Conclusion: Apart from a slightly superior hematologic toxicity, there was no significant difference in outcome or toxicity between elderly and younger patients. PC regimen is an active and well tolerated regimen in selected (PS ≤ 2) elderly patients with MPM.

B51* PREDICTIVE VALUE OF FLUORODEOXYGLUCOSE UPTAKE BY POSITRON EMISSION TOMOGRAPHY AND RESPONSE EVALUATION IN REFRACTORY NON-SMALL-CELL LUNG CANCER TREATED WITH ERLOTINIB

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Purpose: to determine prospectively whether the standardized uptake value (SUV) of fluorodeoxyglucose uptake by positron emission tomography (FDG-PET) could be a prognostic factor for refractory non-small-cell lung cancer NSCLC treated with erlotinib. To prospectively evaluate the use of (FDG-PET) to on response evaluation to erlotinib.

Patients and Methods: Patients with histologically proven NSCLC pretreated with chemotherapy, undergo palliative erlotinib 150 mg/die were eligible for this study. Patients were evaluated by FDG-PET before erlotinib and after 45 days of therapy: A decrease of 20% or more in tumor FDG uptake as measured by standardized uptake value was defined as a metabolic response.

Results: From September 2006 to February 2007, 16 patients were included in the study. Patients characteristics were: median age 65 (range 23-78), male 12 pts, adenocarcinoma 7 pts, second-line erlotinib 10 pts, non-smokers 5 pts. Response assessed with clinical and conventional radiological methods (CT-scan) was: 1 partial response (PR), 10 progression (PD), 2 stable disease (SD). Three pts are on evaluation. Overall disease control was 23%. All patients were evaluated with FDG-PET before erlotinib. Maximum SUV (SUV-max) and SUV tumor/liver ratio was 9 (range 3,5-15) and 5 respectively. Six patients were assessable for response with FDG-PET: 1 PR, 2 SD, 3 PD. One patient with SD on FDG-PET had progression on CT-Scan while 1 pt with PD on FDG-PET had SD on CT. As today the follow-up is too short for meaningful conclusions about prognostic value of FDG-PET in this subset of patients. Accrual is still ongoing and definitive results will be presented at the meeting.

B52* SEQUENTIAL TREATMENT OF ADVANCED NON-SMALL-CELL LUNG CANCER WITH 2 SCHEDULES OF DOCETAXEL (D) AND CISPLATIN (C) COMBINATION, FOLLOWED BY GEMCITABINE (G). PRELIMINARY RESULTS OF A RANDOMIZED PHASE II TRIAL

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Background: Aim of this study was to assess the activity and toxicity of 3 courses of C and D, followed by 3 courses of single agent G, and to investigate the weekly D/C schedule.

Methods: Untreated stage IIIB-IV NSCLC pts, aged 18-70 and PS 0-1, stratified by stage (IIIB vs IV), were randomized to D/C (both 75 mg/m2 on day 1, q21) × 3 (Arm A), or D/C (both 25 mg/m2 on days 1, 8, 15, q28) × 3 (Arm B). Responding or stable pts, were further treated with G (1200 mg/m2 on days 1, 8, q 21) × 3. Primary endpoint was response rate (RECIST). Sample size: 42 pts per arm, considering worthy of further investigation a regimen with ≥14 objective responses. Local ethic committee approval and signed informed consent were required.

Results: Between 05/2005 and 10/2006, 88 pts were enrolled (Arm A/B: 43/45). M/F ratio (62/20), median age (63 yrs), PS 0 (62%) and Stage IV disease (86%), were well balanced in both arms. Data after 3 cycles are available for 35/43 arm A pts, with 5 pts receiving <3 cycles for rapid PD (3), Adverse Experience (1) and other (1). Corresponding figures in arm B were 25/45 pts, with 11 receiving <3 cycles: 5 PD, 4 AE, 2 other. Toxicity (NCI-CTG), consisted of G3/4 neutropenia in 18 pts (18/0), 1 neutropenic fever (1/0), G3/4 thrombocytopenia in 3 (1/2), G3/4 anemia in 2 (2/0). Beside alopecia, non-hematological G3/4 toxicity consisted of 1 anaphylactic reaction (0/1), 2 infections w.o. neutropenia (0/2), fatigue (4/1), diarrhoea (4/1), pain (2/3), stomatitis (1/2) and nausea (2/0). Sixty pts (A/B: 35/25) are evaluable for response after 3 cycles: 18 PR (51%) and 8 NC were observed in arm A and 1 CR+10 PR (42%) and 7 NC in arm B.

Conclusions: Both CD combinations appear active and manageable, however it is too early to draw any conclusion. Data collection is continuing and analysis will be completed by the next few months.

B53* TRIPLETS VERSUS DOUBLETS WITH OR WITHOUT CISPLATIN IN THE FIRST-LINE TREATMENT OF STAGE IIIB-IV NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS: PRELIMINARY RESULTS OF A MULTICENTER RANDOMIZED FACTORIAL STUDY

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on behalf of FAST trial group
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Background: Platinum-based doublets are the standard first-line treatment of stage IIIB-IV NSCLC. This 2x2 factorial trial aimed at answering two unresolved questions: (1) the role of replacing cisplatin (P) with vinorelbine (N), (2) the role of adding a third agent, ifosfamide (I), in a chemotherapy doublet with gemcitabine (G) plus P. Primary endpoint was overall survival (OS). Secondary endpoints were response-rate (RR), progression-free-survival (PFS) and toxicity.

Methods: Stage IIIB-IV NSCLC patients were randomized to one of four arms: gemcitabine 1250 mg/m2 days 1,8 plus cisplatin 80 mg/m2 day 1 (GP); gemcitabine 1250 mg/m2 days 1,8 plus vinorelbine 25 mg/m2 days 1,8 (GN); gemcitabine 1000 mg/m2 days 1,8 plus ifosfamide 2 g/m2 day 1 plus cisplatin 80 mg/m2 day 1 (GIP); gemcitabine 1000 mg/m2 days 1,8 plus vinorelbine 25 mg/m2 days 1,8 plus ifosfamide 3 g/m2 day 1 (GIN). Treatments were repeated every 3 weeks for a maximum of 6 cycles. Considering the 2x2 design, two comparisons were performed: (1) N-containing vs P-containing regimens and (2) I-triplets vs I-non containing doublets.

Results: 433 patients were randomized. As to comparison (1): RR was 24.8 vs 37.2% (p=0.019), PFS 4.9 vs 6.5 months (p=0.220) and OS 10.4 vs 9.8 months (p=0.431) for N-containing vs P-containing regimens, respectively. As to comparison (2): RR was 30.0 vs 32.0% (p=0.719), PFS 6.7 vs 5.1 months (p=0.286) and OS 10.9 vs 9.6 months (p=0.326) for I-triplets vs I-non containing doublets, respectively. Grade 3-4 anaemia, leucopenia and thrombocytopenia were significantly more frequent in P-containing regimens; only grade 3-4 leucopenia was more common in I-triplets. Concerning non-haematological toxicity, only grade 3-4 nausea-vomiting was significantly increased in P-containing regimens.

Conclusions: Results of this unplanned preliminary analysis indicate that replacing P with N or adding I to a chemotherapy doublet did not improve OS in the treatment of these patients. However, P-containing regimens showed a statistically significant advantage in RR over P-free chemotherapy. Updated results will be presented at the meeting.