**9116** POSTER

**First Report of Upfront Treatment With Gefitinib in Comparison With Chemotherapy in Advanced Non-Small Cell Lung Cancer Patients From South India − Analysis of 120 Patients**

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**Background:** Lung Cancer is the commonest cause of cancer deaths in males and sixth among females in South India. Lung cancer is being increasingly recognized among non-smokers.
**Material and Methods:** Stage IIIB and IV advanced non-small cell lung cancer (NSCLC) patients (n = 120) treated from January 2009 to December 2010 were retrospectively analysed. Baseline clinical parameters, treatment protocol, response to therapy and survival were noted. Decision to use upfront Gefitinib was based on parameters like female sex, non-smoking status, adenocarcinoma histology and poor PS as EGFR mutation data was not available in majority. Progression free survival (PFS) and overall survival (OS) were analyzed by the Kaplan Meier method and prognosis by log rank test and Cox regression.
**Results:** *Baseline parameters:* Median age: 60 years (22−78 years); males sex: 83 (69.2%); Stage IV: 95 (79.2%); Adenocarcinoma: 109 (90.8%); Smokers: 66 (55%); PS 2/3:65(54.2%); *First line therapy*: Gefitinib: 47 (39.2%), chemotherapy: 73(60.8%). Among those progressing after chemotherapy, 17 (23%) received second line Gefitinib. After a median follow up of 7.5 months (1−26 mo), median PFS and OS were 5 months (0−23 mo) and 7.5 months (1−26 mo) respectively. On univariate analysis (Table 1), PFS was significantly improved for non-smokers, females, and upfront treatment with Gefitinib. The only significant factor which affected OS was female sex. No factors were significant on multivariate analysis. Among PS 2/3 patients, PFS was significantly more with Gefitinib (n = 36) than with single agent chemotherapy (n = 29) [median PFS of 10 mo (95% CI 6.4–13.5 mo) versus 4 mo (95% CI 3.4–4.8 mo) (p = 0.017)].
**Conclusion:** In the largest series on the use of first line Gefitinib from India, we found it to be a useful agent in the treatment of NSCLC especially in females, patients with poor PS and non-smokers, even without EGFR mutation testing. Second line Gefitinib may have negated overall survival differences. However, EGFR mutation studies may help in further individualization of therapy.

Table 1. Univariate analysis of prognostic factors

| Parameter | N | PFS (months) | P value (log rank) | OS (months) | P value (log rank) |
|---|---|---|---|---|---|
| Age | | | 0.93 | | 0.245 |
| age⩽60 y | 71 | 6 | | 11 mo | |
| age >60 y | 49 | 5 | | 9 mo | |
| Sex | | | **0.024*** | | **0.042*** |
| Male | 83 | 5 | | 9 mo | |
| Female | 37 | 7 | | 18 mo | |
| Histology | | | 0.815 | | 0.77 |
| Adenocarcinoma | 109 | 5 | | 10 mo | |
| Squamous | 11 | 6 | | 13 mo | |
| Smoking status | | | **0.010*** | | 0.110 |
| Smokers | 66 | 4 | | 8 mo | |
| Non-smokers | 54 | 7 | | 11 mo | |
| First-line therapy | | | **0.014*** | | 0.53 |
| Chemotherapy | 73 | 4 | | 10 mo | |
| Gefitinib | 47 | 10 | | 10 mo | |

*Significant p value

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**Randomized Phase II Trial of Zoledronic Acid in Combination With Docetaxel in Previously Treated Non-small Cell Lung Cancer (NSCLC) Patients With Bone Metastases − Result of a West Japan Oncology Group Study**

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**Background:** The aim of this open-label, multicenter, randomized phase II trial was to evaluate the efficacy and safety of zoledronic acid, nitrogen-containing bisphosphonate, in combination with docetaxel in previously treated NSCLC patients with bone metastases.
**Material and Methods:** Previously treated NSCLC patients with bone metastases were randomly assigned to receive either docetaxel 60 mg/m$^2$ with or without zoledronic acid 4 mg on day 1 every 21 days. The study treatment was repeated until disease progression, intolerable toxicity, or discontinuation for another reason. The primary endpoint was progression-free survival (PFS), and secondary endpoints were overall survival (OS), objective response rate (ORR), skeletal-related event (SRE) rate, SRE-free survival, and safety. All patients were followed-up until one year after the last patient enrollment.
**Results:** From May 2007 to March 2010, 100 patients were enrolled from 15 institutions; 50 patients were randomly assigned to docetaxel plus zoledronic acid (DZ) and 50 to docetaxel alone (D). Patient characteristics were well-balanced. Forty-nine patients in the DZ group received zoledronic acid with a median of three cycles (range 1 to 19). Of 94 patients for efficacy analysis (48 for DZ and 46 for D), the median OS was 10.4 (95% CI, 7.0–15.8) months in the DZ group, as compared with 9.7 (95% CI, 6.1–12.5) months in the D group (stratified log-rank test, p = 0.62). The median PFS in the two groups was 2.7 and 2.6 months, respectively (stratified log-rank test, p = 0.89), with corresponding ORRs of 8% (95% CI, 2−20) and 4% (95% CI, 1−14). The median SRE-free survival in the two groups was 7.2 and 6.0 months, respectively (stratified log-rank test, p = 0.84). The SRE rates at one year were 30% (95% CI, 18−48) for the DZ group and 39% (95% CI, 24−57) for the D group. There were no clinically relevant differences in the frequencies of grade 3 to 4 adverse events between the two groups. No treatment-related death was observed in the DZ group.
**Conclusions:** The addition of zoledronic acid to docetaxel was well tolerated, but did not improved PFS and OS in unselected NSCLC patients with bone metastases.

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**Prospective Assesment of Combined Pemetrexed and Erlotinib or Gefitinib Therapy After the Relapse to Erlotinib or Gefitinib in Patients With Advanced Non-Small Cell Lung Cancer Having an Active Epidermal Growth Factor Receptor Mutation**

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**Background:** In patients who develop acquired resistance to erlotinib or gefitinib, some tumour cells may remain sensitive to epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI). Gefitinib suppressed the expression of thymidylate synthase in non-small cell lung cancer (NSCLC) cell lines. Low thymidylate synthase expression is a predictive factor for the treatment efficacy of pemetorexed in NSCLC patients. The purpose of this phase II trial was to evaluate the efficacy and toxicity of pemetrexed combined with erlotinib or gefininib after the relapse to erlotinib or gefitinib in patients with advanced NSCLC having an active EGFR mutation.
**Methods:** Eligibility criteria included histologically or cytologically proven NSCLC with an active EGFR mutation after the relapse to erlotinib or gefitinib, measurable leasions, Eastern Cooperative Oncology Group Scale of Performance Status (ECOG PS) 0−2, and adequate organ function. Pemetrexed (500 mg/m$^2$) was administered on day1, and erlotinib or gefininib was sequentially administered on days 2−16. This combination