Bevacizumab (B) (10 mg/Kg) in combination with Cisplatin (C) and Docetaxel (D) administered every 2 weeks in patients (p) with advanced non-squamous Non-Small Cell Lung Cancer (nsNSCLC): GGCP047/10 study.

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Background:

B in combination with platinum doublets followed by continuation maintenance with B prolongs survival and delays progression in chemo-naïve pts with advanced nsNSCLC. In a phase II trial C, D and B (15 mg/kg) every 3 weeks followed by B showed a promising efficacy, in terms of progression free survival (PFS) and overall survival (OS), and an acceptable toxicity profile. In addition, a biweekly schedule of D and C in p with metastatic NSCLC as a front-line CT has demonstrated effective antitumor activity with a reduction in hematologic toxicity, comparable to the results of previous studies using 3-week schedule. Taken together, these data suggest that the addition of B to C/D administered every 2 weeks could increase the efficacy and reduce the toxicity associated with the other schedules.

Methods:

GGCP 047-10 is a multicenter study in chemo- naïve p diagnosed with advanced nsNSCLC. Eligible p also have measurable disease according to RECIST criteria; age ≥18 years; ECOG PS ≤1; adequate hematological, renal and liver function; life expectancy of at least 2 months and signed informed consent. P receive C (50 mg/m2), D (50 mg/m2), and B (10 mg/kg) every 2 weeks for up to 6 cycles, followed by B alone every 2 weeks until disease progression or unacceptable toxicity. PFS is used as the primary efficacy endpoint. Secondary endpoints include safety profile, overall response rate (ORR), disease control rate (DCR) and OS.

Results:

32 p were enrolled in the study. Median age was 60 years (range 44-72; 28.1% > 65 years); male/female (%): 81/19; ECOG 0/1/2 (%): 28/63/10; adenocarcinoma (%): 84. Median PFS in overall population was 6.4 months (95% CI, 4.2-8.7). Among the 22 p evaluable for response, the ORR was 63.6% and DCR was 95.4%. Most frequent grade 3/4 hematologic toxicity was neutropenia (40.6%) and grade 3/4 nonhematologic toxicities was asthenia (12.5%) followed by mucositis (6.2%) and diarrhea (3.1%). There were no grade 3/4 hemorrhagic events.

Conclusion:

Treatment with B, C and D plus maintenance B every 2 weeks is effective as front-line treatment of p with advanced nsNSCLC with acceptable toxicity. These data provide further evidence that B may be used in combination with multiple standard, platinum-based doublets in this setting.