BI 1200.209

A Single Arm Phase IV Study of Afatinib in Elderly Patients with recurrent or Stage IV Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Have Common Epidermal Growth Factor Receptor (EGFR) mutations (Exon 19 Deletions or Exon 21 L858R Substitution Mutations)

Study Design:

Experimental: Afatinib
Afatinib starting at 40 mg daily dose

Inclusion Criteria:

- Pathologically or cytologically confirmed Stage IV NSCLC (includes cytologically proven pleural effusion or pericardial effusion) or recurrent disease.
- Evidence of common EGFR mutation (Del 19 and/or L858R)
- Age = 70 years or older
- ECOG ps 0-1
- No prior systemic therapy for metastatic or recurrent NSCLC.

Further inclusion criteria apply.

Exclusion criteria:

- Prior participation in an afatinib clinical study, even if not assigned to afatinib treatment
- Concurrent investigational therapy or investigational therapy within 4 weeks of start of afatinib therapy
- Radiotherapy within 4 weeks prior to start of study treatment, except as follows:

  Palliative radiation to target organs other than chest may be allowed up to 2 weeks prior to study treatment, or ii.) Single dose palliative treatment for symptomatic metastasis outside above allowance to be discussed with sponsor prior to enrolling.
- Major surgery within 4 weeks before starting study treatment or scheduled for surgery during the projected course of the study
- Systemic chemotherapy, biological therapy, immunotherapy or investigational agents within 5 half-life of the drug or within four weeks prior to the start of afatinib treatment (if the half-life of the drug is unknown).

Further exclusion criteria apply.