Background: Previous comparative studies have shown similar efficacy and less toxicity with either, the GV or GD combination respect to platinum-based chemotherapies in patients with advanced NSCLC. This trial was designed to test the efficacy and safety of both, GV and GD combination in non-selected patients with advanced NSCLC.

Methods: Patients (n=39) with ≤ 75 years old, KPS ≥60% and adequate haematological, renal and hepatic function were randomly assigned to: G 1250 mg/m^2 i.v. d1 and d8 plus either V 25 mg/m 2 i.v. d1 and d8 or D 35 mg/m 2 i.v. d1 and d8 every 3 weeks. Taxane was given over 30 minutes immediately before Gemcitabine, and prophylactic i.v. ranitidine (50 mg), diphenhydramine (25 mg) and dexamethasone (8 mg) were prescribed just prior its administration.

Results: Baseline characteristics were comparable in GV (n=20) and GD (n=19) arms: median age (67 years) and KPS (70%), most of patients were male (79%), had metastatic disease (85%) and adenocarcinoma histology (55%). Treatment indicated objective response of 7 (35%) versus 6 (31%) patients, median time-to-treatment failure of 120 versus 90 days, and overall survival of 209 versus 177 days in GV and GD arms respectively. The most common non-haematological toxicities were (GV versus GD; no. of patients): grade 2-4 pulmonary toxicity in 1 versus 7 (37%); grade 2-3 diarrhoea in 0 versus 4 (21%) and oedemas 1 versus 3. Grade 2-4 haematological toxicities in 5 versus 2 patients. All side effects were reversible phenomena since resolution was achieved by suspending the treatment and in the case of the pulmonary toxicity, by the prescription of additional corticoids.

Conclusion: The combination of Gemcitabine/Docetaxel does not have favourable safety profile with this schedule of administration, particularly in terms of pulmonary toxicity. Further patients´ accrual was stopped and the study has been terminated. This kind of toxicity and alternative schedules of GD combination warrants further investigation.

P2-255 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Gemcitabine and oral vinorelbine in elderly patients with advanced non-small cell lung cancer (NSCLC). A phase II study conducted by the Galician Lung Cancer Group (GLCG)

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Background: The combination of gemcitabine (G) and vinorelbine is one of the most effective non-cisplatin based treatment regimens for advanced NSCLC. Oral vinorelbine (Ov) has been employed in NSCLC treatment with similar bioavailability and response rates and a more favourable toxicity profile compared to i.v. form. The GLCG conducted a phase II study to determine the efficacy and safety of GOv combination in elderly patients with advanced NSCLC. The primary objective was response rate (RR) Secondary objectives included time to progression (TTP) overall survival (OS) and toxicity.

Methods: 32 chemo-naïve pts histologically confirmed NSCLC, aged>70, stage IIIB/IV, ECOG 0/1, measurable lesions according RECIST criteria and adecuate bone marrow, renal and hepatic function were included. Pts received G 1000 mg/m^2/i.v. followed a Ov 60 mg/m^2 (days 1 and 8 every 3 weeeks for a maximum of 6 cycles)

Results: Between July 2005 and January 2007, 32 pts were included and 130 cycles were administrated. Male / Female 29/3; median age 76,8 years (range 70-86), all ECOG 1, 21 squamous cell carcinoma, 9 adenocarcinoma and 2 large cell. Stage IIIB/IV: 9/23. To date, 26 pts were evaluable for response and 30 for toxicity. The RR was 38% (95% CI:20-56) PR:38%, SD:27% and PD 35%. The median TTP was 4.5 months and the median OS was 9 months. The main toxicities were anemia grade 3-4 in 4 pts, neutropenia grade 3-4 in 3 and plaquetopenia grade 3 in 2; non-haematological grade 3-4 toxicities included grade 3 asthenia in 3 pts and grade 3 emesis in one pt.

Conclusions: The GOv regimen is effective and well tolerated in elderly pts with advanced NSCLC.

P2-256 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Nedaplatin and docetaxel combination therapy in patients with squamous cell lung cancer

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Background: Nedaplatin (CDGP) is a cisplatin derivative developed in Japan. Its response as monotherapy has been reported to be 20.5% in non-small cell lung cancer, while when used in combination with vindesine (VDS), its efficacy is similar to cisplatin (CDDP). Particularly in squamous cell carcinoma (SQCC), it is said to achieve response rates that are superior to CDDP+VDS. With respect to adverse effects, it causes less nausea/vomiting and nephrotoxicity compared to CDDP. Since we have used CDGP in combination with the new agent docetaxel (TXT) principally for SQCC of the lung, the retrospective data to evaluate the efficacy and the safety of this combination are reported here.

Methods: Forty patients (male/female 34/6; mean age 65.9 (42-89) years) with pre-operative (10 IIIA), advanced (IIB/IIIA/IIIB/IV 2/3/8/11) or recurrent (6) SQCC of the lung with measurable lesions and who had previously not been treated with these agents. Thirty two patients were chemo-naive, while 8 patients had been previously treated with chemotherapy. Thoracic radiation was used separately in 6 patients. Treatment consisted of 80-140mg/body CDGP and 80-140mg/body TXT on day one with about 1,000 ml of hydration every 3-4 weeks.

Results: Seventy five cycles were given to 40 patients (mean cycles 1.88) and the mean dosages actually administered were 66.7 mg/m^2 for CGDP and 65.4 mg/m^2 for TXT. An over all response rate was 55.0% (2 CR, 20 PR, 11 NC, 1 PD). The mean survival time was 17.2 months and the survival rate was 63.0% at 1 year, 37.8% at 2 years, and 33.1% at 3 years. Thirty patients without resection after treatment (24 advanced and 6 recurrent cases) had a mean survival time of 14.6 months and a survival rate of 53.7% at 1 year, 20.7% at 2 years, and 10.3% at 3 years. NCI-CTC grades 3-4 neutropenia, thrombocytopenia, nausea/vomiting occurred in 50 (66.7%), 2 (2.7%), 2 (2.7%) cycles, respectively. There was no grade 3-4 anemia and nephrotoxicity .

Conclusions: We conclude that a combination of CDGP and TXT has adequate tolerability, gives high response rates, and thus is a useful therapy for advanced or recurrent squamous cell carcinomas in lung.