For Patients With Non-Small Cell Lung Cancer

S1403 Available Through the CTSU
A Randomized Phase II/III Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)

Patient Population
See Section 5.0 for Full Eligibility Details
- Must have histologically or cytologically confirmed Stage IV (AJCC 7th Edition) or recurrent non-small cell lung cancer (NSCLC).
- Must have documented presence of an EGFR exon 19 deletion or exon 21 (L858R) substitution mutation. T790M mutation or other molecular abnormality will be allowed as long as it accompanies one of the mutations listed above. EGFR testing must be performed using a FDA-approved test or in a CLIA-certified laboratory.
- Must have tissue available and agree to submission of tissue and blood as outlined in section 15.0 of the protocol.
- Patients enrolled at sites participating in the Repeat Biopsy Study must agree to submission of tissue obtained by a repeat biopsy performed at the time of disease progression.
- Must have not received any prior systemic anticancer therapy for advanced or metastatic disease including chemotherapy or EGFR tyrosine kinase inhibitor therapy (including gefitinib, erlotinib, afatinib, or any experimental EGFR TKI agents). See Section 5.1e.
- Must not have any known clinically active interstitial lung disease.
- Must not have significant gastrointestinal disorders with diarrhea as a major symptom (e.g. Crohn’s disease, malabsorption, etc).
- Must be able to swallow medication orally.
- Must not be planning to receive any other investigational agents during the course of protocol treatment.

Treatment Plan
See Section 7.0 for Full Treatment Details

Patients will be randomized to Arm 1 or Arm 2.

Arm 1
Afatinib: 40mg PO, day 1-28 Daily**
Cetuximab: 500mg/m² 2 hour IV, day 1-15 q 28 days

Arm 2
Afatinib: 40mg PO, day 1-28 Daily**

* Note: One cycle = 28 days.
Treatment will continue as above until one of the criteria in Section 7.6 is met.

Number of Participants: 605

Please Enroll Your Eligible Patients!
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Schema

Randomization

Arm 1
Afatinib
+ Cetuximab

Arm 2
Afatinib

Repeat Biopsy at Progression (at select institutions)