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Vinorelbine (NVB) oral (NVBo) in combination with carboplatin (CBDCA) followed by maintenance therapy with single agent vinorelbine oral in stage III/IV non-small cell lung cancer (NSCLC): Final results of a multicenter international phase II trial.

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Abstract: **Background:** NVB i.v. day 1 (25 mg/ m²) & NVBo day 8 (60 mg/ m²) and CBDCA AUC 5 have been previously studied in chemo-naïve NSCLC patients (pts) (O'Brien et al, Ann Oncol 2004; 15: 921). We investigated the efficacy and safety of NVBo weekly with CBDCA AUC 5 q3w for 4 cycles(Cy) followed by maintenance therapy with single agent NVBo in non progressive pts.

Methods: Inoperable NSCLC stage IIIB, stage IV or delayed relapse of any stage becoming unresectable, KPS \geq 80%, treated with combination therapy every 3 weeks for 4 Cy: NVBo 60 mg/m² on days 1, 8 and 15 (Cy1), 80 mg/m² (Cy2-4) in absence of neutropenia NCI CTC V2 G3/4; CBDCA AUC 5 day 1, administered over 1 hour. Maintenance therapy if pts did not have a PD: NVBo 60 mg/m² for the first three weekly administrations, followed by NVBo at 80 mg/m²/week until PD.

Results: from December 2003 to January 2005 57/56 pts have been registered/treated: median age 61 yrs (37-71); median KPS 90%; male 71.4%; Squamous cell 30%, Adenocarcinoma 50%; Stage III/IV 32.1/62.5% ; median dose intensity NVBo (% RDI) : combination, 50.1 mg/m²/w (67.3%), maintenance 56.2 mg/m²/w (70.2%); pts with NVBo dose escalation from 60 to 80 mg/m² during combination : 36/52 (69.2%). Tolerance (% of pts with G3/4 NCI CTC V2) : Neutropenia 23.2/44.6; Platelets 16.1/1.8; Hb 19.6/3.6; Nausea 7.1/0; Vomiting 7.1/0; Diarrhea 5.4/0. No G3/4 toxicity was reported for Infection, Bilirubin, Creatinine, Stomatitis, and motor/sensory Neuropathy. Febrile Neutropenia was reported in 5 patients (8.9%). Efficacy: (RECIST) Percent Overall Response rates (n =56 pts) PR 17.9, SD 53.6, PD 23.2, NE 5.4; Progression-Free Survival 4.3 (95% CI [3.1-5.1]) months; Overall Survival 9.7 (95% CI [7.7-11.9]) months.

Conclusions: NVBo on a weekly schedule and CBDCA AUC5 in combination therapy for 4 Cy followed by NVBo in maintenance therapy is an effective and safe treatment regimen for advanced NSCLC. The avoidance of further CBDCA administrations after 4 Cy and the use of NVBo as a maintenance therapy until PD has promise as an alternative to the 6 Cy option and calls for further comparative studies.