

## 5.

### **Multicenter phase II trial of carboplatin (Cb) and gemcitabine (G) followed by concurrent chemoradiation (CRT) in patients with unresectable stage III non-small-cell-lung cancer (NSCLC): Cher@Nos trial**

P. Germonpré, A. Janssens, L. Van Moorter, D. Verresen, D. Galdermans, R. Devogelaere, H. Ottevaere, Y. Menstens, C. De Pooter, C. Goor (Antwerp, Aalst, Wilrijk, Oostende, Oudenaarde, Herentals, Belgium)

**Background:** In patients (pts) with unresectable stage III NSCLC concurrent CRT improves survival compared to sequential CRT, but results in increased toxicity. Data from the recent HOG 01-24 trial suggest that survival of stage III NSCLC patients is correlated with the FEV1.

**Methods:** Pts with unresectable stage III NSCLC and FEV1  $\geq 1.5$ L were treated with 3 cycles of induction chemotherapy (Cb AUC 5 on d1 and G 1200 mg/m<sup>2</sup> on d1 and d8 Q3 wks) followed by conventional radiotherapy (2.0 Gy/fraction for a total dose of 60 Gy) with concurrent weekly cisplatin (Cis 30 mg/m<sup>2</sup>). The primary endpoint was overall survival at 2 years. An exploratory analysis of the effect of FEV1 on survival was performed.

**Results:** Between 02/2003 and 11/2005 45 pts were enrolled: 34/11 male/female, 14/31 stage IIIA/IIIB, median age 62 y (range 41-81yr), 31/12 FEV1  $\geq 70\%$ / $<70\%$ , 42% squamous cell and 33% adenocarcinoma. The overall response rate was 58% (2% CR, 56% PR). Treatment was well tolerated and no treatment-related deaths were observed. The median progression free and overall survival (OS) are 11.1 m and 20.4 m resp. The 1-, 2- and 3-yr OS rates are 62%, 38% and 17%. An FEV1  $\geq 70\%$  pred. was associated with a better survival: HR 0.37; 95% CI 0.09 – 0.58. The HR (95% CI) was 1.10 (0.56 – 2.18) for PS 0-1 vs 2 and 0.92 (0.47 – 1.79) for stage IIIA vs IIIB.

**Conclusions:** Induction chemotherapy with CbG followed by CRT with concurrent weekly Cis is well tolerated and results in promising overall survival in pts with unresectable stage III NSCLC. In these pts FEV1 appears to be an important prognostic marker.