carcinoma. 8.7% underwent radical surgery, 23.7% received chemotherapy only, 21.6% radiotherapy against the tumour (thereof stereotactic 5,1%), and 1,5% concomitant chemo-radiotherapy. 6,3% received radiotherapy against metastases, and 38% had no therapy. Only 6.3% were given second-line chemotherapy. Survival was 219 and 190 days for patients 75-80 years and >80 years, respectively. Patients with PS=0 survived 533 days, those with PS=4 only 20 days. Survival among smoker or former smokers and never smokers were 212 and 132 days, respectively. Survival among those who received chemotherapy was 573 days, while for the others it was 181 days.

Conclusions: Significant survival among patients given second line chemotherapy ($p<0.036$). Significant survival among patients between 75-80 versus > 80 years old ($P<0.032$). Treatment of elderly patients with lung cancer is feasible if they have a good PS and seems to result in prolonged survival.

P2-274 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Clinical benefits of pemetrexed 500 mg/m² and 1000 mg/m² in a randomized phase II study for pretreated patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)

Kubota, Kaoru[1] Tamura, Tomohide[1] Yamamoto, Nobuyuki[2] Nakagawa, Kazuhiko[3] Morita, Satoshi[4] Nambu, Yoshihiro[5] Adachi, Susumu[6] Nishiwaki, Yutaka[7] Saijo, Nagahiro[7] Fukuoka, Masahiro[3]

[1] National Cancer Center Hospital, Kashiwa, Japan [2] Shizuoka Cancer Center, Shizuoka, Japan [3] Kinki University School of Medicine, Osaka-sayama, Japan [4] Nagoya University Graduate School of Medicine, Nagoya, Japan [5] Eli Lilly and Company, Kobe, Japan [6] Eli Lilly and Company, Indianapolis, IN, USA [7] National Cancer Center Hospital East, Kashiwa, Japan

Background: Pemetrexed is a standard treatment for patients with locally advanced or metastatic NSCLC who had prior chemotherapy. In an international phase III study comparing pemetrexed with docetaxel in pretreated patients with NSCLC, pemetrexed showed clinically similar efficacy to docetaxel with median survival time (MST) of 8.3 months. In our Japanese randomized phase II study, the treatment with either pemetrexed 500 mg/m² (Pem 500) and 1000 mg/m² (Pem 1000) showed favorable response rates of 18.5% and 14.8%, respectively. We report survival and quality of life (QOL) results of the Japanese phase II study.

Methods: Patients with PS 0-2, measurable, stage III/IV NSCLC, who had previously received 1 or 2 chemotherapy regimens, were randomized to receive either Pem 500 or Pem 1000 on day 1 of a 21-day schedule. The primary endpoint was response rate, which has already been reported. The secondary endpoints included overall survival and QOL. Overall survival was calculated with a Kaplan-Meier method. The QOL scores of FACT-L LCS questionnaire were measured at baseline, before the 2nd and 3rd cycle, and also at 3 months after the registration to the first cycle. Changes from the baseline were calculated.

Results: From October 2004 to October 2005, 244 pts were enrolled at 28 centers, 226 patients were randomized and treated, and 216 patients were evaluated for efficacy. Baseline patient characteristics (Pem 500/Pem 1000: 108/108 pts) were well balanced between the two arms: Males 63%/64%; median age 62/62 years (range: 37-74/26-74); PS 0-1 94%/94%; stage IV 81%/78%. The median number of treatment cycles completed on both arms was 3 (range 1-20+ for Pem 500 and 1-14+ for Pem 1000). One year survival rates were 59.2% for Pem 500, and 53.7% for Pem 1000 with MST of 15.7 and 12.6 months, respectively. The QOL scores of LCS questionnaire were obtained from 107/107 patients (Pem 500/Pem 1000) at baseline, 101/98 patients before the 2nd cycle, 84/72 patients before the 3rd cycle, and 59/61 patients at the last time point (Pem 500/Pem 1000). In both arms, the total LCS scores were well sustained from the baseline without aggravation among the patients who completed the questionnaire at the last time point. Detailed QOL results will be reported at the presentation.

Conclusions: Pemetrexed is an active agent for pretreated patients with NSCLC. Pem 500 showed numerically better response rate and survival than Pem 1000. Based on this study, the use of Pem 500 is recommended for pts with NSCLC in a 2nd or 3rd line setting.

P2-275 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Phase ii study of weekly docetaxel (Doc) and gemcitabine (Gem) in relapsed patients (Pts) with advanced, platinum-exposed non-small cell lung cancer (NSCLC)

Langer, Corey J.[1] Huang, Chao[2] Borghaei, Hossein[1] Millenson, Michael[1] Mintzer, David[3] Staddon, Arthur[3] Seldomridge, Judi[4] Tuttle, Holly[4] Ruth, Karen[1] Litwin, Samuel[1]

[1] Fox Chase Cancer Center, Philadelphia, PA, USA [2] Kansas University Medical Center, Kansas City, KS, USA [3] Pennsylvania Oncology Heme Associates, Philadelphia, PA, USA [4] Oncology Physicians Network, Philadelphia, PA, USA

Background: Doc has clear-cut therapeutic superiority compared to best supportive care or ifosfamide/vinorelbine and, as a result, is the standard of comparison in the second line setting. In the pre-pemetrexed era, Gem, in phase II studies, also demonstrated activity in the salvage setting with favorable response and survival rates. We therefore mounted a phase II trial pairing these two agents in pts with progressive disease after prior platinum-based therapy.

Materials and Methods: Pts with advanced NSCLC and ECOG PS 0-1 progressing either during or after prior platinum-based therapy received Doc 40 mg/m² days 1 and 8, in combination with Gem 800 mg/m² days 1 and 8. In the absence of dose limiting myelosuppression or other gr ≥3 toxicities, Gem dose was escalated on an intra-patient basis to 1000 mg/m² days 1 and 8. Pts continued treatment until disease progression or unacceptable toxicity.

Results: 35 pts were enrolled: 20 (57%) were male; 69 % were ECOG PS 1; 57% had received prior XRT. Median age was 61 (range 30-79). Median time from initial diagnosis to enrollment was 12.4 mos. 170 cycles total were administered (median 4, range 1-16). 35% received ≥ 6 cycles. Overall response rate was 24% (95% CI 12-39%). Median event free survival (EFS) was 5.7 mos; median overall survival 12.5 mos. 1 year survival rate was 51%, and 2 year survival rate 20%. Those enrolled within 12 mos of initial diagnosis had poorer EFS compared to those after 12 mos (log rank p=0.04). There were no treatment-related deaths. Typical grade ≥ 3 toxicities included neutropenia (58%), diarrhea (6%), pneumonitis (9%), and dermatitis (9%), including nail changes.

Conclusion: Combination docetaxel and gemcitabine administered on a weekly basis, days 1 and 8 every 3 weeks in good performance NSCLC patients with PD after/during platinum-based therapy appears encouraging, and presents a viable option in this population. Proof of benefit requires phase III testing.