A081105 – 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)

Primary Objective: To assess whether adjuvant therapy with erlotinib will result in improved overall survival (OS) over placebo for patients with completely resected stage IB (≥4 cm)-IIIA EGFR mutant NSCLC (confirmed centrally) following complete resection and standard post-operative therapy.

Eligibility Criteria:
- Previously registered to A151216, with the result of lung cancer harboring an EGFR exon 19 deletion or L858R mutation. The testing must have been performed by one of the following criteria:
  - a) Patient registered to A151216 and the assessment performed centrally by the protocol-specified laboratory.
  - b) By a local CLIA certified laboratory. The report must indicate the result as well as the CLIA number of the laboratory that performed the assay. These patients will also have been registered to A151216, but can be enrolled on A081105 regardless of the central lab results.
  - Patients with known resistant mutations in the EGFR TK domain (T790M) are not eligible.
  - Patients that are both EGFR mutant and 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; the 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, 180 days if adjuvant chemotherapy was administered, and 240 days if adjuvant chemotherapy and radiation therapy was administered.
- Age ≥18 years.
- ECOG Performance Status 0-1.
- No prior or concurrent malignancies within 5 years, except non-melanoma skin carcinoma and in situ carcinomas.
- Non-pregnant and non-lactating.
- No history of cornea abnormalities.
- Required Initial Laboratory Values
  - Granulocytes ≥1,500/µl Platelets ≥100,000/µl
  - Total bilirubin ≤1.5 x ULN SGOT ≤1.5 x ULN
  - Serum Creatinine ≤1.5 x ULN
SCHEMA

Accrual Goal = 450 patients
1 cycle = 21 days

Patients will receive erlotinib/placebo at 150 mg/day for up to 2 years. Treatment will be discontinued at disease progression or excessive toxicity.