Protocol Title: Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

Target Population: Stage IB-IIIA Non-Small Cell Lung Cancer that has been completely removed by surgery.

Summary: To assess whether adjuvant therapy with Erlotinib (Erlotinib Hydrochloride) will result in improved Overall Survival (OS) over placebo for patients with completely resected Stage IB (≥ 4 cm) – IIIA Epidermal Growth Factor Receptor (EGFR) mutant Non-Small Cell Lung Cancer (NSCLC) (confirmed centrally) following complete resection and standard post-operative therapy.

Key Inclusion Criteria:

- Previously registered to A151216, with the result of Lung Cancer harboring an EGFR Exon 19 Deletion or L858R Mutation.
  - Testing must have been performed by 1 of the following criteria:
    - Patient registered to A151216 and the assessment performed centrally.
    - By a local Clinical Laboratory Improvement Amendments (CLIA) certified laboratory.
    - Patients with known resistant mutations in the EGFR Tyrosine-Kinase (TK) domain (T790M) are NOT eligible.
    - Patients that are both EGFR Mutant and Anaplastic Lymphoma Kinase (ALK) Rearrangements will be registered to A081105.
- Completely Resected Stage IB (≥ 4 cm), II, or IIIA Non-Squamous NSCLC with negative margins.
- Complete recovery from surgery and standard post-operative therapy (if required).
  - Patients must be completely recovered from surgery at the time of randomization.
  - Minimum time requirement between date of surgery and randomization must be at least 28 Days, the maximum time requirement between surgery and randomization must be:
    - 90 Days if no adjuvant chemotherapy was administered.
    - 240 days if adjuvant chemotherapy was administered.
    - 300 days if adjuvant chemotherapy and radiation therapy was administered.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02193282

Fast Facts