Results. Pts were divided into two groups according to GTV: < 100 cc (13 pts) and > 100 cc (12 pts). Kaplan-Meier survival analysis showed significant differences between the groups considering both TTP and OS (Logrank p = 0.03 and 0.01 respectively). There were no statistical differences in the two groups regarding age, stage or sex distribution. 9/25 pts (36%) developed RP grade 2 or higher. None of the variables examined correlated significantly to the development of lung toxicity.

Conclusions. Our preliminary results indicate that in NSCLC, GTV plays a prognostic role even in pts at the same clinical stage and receiving the same treatment combination of CRT. None of the dose parameters was a predictor of development of RP. In addition, there was no difference regarding mean lung dose among the pts who developed lung toxicity when compared to those who did not.

825 POSTER

Statistical analysis of survival in patients with advanced non-small-cell lung cancer (NSCLC) treated with gefitinib ('Iressa', ZD1839) in an expanded access program (EAP): preliminary results

M. Wolf, D. Farina-Sisofo, J. Grous, G. Kennealey, J. Ochs. *AstraZeneca, Wilmington, USA*

Background: In patients (pts) with refractory NSCLC for whom no other treatment options are available, there is an unmet clinical need for effective treatments which prolong survival. As part of a global EAP gefitinib ('Iressa', ZD1839), an orally active EGFR-TKI (epidermal growth factor receptor tyrosine kinase inhibitor) has been used to treat pts with NSCLC.

Methods: Of those pts eligible for entry, the majority had received and failed chemotherapy for advanced incurable stage III/IV NSCLC; a small minority were chemo-naïve pts for whom no other treatment options were available due to co-morbidity or low performance status. Pts received 250 mg/day gefitinib orally. Data collection was limited as the EAP was not designed to provide efficacy data. Duration of therapy and survival were measured from the start of initial therapy or earliest resupply date (if date of initial therapy was unavailable), to the last resupply date for ongoing pts or date of last dose for withdrawn pts. Periodic follow-up data for surviving pts after withdrawal was not collected and pts were censored for survival at withdrawal until death was reported.

Results: As of 28 February 2003, data were available on 18,245 pts; 1,093 pts were excluded (missing start or resupply dates) and follow-up was unavailable for 3,504 pts. The earliest resupply date was used as start of therapy for 76 pts. Results for all evaluable pts (confirmed to have started therapy) and for those who entered 1 or more years prior to analysis are shown.

	All evaluable pts (n=17,152)	Pts entered 1 or more years prior to analysis (n=5,755)
Mean duration of treatment, mths	2.61	4.1
No. pts treated for >6 mths	1564	1169
No. pts treated for >12 mths	378	373
Median survival, mths (CI)	5.1 (4.9–5.3)	5.9 (5.6–6.2)
1-year survival, % (CI)	29 (28–30)	33 (31–34)

These data are comparable to those obtained from pretreated pts with advanced NSCLC who received 250 mg/day gefitinib in 2 large Phase II trials (IDEAL 1 and 2) (Fukuoka et al. JCO 2003; in press; Kris et al. Proc ASCO 2002; 21:292a); mean durations of treatment were 2.8 and 2.5 months, median survival was 7.6 and 6.5 months, and 1-year survival rates were 35 and 27%, respectively.

Conclusion: An ad-hoc retrospective analysis has found that gefitinib provides unprecedented, clinically meaningful and durable antitumor activity in a group of pts with incurable NSCLC for whom no other treatment options are available. 'Iressa' is a trademark of the AstraZeneca group of companies

826 POSTER

The role of Her-2/neu expression on the survival of patients with non-small cell lung cancer (NSCLC). A systematic review of the literature with meta-analysis.

T. Berghmans[1], A.P. Meert[1], M. Paesmans[1], B. Martin[1], C. Mascaux[1], J.M. Verdebout[2], P. Delmotte[1], J.J. Lafitte[3], J.P. Sculier[1]. *[1] Institut Jules Bordet, Internal Medicine, Bruxelles, Belgium; [2] Institut Jules Bordet, Pathology, Bruxelles, Belgium; [3] CHU Calmette, Pneumology, Lille, France*

Background: Neu prognostic value for survival in patients with lung cancer remains controversial. We performed a systematic review of the literature to clarify its impact.

Material and methods: Studies related to the assessment of neu in lung cancer patients were identified after an extensive review of the literature by an electronic search, completed by the references found in the selected articles. A team of nine investigators performed a methodological evaluation of each trial by using the European Lung Cancer Working Party scale, as previously described (Eur Respir J 2001; 18: 705). A study was called positive or negative if neu was respectively a significant favourable or unfavourable prognostic factor for survival (significant studies). Otherwise, a study was considered as non-significant. Combined hazard ratio (HR) for survival was obtained by the Peto method.

