Results: After 52 cycles administered, pts received a median of 2 cycles of treatment (1-6). All patients except one were considered evaluable for toxicity, with the recording of five episodes of (22%) nausea/vomiting grade 1-2 and one (4%) of asthenia grade 1. Four (17%) patients developed anaemia grade 2-3 and neutropenia grade 1. Two additional patients (9%) had neutropenia grade 2 and one (4%) grade V. Among twenty evaluable pts for activity, one (4%) showed partial response, seven (29%) stable disease and twelve (50%) progression disease. Median time to progression and overall survival are 54 (12-210) and 60 (12-485) days respectively.

Conclusion: At this time of evaluation, intravenous Topotecan with this schedule and dose shows promising activity. The accrual still continues until the planned sample size following the Simon Two-stage design.

P2-319 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4

Taxotere as salvage chemotherapy in Chinese patients with advanced NSCLC who have failed or relapsed after the gefitinib target treatment

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Background: This Phase II study was conducted to evaluate the efficacy and toxicity of docetaxel single agent in salvage therapy for patients with advanced non-small cell lung cancer (NSCLC) who failed or relapsed after the gefitinib.

Methods: Patients with histologically confirmed and progressive NSCLC after gefitinib were eligible for this study. Performance status (PS) ≤ 2 and Eastern Cooperative Oncology Group (ECOG) PS ≤ 1 were included. The primary objectives were the objective response rate (ORR) and progression-free survival (PFS) for the assessment of activity. Patients were treated with docetaxel 75 mg/m2 intravenously for 30 min repeated every 3 weeks until progression or intolerable toxicity.

Results: Twenty patients were eligible for this study. The TTP for the whole patient population was 6 (1-15) months. The median survival was 16 (4-27) months. The response rate was 25% (95%CI, 6-61). The ORR was 30% (95%CI, 6-61). The median PFS was 3 months (95%CI, 1.7-7). The median overall survival (OS) was 16 months (95%CI, 4-27). The OS of patients with 1-2 brain metastases and >3 brain metastases were 6 months (95%CI, 1.7-7) and 10 months (95%CI, 4-27) respectively. The ORR was 30% (95%CI, 6-61) with 12 patients (60%) relapsed.

Conclusions: Docetaxel appeared to be well tolerated as salvage therapy for patients with NSCLC who failed to gefitinib.

P2-320 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4

Marked response to a cisplatin/docetaxel/temozolomide combination in a heavily pre-treated lung cancer patient with a metastatic large cell neuroendocrine tumour.

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Introduction: Large cell neuroendocrine carcinoma (LCNEC) is rare and differs from other non-small cell lung carcinomas (NSCLC) in that it has a particularly aggressive clinical behaviour with poor prognosis. We report a dramatic response in body and brain metastases in a heavily pre-treated LCNEC patient receiving a fourth-line combination of cisplatin / docetaxel / temozolomide.

Case Report: A 52-year-old female initially presented with increasing breathlessness and superior vena cava obstruction. Histology showed LCNEC. Computed tomography showed bulky mediastinal disease. Over the next 6 months she received two lines of chemotherapy [cisplatin / etoposide (stable disease), followed by carboplatin / paclitaxel / radiotherapy (good partial response)]. She progressed 8 months from diagnosis with brain metastases (one 5cm diameter). She had a partial response to whole brain radiotherapy, but soon after completion she was commenced on gefitinib for progressive intra-abdominal disease. She progressed on gefitinib with marked clinical deterioration and massive radiological progression in mediastinum, liver, adrenal and brain (12 months from presentation). After a request for more treatment a cisplatin, docetaxel and temozolomide triplet combination was administered [cisplatin 40mg/m2 iv day 1; docetaxel 25 mg/m2 iv days 1, 8, 15; temozolomide 150mg/m2 orally days 1-5, every 4 weeks]. The regimen was based on a single previous case report in metastatic NSCLC and the patient received four cycles of treatment. An excellent symptomatic and radiological response (including the brain metastases) was seen, with a marked improvement in her quality of life that enabled her to return to full activity. Unfortunately the disease started to progress again four months later and the patient died 20 months from presentation.

Discussion: LCNEC is a rare tumour. The tumour is traditionally considered to fall within the category of poorly differentiated NSCLC. However, outcomes are similar to SCLC, including a propensity for early brain metastases. This is the second report in the literature on the use of this specific chemotherapy combination in NSCLC and the first report of this cisplatin / docetaxel / temozolomide regimen in LCNEC. This triplet is a well-tolerated novel outpatient combination chemotherapy regimen that treats both systemic and intracranial disease.

The growing evidence form case series and phase II trials on the use of temozolomide containing regimens in patients with recurrent or progressive brain metastases from solid tumours will be reviewed. In patients who have failed WBRT palliative care was usually the only available management option. For fit patients temozolomide singly or preferably in combination may offer a real alternative.

P2-321 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4

Efficacy of cisplatin and vinorelbine in patients with metastatic NSCLC

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Background: Chemotherapy for advanced NSCLC has gained widespread acceptance since it was demonstrated that cisplatin-based chemotherapy improved survival and quality of life. The aim of this study is to evaluate the feasibility in terms of overall survival, response rate and toxicity of the cisplatin-vinorelbine in Turkish patients with metastatic NSCLC.

