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A Phase II Study of Biweekly Dose-Intensified Oral Capecitabine Plus Irinotecan (bXELIRI) for Patients With Advanced or Metastatic Gastric Cancer

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Background: Capecitabine is the prodrug of 5-fluorouracil developed to generate maximal anti-tumor activity at the tumor site and/or improve tolerability. Capecitabine has demonstrated synergistic activity with irinotecan in some solid cancers. A previous study concluded that dose-intensified biweekly capecitabine seems to be more effective than the conventional dose and schedule of capecitabine. We conducted this study to ascertain the efficacy and toxicity of dose-intensified biweekly capecitabine and irinotecan combination chemotherapy in chemotherapy-naïve advanced or metastatic gastric cancer patients.

Methods: Patients with advanced or metastatic gastric cancer who had not received any chemotherapeutic drug except adjuvant chemotherapy were treated with irinotecan 130 mg/m² intravenously (IV) for 90 minutes on days 1 and 15, and capecitabine 3,500 mg/m²/day, in two divided doses, for 7 consecutive days starting from day 1 and day 15, and followed by a 7-day drug-free interval.

Results: Fifty-five eligible patients were enrolled in this study from November 2003 to April 2006, including 22 women and 33 men. The median age was 54 years (range, 27-81 years). A total of 200 courses were administered, and median number of courses per patient was four (range, 1-9 courses). Intent-to-treat analysis showed that one patient had

complete response (1.8%), 23 had partial response (41.8%), 17 stable disease (30.9%), 11 progressive disease (20.0%) and 3 were nonevaluable (5.5%). The overall response rate was 43.6% (95% confidence interval [CI], 30.2-56.9). Grade 3-4 toxicities were neutropenia in 12 patients (21.8%), nausea/vomiting in 3 (5.4%), and diarrhea in 4 (7.2%). Median time to progression was 5 months (range, 0.5-11 months), median survival duration was 11 months (range, 0.5-45 months), and median response duration was 6 months (range, 1-9 months).

Conclusion: Biweekly dose-intensified capecitabine and irinotecan combination chemotherapy was active for the treatment of patients with advanced or metastatic gastric cancers with a tolerable safety profile.