

International Society of Gastrointestinal Oncology  
2009 Gastrointestinal Oncology Conference  
October 1–3, 2009  
ABSTRACTS

**Gastric Cancer**

abstr 0949

**Phase II Study of Weekly Paclitaxel as Third-Line Chemotherapy for Advanced or Recurrent Gastric Cancer (OGSG0602)**

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**Background:** Median survival time was longer than 1 year in recent randomized phase III studies in advanced or recurrent gastric cancer (GC) conducted in Japan. Although progression-free survival after first-line chemotherapy has improved, many patients go on to receive second-line or later therapies with new agents such as paclitaxel or docetaxel, which may contribute to prolongation of overall survival. This study evaluated the efficacy and safety of weekly paclitaxel as third-line chemotherapy in patients with advanced or recurrent GC.

**Materials and Methods:** Eligibility criteria were histologically proven advanced or recurrent GC, treatment with two previous regimens including S-1 and irinotecan, age  $\geq 20$  years, performance status (PS) 0-2, adequate organ function, and informed consent. Patients received paclitaxel 80 mg/m<sup>2</sup> on days 1, 8, and 15 of each 4-week cycle until disease progression occurred. Primary end point is feasibility and secondary end points are safety, overall survival, progression-free survival (PFS), time to treatment failure (TTF), and relative dose intensity.

**Results:** A total of 22 patients, 18 males and 4 females, with median age of 60 years (range, 54-82 yrs), 2/19/1 in PS 0/1/2, were enrolled between December 2006 and September 2008. All patients had received first-line chemotherapy including S-1 and second-line treatment including irinotecan. Patients received a median of four (range, 1-12) cycles of treatment. Reasons for discontinuation were disease progression in 18 and withdrawal in 4 patients. Grade 3 adverse events included neutropenia in 3 patients (14%), anemia in 1 (4%), and appetite loss in 1 (4%) patient. Overall response rate was 14%, disease control (PR+SD) rate was 77%, median TTF was 79 days, median PFS was 78 days, and median overall survival has not been reached.

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**Conclusions:** A weekly regimen of paclitaxel was well tolerated and achieved a good disease control rate, and acceptable TTF considering the advanced or recurrent GC patient population. Follow-up is ongoing and final survival data are pending.