

FAST FACTS

ALLIANCE A151216: Aduvant Lung Cancer Enrichment Marker Identification and Sequencing Trial ALCHEMIST

A screening trial for A081105, E4512, and EA5142

***See Study Schema on last page**

1. Patient Pre-registration Eligibility Criteria

For pre-surgical patients

- Suspected diagnosis of resectable non-small cell lung cancer. Cancers with a histology of “adenosquamous” are considered a type of adenocarcinoma and thus a “nonsquamous” histology. Patients with squamous cell carcinoma are eligible.
- Suspected clinical stage of IIIA, II (IIA or IIB) or large IB (defined as size ≥ 4 cm). Note: IB tumors < 4 cm are NOT eligible. Stage IB cancer based on pleural invasion is not eligible unless the tumor size is ≥ 4 cm. The 7th edition of AJCC staging will be utilized.

For post-surgical patients

- Completely resected non-small cell lung cancer with negative margins (R0). Patients with squamous cell carcinoma are eligible only if they have not received adjuvant therapy.
- Pathologic stage IIIA, II (IIA or IIB) or large IB (defined as size ≥ 4 cm). Note: IB tumors < 4 cm are NOT eligible. Stage IB cancer based on pleural invasion is not eligible unless the tumor size is ≥ 4 cm. The 7th edition of AJCC staging will be utilized.

For all patients

- ECOG Performance Status 0-1
- Age ≥ 18 years
- No patients who have received neoadjuvant therapy (chemo- or radio-therapy) for this lung cancer.
- No locally advanced or metastatic cancer requiring systemic therapy within 5 years prior to registration. No secondary primary lung cancer diagnosed concurrently or within 2 year prior to registration.
- No prior treatment with agents targeting EGFR mutation, ALK rearrangement, and PD-1/PD-L1/CTLA-4.
- No patients known to be pregnant or lactating
- Patients who have had local genotyping are eligible, regardless of the local result.
- No patients with recurrence of lung cancer after prior resection.

Note: Post-surgical patients should proceed to registration immediately following pre-registration.

2. Patient Registration Eligibility Criteria

- Tissue available for the required analysis (either clinical tissue block or slides and scrolls, see section 5.1)

- Completely resected NSCLC with negative margins (R0). Cancers with a histology of “adenosquamous” are considered a type of adenocarcinoma and thus a “nonsquamous” histology.
- Pathologic stage IIIA, IIA or IIB, or large IB (defined as size ≥ 4 cm). Note: IB tumors <4 cm are NOT eligible. Stage IB cancer based on pleural invasion is not eligible unless the tumor size is ≥ 4 cm. **The 7th edition of AJCC staging will be utilized.**
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- Patients with squamous cell carcinoma are eligible only if they have not received adjuvant therapy.
- In order to allow for time for central genotyping and eligibility for the ALCHEMIST treatment trial, patients must register within the following eligibility windows:

Squamous patients:

- No adjuvant therapy permitted, register patient within 77 days following surgery

Non-squamous patients:

1. If no adjuvant therapy, register patient within 77 days following surgery.
2. If adjuvant chemotherapy or radiotherapy only, register patient within 225 days following surgery.
3. If adjuvant chemotherapy and radiation, register patient within 285 days following surgery.

