cisplatin in 5 patients (14 courses), mainly due to nephrotoxicity. Three patients developed pulmonary embolism during treatment. Overall median total dose for radiotherapy was 55 Gy (range 6-60), patients eligible for surgery received a median total dose of 48 Gy (range 46-60). Percentage of normal lung volume receiving 20 Gy (V20) ranged from 0 - 44.6%. Esophagitis >grade I was observed in 35 patients (61.4%): Grade II (n=22) and grade III (n=13). Two patients were not evaluable for radiological response. Forty-one patients had a partial response, 9 stable disease and 5 progressive disease. Objective response rate (ORR) is therefore 74.5% (95% CI: 61.6 - 84.3%). Nineteen patients (15 stage III) underwent a (radical) resection after restaging, and 7 of these had a complete pathological remission (cPR). All cPR patients had a radiological partial response. After a median follow up of 10 months, 38 patients (66.7%) are alive. Local recurrence of NSCLC occurred in 9 patients, 6 developed distant metastatic disease, of whom 4 had brain metastases.

Conclusion: Chemoradiotherapy with cisplatin/gemcitabine followed by cisplatin/etoposide and concurrent thoracic radiotherapy for irresectable or medically inoperable NSCLC patients is relatively well tolerated and shows a high objective response rate.

P2-204 **NSCLC: Combined Modality Therapy Posters, Tue, Sept 4**

Concomitant chemo-radiotherapy with oral vinorelbine and cisplatin after induction chemotherapy with cisplatin-docetaxel in patients with locally advanced non-small-cell lung cancer. A multicenter phase II trial. Interim analysis. GFPC study 05-03

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Background: The most satisfactory treatment for patients with locally advanced NSCLC is combination chemotherapy-radiotherapy (CT-RT). However, the optimal interval between irradiation and chemotherapy as well as the most effective chemotherapy protocol remains to be defined.

Our aim was to conduct a multicenter phase II trial of the cisplatin-oral vinorelbine -radiotherapy combination after induction chemotherapy with cisplatin-docetaxel in patient with NSCLC. Vinorelbine is effective as the intravenous form in concomitance with RT for the treatment of NSCLC and oral form may reduce some disagreements provoked by intravenous injections: stress, infections, hemorrhage, displacement at the hospital and cost of CT.

Method: Patients (pts) with histologically or cytologically confirmed unresected stage IIIA and IIIB NSCLC previously untreated, PS ≤ 1, and weight loss ≤ 10 % received two cycles of induction CT cisplatin (75 mg/m^2) and docetaxel (75mg/m^2) days 1 and 22. Pts with response or stable disease continued with thoracic radiotherapy (2 Gy/day, 5 days/week, total dose of 66 Gy, beginning day 57) concomitant with 2 cycles of cisplatin (80mg/m^2) (days 57 and 78) and oral vinorelbine (40 mg/m^2) (days 57, 64, 78 and 85). The interim analysis was planned on the first 15 evaluated pts for response and toxicity (pts who received the 2 sequences of treatment: induction CT and concomitant CT-RT). The enrollment of pts continued if more than 4 objective responses and less than 4 grade III-IV pulmonary or esophagus toxicity were observed.

Results: Twenty two pts were enrolled to obtain 15 evaluated pts. Seven pts did not receive the concomitant CT-RT because of the following reasons: 3 pts presented progression disease after induction CT, 1 died due to concomitant disease, 1 stopped treatment due to toxicity (pneumopathy), 2 pts were withdrawn from study because of protocol deviation. The characteristics of the 15 evaluated pts are: mean age 57 (46-69), 10 males, PS 0/1 9/6 pts, stage IIIA/IIIB 5/10 pts, histology squamous cell carcinoma/adenocarcinoma/large cell 3/8/4 pts. All these pts received the intended treatment. No complete response was observed neither after induction CT nor after concomitant CT-RT. Response rate to induction CT was 40% (95%CI: 15-65) (6 pts) and to concomitant CT-RT 80% (95%CI: 60-100) (12 pts). The overall response rate in ITT was 54.5% (95%CI: 33-75). One patient presented progression disease after concomitant CT-RT (this patient has a stable disease after induction CT). Median survival was not reached. Seven pts experienced severe toxicities after concomitant CT-RT: esophagitis grade III (1 pt), esophagitis grade IV (1 pt), severe neutropenia (4 pts) and bronchial infection (1 pt). No pulmonary toxicity and treatment related death occurred.

Conclusions: The result of the interim analysis demonstrated that the tested combined treatment modality is feasible and well tolerated by the patients. This result allows us to continue patients enrollment on the study. The total number of patient needed is 30 evaluated pts which we expect to reach when 60 patients will be enrolled. Further results will be given at the time of the abstract presentation.

P2-205 **NSCLC: Combined Modality Therapy Posters, Tue, Sept 4**

Long term results of concurrent chemoradiotherapy with Vinorelbine and a Platinum compound followed by consolidation chemotherapy for advanced stage III Non-Small Lung cancer (NSCLC)

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Background and Purpose: Evidence supports concurrent chemoradiotherapy as an option in the treatment of locally advanced stage III NSCLC. We present the long term results of a prospective phase II study aimed to determine the response rate (RR), toxicity, time to progression (TTP) and survival (S) of concurrent Vinorelbine (Vrb) and Cisplatin (Cis) or Carboplatin (Carbo), with radiotherapy (RT), followed by consolidation ChT with the same drugs, for stage III NSCLC. In order to decrease toxicity the role of protectors like amifostine has been evaluated.

Methods and Materials: 58 eligible pts were included the study from 16.11.2000 to 18.09.2003. Pts characteristics were: median age 59 (44-71), M/F=50/8, PS 1/2=28/30, stage IIIA/IIIB=11/47, squamous cell cc 45, adenocc 7, adenoid chistic cc 1, large cell cc 5. Treatment consisted of 2 cycles of ChT with Vrb (15 mg/sqm, d 1, 8, q21) and Cis (80 mg/sqm, d 1, q 21) or Carbo (AUC 2.5) given concurrently with RT (56-60 Gy/ 28-30 fractions/5.5- 6 weeks), followed by 2-4 cycles of consolidation ChT with the same drugs (Vrb 25 mg/sqm d 1,8, Cis 100 mg/sqm, or Carbo AUC 5 d1, q 21). 22 pts received Amifostine 740 mg/sqm, d1, 8, q 21, given intravenously. At least 4 cycles of ChT have been completed by 64% and optimal doses of RT by 79% of pts.

Results: 58 pts were evaluable for toxicity. Severe grade 3 or 4 toxicities were: neutropenia in 11(19%) pts, esophagitis in 11(19%) pts,