PHASE II OF gefitinib (‘IRESSA’) ADMINISTERED AS FIRST-LINE TREATMENT IN PATIENTS WITH NON-RESECTABLE PNEUMOCARCINOMA (P-ADC) IFCT-0401 TRIAL

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BACKGROUND

• Definition of pneumonic-type adenocarcinoma (P-ADC) - 1. peripheral lung ADC, usually referred to ADC with bronchioloalveolar carcinoma (BAC) features (BAC features: 2004 WHO Classification)

• Rationale for treatment of BAC by epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI) – BAC response to chemotheraphy is still questionable

METHODS

• STUDY DESIGN
  Multicentric phase II study

• ELIGIBILITY CRITERIA
  Pathologic diagnosis of P-ANC in 2004 WHO Classification

• BIOLOGICAL MARKERS
  EGFR gene amplification/mutation, which are associated with dramatic response to EGFR-TKIs

ABSTRACT

Background: P-ADC is a peripheral lung ADC with a bronchioloalveolar carcinoma (BAC) features, very often containing the bronchioloalveolar carcinoma variant in the 2004 classification. In this setting, EGFR is the only known oncogene that is overexpressed in BSAC. Literature suggests that gefitinib (G) (250 mg/d) is active as first-line treatment of non-resectable P-ADC. A multicentric phase II trial to evaluate gefitinib (G) (250 mg/d) as first line treatment in non-resectable P-ADC with BAC features (2004 WHO Classification).

Methods: Patients over 18 yrs with histologically confirmed non-resectable P-ADC with BAC features (2004 WHO Classification). Patients excluded if they had received prior chemotherapy or radiation therapy. Gefitinib was administered orally daily for 21 days of a 28-day cycle. Median follow-up 16.5 months.

Results: 90 patients enrolled April 2004 - July 2004. All patients assessed by clinical panel. 90 patients enrolled April 2004 - July 2004. All patients assessed by clinical panel.

CONCLUSIONS

Gefitinib is active and well-tolerated as first-line treatment of non-resectable P-ADC with BAC features (2004 WHO Classification). In this setting, gefitinib is an active and well-tolerated treatment option for patients with advanced non-resectable P-ADC. All authors declare no conflict of interest.