A randomized Phase II trial of weekly docetaxel plus either cisplatin or oxaliplatin in patients with advanced gastric cancer

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Background: Docetaxel, in combination with cisplatin or oxaliplatin, has demonstrated efficacy against AGC. This randomized phase II trial evaluated two weekly docetaxel-based regimens to see which would be most promising according to objective response rate (ORR) as first-line therapy in AGC.

Methods: Chemotherapy-naive patients with measurable unresectable and/or metastatic gastric adenocarcinoma and a performance status 2 or less were randomly assigned to receive docetaxel (35 mg/m2) weekly on days 1 and 8 of a 21-day cycle plus either cisplatin (60 mg/m2 on day 1) (arm A) or oxaliplatin (120 mg/m2 on day 1) (arm B). Toxicity was assessed on days 1, 8, and 21 of each cycle, and response was evaluated every 2 cycles.

Results: Between March 2007 and April 2009, 75 eligible patients entered. In Arm A, 35 patients were evaluable for objective response and 36 for safety. In Arm B, 37 patients were evaluable for objective response and 37 for safety. Median age was 57 years and disease status was comparable for both arms. Fourteen of 35 (40.0%) patients had a confirmed objective response in the arm A (95% confidence interval [CI] 23.7-56.2%) and 16 of 37 (43.2%) patients had a confirmed objective response in the arm B (95% CI 27.2- 59.2%). No significant difference was noted between the arms both for ORR (p=0.641) or for disease control (62.9% and 81.1%, respectively, p=0.116). Median progression free survival time was 4.8 month in the arm A and 4.3 months in the arm B (Hazard ratio = 1.040; 95% CI, 0.602-1.797; p = 0.889). Median overall survival time was 9.6 months in the arm A and not reached in the arm B (Hazard ratio = 0.501; 95% CI, 0.243-1.036; p = 0.062). There was no relevant difference in the occurrence of overall grade 3 or 4 toxicity between the two arms (58.3% vs. 54.1%, respectively; p=0.815). Neutropenia was the most common grade 3/4 toxicity (33.3% vs. 37.8%, respectively). There was one treatment related death in each arm.

Conclusions: The preliminary results showed that both treatment arms have similar clinical efficacy as front-line treatment in AGC. Each regimen has a manageable tolerability profile. The accrual is ongoing.