at P. Incidence of grade III and IV neutropenia was 9% on D and none on P. Incidence of grade III and IV respiratory infection was 12% on D and 5% on P. Median OS was 17.94 months (95%CI: 14.82-21.06) for D and 18.92 months (95%CI: 13.24-24.61) for P (p=0.849). Median TTP from 1st line was 7.36 months (95%CI: 6.46-8.26) for D and 5.55 months (95%CI: 4.43-6.67) for P (p=0.080). Median TTP from 2nd line was 3.75 months (95%CI: 1.98-5.52) for D and 3.18 months (95%CI: 0.44-5.94) for P (p= 0.520).

Conclusions: As published, these results shows on our unselected daily practice population with NSCLC, a similar TTP and OS using docetaxel or pemetrexed as 2nd line treatment, but this later drug option shows a clear more favourable safety profile.

P2-228 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Bi-weekly administration of gemcitabine plus vinorelbine in elderly patients with advanced non-small-cell lung cancer: Multi-center phase II trial

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Purpose: Gemcitabine (GEM) and Vinorelbine (VNR) have demonstrated activity as a first-line treatment in elderly patients with advanced non-small-cell lung cancer (NSCLC). We conducted a multicenter phase II trial to evaluate the efficacy and toxicity of bi-weekly administration of gemcitabine plus vinorelbine in elderly patients with advanced NSCLC.

Patients and methods: Forty-six chemotherapy-naive elderly (age: 70 years or older) NSCLC patients were enrolled. Patients were eligible if they had histologically or cytologically confirmed unresectable NSCLC with measurable and/or assessable disease. Patients received GEM (1000 mg/m^2) and VNR (25 mg/m^2) every 2 weeks.

Results: The objective response rate of this treatment was 22.7% (95% Confidence Interval (CI), 10.3-35.1%), median survival time was 310 days, and median time to progression was 133 days. The one-year survival rate was 40.9% (95% CI, 26.3-55.4%), and most adverse events were mild. Only 3 (6.8%) patients needed to omit GEM because of grade 4 neutropenia or due to physician judgment. No patients suffered treatment-related death.

Conclusions: Bi-weekly administration of gemcitabine plus vinorelbine in elderly patients was an effective, feasible and well-tolerated treatment schedule.

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Phase II study of docetaxel and S-1 combination therapy in patients with previously treated non-small-cell lung cancer

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Background: Docetaxel is active against chemotherapy-pretreated non-small-cell lung cancer (NSCLC). S-1 is a novel oral fluoropyrimidine, composed of tegafur, 5-chloro-2,4-dihydroxypyridine (dihydropyrimidine dehydrogenase inhibitor), and potassium oxonate (orotate phosphoribosyl transferase inhibitor). It has been commercially available and used for NSCLC in Japan. We conducted this study to evaluate the efficacy and safety of docetaxel combined with S-1 in NSCLC patients (pts) who were previously treated with one or more regimens.

Methods: Eligible pts were required to have histologically or cytologically confirmed measurable or evaluable stage IIIB or IV NSCLC, age≥ 20 years, one or more previous chemotherapy, a performance status (PS) 0-1, and adequate organ function and bone marrow reserve. In this study, pts received S-1 (80mg/m^2 orally on days 1-14) and docetaxel (40mg/m^2 IV on days 1). Treatment was repeated every 3 weeks.

Results: Between January 2005 and May 2006, 30 pts were enrolled on this study. 29 pts were eligible and evaluable. Median age was 67 (48-79), male/female (23/6), PS 0/1 (9/20), stage IIIB/IV (7/22), and prior chemotherapy regimen 1/2/3 (23/4/2). 28 pts received a platinum-based chemotherapy. Response: PR=7(24%), SD=13, PD=7, NE=2. Median survival time was 10.2 months. Grade 3/4 toxicities (% of pts) were as follows: leukocytes 6/0 (20.6%), neutrophils 7/3 (34.4%), platelets 0/0, infection 0/1 (3.4%), fever 2/0 (6.9%), diarrhea 1/0 (3.4%), neurology 0/1 (3.4%), and mucositis 1/0 (3.4%). There were no treatment-related deaths.

Conclusions: The combination of docetaxel and S-1 was effective with acceptable toxicity in pts with previously treated NSCLC. These results warrant further investigations of this regimen a randomized controlled trial as a second-line treatment for NSCLC.

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A Phase I Study of Nontoxic Suramin As A Chemosensitizer In Pretreated/Refractory Non-Small Cell Lung Cancer (NSCLC) Patients

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Background: Primary and acquired resistance to chemotherapy have been primary determinants of poor outcome in pts with metastatic NSCLC. Our group has shown that non-cytotoxic dose of suramin (10-50 ?M) produces chemosensitization in multiple preclinical tumor models, including chemo-pretreated tumors.

Methods: Platinum-pretreated pts with stage IIIB/IV NSCLC (no prior docetaxel or gemcitabine allowed, allowed prior suramin) were randomized to receive 3 cycles of docetaxel (75 mg/m^2 IV over 1 h q 3 wks) + suramin (Arm A) or gemcitabine (1250 mg/m^2 IV over 30 min d 1 and 8 q 3 wks) + suramin (Arm B). Suramin was infused over 30 min, 2.5 hr prior to the chemotherapy. Suramin dose was calculated using a previously established dosing nomogram: Dose in mg = FACTOR x (actual body surface area) ^{2}. Factor was 125 for the first dose, and, for subsequent doses, was adjusted based on the time elapsed since the previous dose. Pts received either Arm A or Arm B and, after radiologic evaluation at 9 weeks (3 cycles), pts showing objective response (CR/PR) were continued on the same Arm until progressive disease (PD) at which time pts crossed over to the other Arm, whereas pts with stable or PD immediately crossed over to the other Arm. Radiologic evaluation was repeated after 3 cycles of treatments.