Methods: In this prospective study, ECOG performance 0-1, chemotherapy-naive stage IV NSCLC patients (pts) were treated with cisplatin (75 mg/m2, d1, IV) and vinorelbine (30 mg/m2, d1 and d8, IV) every 21 days until progression or unacceptable toxicity for a maximum of 6 cycles in single center. Tumor responses were evaluated by WHO criteria. Survival was calculated with the Kaplan-Meier method.

Eight
patients were still alive. For these patients, the survival was calculated until March 8, 2007.

Results: Between October 2001 and December 2006, a total of 46 NSCLC patients were treated. Two patients were not evaluable because we could not find his data file. Characteristics of patients were as follows: Median age 56 years (range 41-72), male 41, female 3 and PS 0 = 7/1 = 37. Histologic diagnosis was adenocarcinoma in 17 patients, squamous cell carcinoma in 5 and undifferentiated NSCLC in 22. Brain metastasis were present 7 patients (16%) prior starting the treatment. Median number of cycles were 3.0 (range 1-6). In 45 evaluable patients, complete responses were seen in 1 patient (2.3%), partial response in 15 (34.1%) and disease stabilization in 19 (43.2%). In total of 140 cycles, grade 3-4 neutropenia, grade 3-4 leukopenia and grade 3-4 anemia occurred in 16.5%, 10% and 0.7% respectively. One fatal event was observed. The median survival was 285 days (95% CI [172-397]) and at 1 and 2 years survival were 39% and 9.5%, respectively. Conclusion: The combination of cisplatin plus vinorelbine is an active and tolerable regimen in Turkish patients with metastatic NSCLC.

P2-322 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4
Phase II study of docetaxel and carboplatin in elderly patients with advanced non-small cell lung cancer: final results
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Background: Single-agent chemotherapy has been considered as standard treatment for elderly patients with non-small cell lung cancer (NSCLC). However recent subset analyses suggest that platinum-based combination chemotherapy may be safely administered to the elderly with good performance status (PS). We evaluated the efficacy and safety of carboplatin and docetaxel in a phase II study of elderly patients aged 70 years or older.

Methods: Chemotherapy-naive patients aged ≥70 years with advanced NSCLC (IIIB-IV), ECOG performance status (PS) of 0-2, a measurable lesion, and adequate organ functions were enrolled. Patients received carboplatin (AUC 5) and docetaxel (60 mg/m2) administered on day 1. Histologic diagnosis was adenocarcinoma in 17 patients, squamous cell carcinoma in 5 and undifferentiated NSCLC in 22. Brain metastasis were present 7 patients (16%) prior starting the treatment. Median number of cycles were 3.0 (range 1-6). In 45 evaluable patients, complete responses were seen in 1 patient (2.3%), partial response in 15 (34.1%) and disease stabilization in 19 (43.2%). In total of 140 cycles, grade 3-4 neutropenia, grade 3-4 leukopenia and grade 3-4 anemia occurred in 16.5%, 10% and 0.7% respectively. One fatal event was observed. The median survival was 285 days (95% CI [172-397]) and at 1 and 2 years survival were 39% and 9.5%, respectively.

Conclusion: The combination of cisplatin plus vinorelbine is an active and tolerable regimen in Turkish patients with metastatic NSCLC.

P2-323 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4
Outcome of patients with stage III and IV non-small cell lung cancer in Marmara University Hospital, Istanbul, Turkey
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Background: Lung Cancer is one of the five most diagnosed cancers in Turkey. Treatment outcomes of 353 patients with advanced NSCLC who were treated in Marmara University Oncology Clinics between April 1997 and March 2007 were evaluated.

Methods: All patients were diagnosed histologically or cytologically and staged with CAT scans. Patients with WHO performance status (PS) 2 and lower received chemotherapy (CT). A platinum analogue was used in combination with etoposide, vinorelbine, gemcitabine or taxanes as the first line treatment in 83% patients. Elderly (65 years and older) or patients with poor PS (PS=2) were treated with single agent CT. Three to 6 cycles of treatment was administered depending on clinical or radiological response. Radiation therapy to primary tumor was administered to stage III patients after completion of first line CT and to symptomatic stage IV patients for palliation. Eligible stage IIIA patients (16%) were operated. Second line treatment was offered to patients with progressive disease for 3 to 6 cycles.

Results: Median age was 60 years (range: 29-87) and 80% of patients were male. Histological subtypes were squamous cell in 33%, adenocarcinoma in 35%, NSCLC in 30% and large cell cancer 2%. PS was 0 in 53% of the patients. Fifteen percent of the patients were stage IIIA, 22% were stage IIIB, and 63% were stage IV. The median number of cycles administered was 3. At a median follow-up was 11 months (range 1-82), 71% of patients died. Median overall survival (OS) was 14 months, 1-year and 2-year OS ratios were 54% and 27%, respectively. Median time to progression (TTP) was 5 months; 1-year progression free survival (PFS) ratio was 16%. Women, patients with stage III disease, and PS 0 or 1 lived significantly longer (p=0.01, p=0.03, and p<0.001, respectively). Age, histology, smoking history or type of CT didn’t have any statistically significant effect on survival in univariate analysis. Only stage had an impact on OS in multivariate analysis. Stage was also the only factor on PFS (p<0.001).

Conclusion: Advanced staged NSCLC patients has poor prognosis. Our results are consistent with the world literature.

P2-324 NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4
Is there a survival benefit in patients with NSCLC under taxane administration? A multi-centre study
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Conclusion: The combination of carboplatin and docetaxel was safe and promising for the treatment of chemotherapy-naive elderly patients with advanced NSCLC. This regimen warrants further evaluation in a phase III trial.