A151216
Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)

Study Design:

Correlative (marker identification and sequencing)
Patients undergo collection of blood and tissue samples for EGFR and ALK and PDL-1. EGFR patients enrolled into A081105, ALK+ patients enrolled into E4512 and non-squamous EGFR/ALK wild-type and squamous patients may be enrolled into EA5142.

Criteria

PATIENT PRE-REGISTRATION ELIGIBILITY CRITERIA:

- For pre-surgical patients
  - Suspected diagnosis of resectable non-small cell lung cancer
  - Suspected clinical stage of IIIA, II or large IB (defined as size >= 4cm)
- For post-surgical patients
  - Completely resected non-small cell lung cancer
  - Pathologic stage IIIA, II or IB (defined as size >= 4 cm)
- ECOG performance status 0-1
- No patients who have received neoadjuvant therapy (chemo- or radio-therapy) for this lung cancer
- No prior or concurrent malignancies within 5 years, except non-melanoma skin carcinoma or in situ carcinomas; a secondary primary lung cancer is considered a concurrent malignancy and would make a patient ineligible for A151216
- No prior treatment with agents targeting EGFR mutation or ALK rearrangement and PD-1/PD-L1/CTLA-4
- Patients who have had local genotyping are eligible, regardless of the local result
- Note: Post-surgical patients should proceed to registration immediately following preregistration

PATIENT REGISTRATION ELIGIBILITY CRITERIA:

- Completely resected non-squamous NSCLC; eligible histologic subtypes include adenocarcinoma, adenosquamous carcinoma, or large cell/poorly differentiated non-small cell lung cancer (NSCLC) as long as squamous carcinoma is not favored; patients with pure squamous carcinoma are not eligible
- Pathologic stage IIIA, II, or large IB (defined as size >= 4 cm)
- Adequate formalin-fixed, paraffin-embedded (FFPE) tissue available for central EGFR and ALK genotyping for all patients, including those already locally tested for EGFR and ALK
- In order to allow for time for central genotyping and eligibility for the ALCHEMIST treatment trial, patients must register within the following eligibility windows, depending on the adjuvant treatment approach:
  - If no adjuvant therapy, register patient within 75 days following surgery
  - If adjuvant chemotherapy only, register patient within 165 days following surgery
  - If adjuvant chemotherapy and radiation, register patient within 225 days following surgery