일반연제

# Phase I Study of the Escalation of Docetaxel with Fixed Dose of TS1 in Advanced Gastric Cancer

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**Background:** TS1 and docetaxel are known to be active antitumor agents for gastric cancer with preclinical evidence of synergism each other in vitro. We conducted a phase II escaiating dose study of docetaxel with a fixed dose of TS1 (80 mg/m$^2$) to obtain the maximal tolerated dose (MTD) and the recommended dose (RD) to be used.

**Methods:** Major inclusion criteria comprised of: histologically proven gastric cancer, no prior chemo- or radiotherapy or patients (pts) who recovered from 1 adjuvant chemotherapy, measurable lesions, and other standard criteria. The docetaxel dose studied were 40 mg/m$^2$, 50 mg/m$^2$ and 60 mg/m$^2$ for level 0, level 1 and level 2 respectively. Three pts were enrolled at each dose level. If no pts developed DLT, then enrollment would continue at the next level. If 1 or 2 pts developed DLT, 3 additional pts enrolled on the same level. If 3 of 3 or 3 of 6 pts developed DLT, the level was defined as MTD. The definitions of DLT included grade 3 febrile neutropenia, or grade 4 neutropenia more than 7 days, or grade 4 thrombocytopenia or thrombocytopenic bleeding, or any grade 3, 4 non-hematologic toxicities other than allopecia and N/V.

**Results:** From Nov 2004 to May 2005, 12 pts were enrolled from 2 institutions (3 on level 0, 6 on level 1 and 3 on level 2). No pts developed DLT on level 0. On level 1, 2 pts developed DLTs (grade 4 neutropenia for 8 days, elevation of alkaline phosphatase). The dose of level 2 was defined as MTD in which 3 of 3 pts developed DLTs (grade 3 GI bleeding, grade 4 metabolic acidosis, grade 3 febrile neutropenia). There were 4 partial responders out of 6 in level 1.

**Conclusion:** The RD of docetaxel for Phase II study in advanced gastric cancer was 50 mg/m$^2$ with fixed dose of TS1 80 mg/m$^2$.

**Key Words:** Gastric cancer, Docetaxel, TS1

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