Journal of Clinical Oncology, 2005 ASCO Annual Meeting Proceedings.
Vol 23, No 16S (June 1 Supplement), 2005: 7098

Abstract

An open-label, multi centre, phase II, non-comparative trial of ZD1839 monotherapy in chemotherapy-naive patients with stage IV or stage III non-operable non-small cell lung cancer (NSCLC)

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Background: Second- or third-line gefitinib (IRESSA) monotherapy is active and well tolerated in patients with advanced non-small-cell lung cancer (NSCLC). The aim of this study was to determine the efficacy and safety of gefitinib as monotherapy in chemotherapy-naïve patients with good performance status (PS). **Methods:** Chemotherapy-naïve patients who had PS 0–2 with histologically confirmed, non-operable, stage III/IV NSCLC were enrolled. Patients received gefitinib 250 mg/day until disease progression. To ensure that the best available treatment was not withheld for an undue length of time, tumors were assessed by X-ray at weeks 3 and 9, and by computed tomography every 6 weeks following start of treatment. **Results:** 58 out of 59 patients were evaluable: Histology: Adeno carcinoma (CA) (32); bronchioalveolar CA (10); squamous cell CA (8); large cell CA (4); other (4). Median age: 67 years (range 41–84). Smoking history: current 33%, former 48%, never 19%. PS 0/1/2: 10%;66%,24%. Response: complete response (CR; n=1; 2%), partial response (PR; n=2; 3%), stable disease (SD; n=23; 40%); progressive disease (PD; n=28; 48%). Median progression free survival to date: 52 days. 14 patients are still undergoing treatment. There were no therapy-related serious adverse events. Grade 3 toxicities were rash 1,7%, nausea 1,7%, fatigue 6,9%, cough 3,4%, pain 1,7%. **Conclusions:** Gefitinib as first-line monotherapy has activity in patients with advanced NSCLC, with clinical benefit (CR+PR+SD) observed in 45% (26/58) of patients. Due to the favorable tolerability profile, gefitinib should be investigated further in controlled, randomized studies in those patients who are unable to tolerate, or who refuse, chemotherapy. IRESSA is a trademark of the AstraZeneca group of companies

Author Disclosure

Employment or Leadership	Consultant or Advisory Role	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Remuneration
AstraZeneca						

Abstract presentation from the 2005 ASCO Annual Meeting