Results: Thirty studies were eligible: 24 dealt with NSCLC, 5 with adenocarcinoma and 1 with small cell carcinoma. Thirty-one % of the 4582 patients were positive for neu, without difference according to disease extent or histological type. According to neu expression, 13 studies were "negative", 1 "positive" and 16 not significant. The median quality score for the pooled trials was 57.6% (range: 37.4% to 82.6%). Significant studies had a statistically significant better quality score than non-significant studies (61.2% vs 52.6%, p = 0.03). Respectively 86% and 56% of the significant and non-significant studies were evaluable for the meta-analysis. This suggested a potential bias favouring significant studies, when aggregating survival results. We calculated a HR by a random-effect method, including 20 studies assessing the role of neu in NSCLC (test of heterogeneity p = 0.001). The HR was 1.55 (95% CI: 1.29-1.86), meaning that tumours without neu expression had a better prognosis. When we compared the studies with a quality score above and below the median quality score, we found respectively HR = 1.59 (95% CI: 1.23-2.04) and 1.50 (95% CI: 1.13-2.00).

Conclusion: Overexpression of neu might be a factor of poor prognosis for survival in NSCLC. Nevertheless, the potential bias in favour of the significant studies that we observed justified further prospective large size confirmatory study

827 POSTER

A phase II randomized study comparing docetaxel/cisplatin induction therapy followed by thoracic radiotherapy with or without weekly docetaxel in unresectable stage IIIA–IIIB non-small cell lung cancer

C. Manegold[1], J. Debus[1], E. Buchholz[1], G.V. Scagliotti[2], U. Ricardi[2], F. Cardenal[3], K. Mattson[4], R. Ramlau[5], A. Szczesna[6], N. van Zandwijk[7], A. Price[8], A. Morel[9]. *[1] Heidelberg University, Thorax Hospital; Heidelberg, Germany; [2] Turin University, Turin, Italy; [3] Instituto Catalan de Oncologia, Barcelona, Spain; [4] Helsinki University Central Hospital, Helsinki, Finland; [5] Regional Lung Disease Hospital, Poznan, Poland; [6] Regional Lung Disease Hospital, Otwock, Poland; [7] Antoni van Leeuwenhoek ziekenhuis, Amsterdam, The Netherlands; [8] University of Edinburgh, Edinburgh, Scotland; [9] Aventis Pharma, Antony, France*

A phase II randomized study comparing docetaxel/cisplatin induction therapy followed by thoracic radiotherapy with or without weekly docetaxel in unresectable stage IIIAIIIB non-small cell lung cancer

Background: This study evaluated the efficacy and safety of induction chemotherapy (docetaxelcisplatin) followed by either concomitant docetaxel-based chemotherapy plus radiotherapy or radiotherapy alone in locally advanced NSCLC.

Material and methods: 108 chemoradiotherapy-naïve patients with unresectable Stage IIIA or IIIB NSCLC, and WHO performance status ≤1, received 2 cycles of induction chemotherapy (docetaxel 85 mg/m^2 d1 + cisplatin 40 mg/m^2 d1, 2 q3w). In cases of complete response, partial response or no change following 2 cycles of induction chemotherapy, patients were randomized to either thoracic radiotherapy (2 Gy for 5 d/w, total 60 Gy) with weekly docetaxel (20 mg/m^2) [Group A] or radiotherapy alone (total 60 Gy) [Group B] q6w.

Results: An overall response rate (ORR) of 44% [95% CI: 34.252.9] was achieved after induction chemotherapy, with disease control reported in 86% of patients (PR 44%, SD 42%, progressive disease [PD] 12%, early death 2% [lung haemorrhage, sudden death]). Although NCI-CTC-defined grade 34 neutropenia occurred in 46% of patients, febrile neutropenia occurred in only 4%. Characteristics of the 89 patients randomized to local therapy were well balanced between the treatment arms. In the 89 treated patients (n=43 [A], n=46 [B]), a higher ORR of 58% was achieved for Group A (CR 5%, PR 53%, SD 7%, PD 26%) versus 48% for Group B (CR 2%, PR 46%, SD 9%, PD 35%). Despite a high incidence of grade 3-4 lymphocytopenia in the chemoradiotherapy arm (80% in Group A and 20% in Group B), infection only occurred in 5% of patients in Group A. Grade 34 neutropenia was low in both groups with no patient receiving radiotherapy plus docetaxel experiencing this toxicity; 2% of patients experienced grade 3 neutropenia in Group B. Since the cutoff date of 1 March 2002, 70%