1/76; hypokalemia 1/76. Nine patients were discontinued from study due to toxicity. There was one treatment-related death (pneumonitis). Response: CR 0, PR 8 (12%; 95% CI 5–23%), SD 32 (48%; 95% CI 37–60%), and PD 26 (39%; 95% CI 28–51%). Median duration of PR has not been reached. Median duration of SD was 6 months. Survival: Median overall survival was 11.0 months (95% CI 8–14 mo). Median survival by response: PR: median survival not yet reached; SD: 12 mo (95% CI 10–16 mo); PD: 7 mo (95%CI 4–11 mo). In 28 pts with available tissue, EGFR mutations were found only in 3/5 responders. K-ras mutations were found in 2/9 with disease progression and 2/13 with stable disease. EGFR CN did not correlate with treatment outcome.
Conclusions: Erlotinib appears to be relatively well tolerated and demonstrates encouraging activity and median survival in patients $\geqslant$70 years of age with previously untreated advanced NSCLC. We have recently completed accrual, and results will be updated.

1129 POSTER

Sequential versus concomitant administration of docetaxel and gemcitabine as first-line treatment of advanced non-small cell lung cancer (NSCLC): results of a phase II/III randomised study

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Background: Docetaxel (D) and gemcitabine (G) – alone or in combination – have shown encouraging activity and relatively favourable toxicity in patients (pts) with advanced NSCLC. However, the optimum schedule requires definition. This Phase II/III study evaluated the clinically relevant haematological toxicity (CRHT) of first-line treatment with G and D given either concomitantly or sequentially. Interim results have been presented previously (J Clin Oncol 2005; 23: 634S [abstract 7057]).
Methods: Pts were randomised to receive 3-weekly cycles of G 1000 mg/m^{2}and D 75 mg/m^2 either concomitantly (Arm A: G, Days 1, 8 and D, Day 8 for 6 cycles) or sequentially (Arm B: G, Days 1, 8 for 3 cycles followed by D, Day 1 for 3 cycles). CRHT was defined as NCI-CTC Grade 3–4 thrombocytopenia requiring platelet transfusion, anaemia requiring red blood cell transfusion or febrile neutropenia requiring intravenous (iv.) antibiotics.

	Arm A, G + D (N = 166) n (%)	Arm B, G → D (N = 160) n (%)
CRHT		
At least one event	26 (16)	8 (5)
Anaemia + transfusion	19 (11)	8 (5)
Thrombocytopenia + transfusion	2 (1)	1 (1)
Febrile neutropenia + iv antibiotics	7 (4)	1 (1)
Overall Grade 3–4 haematological toxicity		
At least one event	67 (40)	46 (29)
Anaemia	7 (4)	3 (2)
Thrombocytopenia	10 (6)	4 (3)
Neutropenia	61 (37)	42 (26)

Results: The Phase II study included 339 pts; data from 336 pts are reported in this abstract (Arms A/B: 174/162 pts; median age 62.1/64.9 years). Arms were well matched for standard demographics. At baseline, 87% of pts had stage IV disease; 85% had WHO PS $\leqslant$ 1. Median survival was 7.1 and 7.2 months in Arms A and B, respectively ($p > 0.05$); overall response was 32% and 23%, respectively ($\div^2$ test, $p = 0.097$) and median time to progression was 6.2 and 4.7 months, respectively (log-rank test, $p = 0.016$). Arm B received 64% and 44% of the total doses of G and D, respectively, given in Arm A. CRHT occurred less often in Arm B ($p = 0.002$): the proportion of patients with CRHT was 31% of those with CRHT in Arm A. Transfusions and iv antibiotic treatment days were less common in Arm B (Table, 326 evaluable pts). QoL (EORTC-LC13 and SS14 measurements) also favoured Arm B. Final Phase II analysis results for 339 patients will be presented.
Conclusion: G and D given sequentially is as effective as concomitant administration of G and D as first-line treatment for advanced NSCLC, and is associated with significantly reduced CRHT, less iv antibiotic use and a trend towards improved QoL.

1130 POSTER

Docetaxel/gemcitabine vs. a sequential protocol comprising cisplatin/gemcitabine/docetaxel in the first-line treatment of patients with stage IV non-small cell lung cancer (NSCLC): results of a randomised phase II trial

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Background: Patients with metastatic non-small cell lung cancer (NSCLC) are most frequently treated with a platinum-based chemotherapy doublet combination. However, recent studies have demonstrated that triple-agent therapies allow improvement in the treatment response but can be associated with frequent intolerability. A sequential triple-agent schedule may combine acceptable tolerability and good efficacy. We therefore conducted a multicentric, prospectively randomised study that evaluates a sequential three-drug schedule and a platinum-free doublet regimen.
Methods: Patients with histologically confirmed metastatic (UICC stage IV) NSCLC were randomised to one of two protocols: gemcitabine (900 mg/m^2, 30 min. infusion) on days 1 and 8, and docetaxel (75 mg/m^2, 1 hour infusion) on day 1, repeated every three weeks up to six cycles (DOC-GEM). In regimen CIS-GEM-DOC, gemcitabine (900 mg/m^2, days 1 and 8) and cisplatin (70 mg/m^2, 1 hour infusion, day 1) were given for three cycles, followed by three cycles of docetaxel (100 mg/m^2, day 1, every three weeks).
Results: 113 patients (pts.) were totally included. 55/58 pts. were randomised to DOC-GEM and CIS-GEM-DOC, respectively. One patient was excluded from analysis due to violation of inclusion criteria. 20.4% of the pts. responded in the DOC-GEM arm whereas 31.0% responded in the CIS-GEM-DOC protocol (intent-to-treat, WHO criteria, difference not significant). The median time to progression was 3.6 months for patients receiving DOC-GEM (95% confidence interval 1.4 to 5.9) and 5.2 months in the CIS-GEM-DOC schedule (95% confidence interval 3.1 to 7.3, $p = 0.06$). The median survival was 8.7 months with DOC-GEM (95% confidence interval 5.7 to 11.6) and 9.4 months for patients receiving CIS-GEM-DOC (95% confidence interval 7.8 to 11.0, difference not significant). The 1-year survival rates were 34% and 35%, respectively. Mild to moderate leukopenia was frequently seen in both schedules. Other frequent adverse effects were nausea/vomiting, thrombocytopenia, anemia, diarrhea, and skin toxicity.
Conclusions: In the present study, both schedules demonstrated good efficacy and acceptable toxicity. No significant differences were demonstrated in terms of response rate or survival. However, the sequential triple-agent schedule approached statistical significance in response duration.

1131 POSTER

Addition of CPG 7909 to taxane/platinum regimen for first-line treatment of unresectable NSCLC improves objective response in phase II clinical trial

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Background: A taxane/platinum regimen remains first-line treatment of stage IIIb/IV (unresectable) non–small cell lung cancer (NSCLC), yet expected partial response is only 20%-30%. Tumor response and survival have been significantly improved in many preclinical models with the addition of synthetic oligodeoxynucleotide CPG 7909, a Toll-like receptor 9 agonist with immunostimulatory activity. Previous trials have established the dosing ranges, biologic response, and safety of weekly subcutaneous CPG 7909.
Materials and Methods: To investigate the effect of adding CPG 7909 to standard chemotherapy for first-line treatment of stage IIIb/IV NSCLC,