evidence of disease.
  - If clinically indicated, additional imaging studies must be performed to rule out metastatic disease.
- Patients must be registered to the ALCHEMIST-SCREEN (ALLIANCE A151216) Trial prior to randomization.
- Non-Squamous Tumors must be Epidermal Growth Factor Receptor (EGFR) and Anaplastic Lymphoma Receptor Tyrosine Kinase (ALK) Wild-Type.
  - Results ascertained in centrally as part of ALCHEMIST-SCREEN Protocol.
- Tumors must have PD-L1 Status tested centrally as part of the ALCHEMIST-SCREEN Protocol.
- Patients must have adequately recovered from surgery and chemotherapy at the time of randomization
  - Minimum time between date of surgery and randomization is 4 Weeks (28 Days).
  - Maximum time allowed between surgery and randomization:
    - 3 Months (90 Days) if no chemotherapy is administered.
    - 8 Months (240 Days) if adjuvant chemotherapy was administered.
    - 10 Months (300 Days) if adjuvant chemotherapy and radiation therapy was administered.
- Patients must have completed and recovered from any adjuvant chemotherapy 2 or more Weeks prior to randomization.
  - 6 Weeks for Mitomycin and Nitrosoureas.
  - 4 Weeks for post-operative radiation therapy.
- Prior to randomization patients with any non-hematologic toxicity from surgery, chemotherapy, and radiation therapy must have recovered to Grade ≤ 1 with the exception of alopecia, ototoxicity, and neuropathy.
- Patients must not have a condition requiring systemic Corticosteroids equivalent to > 10 mg Prednisone per day or other immunosuppressive medications within 2 Weeks of randomization.
- Patients must not have a history of allergic reactions attributed to compounds of similar chemical or biologic composition to Nivolumab.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02595944