Feasibility of Adjuvant carboplatin/docetaxel (C/D) in patients (pts) resected stage I-IIIB non-small cell lung cancer (NSCLC): Preliminary report of a phase II trial

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Background: Adjuvant cisplatin-based chemotherapy has been shown to improve survival in patients with resected NSCLC; however, compliance with chemotherapy has been problematic. Carboplatin (C) is better tolerated than cisplatin, and carboplatin-based treatment may improve adjuvant chemotherapy compliance. C/D is a commonly used in the treatment of advanced NSCLC with an acceptable toxicity profile.

Methods: Pts with resected NSCLC with a good functional status, preserved renal, hepatic, and bone marrow function were enrolled. Therapy was initiated therapy at least 2 weeks from surgery, and consisted of 4 cycles C (area under curve of 6), and docetaxel (D) 75 mg/m2 every 3 weeks. The primary end-point was the feasibility of delivering C/D. An "adequate exposure" was defined as receiving 4 cycles of C/D within 12 weeks of initiating therapy. A sample size of 72 pts provided 88% "adequate exposure" was defined as receiving 4 cycles of C/D within 12 weeks of initiating therapy. A sample size of 72 pts provided 88% power to detect a true adequate exposure rate of at least 80%.

Results: 75 patients have been enrolled on the protocol, and 71 patients have completed therapy. Pts withdrew consent prior to initiating therapy, 3 patients withdrew consent prior to initiating therapy. Of 1653 pts included, only 280 pts (17%) were >70 y. No significant differences were found between the two groups with respect to gender, stage, response rate or histology. However, a higher frequency of squamous cell carcinoma was found in pts >70 y. No differences were found in median number of cycles administered. The only significant difference was found in median number of cycles administered. The only significant difference was found in the higher frequency of grade 3-4 neutropenia among pts >70 y (Table).

Conclusions: Preliminary results indicate that adjuvant therapy with CD was well tolerated with the majority of received 4 cycles of therapy within 12 weeks.