EA5142

Lung– Non Small Cell, Squamous and Non Squamous (EGFR/ALK Wildtype)

(Stage IB≥ 4cm-IIIA)

Adjuvant Nivolumab in Resected Lung Cancers (ANVIL)-A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers

Treatment Plan
Arm I (nivolumab**)** Patients receive nivolumab IV over 30 minutes on day 1. Courses repeat every 2 weeks for up to 1 year in the absence of disease progression or unacceptable toxicity. **Arm II (observation)** Patients are followed serially with imaging

- Complete surgical resection of their stage IB (>= 4 cm), II or IIIA NSCLC with negative surgical margins.
- Baseline chest CT performed within 1 month (30 days) of randomization.
- Must be registered to the ALCHEMIST-SCREEN (ALLIANCE A151216) trial prior to randomization.
- Non-squamous tumors must be EGFR and ALK wild-type (results ascertained in centrally as part of ALCHEMIST-SCREEN protocol). Squamous and non-squamous tumors must have PD-L1 status tested centrally
- Patients must NOT have uncontrolled intercurrent illness including, but not limited to, serious ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, uncontrolled cardiac arrhythmia, or psychiatric illness/social situation that would limit compliance with study requirements.
- No prior immune checkpoint inhibitor treatment.
- Minimum time between date of surgery and randomization: 4 weeks
- Maximum time allowed between surgery and randomization: 10mo (if adjv chemo/rad therapy administered); 8mo if adjv chemo administered; 3mo if no chemo administered .
- No history of active malignancy within two years from randomization deemed by the investigator to pose a higher risk of recurrence than the lung cancer in question
- No investigational anti-cancer agents while on study; No known or suspected autoimmune disease; type I diabetes mellitus, hypothyroidism or skin disorders
- No condition requiring systemic corticosteroids or other immunosuppressive medications within 2 weeks of randomization